



June 10, 2021

(b) (6), (b)

Case Number: (b) (6), (b)

Dear Mrs. (b) (6), (b)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted as the survivor of (b) (6), (b). The Program wishes to express our sincere condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 CFR § 110.20(c). An injury sustained as the direct result of the covered condition or disease (e.g. COVID-19) for which the countermeasure was administered or used, is not a covered injury. 42 CFR § 110.20(d). Therefore, if an injury was caused by a disease, and not as a direct result of the administration or use of a covered countermeasure, it cannot qualify as a covered injury.

On your Request for Benefits Form, you alleged that the use of a ventilator during Mr. (b) (6), (b) (b) (6), (b) (b) (6), (b)

Based on a review Mr. (b) (6), (b) submitted medical records and compelling, reliable and valid medical and scientific literature, the Program did not find the requisite evidence of direct causation between use of the ventilator and Mr. (b) (6), (b) death. The submitted medical records indicate that Mr. (b) (6), (b)

(b) (6), (b) There is no evidence to indicate that the (b) (6), (b) or led to his death. Instead, the evidence indicates that Mr. (b) (6), (b) experienced a (b) (6), (b)

(b) (6), (b) (b) (6), (b) As there is no compelling, reliable, valid, medical and scientific evidence that the ventilator directly caused Mr. (b) (6), (b) and subsequent death, the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 CFR § 110.90. Requests for reconsideration must be in writing, describe

the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator, Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel independent of the Program will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

Tamara Overby
Acting Director, Division of Injury Compensation Programs

June 10, 2021

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

September 23, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you stated (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation. The submitted medical records indicate that you

(b)(6)

CICP Decision Letter (b)(6)

(b)(6)

The submitted medical records also show that you (b)(6)

(b)(6)

The medical records do not provide sufficient evidence, with any level of diagnostic certainty, that your symptoms met the case definition o (b)(6)

(b)(6)

(b)(6)

the CICP has determined that you are not eligible for

Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

9/23/2022

Date



June 4, 2022

(b)(6)

Case Number

(b)(6)

Dea

(b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you state that

(b)(6)

(b)(6)

(b)(6)

(b)(6)

The submitted medical records show that (b)(6)

(b)(6)

Currently, there is no compelling, reliable, and valid medical and scientific evidence that the

(b)(6)

(b)(6)

the CICP has

determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

6/4/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

April 4, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and currently available compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you sustained a serious injury that was directly caused by the (b)(6). The submitted medical records indicate that you reported (b)(6)

(b)(6)

(b)(6)

(b)(6)

Therefore, the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. *See* 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs

04/04/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

April 4, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, yo (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable, valid, medical and scientific evidence, the Program did not find the requisite evidence that th (b)(6)

(b)(6)

(b)(6)

(b)(6)

the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

04/04/2022

Date



Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

March 2, 2022

(b)(6)

Case Number (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable medical

(b)(6)

(b)(6)

(b)(6) Therefore, the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar

days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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Rockville, MD 20857

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/s/

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

3/2/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

April 15, 2022

(b)(6)

Case Number (b)(6)

Dea (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, yo (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you met the requirements for eligibility for compensation. The medical records indicate tha (b)(6)

(b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

4/15/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

August 24, 2022

(b)(6)

Case Number

(b)(6)

Dear

(b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you

(b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program has determined that you have not met the requirements for eligibility for compensation.

The submitted medical records indicate tha

(b)(6)

(b)(6)

(b)(6)

CICP Decision Letter (b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

Therefore, the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

8/24/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

May 5, 2022

(b)(6)

Case Number (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted as a survivor of (b)(6). The Program would like to express our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and scientific evidence, the Program did not find the requisite evidence that th (b)(6) ical
(b)(6)

(b)(6)

(b)(6)

the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/5/2022

Date



Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

February 22, 2022

(b)(6)

Case Number: (b)(6)

Dea (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, yo (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you sustained a serious injury that was directly caused by (b)(6)

(b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. *See* 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs

2/22/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

June 13, 2022

(b)(6)

Case Number: (b)(6)

Dea (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you have requirements for eligibility for compensation. The submitted medical records indicate (b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

the CICP

has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

6/13/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

September 28, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation.

The submitted medical records indicate that (b)(6)

(b)(6)

CICP Decision Letter (b)(6)

(b)(6)

(b)(6)

(b)(6)

the CICP

has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when this determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then

CICP Decision Letter (b)(6)

review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

9/28/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

June 3, 2022

(b)(6)

Case Number: (b)(6)

Dea (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6) Your medical records indicate that (b)(6)
(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

6/3/2022

Date



Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

February 22, 2022

(b)(6)

CICP Case Number (b)(6)

Dea (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you sustained a serious injury that was directly caused by (b)(6) The

(b)(6)
(b)(6)

You have a right to request reconsideration of the CICIP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICIP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs

2/22/2022

Date



Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

March 10, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

(b)(6) Therefore, the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar

days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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Health Systems Bureau, Health Resources and Services Administration
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Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

CDR George Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

May 25, 2022

(b)(6)

Case Number: (b)(6)

Dea (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) and the Request for Benefits Package you submitted on behalf of your client, (b)(6)

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

The Request for Benefits Form stated that (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and scientific evidence, the Program did not find the requisite evidence that the (b)(6)

(b)(6) The submitted medical records indicate that
(b)(6)

(b)(6)

(b)(6)

(b)(6)

the CICIP has determined that he is not

eligible for Program benefits.

(b)(6)

has a right to request reconsideration of the CICIP's decision that he is not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICIP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICIP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you as his representative.

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/25/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

April 26, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation. The submitted medical records indicate that

(b)(6)

(b)(6)

(b)(6)

(b)(6)

the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when this determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

4/26/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

May 4, 2022

(b)(6)

Case Number: (b)(6)

Dea (b)(6)

The Countermeasures Injury Compensation Program (CICP) or (b)(6) wed the Request for Benefits Package you submitted on behalf of you (b)(6) The Program would like to express our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On the Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable, valid, medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation. The submitted records state tha (b)(6)

(b)(6)

(b)(6) the CICP has determined you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any

documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/4/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

August 5, 2022

(b)(6)

Case Number

(b)(6)

Dear

(b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits (RFB) Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your RFB Form, you

(b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation.

The submitted medical records indicated that

(b)(6)

(b)(6)

CICP Decision Letter for

(b)(6)

(b)(6)

(b)(6)

the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

8/5/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

May 31, 2022

(b)(6)

Case Number: (b)(6)

Dea (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries. This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

indicate that (b)(6)

(b)(6)

(b)(6)

Therefore, the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/31/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

May 16, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of your (b)(6). The Program would like to express our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and the compelling, reliable, valid, medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

(b)(6)

the CICP has

determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/16/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

March 31, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. §110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you sustained a serious injury that was directly caused by (b)(6). The submitted medical records indicate that (b)(6)

(b)(6)

(b)(6)

the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. *See* 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs

3/31/2022

Date



Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

March 8, 2022

(b)(6)

Case Number: (b)(6)

Dea (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. §110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that the (b)(6) caused you to sustain a serious injury that was directly caused by (b)(6). The submitted medical records indicate that, (b)(6)

(b)(6)
(b)(6)

are not eligible for Program benefits.

You have a right to request reconsideration of the CICP’s decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the

On pages where (b)(6) redactions appear, Privacy Act 552a(b) also applies
reconsideration process, your reconsideration request may not include or refer to any
documentation that was not before the CICP at the time of its determination. The letter seeking
reconsideration may be sent through the U.S. Postal Service, commercial carrier or private
courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel,
independent of the Program, will meet to review the Program's decision. The reconsideration
panel will base its recommendation on the documentation before the CICP when the
determination was made. The panel will perform its own review and make its own findings,
which will be submitted to the Associate Administrator. The Associate Administrator will then
review the panel's recommendation(s) and make a final determination, which will be sent to you
(or your representative, if applicable).

/s/



CDR George Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs

2 22

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

March 31, 2022

(b)(6)

Case Number: (b)(6)

Dea (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you sustained a serious injury that was directly caused by (b)(6). The submitted medical records indicate that (b)(6)

(b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

September 16, 2022

(b)(6)

Case Number (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable, valid medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation. The submitted medical records indicate tha (b)(6)

(b)(6)

The medical evidence has not established a causal association between (b)(6)

(b)(6)

CICP Decision Letter

(b)(6)

(b)(6)

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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Rockville, MD 20857

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/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

9/16/2022

Date



Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

March 2, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted in your name.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

The submitted medical records indicate that (b)(6)

(b)(6)

(b)(6)

the CICP has

determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. *See* 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any

documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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Health Systems Bureau, Health Resources and Services Administration
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Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

3/2/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

March 31, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical evidence that (b)(6)

(b)(6) The submitted medical records indicate tha (b)(6)

(b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. *See* 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs

3/31/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

August 25, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of (b)(6)

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition.

The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence tha (b)(6)

(b)(6)

CICP Decision Letter (b)(6)

(b)(6)

(b)(6)

the CICP has determined

that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that (b)(6) is not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

8/25/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

September 29, 2022

(b)(6)

Case Number: (b)(6)

Dea (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the (b)(6) (RFB) Package and the amended RFB submitted concerning your (b)(6) (b)(6). The Program wishes to express our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. This includes an injury, or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

The initial RFB Form stated tha (b)(6) (b)(6)

According to the medical records reviewed (b)(6) (b)(6)

CICP Decision Letter (b)(6)

(b)(6)

(b)(6)

Based on a review of the medical records, and the compelling, reliable, valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

(b)(6)

(b)(6)

the

CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

CICP Decision Letter (b)(6)

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/



CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

9/29/2022

Date



September 23 2021

(b)(6)

CICP Case Number:

(b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, yo (b)(6)

(b)(6)

Based on our medical review, the CICP has determined that you are eligible for Program benefits. The CICP requires "compelling, reliable, valid, medical and scientific evidence" showing that the covered countermeasure directly caused the serious injury. We have determined that, in your case, you have proved that the (b)(6)

(b)(6)

You will receive a separate letter that will outline the next steps and the documentation you will need to submit to determine the Program benefits that may be available to you.

/s/

Tamara Overby,
Acting Director, Division of Injury Compensation Programs

9/23/2021

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

April 18, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific literature, the Program did not find the requisite evidence that (b)(6)

(b)(6)

(b)(6)

the

CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. *See* 42 CFR § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs

4/18/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

May 31, 2022

(b)(6)

Case Number (b)(6)

Dea (b)(6)

The Countermeasures Injury Compensation Program (CICP) or the Request for Benefits Package you submitted as a survivor of you (b)(6) The Program would like to express our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical (b)(6)

(b)(6)

The compelling, reliable, and valid medical and scientific evidence does not support an association between (b)(6)

(b)(6)

(b)(6)

CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/31/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

May 31, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c).

The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries. This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition.

On your Request for Benefits Form, you (b)(6)

Based on a review of the submitted medical records and compelling, reliable medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

(b)(6) the
CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. *See* 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/



George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/31/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

April 29, 2022

(b)(6)

Case Number: (b)(6)

Dea (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you stated that (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6) The submitted medical records indicate that (b)(6)
(b)(6)

The compelling, reliable, valid, medical and scientific evidence does not show a causal association between (b)(6)

(b)(6)

(b)(6)

that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICIP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICIP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICIP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

4/29/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

September 29, 2022

(b)(6)

Case Number (b)(6)

Dea (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). Temporal association between receipt of the countermeasure and onset of the injury is not sufficient by itself to prove the countermeasure caused the injury. 42 C.F.R. § 110.20(c). The CICP’s regulation define “serious injury” as a serious physical injury. 42 CFR §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries. This includes an injury, or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition.

On your Request for Benefits Form, vo (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6) The submitted medical records indicate that (b)(6)
(b)(6)

CICP Decision Letter

(b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 CFR § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

9/29/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

September 26, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted records and compelling, reliable, valid, medical and scientific evidence, the CICP has determined that you are eligible for Program benefits. The CICP has determined that (b)(6)

(b)(6)

(b)(6) You will receive a separate letter that will outline the next steps and the documentation you will need to submit to determine the Program benefits that may be available to you.

CICP Decision Letter (b)(6)

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when this determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

9/26/2022

Date



February 23, 2023

(b)(6)

Case Number: (b)(6)

Dear (b)(6),

It has come to our attention that the Decision Letter dated September 26, 2022, contained some conflicting language about your medical eligibility for compensation. This letter is intended to replace that letter and confirms that you are medically eligible for compensation. If you have not done so already, please refer to the Compensation Letter explaining potential benefits that was also sent on September 26, 2022 for further instructions.

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted records and compelling, reliable, valid, medical and scientific evidence, the CICP has determined that you are eligible for Program benefits. The CICP has determined that (b)(6)

(b)(6)

(b)(6) You will receive a separate letter that will outline the next steps and the documentation you will need to submit to determine the Program benefits that may be available to you.

/s/



CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

22 22

Date

Enclosure: CICP Compensation Letter



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

May 4, 2022

(b)(6)

Case Number: (b)(6)

Dea (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

(b)(6)

Based on a review of the submitted medical records and compelling, reliable, valid, medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6) The submitted medical records indicate that (b)(6)

(b)(6)

(b)(6)

(b)(6)

the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. *See* 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/4/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

September 29, 2022

(b)(6)

Case Number: (b)(6)

Dea (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted concerning your (b)(6). The Program would like to offer our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program has determined that you have not met the requirements for eligibility for compensation.

The submitted medical records indicate that (b)(6)

(b)(6)

CICP Decisio

(b)(6)

(b)(6)

(b)(6)

the CICP has determined that you are not eligible for

Program benefits.

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when this determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

9/29/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

August 25, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of your (b)(6)

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

The submitted medical records show that (b)(6)

CICP Decision Letter (b)(6)

(b)(6)

Based on a review of the submitted records and c (b)(6) ng, reliable, valid, medical and scientific evidence, the CICP has determined tha (b)(6) s eligible for Program benefits. The CICP has determined that (b)(6) and, in this case, the injury meets the CICP's regulatory definition of a serious injury. You will receive a separate letter that will outline the next steps and the documentation you will need to submit to determine the Program benefits that may be available to (b)(6)

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

8/25/2022

Date



June 23, 2021

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

The CICP provides compensation to eligible individuals who sustain serious physical injuries or deaths as the direct result of the administration or use of a covered countermeasure. The Program's determination as to whether an injury was caused by the administration or use of a covered countermeasure must be based on compelling, reliable, valid, medical and scientific evidence.

On your Request for Benefits Form, you (b)(6)
(b)(6)

(b)(6) program reviewed your submitted medical records from (b)(6)
(b)(6) Based on the compelling, reliable, valid medical and scientific literature the Program determined that (b)(6) may have been responsible for (b)(6)
(b)(6)

(b)(6) Therefore, we have determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation through the Program. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the Program at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by electronic mail or facsimile) to:

Associate Administrator, Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the same documentation submitted to the CICP. The panel will perform its own review of the documents submitted and of the Program's decision. The panel will then make its own findings and submit them to the Associate Administrator. The Associate Administrator will review the panel's recommendation(s) and make a final decision, which will be sent to you. This will be the agency's final action on the request for reconsideration and will be the final determination on the request for Program benefits for the injury that is the subject of that request. Requesters may not seek review of a decision made on reconsideration.

/s/

Tamara Overby,
Acting Director, Division of Injury Compensation Programs

June 23, 2021

Date



September 3, 2021

(b)(6)

Case Number: (b)(6)

Dea (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific literature, the Program did not find the requisite evidence that (b)(6)

(b)(6)

(b)(6) Additionally, your medical records do not indicate that (b)(6)

Additionally, your injury does not meet the Program's definition of a serious injury as it did not (b)(6) The medical

records (b)(6)

(b)(6)

(b)(6)

(b)(6)

the CICIP has determined that you are not eligible for

Program benefits.

You have a right to request reconsideration of the CICIP's decision that you are not eligible for compensation. See 42 CFR § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICIP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICIP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you.

/s/

Tamara Overby,
Acting Director, Division of Injury Compensation
Programs

September 3, 2021

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

August 24, 2022

(b)(6)

Case Number:

(b)(6)

Dear

(b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of (b)(6)

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

In the request for benefits, you

(b)(6)

(b)(6)

The submitted medical records show tha

(b)(6)

(b)(6)

(b)(6)

CICP Decision Letter

(b)(6)

(b)(6)

Based on a review of the submitted records and compelling, reliable, valid, medical and scientific evidence, the CICP has determined that (b)(6) is eligible for Program benefits. The CICP has determined that, in this case, (b)(6)

(b)(6)

(b)(6)

You will receive a separate letter that will outline the next steps and the documentation you will need to submit to determine the Program benefits that may be available to (b)(6)

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

8/24/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

July 22, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

The medical record shows that (b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar

days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when this determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs

7/22/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

May 13, 2022

(b)(6)

Case Number

(b)(6)

Dear

(b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you

(b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable, valid, medical and scientific evidence, the Program did not find the requisite evidence that

(b)(6)

(b)(6)

The medical records show that

(b)(6)

(b)(6)

(b)(6)

(b)(6)

the CICP has determined that you are not eligible for Program benefits.

(b)(6)

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. *See* 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

5/13/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

April 15, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of your (b)(6). The Program would like to express our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

the CICIP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICIP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICIP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICIP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

4/15/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

July 20, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition.

The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you stated (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you (b)(6)

(b)(6)

(b)(6)

The compelling, reliable, and valid medical and scientific evidence does not support that the

(b)(6)

(b)(6)

(b)(6)

the CICP has

determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

7/20/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

April 13, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you stated (b)(6)

(b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that the (b)(6)

(b)(6)

(b)(6)

(b)(6), the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar

days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

4/13/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

August 31, 2022

(b)(6)

Case Number (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you state that (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable valid medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation. (b)(6)

(b)(6)

(b)(6)

the CICP has determined that you are not eligible for Program benefits.

CICP Decision Letter (b)(6)

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

8/31/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

September 23, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you stated (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation. The submitted medical records indicate that you

(b)(6)

CICP Decision Letter (b)(6)

(b)(6)

The submitted medical records also show that you (b)(6)

(b)(6)

The medical records do not provide sufficient evidence, with any level of diagnostic certainty, that your symptoms met the case definition of (b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when this determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

9/23/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

June 4, 2022

(b)(6)

Case Number:

(b)(6)

Dear

(b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you state that

(b)(6)

(b)(6)

(b)(6)

(b)(6)

The submitted medical records show that (b)(6)

(b)(6)

Currently, there is no compelling, reliable, and valid medical and scientific evidence that the

(b)(6)

(b)(6)

the CICP has

determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

6/4/2022

Date



June 10, 2021

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted as the survivor of (b)(6). The Program wishes to express our sincere condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 CFR § 110.20(c). An injury sustained as the direct result of the covered condition or disease (e.g. COVID-19) for which the countermeasure was administered or used, is not a covered injury. 42 CFR § 110.20(d). Therefore, if an injury was caused by a disease, and not as a direct result of the administration or use of a covered countermeasure, it cannot qualify as a covered injury.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review (b)(6) submitted medical records and compelling, reliable and valid medical and scientific literature, the Program did not find the requisite evidence of direct causation between (b)(6). The submitted medical records indicate that (b)(6)
(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 CFR § 110.90. Requests for reconsideration must be in writing, describe

the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator, Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel independent of the Program will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

Tamara Overby
Acting Director, Division of Injury Compensation Programs

June 10, 2021

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

April 4, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and currently available compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you sustained a serious injury that was directly caused by the COVID-19 vaccine. The submitted medical records indicate that you reported (b)(6)

(b)(6)

(b)(6)

(b)(6)

Therefore, the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. *See* 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs

04/04/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

April 4, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

Based on a review of the submitted medical records and compelling, reliable, valid, medical and scientific evidence, the Program did not find the requisite evidence that the (b)(6)

(b)(6)

(b)(6)

(b)(6)

the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

04/04/2022

Date



Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

March 2, 2022

(b)(6)

Case Number (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

(b)(6) Therefore, the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar

days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

3/2/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

April 15, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you met the requirements for eligibility for compensation. The medical records indicate that (b)(6)

(b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

4/15/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

August 24, 2022

(b)(6)

Case Number:

(b)(6)

Dear

(b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you

(b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program has determined that you have not met the requirements for eligibility for compensation.

The submitted medical records indicate that

(b)(6)

(b)(6)

(b)(6)

CICP Decision Letter (b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

Therefore, the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

8/24/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

May 5, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted as a survivor of (b)(6). The Program would like to express our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that the (b)(6)

(b)(6)

(b)(6)

(b)(6)

the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

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/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/5/2022

Date



Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

February 22, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you sustained a serious injury that was directly caused by (b)(6)

(b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. *See* 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs

2/22/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

June 13, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation. The submitted medical records indicate (b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

the CICP

has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when this determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

6/13/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

September 28, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation.

The submitted medical records indicate that (b)(6)

(b)(6)

CICP Decision Letter (b)(6)

(b)(6)

(b)(6)

(b)(6)

the CICP

has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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CICP Decision Letter (b)(6)

review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

9/28/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

June 3, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6) Your medical records indicate that (b)(6)
(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

6/3/2022

Date



Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

February 22, 2022

(b)(6)

CICP Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you sustained a serious injury that was directly caused by (b)(6). The medical records submitted indicate that (b)(6)

(b)(6)

You have a right to request reconsideration of the CICIP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICIP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICIP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs

2/22/2022

Date



Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

March 10, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

(b)(6) Therefore, the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar

days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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Rockville, MD 20857

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CDR George Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

May 25, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of your client, (b)(6)

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

The Request for Benefits Form stated that (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that the (b)(6)

(b)(6) The submitted medical records indicate that
(b)(6)

(b)(6)

(b)(6)

(b)(6)

the CICIP has determined that he is not

eligible for Program benefits.

(b)(6)

has a right to request reconsideration of the CICIP's decision that he is not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICIP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/25/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

April 26, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation. The submitted medical records indicate that

(b)(6)

(b)(6)

(b)(6)

(b)(6)

the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

4/26/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

May 4, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of your (b)(6). The Program would like to express our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On the Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable, valid, medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation. The submitted records state that (b)(6)

(b)(6)

(b)(6) the CICP has determined you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any

documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/4/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

August 5, 2022

(b)(6)

Case Number:

(b)(6)

Dear

(b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits (RFB) Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your RFB Form, you

(b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation.

The submitted medical records indicated that

(b)(6)

(b)(6)

CICP Decision Letter for

(b)(6)

(b)(6)

(b)(6)

the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when this determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

8/5/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

May 31, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries. This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

indicate that (b)(6)

(b)(6)

(b)(6)

Therefore, the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/31/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

May 16, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of your (b)(6). The Program would like to express our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and the compelling, reliable, valid, medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

(b)(6)

the CICP has

determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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5600 Fishers Lane, 8W-37
Rockville, MD 20857

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/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/16/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

March 31, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. §110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you sustained a serious injury that was directly caused by (b)(6). The submitted medical records indicate that (b)(6)

(b)(6)

(b)(6)

the CICIP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICIP's decision that you are not eligible for compensation. *See* 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICIP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICIP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

George Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs

3/31/2022

Date



Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

March 8, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. §110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that the vaccine caused you to sustain a serious injury that was directly caused by (b)(6). The submitted medical records indicate that, (b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the

reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

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CDR George Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

March 31, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you sustained a serious injury that was directly caused by (b)(6). The submitted medical records indicate that (b)(6)

(b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

3/31/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

September 16, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable, valid medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation. The submitted medical records indicate that (b)(6)

(b)(6)

The medical evidence has not established a causal association between (b)(6)

(b)(6)

CICP Decision Letter (b)(6)

(b)(6)

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when this determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

9/16/2022

Date



Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

March 2, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted in your name.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

The submitted medical records indicate that (b)(6)

(b)(6)

(b)(6)

the CICP has

determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. *See* 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any

documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

3/2/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

March 31, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6) The submitted medical records indicate that (b)(6)

(b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. *See* 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs

3/31/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

August 25, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of (b)(6)

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition.

The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

CICP Decision Letter (b)(6)

(b)(6)

(b)(6)

the CICP has determined

that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that (b)(6) is not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

8/25/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

September 29, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits (RFB) Package and the amended RFB submitted concerning your (b)(6) (b)(6). The Program wishes to express our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. This includes an injury, or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

The initial RFB Form stated that (b)(6)

(b)(6)

According to the medical records reviewed (b)(6)

(b)(6)

CICP Decision Letter (b)(6)

(b)(6)

(b)(6)

Based on a review of the medical records, and the compelling, reliable, valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

(b)(6)

(b)(6)

the

CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

CICP Decision Letter (b)(6)

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

9/29/2022

Date



September 23 2021

(b)(6)

CICP Case Number:

(b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on our medical review, the CICP has determined that you are eligible for Program benefits. The CICP requires "compelling, reliable, valid, medical and scientific evidence" showing that the covered countermeasure directly caused the serious injury. We have determined that, in your case, you have proved that the (b)(6)

(b)(6)

You will receive a separate letter that will outline the next steps and the documentation you will need to submit to determine the Program benefits that may be available to you.

/s/

Tamara Overby,
Acting Director, Division of Injury Compensation Programs

9/23/2021
Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

April 18, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific literature, the Program did not find the requisite evidence that (b)(6)

(b)(6)

(b)(6)

the

CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. *See* 42 CFR § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs

4/18/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

May 31, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted as a survivor of your (b)(6). The Program would like to express our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

The compelling, reliable, and valid medical and scientific evidence does not support an association between (b)(6)

(b)(6)

(b)(6)

CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/31/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

May 31, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c).

The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries. This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

(b)(6)

the

CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. *See* 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/



George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/31/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

April 29, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you stated that (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6) The submitted medical records indicate that (b)(6)
(b)(6)

The compelling, reliable, valid, medical and scientific evidence does not show a causal association between (b)(6)

(b)(6)

(b)(6)

the CICP has determined

that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

4/29/2022

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

September 29, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). Temporal association between receipt of the countermeasure and onset of the injury is not sufficient by itself to prove the countermeasure caused the injury. 42 C.F.R. § 110.20(c). The CICP’s regulation define “serious injury” as a serious physical injury. 42 CFR §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries. This includes an injury, or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6) The submitted medical records indicate that (b)(6)
(b)(6)

CICP Decision Letter

(b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 CFR § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

9/29/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

September 26, 2022

(b)(6)

Case Number:

(b)(6)

Dear

(b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you

(b)(6)

(b)(6)

Based on a review of the submitted records and compelling, reliable, valid, medical and scientific evidence, the CICP has determined that you are eligible for Program benefits. The CICP has determined that

(b)(6)

(b)(6)

(b)(6)

You will receive a separate letter that will outline the next steps and the documentation you will need to submit to determine the Program benefits that may be available to you.

CICP Decision Letter (b)(6)

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when this determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

9/26/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

July 8, 2022

(b)(6)

Case Number:

(b)(6)

Dear

(b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of your (b)(6). The Program would like to express our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries. This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition.

On your Request for Benefits Form, you

(b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable, valid, medical and scientific evidence, the Program has determined that (b)(6)

(b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program Benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 CFR § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

7/8/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

May 4, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable, valid, medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

The submitted medical records

indicate that (b)(6)

(b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. *See* 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/4/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

September 29, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted concerning your (b)(6). The Program would like to offer our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program has determined that you have not met the requirements for eligibility for compensation.

The submitted medical records indicate that (b)(6)

(b)(6)

CICP Decision (b)(6)

(b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when this determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

9/29/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

August 25, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of your (b)(6)

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

The submitted medical records show that (b)(6)

CICP Decision Letter (b)(6)

(b)(6)

Based on a review of the submitted records and compelling, reliable, valid, medical and scientific evidence, the CICP has determined that (b)(6) is eligible for Program benefits. The CICP has determined that (b)(6) and, in this case, the injury meets the CICP's regulatory definition of a serious injury. You will receive a separate letter that will outline the next steps and the documentation you will need to submit to determine the Program benefits that may be available to (b)(6)

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

8/25/2022

Date



June 23, 2021

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

The CICP provides compensation to eligible individuals who sustain serious physical injuries or deaths as the direct result of the administration or use of a covered countermeasure. The Program's determination as to whether an injury was caused by the administration or use of a covered countermeasure must be based on compelling, reliable, valid, medical and scientific evidence.

On your Request for Benefits Form, you (b)(6)

(b)(6)

The Program reviewed your submitted medical records from (b)(6)

(b)(6)

Based on the compelling, reliable, valid medical and scientific literature the Program determined that (b)(6) may have been responsible for (b)(6)

(b)(6)

(b)(6)

Therefore, we have determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation through the Program. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the Program at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by electronic mail or facsimile) to:

Associate Administrator, Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the same documentation submitted to the CICP. The panel will perform its own review of the documents submitted and of the Program's decision. The panel will then make its own findings and submit them to the Associate Administrator. The Associate Administrator will review the panel's recommendation(s) and make a final decision, which will be sent to you. This will be the agency's final action on the request for reconsideration and will be the final determination on the request for Program benefits for the injury that is the subject of that request. Requesters may not seek review of a decision made on reconsideration.

/s/

Tamara Overby,
Acting Director, Division of Injury Compensation Programs

June 23, 2021

Date



September 3, 2021

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific literature, the Program did not find the requisite evidence that (b)(6)

(b)(6)

(b)(6) Additionally, your medical records do not indicate that (b)(6)

Additionally, your injury does not meet the Program's definition of a serious injury as it did not

(b)(6) The medical records (b)(6)

(b)(6)

(b)(6)

(b)(6)

the CICIP has determined that you are not eligible for

Program benefits.

You have a right to request reconsideration of the CICIP's decision that you are not eligible for compensation. See 42 CFR § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICIP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICIP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you.

/s/

Tamara Overby,
Acting Director, Division of Injury Compensation
Programs

September 3, 2021

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

August 24, 2022

(b)(6)

Case Number:

(b)(6)

Dear

(b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of (b)(6)

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

In the request for benefits, you

(b)(6)

(b)(6)

The submitted medical records show that

(b)(6)

(b)(6)

(b)(6)

CICP Decision Letter

(b)(6)

(b)(6)

Based on a review of the submitted records and compelling, reliable, valid, medical and scientific evidence, the CICP has determined that (b)(6) is eligible for Program benefits. The CICP has determined that, in this case, (b)(6)

(b)(6)

(b)(6)

You will receive a separate letter that will outline the next steps and the documentation you will need to submit to determine the Program benefits that may be available to (b)(6)

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

8/24/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

July 22, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)
The medical record shows that (b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar

days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when this determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs

7/22/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

May 13, 2022

(b)(6)

Case Number:

(b)(6)

Dear

(b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you

(b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable, valid, medical and scientific evidence, the Program did not find the requisite evidence that

(b)(6)

(b)(6)

The medical records show that

(b)(6)

(b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

(b)(6)

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. *See* 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

5/13/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

April 15, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of your (b)(6). The Program would like to express our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

the CICIP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICIP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICIP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICIP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

4/15/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

July 20, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition.

The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you stated (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you (b)(6)

(b)(6)

(b)(6)

The compelling, reliable, and valid medical and scientific evidence does not support that the

(b)(6)

(b)(6)

(b)(6)

, the CICP has

determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

7/20/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

July 28, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits (RFB) Package you submitted on behalf of (b)(6). The Program would like to offer our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). An injury sustained as the direct result of the covered condition or disease (e.g. COVID-19 viral infection) for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury (e.g., if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease). 42 CFR § 110.20(d). Therefore, if an injury or death was caused by a disease, and not as a direct result of the administration or use of a covered countermeasure, it cannot qualify as a covered injury.

On your RFB Form, you stated (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation. The submitted medical records indicate (b)(6)

(b)(6)

(b)(6)

(b)(6)



Based on the medical records and the compelling, reliable, valid, medical and scientific evidence, (b)(6)

(b)(6)



(b)(6) death was caused by the (b)(6)

(b)(6), the CICIP has determined that you are not eligible for Program Benefits.

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICIP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICIP when this determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then

review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

7/28/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

April 13, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you stated (b)(6)
(b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that the (b)(6)

(b)(6)
(b)(6)
(b)(6)

(b)(6), the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP’s decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar

days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D. M.P.H.
Director, Division of Injury Compensation Programs

4/13/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

August 31, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you state that (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable valid medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation. (b)(6)

(b)(6)

(b)(6)

the CICP has determined that you are not eligible for Program benefits.

CICP Decision Letter (b)(6)

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

8/31/2022

Date

August 31, 2022

(b)(6)

Subject: Request for Reconsideration

Case Number: (b)(6)

Dear (b)(6)

This is in response to your request dated (b)(6), seeking reconsideration of your denied request for benefits under the Countermeasures Injury Compensation Program (CICP or "Program").

In accordance with the regulations governing the CICP reconsideration process, a Panel of qualified individuals who are independent of the Program has reviewed your request. The Panel reviewed and discussed the documentation that was submitted to and evaluated by the Program when it made its determination.

In summary, the Panel determined that the relationship between (b)(6) death and (b)(6). The Panel determined that (b)(6). (b)(6) The Panel agreed that (b)(6) which was (b)(6) The (b)(6)

(b)(6) (b)(6) that all standards of care were met in the treatment of (b)(6)

In conclusion, the Panel determined that the information contained within (b)(6) medical records did not meet demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. See 42 CFR 110.20(c). An injury sustained as the direct result of the covered condition or disease for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury. 42 CFR 120.20(d).

For these reasons, I uphold the Program's determination that you are not eligible for CICIP benefits. This decision constitutes the final action by the Department of Health and Human Services on your request for reconsideration. The Department has no appeals process beyond this reconsideration. In addition, under the Public Readiness and Emergency Preparedness Act (PREP Act), there is no judicial review of a final action concerning CICIP eligibility and benefits determination. See also 42 CFR §110.92(a).

Sincerely,

/s/

Cheryl R. Dammons
Associate Administrator

September 22, 2022

(b)(6)

Subject: Request for Reconsideration

Case Number: (b)(6)

Dear (b)(6)

This is in response to your request seeking reconsideration of your denied request for benefits under the Countermeasures Injury Compensation Program (CICP or “Program”).

In accordance with the regulations governing the CICP reconsideration process, a Panel of qualified individuals who are independent of the Program has reviewed your request. The Panel reviewed and discussed the documentation that was submitted to and evaluated by the Program when it made its determination.

In summary, the Panel determined that the (b)(6) COVID-19 vaccination likely

(b)(6)

(b)(6) However, the Panel further determined that (b)(6)

(b)(6)

as defined within 42 C.F.R. 110.3(z), as a result of receiving the (b)(6)

(b)(6)

COVID-19 vaccination. The Panel further noted that you remained (b)(6)

(b)(6)

In conclusion, the Panel determined that the information contained within your medical records did not demonstrate that a serious/permanent injury occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. §§ 110.3(z), 110.20(c).

For these reasons, I uphold the Program’s determination that you are not eligible for CICP benefits. This decision constitutes the final action by the Department of Health and Human Services on your request for reconsideration. The Department has no appeals process beyond this reconsideration. In addition, under the PREP Act, there is no judicial review of a final action concerning CICP eligibility and benefits determination.

Sincerely,

/s/

Cheryl R. Dammons
Associate Administrator

FINAL REPORT OF FINDINGS – (b)(6)

HRSA/HSB Countermeasures Injury Compensation Program (CICP) Reconsideration Panel

Date: August 24, 2022

To: Associate Administrator for Healthcare Systems

From: Chair, HRSA/HSB/CICP Reconsideration Panel

Subject: Request for Reconsideration Case Number (b)(6)

I am responding to the request submitted by (b)(6), seeking reconsideration of the denied request for benefits for (b)(6) under the Countermeasures Injury Compensation Program (CICP or “Program”). In (b)(6) request for benefits, signed (b)(6), (b)(6) reported that (b)(6) had (b)(6)

(b)(6)

The Program requested that the Requestor submit medical records dated within one year prior to the (b)(6); however, the records provided were limited to the (b)(6) associated with the Request for Benefits.

Under the Countermeasures Injury Compensation Program (CICP) Requestors must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 CFR 110.20(c). An injury sustained as the direct result of the covered condition or disease for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury. 42 CFR 120.20(d).

According to the submitted medical documentation, (b)(5)(PP), (b)(6)

(b)(5)(PP), (b)(6)

The medical records document that on (b)(5)(PP), (b)(6)

(b)(5)(PP), (b)(6)

(b)(5) (PP), (b)(6)



In a letter dated (b)(6) the CICP informe (b)(5)(PP), (b)(6)
(b)(5)(PP), (b)(6)



On July 8, 2022, I convened a meeting of the CICP Reconsideration Panel. This meeting was held at 1:00 PM Eastern Standard Time (EST). All parties participated via telephone.

Participants included: (b)(6), (b)(6), (b)(6), MD, (b)(6), MD, and (b)(6), MD. (b)(6)

U.S. Department of Health and Human Services (HHS) (b)(6) was also in attendance via telephone. The record had been assigned to all panel members, as well as (b)(6), for review prior to the panel meeting.

The Panel reviewed and discussed (b)(5)(PP), (b)(6)
(b)(5)(PP), (b)(6)

(b)(5) (PP), (b)(6)

In summary, the Panel determined that

(b)(5) (PP), (b)(6)

(b)(5) (PP), (b)(6)

In conclusion, the Panel determined that

(b)(5) (PP), (b)(6)

(b)(5) (PP), (b)(6)

For these reasons, the Panel recommends that

(b)(5)

(b)(5)

Sincerely,

(b)(6)

Chair, HRSA/HSB/CICP Reconsideration Panel

FINAL REPORT OF FINDINGS – (b)(6)

HRSA/HSB Countermeasures Injury Compensation Program (CICP) Reconsideration Panel

Date: September 12, 2022

To: Associate Administrator for Healthcare Systems

From: Chair, HRSA/HSB/CICP Reconsideration Panel

Subject: Request for Reconsideration Case Number (b)(6)

I am responding to the request submitted by (b)(6), seeking reconsideration of the denied request for benefits under the Countermeasures Injury Compensation Program (CICP or “Program”). In (b)(6) request for benefits, signed (b)(6), (b)(6) reported that (b)(6) had reason to believe that after receiving the (b)(6) used to treat COVID-19, (b)(6) experienced a (b)(6) (b)(6) after receiving the injection.

The Program requested that the Requester submit all medical records associated with the Claimant’s Request for Benefits. The Program received the medical records from (b)(6) (b)(6) dated (b)(6) and the Claimant’s COVID-19 vaccination card.

Under the Countermeasures Injury Compensation Program (CICP), to be eligible for CICP compensation, requesters must establish that a covered injury was sustained. 42 U.S.C. § 247d-6e(b)(4), (5)(A). A covered injury is a serious injury or death found to be directly caused by the administration or use of a covered countermeasure or determined to meet the requirements of a countermeasure injury table. 42 C.F.R. § 110.3(g).

According to 42 C.F.R. § 110.3(z), serious injury means serious physical injury. Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

Requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). An injury sustained as the

direct result of the covered condition or disease for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury. 42 C.F.R. § 110.20(d).

According to the submitted Request for Benefits, (b)(6) at the time of the occurrence, received a (b)(6) COVID-19 vaccine on (b)(6), at the (b)(6). Per (b)(6) description of the events that occurred on (b)(6), (b)(6)

(b)(6)

According to the submitted medical documentation from the (b)(6), (b)(6) arrived at the facility on (b)(6) at (b)(6) hours, after experiencing a (b)(6) (b)(6). Upon arrival, (b)(6)

(b)(6)

(b)(6) COVID-19 vaccination. Per the medical record, (b)(6)

(b)(6)

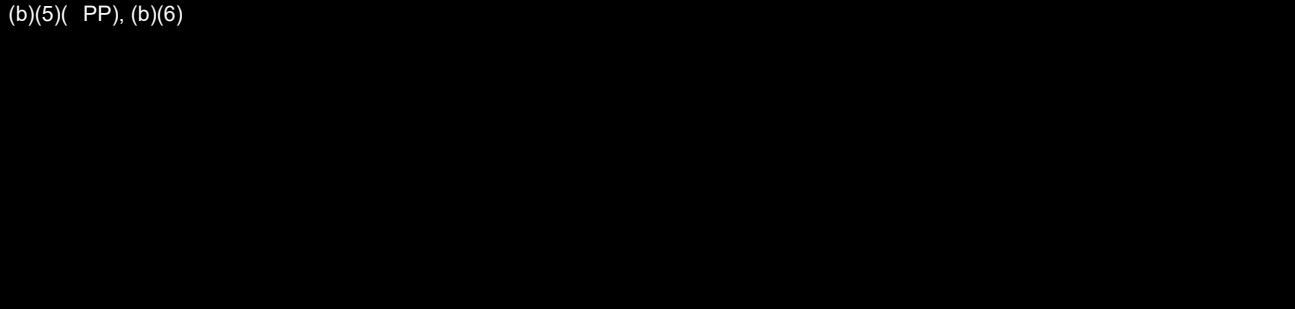
On (b)(6) at (b)(6) hours, (b)(6)

(b)(6)

On (b)(6) the CICP informed (b)(5)(PP), (b)(6)

(b)(5)(PP), (b)(6)

(b)(5)(PP), (b)(6)



On August 3, 2022, I convened a meeting of the CICP Reconsideration Panel. This meeting was held at 1:00 PM Eastern Standard Time (EST). All parties participated via telephone.

Participants included: (b)(6), (b)(6), (b)(6) MD, and (b)(6), (b)(6) U.S. Department of Health and Human Services (HHS) (b)(6) was also in attendance via telephone. The record had been assigned to all panel members, as well as (b)(6), for review prior to the panel meeting.

The Panel reviewed and discussed

(b)(5)(PP), (b)(6)



(b)(5)(PP), (b)(6)

In summary, the Panel determined that

(b)(5)(PP), (b)(6)



(b)(5)(PP), (b)(6)

In conclusion, the Panel determined that

(b)(5)(PP), (b)(6)



(b)(5)(PP), (b)(6)

For these reasons, the Panel recommends that (b)(5)

(b)(5)

Sincerely,

(b)(6)

Chair, HRSA/HSB/CICP Reconsideration Panel



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

July 28, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits (RFB) Package you submitted on behalf of (b)(6). The Program would like to offer our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). An injury sustained as the direct result of the covered condition or disease (e.g. COVID-19 viral infection) for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury (e.g., if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease). 42 CFR § 110.20(d). Therefore, if an injury or death was caused by a disease, and not as a direct result of the administration or use of a covered countermeasure, it cannot qualify as a covered injury.

On your RFB Form, you stated (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation. The submitted medical records indicate (b)(6)

(b)(6)

(b)(6)

(b)(6)



Based on the medical records and the compelling, reliable, valid, medical and scientific evidence, (b)(6)

(b)(6)



(b)(6) death was caused by the (b)(6)

(b)(6), the CICIP has determined that you are not eligible for Program Benefits.

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICIP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICIP when this determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then

review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

7/28/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

May 4, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of your (b)(6). The Program would like to express our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. §110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On the Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable, valid, medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation. The submitted records state that (b)(6)

(b)(6)

(b)(6) the CICP has determined you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any

documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/4/2022

Date

August 31, 2022

(b)(6)

Subject: Request for Reconsideration

Case Number: (b)(6)

Dear (b)(6)

This is in response to your request dated (b)(6), seeking reconsideration of your denied request for benefits under the Countermeasures Injury Compensation Program (CICP or “Program”).

In accordance with the regulations governing the CICP reconsideration process, a Panel of qualified individuals who are independent of the Program has reviewed your request. The Panel reviewed and discussed the documentation that was submitted to and evaluated by the Program when it made its determination.

In summary, the Panel determined that there was no evidence to support an association between (b)(6) death and (b)(6). The Panel

determined that (b)(6)

(b)(6)

(b)(6)

The Panel agreed that (b)(6)

(b)(6)

(b)(6)

(b)(6)

The Panel further noted the (b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

In conclusion, the Panel determined that the information contained within (b)(6) medical records did not meet demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. See 42 CFR 110.20(c). An injury sustained as the direct result of the covered condition or disease for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury. 42 CFR 120.20(d).

For these reasons, I uphold the Program's determination that you are not eligible for CICIP benefits. This decision constitutes the final action by the Department of Health and Human Services on your request for reconsideration. The Department has no appeals process beyond this reconsideration. In addition, under the Public Readiness and Emergency Preparedness Act (PREP Act), there is no judicial review of a final action concerning CICIP eligibility and benefits determination. See also 42 CFR §110.92(a).

Sincerely,

/s/

Cheryl R. Dammons
Associate Administrator



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

May 5, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted as a survivor of (b)(6). The Program would like to express our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that the (b)(6)

(b)(6)

(b)(6)

(b)(6)

the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/5/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

Rockville, Maryland 20857
Health Systems Bureau

May 31, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted as a survivor of your (b)(6). The Program would like to express our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that (b)(6)

(b)(6)

The compelling, reliable, and valid medical and scientific evidence does not support an association between (b)(6)

(b)(6)

(b)(6)

CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

5/31/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

July 8, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of your (b)(6). The Program would like to express our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries. This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition.

On your Request for Benefits Form, you (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable, valid, medical and scientific evidence, the Program has determined that (b)(6)

(b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program Benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. See 42 CFR § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

7/8/2022

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Countermeasures Injury Compensation Program

**Rockville, Maryland 20857
Health Systems Bureau**

September 29, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted concerning your (b)(6). The Program would like to offer our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP’s regulations define “serious injury” as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

On your Request for Benefits Form, you (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program has determined that you have not met the requirements for eligibility for compensation.

The submitted medical records indicate that (b)(6)
(b)(6)

CICP Decision (b)(6)

(b)(6)

(b)(6)

the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when this determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

9/29/2022

Date



December 15, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted regarding (b)(6). The Program would like to offer our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury, or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

An injury sustained as the direct result of the covered condition or disease (COVID-19 viral infection) for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury (*e.g.*, if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease). 42 C.F.R. § 110.20(d). Therefore, if an injury or death was caused by a disease, and not as a direct result of the administration or use of a covered countermeasure, it cannot qualify as a covered injury.

On your Request for Benefits Form, you stated that: (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program has determined that the requirements for eligibility for compensation have not been met.

(b)(6)

Decision Letter (b)(6)

(b)(6)

(b)(6)

The submitted medical records indicate that (b)(6)

(b)(6)

You have a right to request reconsideration of this decision disapproving the Request for Benefits. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, the reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

12/15/2022

Date



October 17, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of (b)(6). The Program would like to offer our condolences for the family's loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury, or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries. This includes an injury, or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition.

An injury sustained as the direct result of the covered condition or disease (COVID-19 viral infection) for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury (*e.g.*, if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease). 42 C.F.R. § 110.20(d). Therefore, if an injury was caused by a disease, and not as a direct result of the administration or use of a covered countermeasure, it cannot qualify as a covered injury.

On your Request for Benefits Form, you stated (b)(6)
(b)(6)

CICP Decision Letter (b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program has determined that you have not met the requirements for eligibility for compensation.

The submitted medical records indicate that

(b)(6)

(b)(6)

(b)(6)

The submitted medical records indicate that

(b)(6)

(b)(6)

(b)(6)

the CICP has

determined that you are not eligible for Program Benefits.

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

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(b)(6)

review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

10/17/2022

Date



December 13, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted regarding (b)(6). The Program would like to offer our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury, or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

An injury sustained as the direct result of the covered condition or disease (COVID-19 viral infection) for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury (*e.g.*, if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease). 42 C.F.R. § 110.20(d). Therefore, if an injury was caused by a disease, and not as a direct result of the administration or use of a covered countermeasure, it cannot qualify as a covered injury.

On your Request for Benefits Form, you stated that: (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program has determined that the requirements for eligibility for compensation have not been met.

The submitted medical records indicate that (b)(6)
(b)(6)

(b)(6)

(b)(6)

You have a right to request reconsideration of this decision disapproving the Request for Benefits. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, the reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when this determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to the requester (or representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

12/13/2022

Date



December 5, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of (b)(6). The Program would like to offer our condolences for your family's loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury, or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

An injury sustained as the direct result of the covered condition or disease (COVID-19 viral infection) for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury (*e.g.*, if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease). 42 C.F.R. § 110.20(d). Therefore, if an injury was caused by a disease, and not as a direct result of the administration or use of a covered countermeasure, it cannot qualify as a covered injury.

On your Request for Benefits Form, you stated that (b)(6) countermeasure recipient (b)(6). The types of countermeasures you indicated on the form were (b)(6).

Decision Letter (b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that you have met the requirements for eligibility for compensation.

The submitted medical records indicate that (b)(6)

(b)(6)

(b)(6)

The submitted medical records indicate that (b)(6)

(b)(6)

(b)(6) the CICP is disapproving the Request for Benefits.

You have a right to request reconsideration of this decision that you are not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, the reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when this determination was made. The panel will perform its own review and make its own findings,

Decision Letter (b)(6)

which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

12/5/2022

Date



November 28, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of (b)(6). (b)(6) The Program would like to offer our condolences for the family's loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury, or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

An injury sustained as the direct result of the covered condition or disease (COVID-19 viral infection) for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury (*e.g.*, if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease). 42 C.F.R. § 110.20(d). Therefore, if an injury or death was caused by a disease, and not as a direct result of the administration or use of a covered countermeasure, it cannot qualify as a covered injury.

On the Request for Benefits Form, you stated that: (b)(6)
(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that the requirements for eligibility for compensation have been met.

Decision Letter (b)(6)

The submitted medical records indicate that (b)(6)

(b)(6)

(b)(6)

The submitted medical records indicate (b)(6)

(b)(6)

the CICIP is disapproving the Request for Benefits.

You have a right to request reconsideration of this decision that the requester is not eligible for compensation. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, the reconsideration request may not include or refer to any documentation that was not before the CICIP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICIP when this determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then

Decision Letter (b)(6)

review the panel's recommendation(s) and make a final determination, which will be sent to you (or representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

11/28/2022

Date

June 10, 2021

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted as the survivor of (b)(6). The Program wishes to express our sincere condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 CFR § 110.20(c). An injury sustained as the direct result of the covered condition or disease (e.g. COVID-19) for which the countermeasure was administered or used, is not a covered injury. 42 CFR § 110.20(d). Therefore, if an injury was caused by a disease, and not as a direct result of the administration or use of a covered countermeasure, it cannot qualify as a covered injury.

On your Request for Benefits Form, you alleged that (b)(6)

(b)(6)

(b)(6)

(b)(6) the CICP has determined that you are not eligible for Program benefits.

You have a right to request reconsideration of the CICP's decision that you are not eligible for compensation. *See* 42 CFR § 110.90. Requests for reconsideration must be in writing, describe

the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, your reconsideration request may not include or refer to any documentation that was not before the CICP at the time of its determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator, Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel independent of the Program will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

Tamara Overby
Acting Director, Division of Injury Compensation Programs

June 10, 2021

Date



October 19, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of (b)(6)

(b)(6) The Program would like to offer our condolences for the family's loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury, or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries. An injury sustained as the direct result of the covered condition or disease (COVID-19 viral infection) for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury (*e.g.*, if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease). 42 C.F.R. § 110.20(d). Therefore, if an injury was caused by a disease, and not as a direct result of the administration or use of a covered countermeasure, it cannot qualify as a covered injury.

On the Request for Benefits Form, it states that (b)(6)

(b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable and valid medical and scientific evidence, the Program did not find the requisite evidence that the requirements for eligibility for compensation have been met.

The submitted medical records indicate that (b)(6)

(b)(6)

(b)(6)

The submitted medical records indicate that (b)(6)

(b)(6)

(b)(6)

the CICP is disapproving the Request for Benefits.

The requester has a right to request reconsideration of this decision disapproving the Request for Benefits. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, the reconsideration request may not include or refer to any documentation that was not before the CICP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICP when this determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then

review the panel's recommendation(s) and make a final determination, which will be sent to the requester (or representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

10/19/2022

Date



November 28, 2022

(b)(6)

Case Number: (b)(6)

Dear (b)(6)

The Countermeasures Injury Compensation Program (CICP or the Program) has reviewed the Request for Benefits Package you submitted on behalf of (b)(6). The Program would like to express our condolences for your loss.

To be eligible for compensation under the CICP, requesters must demonstrate that a serious injury or death occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. 42 C.F.R. § 110.20(c). This includes an injury, or its health complications and serious aggravation caused by a covered countermeasure of a pre-existing condition. The CICP's regulations define "serious injury" as a serious physical injury. 42 C.F.R. § 110.3(z). Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

An injury sustained as the direct result of the covered condition or disease (COVID-19 viral infection) for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury (*e.g.*, if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease). 42 C.F.R. § 110.20(d). Therefore, if an injury was caused by a disease, and not as a direct result of the administration or use of a covered countermeasure, it cannot qualify as a covered injury.

On your Request for Benefits Form, it states (b)(6)

(b)(6)

Based on a review of the submitted medical records and compelling, reliable, valid, medical and scientific evidence, the Program did not find the requisite evidence that the requirements for eligibility for compensation have been met.

(b)(6)

(b)(6)

The submitted medical records indicate that (b)(6)

(b)(6)

(b)(6)

the CICIP is disapproving the Request for Benefits.

You have a right to request reconsideration of this decision disapproving the Request for Benefits. See 42 C.F.R. § 110.90. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of this decision letter. Because no new documentation will be considered in the reconsideration process, the reconsideration request may not include or refer to any documentation that was not before the CICIP at the time of this determination. The letter seeking reconsideration may be sent through the U.S. Postal Service, commercial carrier or private courier service (but not by hand, electronic mail, or facsimile) to:

Associate Administrator
Health Systems Bureau, Health Resources and Services Administration
5600 Fishers Lane, 8W-37
Rockville, MD 20857

When the Associate Administrator receives a request for reconsideration, a qualified panel, independent of the Program, will meet to review the Program's decision. The reconsideration panel will base its recommendation on the documentation before the CICIP when this determination was made. The panel will perform its own review and make its own findings,

Decision Letter (b)(6)

which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to you (or your representative, if applicable).

/s/

CDR George Reed Grimes, M.D., M.P.H.
Director, Division of Injury Compensation Programs

11/28/2022

Date