
FEHB Program Carrier Letter

All FEHB Carriers

U.S. Office of Personnel Management
Healthcare and Insurance

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SUBJECT: Update on Coverage for FDA Approved Drugs, Devices and Biological Products

This letter supersedes guidance published in Carrier Letter No. 2001-27 on coverage of U.S. Food and Drug Administration (FDA) approved drugs, devices and biological products. In Section 6 of all FEHB brochures, carriers are required to exclude “experimental or investigational procedures, treatments, drugs or devices” from coverage. This updated guidance clarifies FDA approval pathways and the extent to which FEHB carriers are expected to defer to FDA processes.

In every case, deference to FDA approval is dependent upon the drug, device or biological product being used for its intended purposes and labeled indications.¹ As with all other covered benefits, the treatment or services must be medically necessary and appropriate for the member’s condition. The determination of medical necessity is within each plan’s medical policy/procedure guidelines.

For several categories described in this letter, FEHB carriers should consider the FDA’s determination, along with other available information, before making an independent decision as to whether a device or biological is considered experimental or investigational for their health insurance plan. For these categories, carriers should review relevant medical evidence and consider, if applicable, Medicare coverage decisions and state mandates, to make their own determinations.

FDA Approved Drugs²

CDER New Drug Application. Under the Federal Food, Drug and Cosmetic Act, a drug is considered investigational until the FDA Center for Drug Evaluation and Research (CDER) evaluates the new drug application (NDA) and finds that the sponsor has provided “substantial evidence” that the drug was proven safe and effective for its intended use. Once such a finding is made, FDA approves the drug for marketing and no longer considers it investigational. We expect all FEHB carriers to accept this FDA approval and not deny benefits based upon a separate determination for their plan that the drug is experimental or investigational.

¹ OPM takes no position on off-label use of drugs, devices or biological products.

² <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm>

FDA Approved Devices³

FDA classifies medical devices as Class I, II and III, where Class I includes devices with the lowest risk and Class III includes those with the greatest risk. The class to which a device is assigned determines the type of review FDA requires:

- Class I: usually exempt from any review prior to being marketed; reliant on general controls such as registration, listing and good manufacturing practices to assure safety and effectiveness
- Class II: typically require FDA clearance through premarket notification submission (called a 510(k))
- Class III: require full Premarket Approval

Details of these approval pathways are described below, with a summary chart at the end of this letter. Some types of laboratory diagnostic testing, including gene expression profiling, are submitted for approval through the FDA medical device program. The Premarket Approval process and the 510(k) process are also used for some devices regulated by the FDA Center for Biologics Evaluation and Research and carriers should follow the same processes for them.

- The Premarket Approval (PMA) for devices is similar to the pathway for new drug approval and typically requires clinical trials. Approval is based on FDA determination that the application contains sufficient scientific evidence to assure that the device is safe and effective for its intended use(s). If a device has gone through the PMA, FEHB carriers may not deny coverage on the basis that it is investigational.
- “Category B” Non-experimental/investigational devices. This category includes items that are considered safe and effective because, for example, other manufacturers obtained FDA approval for that type. They represent a new generation of a previously approved device or one similar to what another manufacturer already offers. Studies are intended to establish evidence related to the specific device or to assess incremental risk. Carriers should consider the FDA’s determination, along with other available information, but may make an independent determination whether such devices are experimental or investigational.
- In the 510(k) or Premarket Notification (PMN), FDA clears new medical devices that are determined "substantially equivalent" to a previously marketed one. This clearance level rarely requires clinical trials. The vast majority of new medical devices enter the marketplace via this pathway. Carriers should consider the FDA decision, along with other available information, but may make an independent determination whether such devices are experimental or investigational.
- Humanitarian Device Exemption (HDE).⁴ Under provisions of the Safe Medical Devices Act of 1990, a Humanitarian Use Device is intended to diagnose or treat a condition that affects fewer than 4,000 individuals in the United States per year. While HDEs are similar to the premarket approval process, they are exempt from the effectiveness requirements. Scientifically valid clinical investigations demonstrating that the devices are effective for their intended purpose are not required. However, FDA must receive sufficient information to determine that the probable

³ <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/>

⁴ <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals>

benefit to health outweighs the risk of injury or illnesses, taking into account the risks and benefits of alternative devices or treatments. Carriers should consider the FDA decision, along with other available information, but may make an independent determination whether such a device is experimental or investigational.

FDA Approved Biological Products⁵

The FDA Center for Biologics Evaluation and Research (CBER) regulates biologicals, such as blood component derivatives, immunoglobulins, and vaccines. Devices associated with blood donor testing are also regulated as biological products. There are several FDA application routes for this category described below and in the chart at the end of this letter:

- CBER oversees a New Drug Application process for biological products. This process ensures the drug/biological is safe and effective in its proposed use(s), the benefits outweigh the risks, the proposed labeling is appropriate, and the manufacturing methods include quality controls. As with FDA approved drugs, we expect all FEHB carriers to accept FDA approval and not deny benefits on the basis that the drug is experimental or investigational.
- The Biologics License Application (BLA) is a request to introduce a biologic product. The process requires manufacturing information, pre-clinical studies, clinical studies, and labeling information. We expect all FEHB carriers to accept FDA decisions when the agency has approved an application and issued a license for the product.
- Biosimilars. In accordance with the Biologics Price Competition and Innovation Act of 2009, the FDA released draft guidelines in 2012 addressing biosimilars or follow-on biological product development. Since policies are still evolving for this category, carriers must consider any relevant FDA documentation, but should review all available information and make an independent determination whether such products are experimental or investigational.

Special Circumstances Regarding Drugs, Devices and Biological Products

- FDA Fast Track. FDA makes determinations regarding drugs, devices and biological products intended to treat serious or life-threatening conditions that were approved through the Accelerated Approval, Breakthrough Therapy, and Fast Track processes. Such approvals signify that, based on assessment of preliminary studies, the product provides meaningful therapeutic benefits to individuals over existing treatments. FDA may approve products subject to a requirement that the sponsor conduct further clinical trials post-approval to confirm the effect on clinical outcomes. Carriers must accept these FDA determinations and may not use such post-marketing approval trials as justification to deny benefits on the basis that the items are experimental or investigational.
- Emergency Use. FDA has protocols to authorize use of an experimental drug or biologic product in an emergency situation. A similar process is available for individuals who do not meet criteria

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of an existing study protocol; when an approved study protocol does not exist; or to gain access to experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while final clinical evaluation and the FDA review are conducted. Each Emergency Use decision is unique to the facts of a specific case. FDA authorization to use such a drug or product in extreme circumstances is not a determination that the drug/product is no longer experimental. In these cases, carriers should carefully consider all available information when determining coverage.

Other Pathways to Market

OPM recognizes that companies commonly market laboratory diagnostic tests through pathways other than those available through the FDA. One example of another pathway is used by the Centers for Medicare & Medicaid Services (CMS). CMS regulates laboratories that perform testing on patient specimens in order to ensure accurate and reliable test results and approves Clinical Laboratory Improvement Amendments (CLIA) certificates. The CLIA program regulates the laboratories, while the FDA ensures that devices are safe and effective for market use. A product may be marketed with only a CLIA certificate and without FDA approval. When a test is marketed under a CLIA certificate or any other non-FDA pathway, we rely on carriers to consider carefully all relevant information before making coverage determinations.

Summary Chart: FDA Approval Pathways

Name/Classification	Product Type	Decision Authority
CDER New Drug Application	Drugs	Defer to FDA
Premarket Approval	Devices	Defer to FDA
Category B/Non-Experimental/Investigational	Devices	Carrier determination
Premarket Notification – 510(k)	Devices	Carrier determination
Humanitarian Exemption	Devices	Carrier determination
CBER New Drug Application	Biologicals	Defer to FDA
CBER Biologics License Applications	Biologicals	Defer to FDA
Biosimilars	Biologicals	Carrier determination
Fast Track	Drugs, Devices & Biologicals	Defer to FDA

Please direct any questions regarding this letter to your contract specialist.

Sincerely,

John O’Brien
 Director for Healthcare and Insurance