



**OCT 26 2018**

Dear Ryan White HIV/AIDS Program (RWHAP) Part B AIDS Drug Assistance Program (ADAP) Colleagues,

On March 6, 2018, the U.S. Food and Drug Administration (FDA) approved Trogarzo (ibalizumab-uiyk) from TaiMed Biologics USA Corp. The FDA describes Trogarzo as a new type of antiretroviral medication (a CD4 post-attachment HIV-1 inhibitor) for heavily treatment-experienced adult patients living with HIV with multidrug resistant HIV-1 infection failing their current antiretroviral regimen. Trogarzo is administered intravenously once every 14 days by a trained medical professional and is used in combination with other antiretroviral medications.

The U.S. Department of Health and Human Services' Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV have been updated to include this new class of antiretroviral medications, CD4 Post-Attachment Inhibitors. ADAPs are required by the RWHAP statute to include at least one drug from each class of antiretroviral medications (section 2616(c)(1) of the Public Health Service Act). Since this is the first drug in a new class of antiretroviral medications, ADAPs are required to add Trogarzo to their formularies. To ensure equity, each State/Territory should determine whether specific criteria are needed for ADAP clients to access this or other medications on their formulary (e.g., prior authorization, drug-specific enrollment cap due to cost). Please refer to the ADAP Manual for more information on HRSA HAB's requirements regarding ADAP formularies and the availability of medications.

If you have any questions regarding this requirement, please contact Glenn Clark, ADAP Advisor, HIV/AIDS Bureau, Health Resources and Services Administration, at [GLClark@HRSA.gov](mailto:GLClark@HRSA.gov).

Sincerely,

/Laura W. Cheever/  
Laura W. Cheever, MD, ScM  
Associate Administrator  
HIV/AIDS Bureau  
Health Resources and Services Administration