



April 3, 2023

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

On December 22, 2022, the U.S. Food and Drug Administration (FDA) approved the antiretroviral medication Sunlenca (lenacapavir) from Gilead Sciences. The FDA describes Sunlenca as a new type of antiretroviral medication for adult patients with human immunodeficiency virus type 1 (HIV-1), whose HIV infections cannot be successfully treated with other available treatments due to resistance, intolerance, or safety considerations. After the starting dose is completed, Sunlenca is administered as subcutaneous (under the skin) injections once every six months, allowing convenient dosing for patients. Sunlenca is given in combination with other antiretroviral(s).

The [U.S. Department of Health and Human Services' Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV](#) have been updated to include this new class of antiretroviral medications, capsid 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 Sunlenca 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 its formulary (e.g., prior authorization, drug-specific enrollment cap due to cost). Please refer to the [ADAP Manual](#) for more information on the Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau's (HAB) requirements regarding ADAP formularies and the availability of medications.

If you have any questions regarding this requirement, please contact Glenn Clark, ADAP Advisor, HAB, HRSA, at [GLClark@HRSA.gov](mailto:GLClark@HRSA.gov).

Sincerely,

/Laura W. Cheever/

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