Edurant (rilpivirine)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Edurant (rilpivirine)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Edurant (rilpivirine) may be approved if the following criteria are met:

I. Individual is using to treat human immunodeficiency virus (HIV) infection; **AND**
II. Individual is using in combination with other antiretroviral agents;

AND

III. Individual has no antiretroviral treatment history; **AND**
IV. Individual has a HIV RNA of less than or equal to 100,000 copies/mL; **AND**
V. Individual has a CD4 cell count greater than or equal to 200 cells/mm^3 (DHHS);

OR

VI. Individual is antiretroviral treatment-experienced and virologically suppressed (HIV RNA less than 50 copies/mL) on their current regimen (NCT02429791, NCT02422797);

OR

VII. Individual is using for postexposure prophylaxis of HIV infection following exposure to blood, tissues or other body fluids associated with a risk for transmission of the HIV virus (AHFS, CDC, USPHS).

Key References:

1. Centers for Disease Control and Prevention. Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV – United States, 2016. Available at: https://stacks.cdc.gov/view/cdc/38856. Accessed: October 10, 2019.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 9, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Fletcher CV. Overview of antiretroviral agents used to treat HIV. Last updated: October 7, 2018. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: September 29, 2019.
5. Kuhar DT, Henderson DK, Struble KA, et al. Updated US Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis. *Infect Control Hosp Epidemiol*. 2013; 34:875-92.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
7. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Last Updated: July 10, 2019. Available at https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/0 Accessed: September 29, 2019.
8. ViiV Healthcare. Regimen Switch to Dolutegravir + Rilpivirine From Current Antiretroviral Regimen in Human Immunodeficiency Virus Type 1 Infected and Virologically Suppressed Adults (SWORD-1). NLM Identifier: NCT 02429791. Last updated: July 30, 2019. Available at: https://clinicaltrials.gov/ct2/show/NCT02429791?term=02429791&rank=1. Accessed: October 10, 2019.
9. Viiv Healthcare. Regimen Switch to Dolutegravir + Rilpivirine From Current Antiretroviral Regimen in Human Immunodeficiency Virus Type 1 Infected and Virologically Suppressed Adults (SWORD-2). NLM Identifier: NCT 02422797. Last updated: August 6, 2019. Available at: https://clinicaltrials.gov/ct2/show/NCT02422797?term=02422797&rank=1. Accessed: October 10, 2019.