

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	NA	X	X	X	X	NA	NA

Dovato (dolutegravir/lamivudine)

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

Medications	Quantity Limit
Dovato (dolutegravir/lamivudine)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Dovato (dolutegravir/lamivudine) may be approved if the following criteria are met:

- I. Individual is using to treat human immunodeficiency virus (HIV) infection; **AND**
- II. Individual has no antiretroviral treatment history; **AND**
- III. Documentation has been provided for why the combination agent is clinically necessary and not for convenience.

Requests for Dovato (dolutegravir/lamivudine) may not be approved for the following:

- I. Individual with a creatinine clearance less than 50 mL/min; **OR**
- II. Individual with severe hepatic impairment (Child-Pugh Class C); **OR**
- III. Individual has hepatitis B co-infection and is not using additional treatment for hepatitis B.

Note:

Dovato has a black box warning for the emergence of lamivudine-resistant hepatitis B virus (HBV). All individuals should be tested for HBV prior to initiating Dovato. Emergence of lamivudine-resistant HBV associated with lamivudine-containing antiretroviral regimens has been reported. If Dovato is used in individuals co-infected with HIV and HBV, additional treatment should be considered for appropriate treatment of chronic HBV.

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	NA	X	X	X	X	NA	NA

Key References:

- 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.
- 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.
- DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 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.
- 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.
- Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
- 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.
- 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.
- 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.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.