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

Rukobia (fostemsavir)

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

Medications	Quantity Limit
Rukobia (fostemsavir)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Rukobia (fostemsavir) 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 is heavily antiretroviral treatment-experienced with resistance, intolerability or contraindication to at least one antiretroviral in three different classes (NCT 02362503); **AND**
IV. Individual is failing their current antiretroviral regimen with a viral load greater than or equal to 400 copies/mL.

Key References:

1. 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.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Viiv Healthcare. Attachment Inhibitor Comparison in Heavily Treatment Experienced Patients. NLM Identifier: NCT 02362503. Last updated: February 17, 2020. Available at: https://www.clinicaltrials.gov/ct2/show/NCT02362503?term=02362503&draw=2&rank=1. Accessed: July 13, 2020.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.

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

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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.