MEDICAL MUTUAL®

Drug Policy

Policy:	Vocabria (cabotegravir)	Annual Review Date: 03/18/2021 Last Revised Date: 06/17/2021

OVERVIEW

Vocabria, a human immunodeficiency virus type-1 (HIV-1) integrase strand-transfer inhibitor, is indicated in combination with Edurant® (rilpivirine tablets) for the short-term treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine. Vocabria can be used as an oral lead-in to assess to tolerability to cabotegravir prior to administration of Cabenuva or as an oral therapy for patients who will miss planned injection dosing with Cabenuva.

POLICY STATEMENT

This policy involves the use of Vocabria. Prior authorization is recommended for pharmacy benefit coverage of Vocabria. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vocabria is recommended in those who meet the following criteria:

1. **Human Immunodeficiency Virus (HIV), Oral Lead-In to Assess the Tolerability of cabotegravir.** Approve for 1 month if the patient meets the following criteria (A, B, C, D, E, F, and G):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has HIV type-1 (HIV-1) infection; AND
   - **C)** Patient has HIV-1 RNA < 50 copies/mL (viral suppression) **[documentation required]**; AND
   - **D)** Patient is currently receiving antiretrovirals for the treatment of HIV-1 with a stable regimen (≥ 4 months) **[documentation required]**; AND
   - **E)** The medication will be prescribed in combination with Edurant (rilpivirine tablets); AND
   - **F)** According to the prescriber, the patient meets ONE of the following (i or ii):
     - **i.** Patient has difficult maintaining compliance with a daily antiretroviral regimen for HIV-1; OR

ii. Patient has severe gastrointestinal issues that may limit absorption or tolerance of oral medications; AND

G) If tolerated, Cabenuva (cabotegravir extended-release injectable suspension; rilpivirine extended-release injectable suspension, co-packaged) will be started upon completion of approximately 1 month of therapy with Vocabria + Edurant; AND

H) The medication is prescribed by or in consultation with a physician who specializes in the treatment of HIV infection.

2. **Human Immunodeficiency Virus (HIV), Oral Therapy for Planned Missed Doses of Cabenuva.** Approve for up to 2 months if the patient meets the following criteria (A, B, C, D, E, F, and G):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has HIV type 1 (HIV-1) infection; AND
   - **C)** Patient has HIV-1 RNA < 50 copies/mL (viral suppression) **[documentation required]**; AND
   - **D)** Patient has received ≥ 1 maintenance dose of Cabenuva (400 mg/600 mg); AND
   - **E)** Patient plans to miss up to two scheduled doses of Cabenuva by > 7 days, according to the prescriber; AND
   - **F)** The medication will be prescribed in combination with Edurant (rilpivirine tablets); AND
   - **G)** The medication is prescribed by or in consultation with a physician who specializes in the treatment of HIV infection.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Vocabria is not recommended in the following situations:

1. **Pre-exposure Prophylaxis (PrEP).** Vocabria is not currently indicated for the prevention of human immunodeficiency virus (HIV) in patients who are uninfected, but at risk of acquisition of HIV. Data from two unpublished trials have demonstrated the superiority of cabotegravir extended-release injectable suspension to Truvada® (tenofovir disoproxil fumarate/emtricitabine tablets, generics) in cisgender men and transgender men who have sex with men as well as in cisgender women.[5] IAS-USA guidelines recommend cabotegravir extended-release injectable suspension in cisgender men and transgender women who have sex with men; every 8 week maintenance dosing is recommended and oral lead-in with Vocabria is optional.[4] The other recommended regimens for PrEP are daily Truvada (all at-risk populations) or Descovy® (tenofovir alafenamide/emtricitabine tablets) [MSM with/at risk for kidney dysfunction, osteopenia, or osteoporosis]. Truvada and Descovy are FDA-approved for PrEP; neither Vocabria nor Cabenuva are FDA-approved for PrEP.

2. **Human Immunodeficiency Virus, Antiretroviral Treatment-Naïve Patients.** Vocabria is indicated in combination with Edurant (rilpivirine tablets) for the short-term treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.[1] In two

pivotal trials, patients were either previously treated for 4 months (20 weeks) with Triumeq® (abacavir/dolutegravir/lamivudine tablets) or were on a stable antiretroviral regimen for ≥ 6 months.[2,3]

3. **Duration of Use for > 2 Consecutive Months.** The recommended duration of Vocabria therapy is 1 month for oral lead-in.[1] Vocabria is also indicated as a daily regimen to replace up to two planned missed injections of Cabenuva (administered once monthly) for up to two consecutive months.

4. **Co-administration with Antiretrovirals for Human Immunodeficiency Virus other than Edurant.** Because Vocabria in combination with Edurant (rilpivirine tablets) is a complete regimen, co-administration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended.[1]

5. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Vocabria has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Vocabria® tablets [prescribing information]. Research Triangle Park, NJ: ViiV Healthcare/GlaxoSmithKline; January 2021.
2. Orkin C, Arasteh K, Hernandez-Mora G, et al. Long-acting cabotegravir and rilpivirine after oral induction for HIV-1 infection. *N Engl J Med.* 2020;382:1124-1135.

3. Swindells S, Andrade-Villaneuva JF, Richmond GJ, et al. Long-acting cabotegravir and rilpivirine for maintenance of HIV-1 suppression. *N Engl J Med*. 2020; 382;12:1112-1123.
4. Saag MS, Gandhi RT, Hoy JF, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults. 2020 recommendations of the International Antiviral Society-USA Panel. *JAMA*. 2020;324(16):1651-1669.
5. 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. Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Updated December 18, 2019. Accessed January 27, 2021.
6. Personal communication. ViiV Healthcare. January 28, 2021