HIV-1 Co-Receptor Tropism Assay
Clinical Coverage Criteria

Overview

Selzentry (miraviroc) is a CCR5 co-receptor antagonist indicated in combination with other antiretroviral agents for the treatment of only CCR5-tropic HIV-1 infection. Prior to initiation of miraviroc for treatment of HIV-1 infection, patients must be testing for CCR5 tropism using a tropism assay. HIV tropism testing is available by either phenotypic or genotypic methods. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescent Living with HIV recommend the use of a phenotypic tropism assay to determine HIV-1 co-receptor usage. A genotypic tropism assay can be considered as an alternative (HHS, p. C22-C25). Trofile™ (Monogram Biosciences, South San Francisco, CA) is a phenotypic assay.

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial
☒ Medicare Advantage
☒ MassHealth ACO
☒ NaviCare
☒ PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare has an NCD for Human Immunodeficiency Virus (HIV) Testing (Prognosis Including Monitoring) (190.13). National Government Services, Inc. does not have an LCD or LCA for HIV-1 Co-Receptor Tropism Assay (MCD search 06-23-2021).

For plan members enrolled in NaviCare and PACE plans, Fallon Health follows guidance from CMS for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health will follow guidance published by MassHealth. When there is no Medicare or MassHealth guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Each PACE plan member is assigned to an Interdisciplinary Team. When there is no Medicare or MassHealth guidance, the member's Interdisciplinary Team is responsible for coverage determinations.

Prior authorization is required. CCR5 tropism testing is considered medically necessary for individuals with HIV-1 infection considering treatment with a CCR5 inhibitor.

Fallon Health utilizes InterQual® Clinical Criteria for this policy as of 11/01/2014.

Exclusions

- Any use of HIV-1 co-receptor tropism testing not described above.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Code	Description
87901	HIV-1, reverse transcriptase and protease regions
87906	HIV-1, other region (eg, integrase, fusion)
87999	Unlisted microbiology procedure

References

1. Selzentry™ (ViiV Healthcare, Research Triangle Park, NC) Full Prescribing Information. Issued 2007. Revised 10/2020. Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.
2. Department of Health and Human Services. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Last updated June 3, 2021. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf. Accessed June 24, 2021.

Policy history

Origination date: 11/01/2014

Approval(s): Technology Assessment Committee: 06/25/2014 (adopted Interqual criteria), 01/28/2015 (annual review), 01/27/2016 (annual review), 01/25/2017 (annual review), 01/24/2018 (annual review), 01/23/2019 (annual review)

06/25/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section.