SmartPA Criteria Proposal

Drug/Drug Class:	Selzentry Clinical Edit
First Implementation Date:	April 7, 2010
Proposed Date:	December 15, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Selzentry® (maraviroc)

Why Issue Selected: Selzentry® (maraviroc) is a CCR5 (C-C chemokine receptor type 5) co-receptor antagonist indicated for the treatment of only CCR5-tropic HIV-1 infection with other antiretroviral agents. In 2020, Selzentry received FDA approval to expand its indication to include treatment of full-term infants weighing ≥ 2 kg. Selzentry works by selectively binding to the human chemokine receptor CCR5 present on the cell membrane and preventing the interaction of HIV-1 gp 120 and CCR5; this interaction is necessary for CCR5-tropic HIV-1 to enter cells. Selzentry is not recommended in patients with CXCR4-tropic or dual/mixed HIV-1 as it is ineffective in these cases. The Trofile® test is used to determine if a patient's virus is suitable for a CCR5 co-receptor antagonist therapy; the results of the Trofile test will determine if Selzentry is an appropriate treatment choice for the patient. Also, as compared to treatment with Sustiva® (efavirenz), treatment-naïve adults treated with Selzentry experienced more virologic failure and lamivudine resistance; therefore, Selzentry is not recommended for use in treatment-naïve patients. Due to the specific approved indication, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Selzentry.

Program-Specific Information:

Date Range FFS 10-01-2021 to 9-30-2022			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
SELZENTRY 25 MG TABLET	0	-	-
SELZENTRY 75 MG TABLET	0	-	-
SELZENTRY 150 MG TABLET	13	$12,556.49	$965.88
SELZENTRY 300 MG TABLET	37	$41,844.07	$1,130.92
SELZENTRY 20 MG/ML SOLN	0	-	-

Type of Criteria:
☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **Clinical Edit**

Data Sources:
☐ **Only Administrative Databases**
☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Selzentry® (maraviroc)
- Age range: All appropriate MO HealthNet participants ~~aged 2 years and older~~

Approval Criteria

- ~~Participant is aged ≥ 2 years AND~~
- Participant is HIV infected **AND**
- Participant has history of positive viral tropism for CCR5-tropic HIV **AND**
- Participant is not treatment naïve (participant has been on antiretroviral medication before) **AND**
- Participant is currently on additional antiretroviral medication besides Selzentry (maraviroc)

Denial Criteria

- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:	X	Progress Notes:	X
MedWatch Form:		Other:	

Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)
Rule Type: CE

Default Approval Period

1 year

References

- Selzentry (maraviroc) [package insert]. Research Triangle Park, NC: ViiV Healthcare; October 2020.
- 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 https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv. Accessed October 27, 2022.
- Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. Available at https://clinicalinfo.hiv.gov/en/guidelines/pediatric-arv. Accessed October 27, 2022.