Clinical Policy: Maraviroc (Selzentry)

Reference Number: AZ.CP.PHAR.32
Effective Date: 11.16.16
Last Review Date: 09.12.18
Line of Business: Arizona Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Maraviroc (Selzentry™) is a CCR5 co-receptor antagonist.

FDA approved indication
Selzentry is indicated in combination with other antiretroviral agents for treatment of only CCR5-tropic HIV-1 infection in patients 2 years of age and older and weighing at least 10 kg.

Limitation of use: Not recommended for patients with dual/mixed- or CXCR4-tropic HIV-1.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Selzentry is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. CCR5-Tropic HIV-1 (must meet all)**:**

1. Diagnosis of CCR5-topic HIV-1 infection documented via Trofile™ (diagnostic tropism assay);
2. Dose does not exceed 600 mg BID.

Approval duration: One year

B. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. CCR5-tropic HIV-1 infection (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;
2. Documentation of positive response to therapy [labs, sign/symptom reduction, etc.];
3. If request is for a dose increase, new dose does not exceed 600 mg BID.

Approval duration: One year

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.PMN.53 or evidence of coverage documents;

B. Treatment of dual/mixed or CXCR4-tropic HIV-1 virus.

IV. Appendices/General Information

Appendix A: Abbreviation / Acronym Key
N/A

Appendix B: General Information

- Selzentry is contraindicated in patients with severe renal impairment or end-stage renal disease (ESRD / CrCl <30 ml/min) who are taking potent CYP3A inhibitors or inducers (See Dosage and Administration).
- Trofile is the only commercially available diagnostic co-receptor tropism assay that predicts a patient's response to Selzentry, a CCR5 antagoist.
- Selzentry is ineffective against CXCR4 or dual (targets both CCR5 and CXCR4 pathways) topic HIV strains. Pretreatment testing with Trofile distinguishes between those infected with CCR5-tropic virus, CXCRC4 or dual tropic virus.
- More virologic failures occurred in **treatment-naïve** subjects with the combination of Selzentry / Combivir versus Sustiva / Combivir.
- **Boxed Warning: Evaluation and/or** discontinuation of Selzentry should be considered in any patient with signs or symptoms of hepatitis, or with increased liver transaminases combined with rash or other systemic symptoms.

Appendix C: Therapeutic Alternatives
N/A

V. Dosage and Administration

Selzentry for CCR5-tropic HIV-1 infection:

Concomitant Medications	Dosing Regimen	Dosing in Renal Impairment	Maximum Dose
Potent CYP3A inhibitors with / without a potent CYP inducer including: • Protease inhibitors (except tipranavir/ritonavir) • Delavirdine • Ketoconazole,	150 mg PO BID	Not recommended	300 mg daily

itraconazole, clarithromycin • Other potent CYP 3A4 inhibitors (nefazdone			
Other concomitant medications including: • Tipranavir/ritonavir • Nevirapine • Raltegravir • All NRTI's • Enfuvirtide	300 mg PO BID	300 mg PO BID Reduce to 150 mg PO BID if symptoms of postural hypotension	600 mg daily
Potent CYP3A inducers (with / without a potent CTP3A inhibitor) including: • Elfavirenz • Rifampin • Etravirine • Carbamazepine, phenobarbital and phenytoin	600 mg PO BID	Not recommended	1200 mg daily

VI. Product Availability

Tablet: 25 mg, 75 mg, 150 mg, 300 mg
Solution: 20 mg/ml – 230 ml

VII. References

1. Selzentry Prescribing Information. Research Triangle Park, NC: ViiV HealthCare; September 2018.
2. Maraviroc Drug Monograph. Clinical Pharmacology . Available at http://clinicalpharmacology-ip.com. Accessed June 6, 2017.
3. Micromedex Healthcare Series [Internet Database]. Greenwood Village, CO: Thomson Healthcare. Updated periodically. Accessed June 6, 2017.
4. Maraviroc. American Hospital Formulary Service Drug Information. Available at http://medicinescomplete.com/mc/ahfs/current/. Accessed June 6, 2017.
5. Whitcomb JM, Huang W, Fransen S, et al. Development and characterization of a novel single-cycle recombinant-virus assay to determine human immunodeficiency virus type 1 coreceptor topism. Antimicrob Agts Chemother 2007; 51(2): 566-576.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template; minor changes to verbiage and grammar. References updated.	06.05.17	11.17
Reviewed, renumbered for AZ and rebranded.	9/12/18	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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