AllCare CCO - Prior Authorization Criteria Summary:

Criteria number: 079.1

Criteria title: Antiretroviral therapy, HIV

Date of origin: 08/09/2016

Classification: Class Specific

Date of Last Review: 03/19/2019

Drug Class: Antiretroviral therapy, HIV

Date of Next Review: 03/18/2021

References:

- Oregon Health Authority, Department of Medical Assistance, OAR 410-120-0250 (3)
- Oregon Medicaid Pharmaceutical Services Prior Authorization Criteria
- Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Update October 25, 2018 https://aidsinfo.nih.gov/contentfiles/lvguidelines/AA_Tables.pdf
- Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults. 2018 Recommendations of the International Antiviral Society-USA Panel. JAMA. 2018; 320(4): 379-396. doi: 10.1001/jama.2018.8431. https://jamanetwork.com/journals/jama/article-abstract/2688574

FDA approved indication: Human immunodeficiency virus (HIV) treatment and/or prophylaxis

Purpose: To define the process and coverage for antiretroviral therapy (ART)

Clinical Rationale: Restrict certain ART agents with PA to ensure proper use according to most up-to-date treatment guideline recommedations and FDA-approved indications. To maximize safety, efficacy, and adherence.

Policy: Cover all ART agents for treatment or prophylaxis of HIV in accordance with the most up-to-date treatment guideline recommendations and FDA-approved indications. Certain medications require specific genotype or tropism screening prior to approval. Medications with specific FDA-approved indications will be subject to review to ensure the member meets the labeled criteria. Medications that are not recommended as first-line treatment by evidence-based treatment guidelines will require previous trial of preferred agents in addition to review of pertinent diagnostics to avoid the possibility of adverse reactions or toxicities. Monitoring to avoid toxicity and to ensure medication adherence and efficacy may be required for renewal. Approval of liquid formulations (i.e. solutions, powder packs, etc.) will require prior authorization for members age 12 and older to ensure that there is sufficient need for a liquid formulation over other preferred formulations.

Approval criteria for Antiretroviral therapy, HIV:		**Met**	**Not Met**
Criteria #1:	Is the request for a product containing abacavir (e.g. Triumeq, abacavir, abacavir/lamivudine/zidovudine, Epzicom, or Ziagen*)	Go to #2	Go to #3
Criteria #2:	Has the provider submitted documentation that the member is HLA-B*5701 negative	Approve x lifetime with QL	Deny for PA and request HLA-B*5701 screening or deny for M60 if member is HLA-B*5701 positive
Criteria #3:	Is the request for Selzentry (maraviroc)	Go to #4	Go to #5
Criteria #4:	Has the provider submitted documentation that the member has CCR5-tropic HIV infection	Approve x 1 year with QL¥	Deny for PA and request CCR5 tropism testing or deny for M60 if member has dual/mixed or CXCR4-tropic HIV
Criteria #5:	Is the request for Aptivus, Crixivan, Invirase, or Viracept	Go to #6	Go to #7
Criteria #6:	Has the member had a previous trial of one of the following: darunavir, atazanavir, or lopinavir -OR- has the provider submitted documentation that the member has a genotype supporting use of the requested medication over the preferred medications	Go to #11	Deny for PA. Suggest a trial of darunavir, atazanavir, or lopinavir
Criteria #7:	Is the request for stavudine*, didanosine, or Videx powder for solution*	Go to #8	Go to #9

Criteria #8:	Has the member had a previous trial of one of the following: tenofovir, emtricitibine, lamivudine, or abacavir -OR- has the provider submitted documentation that the member has a genotype supporting use of the requested medication over the preferred medications (ie. tenofovir, emtricitibine, lamivudine, and abacavir)	Go to #11	Deny for PA. Suggest a trial of abacavir (requires PA), tenofovir, emtricitibine, or lamivudine
Criteria #9:	Is the request for Rescriptor, Viramune XR, or nevirapine*	Go to #10	Go to #13
Criteria #10:	Has the member had a previous trial of one of the following: efavirenz or rilpivirine -OR- has the provider submitted documentation that the member has a genotype supporting use of the requested medication over the preferred medications	Go to #11	Deny for PA. Suggest a trial of efavirenze or rilpivirine.
Criteria #11:	Has the provider submitted a recent comprehensive metabolic panel (CMP) and complete blood count (CBC)	Go to #12	Deny for PA. Request a recent CMP and CBC.
Criteria #12:	Are the member's liver function tests (LFT) and pancreatic enzymes within normal limits with no evidence of neutropenia on the CBC	Approve x 1 year with QL	Deny for PA; use clinical discretion. May contact HIV Alliance for consult
Criteria #13:	For other ART products that are restricted at point-of-sale: has the prescriber submitted documentation to support that the member is being treated in accordance with the FDA-approved labeling	Approve x 1 year with QL	Go to #14
Criteria #14:	Has the provider submitted documented rationale that supports off-label use of the medication	Approve x 1 year with QL	Deny for PA; use clinical discretion. May contact HIV Alliance for consult

Renewal criteria for Antiretroviral therapy, HIV:		**Met**	**Not Met**
Renewal #1:	Has the member been adherent to the regimen	Go to #2	Refer to clinical pharmacy adherence services at pharmacist discretion
Renewal #2:	Does documentation support member is being appropriately monitored and that viral load remains suppressed	Approve x 1 year with QL	Consult with HIV Alliance at pharmacist discretion

Reviewed and approved by: AllCare CCO P&T Committee | Date: 09/28/2016