Truvada (emtracitabine/tenofovir disoproxil fumarate) & Descovy (emtricitabine; tenofovir alafenamide) Policy Number: C11359-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
6/1/2018	11/6/2019	11/6/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
J8499 (NOC)	RxPA	Q1 2020 20200122C11359-A

PRODUCTS AFFECTED:
Truvada (emtracitabine/tenofovir disoproxil fumarate), Descovy (emtricitabine; tenofovir alafenamide

DRUG CLASS:
Anti-infective (HIV); Anti-Retroviral Nucleoside Reverse Transcriptase Inhibitor (NRTI)/Anti-Retroviral Nucleotide Reverse Transcriptase Inhibitor Combinations

ROUTE OF ADMINISTRATION:
Oral

PLACE OF SERVICE:
Retail Pharmacy

AVAILABLE DOSAGE FORMS:
Truvada TABS 100-150MG, Truvada TABS 133-200MG, Truvada TABS 167-250MG, Truvada TABS 200-300MG, Descovy TABS 200-25MG

FDA-APPROVED USES:
HIV-1 infection, HIV-1 Pre-exposure Prophylaxis (PrEP)

COMPENDIAL APPROVED OFF-LABELED USES:

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS:
DIAGNOSIS: HIV treatment, HIV Pre-exposure prophylaxis (PrEP), Post Exposure Prophylaxis (PEP)

REQUIRED MEDICAL INFORMATION:
A. HIV TREATMENT:
1. Diagnosis of HIV-1
   AND
2. FOR THERAPY NAÏVE PATIENTS ONLY: Documenation of a trial and failure or labeled contraindication to Cimduo(lamivudine; tenofovir disoproxil Fumarate)

B. PRE-EXPOSURE PROPHYLAXIS:
1. Prescriber attestation of need for PrEP, which may include the following risk factors for acquiring HIV infection (i.e. blood transfusion, needle sharing, receptive anal intercourse,

and percutaneous needle stick injuries)

C. POST-EXPOSURE PROPHYLAXIS: (non-occupational and occupational post exposure prophylaxis)

1. Prescriber attests that member has had an exposure that presents a substantial risk of HIV acquisition within the previous 72 hours (Consideration to exposure >72 hours may be made as a medical exception).

DURATION OF APPROVAL:
All indications: Indefinite approval or up to state mandated re-authorization limit

QUANTITY:
Maximum 1 tablet daily.

PRESCRIBER REQUIREMENTS:
Prescribed by or in consult with an HIV specialist or infectious disease specialist

AGE RESTRICTIONS:
HIV-1 Treatment: Pediatric (over 17kg) and up, PrEP: Adolescent (over 35kg) and up, PEP: Pediatric (over 17kg) and up

CONTINUATION OF THERAPY:
NA

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
Uses outside of FDA indications of Truvada, with the exception of post-exposure prophylaxis, are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. PrEP: Unknown or positive HIV status, NOT for coitally-timed (on demand) or other non-continuous daily use, Renal insufficiency, CrCL < 60 mL/min. Discontinue treatment in patients who develop symptoms or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity

OTHER SPECIAL CONSIDERATIONS:
Avoid administering TRUVADA with concurrent or recent use of nephrotoxic drugs. Tenofovir disoproxil fumarate increases didanosine concentrations. Dose reduction and close monitoring for didanosine toxicity are warranted. Coadministration decreases atazanavir concentrations. W hen coadministered with TRUVADA, use atazanavir given with ritonavir . Co-administration of TRUVADA with certain HIV-1 protease inhibitors or certain drugs to treat HCV increases tenofovir concentrations. Monitor for evidence of tenofovir toxicity. Lactation: W omen infected with HIV-1 or suspected of having acquired HIV-1 infection should be instructed not to breastfeed. Geriatric use: Age over 65 was not studied to determine whether they would respond differently from younger subjects. DEXA considered if there is history of pathologic or fragility bone fractures or significant risk for osteoporosis. Avoid use with dolutegravir for non-pregnant women of childbearing potential who are sexually active or have been sexually assaulted and who are not using an effective birth control method and pregnant women early in pregnancy since the risk of an unborn infant developing a neural tube defect is during the first 28 days. The preferred PEP regimen for these women is raltegravir, tenofovir, and emtricitabine.

BACKGROUND:

APPENDIX:
None

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

REFERENCES:

1. Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention
2. Truvada package insert . Gilead Sciences. Foster City, CA. May 2018
3. Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf May2018 update
4. Preexposure prophylaxis for the prevention of HIV infection in the united states-2017 update clinical practice guidelines. Centers for Disease Control and Prevention.
5. Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016, accessed at https://stacks.cdc.gov/view/cdc/38856
6. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis, accessed at https://stacks.cdc.gov/view/cdc/20711