MEDICATION POLICY:

Descovy™

Generic Name: Emtracitibine/Tenofovir Alfenamide

Therapeutic Class or Brand Name: Descovy®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 121099022903

Preferred: N/A

Non-preferred: N/A

Date of Origin: 6/1/2018

Date Last Reviewed / Revised: 8/7/2020

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when EITHER criteria I OR II is met)

I. Documented diagnosis of HIV-1 infection and criteria A OR B below are met:

A. Adult or pediatric patient with minimum body weight of 35 kg and criteria 1 and 2 below are met:

1. Documented clinically significant treatment failure, adverse event or contraindication to Cimduo® (Lamivudine-Tenofovir disoproxil) or lamivudine.
2. Descovy is prescribed in combination with other antiretroviral agents.

B. Pediatric patient with body weight of 25 to 34 kilograms AND Descovy is prescribed in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor.

II. Pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sexual acquisition AND criteria A through G below are met:

A. Adult or adolescent patient weighing at least 35 kilograms.

B. The patient is at high risk for HIV-1 infection. Any of the following factors identified by the Centers for Disease Control (CDC) may be used to identify high-risk patients:

1. Patient has a HIV-positive partner(s), especially if partner has unknown or detectable viral load OR
2. Patient has partner(s) of unknown HIV-1 status AND
   a) There is no or inconsistent condom use OR
   b) There is diagnosis of a STD in the past 6 months OR
3. Patient has an injection partner with HIV or shares needles, syringes, or other equipment to inject drugs.

C. The Patient has received counseling on safe sex practices and HIV risk reduction.

D. The Patient has no clinical symptoms consistent with acute viral infection.

E. No HIV exposures are suspected within the past month.

F. The patient has documented clinically significant treatment failure, adverse event or contraindication with combination therapy of individual components emtricitabine (Emtriva®) and generic tenofovir disoproxil or emtricitabine/tenofovir disoproxil (Truvada®).

G. The patient has a confirmed negative HIV-1 test within a week prior to initiation of therapy and every 3 months thereafter while on Descovy.

EXCLUSION CRITERIA

- Patient is prescribed Descovy for PrEP due to risk for HIV-1 infection from receptive vaginal sex.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 30 tablets per 30 days.

APPROVAL LENGTH

- **Authorization:**
  - Treatment of HIV-1 infection: 1 year.
  - Pre-exposure prophylaxis (PrEP): 6 months.
- **Re-Authorization:**
  - Treatment of HIV-1 infection: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and the medication is effective.
  - Pre-exposure prophylaxis (PrEP): An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the patient has negative HIV-1 screening tests documented at least every 3 months.

APPENDIX

N/A

REFERENCES

1. https://www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi.pdf .
2. https://aidsinfo.nih.gov/guidelines.
3. Medi-Span®.
4. https://www.cdc.gov/hiv/risk/prep/index.html.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
8/7/2020	**1. Changed** IIF **From "**The Patient has documented clinically significant treatment failure, adverse event or contraindication to emtricitabine/tenofovir disoproxil" **To** "The patient has documented clinically significant treatment failure, adverse event or contraindication with combination therapy of individual components emtricitabine (Emtriva) and generic tenofovir disoproxil or emtricitabine/tenofovir disoproxil (Truvada)".
3/18/2020	2. **Changed** I.A.A **From** "history of intolerance or resistance to" To "clinically significant treatment failure, adverse event or contraindication" under Prior Authorization Criteria. 3. **Changed** IIB **From** "The patient is at high risk of HIV-1 infection" **To** "The patient is at high risk of HIV-1 infection". Any of the following factors identified by the CDC may be used to identify high risk patients: 1. Patient has a HIV-positive partner(s), especially if partner has unknown or detectable viral load OR 2. Patient has partner(s) of unknown HIV-1 status AND a.There is no or inconsistent condom use OR b. There is diagnosis of an STD in the past 6 months OR 3. Patient has an injection partner with HIV or shares needles, syringes, or other equipment to inject drugs" **Under** Prior Authorization Criteria 4. **Added "**F. Patient has documented clinically significant treatment failure, adverse event or contraindication to Emtricitabine/Tenofovir disoproxil (Truvada®)**Under** Prior Authorization Criteria. 5. **Added** "4. https://www.cdc.gov/hiv/risk/prep/index.html" **Under** References.
12/19/2019	6. **Changed** item #1 "https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208215s005lbl.pdf" to https://www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi.pdf **under References**. 7. **Changed under Prior Authorization Criteria** to reflect new indication for PrEP: FROM: **(MAY BE CONSIDERED MEDICALLY NECESSARY WHEN EITHER CRITERIA I OR II IS MET)** I. Adult or pediatric patient with minimum body weight of 35 kilograms AND criteria A and B are met: A. Documented diagnosis of HIV-1 infection. B. Descovy is to be coadministered in combination with other antiretroviral agents. II. Pediatric patient with body weight of 25 to 34 kilograms AND criteria A and B below are met: A. Documented diagnosis of HIV-1 infection. B. Descovy is to be coadministered in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor.

	TO: **(MAY BE CONSIDERED MEDICALLY NECESSARY WHEN EITHER CRITERIA I OR II IS MET)** I. Documented diagnosis of HIV-1 infection and criteria A OR B below are met: A. Adult or pediatric patient with minimum body weight of 35 kg and criteria 1 and 2 below are met: 1. Documented history of intolerance or resistance to Cimduo® (Lamivudine-Tenofovir disoproxil) or lamivudine. 2. Descovy is prescribed in combination with other antiretroviral agents. B. Pediatric patient with body weight of 25 to 34 kilograms AND Descovy is prescribed in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor. II. Patient is prescribed Descovy for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sexual acquisition AND criteria A through F below are met: A. Adult or adolescent patient weighing at least 35 kilograms. B. The patient is at high risk for HIV-1 infection. C. The patient has received counseling on safe sex practices and HIV risk reduction. D. The patient has no clinical symptoms consistent with acute viral infection. E. No HIV exposures are suspected within the past month. F. The patient has a confirmed negative HIV-1 test within a week prior to initiation of therapy and every 3 months thereafter while on Descovy. 8. **Added** PrEp approval duration **under Approval Length:** FROM: • **Authorization:** 1 year. • **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and the medication is effective. TO: • **Authorization:** o Treatment of HIV-1 infection: 1 year. o Pre-exporsure prophylaxis (PrEp): 6 months. • **Re-Authorization:** o Treatment of HIV-1 infection: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and the medication is effective. o Pre-exposure prophylaxis (PrEP): An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the patient has negative HIV-1 screening tests documented at least every 3 months.
5/22/2019	1. **Changed** item #1 "https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208215s005lbl.pdf" to https://www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi.pdf **under References**.
6/1/2018	2. Policy created.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.