Clinical Policy Title:	enfuvirtide
Policy Number:	RxA.125
Drug(s) Applied:	Fuzeon®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Enfuvirtide (Fuzeon®) is a human immunodeficiency virus-1 (HIV-1) fusion inhibitor. It is indicated for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment experienced patients with HIV-1 replication despite ongoing antiretroviral therapy.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
enfuvirtide (Fuzeon®)	HIV-1 infection	Adults: 90 mg SC twice daily Pediatric patients weighing at least 11 kg: 2 mg/kg SC twice daily up to 90 mg SC twice daily.	180 mg/day

Dosage Forms

- Lyophilized powder in vial: 108 mg (90 mg/mL when reconstituted)

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

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

1. Diagnosis of HIV-1 infection;
2. Prescribed by or in consultation with an infectious disease or HIV specialist;
3. Age 6 years of age or older;
4. Failure of ≥ 12 weeks of antiretroviral therapy which includes 2 nucleoside analogue reverse transcriptase inhibitors and 1 drug from one of the following classes: an integrase strand transfer inhibitor, a nonnucleoside analogue reverse transcriptase inhibitor, or a pharmacokinetic enhanced protease inhibitor;
5. Current (within the past 30 days) HIV ribonucleic acid viral load ≥ 200 copies/mL;
6. Fuzeon® is prescribed concurrently with additional antiretroviral agents to which member is susceptible;
7. Dose does not exceed 180 mg per day.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria for the covered indications and has received this medication for at least 30 days
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 180 mg per day.

Approval Duration
Commercial: 6 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
HIV-1: human immunodeficiency virus-1
RNA: ribonucleic acid

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Nucleos(t)ide reverse transcriptase inhibitors (NRTIs) (e.g., abacavir, tenofovir disoproxil fumarate, Emtriva®, etc.)	Refer to prescribing information	Refer to prescribing information
Non-nucleoside reverse transcriptase inhibitors (NNRTIs) (e.g., efavirenz, nevirapine, Edurant®, etc.)	Refer to prescribing information	Refer to prescribing information
Integrase strand transfer inhibitors (INSTIs) (e.g., Tivicay®, Isentress®)	Refer to prescribing information	Refer to prescribing information
Protease inhibitors (PIs) (e.g., atazanavir, fosamprenavir, Invirase®, Viracept®, etc.)	Refer to prescribing information	Refer to prescribing information
Fixed-dose combinations (e.g., Genvoya®, Stribild®, Odefsey®, Descovy®, Truvada®, etc.)	Refer to prescribing information	Refer to prescribing information

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and

generic (Brand name®) when the drug is available by both brand and generic

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Hypersensitivity to Fuzeon® or any of its components.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

Per the Department of Health and Human Services Antiretroviral Guidelines:

- Evaluation of virologic failure should include as assessment of adherence, drug-drug or drug-food interactions, drug tolerability, HIV ribonucleic acid (RNA) and CD4 T lymphocyte (CD4) cell count trends over time, treatment history, and prior and current drug-resistance testing results.
- Virologic failure is defined as the inability to achieve or maintain suppression of viral replication to an HIV RNA level < 200 copies/mL. Patients with levels persistently above 200 copies/mL, especially > 500 copies/mL, often develop drug resistance.
- Virologic suppression is defined as a confirmed HIV RNA level below the limit of assay detection (e.g., < 48 copies/mL).
- There is no consensus regarding how to manage patients with HIV RNA levels > 48 copies/mL and < 200 copies/mL. The risk of emerging resistance is believed to be relatively low. HIV RNA levels should be monitored at least every 3 months to assess the need for changes in antiretroviral therapy in the future.

References

1. Fuzeon Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; December 2019. Available at https://www.gene.com/download/pdf/fuzeon_prescribing.pdf . Accessed January 31, 2021.
2. 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. Available at http://www.aidsinfo.nih.gov. Last updated December 18, 2019. Accessed January 31, 2021.
3. Gunthard HF, Saaq MS, Benson CA et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults: 2016 recommendations of the International Antiviral Society- USA Panel. JAMA. 2016 Jul 12;316(2):191-210. doi: 10.1001/jama.2016.8900. Accessed January 31, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Policy was reviewed: • Continue Therapy II.A.1 was rephrased to " Currently receiving medication that has been authorized by RxAdvance…" • References were reviewed and updated	05/2020	05/21/2020
Policy was reviewed. 1. Clinical policy title was	01/31/2021	03/09/2021

updated. 2. Removed HIM from initial and continued therapy criteria approval duration. 3. Continued therapy criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria for the covered indications and has received this medication for at least 30 days”. 4. References were reviewed and updated.		