# Clinical Policy: Enfuvirtide (Fuzeon)

Reference Number: ERX.SPA.196
Effective Date: 01.11.17
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

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

**Description**
Enfuvirtide (Fuzeon®) is a human immunodeficiency virus-1 (HIV-1) fusion inhibitor.

**FDA Approved Indication(s)**
Fuzeon 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.

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

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Fuzeon is **medically necessary** when the following criteria are met:

**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;
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 the member is susceptible;
7. Dose does not exceed 180 mg per day.

**Approval duration: 6 months**

**B. Other diagnoses/indications**

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Fuzeon for HIV-1 infection 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: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 6 months (whichever is less)**; or
2. Refer to ERX.PA.01 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 – ERX.PA.01 or evidence of coverage documents.

## IV. Appendices/General Information

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

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| 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 and 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 lower limit of assay detection (LLOD).
- There is no consensus regarding how to manage patients with HIV RNA levels above LLOD 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.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| HIV-1 infection | Adults: 90 mg SC BID<br>Pediatric patients weighing at least 11 kg: 2 mg/kg SC BID up to 90 mg SC BID | 180 mg/day |

## VI. Product Availability

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

## VII. References

1. Fuzeon Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; December 2019. Available at http://www.gene.com/. Accessed March 18, 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 February 24, 2021. Accessed March 18, 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.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 12.16 | 01.17 |
| 4Q17 Annual Review<br>- Converted to new template.<br>- Updated and confirmed validity of references. | 09.22.17 | 11.17 |
| 3Q 2018 annual review: HIV specialist added as prescriber option; age added; removed re-auth requirement for drug resistance testing if current HIV RNA is at least 500 copies/mL; continuity of care added; references reviewed and updated. | 04.02.18 | 08.18 |
| 3Q 2019 annual review: no significant changes; references reviewed and updated. | 04.22.19 | 08.19 |
| 3Q 2020 annual review: no significant changes; references reviewed and updated. | 04.20.20 | 08.20 |
| 3Q 2021 annual review: no significant changes; references reviewed and updated. | 03.18.21 | 08.21 |

**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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.