Clinical Policy: Enfuvirtide (Fuzeon)

Reference Number: PA.CP.PHAR.41
Effective Date: 01/18
Last Review Date: 07/17/19

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by It is the policy of Pennsylvania Health and Wellness® clinical policy for enfuvirtide (Fuzeon®).

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.

It is the policy of health plans affiliated with Pennsylvania Health and Wellness that Fuzeon is **medically necessary** when one of the following criteria are met:

I. Initial Approval Criteria

A. Human Immunodeficiency Virus (must meet all):

1. Diagnosis of HIV-1 infection;
2. Prescribed by or in consultation with an infectious disease or HIV specialist;
3. 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;
4. Current (within the past 30 days) HIV ribonucleic acid viral load ≥ 200 copies/mL;
5. Fuzeon is prescribed concurrently with additional antiretroviral agents to which member is susceptible;
6. Dose does not exceed 180 mg/day.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 180 mg/day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

Background
Description/Mechanism of Action:
Enfuvirtide is an inhibitor of the fusion of HIV-1 with CD4 cells. Enfuvirtide is an antiviral drug that interferes with the entry of HIV-1 into cells by inhibiting fusion of viral and cellular membranes. Enfuvirtide binds to the first heptad-repeat (HR1) in the gp41 subunit of the viral envelope glycoprotein and prevents the conformational changes required for the fusion of viral and cellular membranes.

III. 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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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
Not applicable

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.

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
HIV-1 infection	Adults: 90 mg SC BID Pediatric patients (6-16 years): 2 mg/kg SC BID up to 90 mg/dose	180 mg/day

V. Product Availability

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

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1324	Injection, enfuvirtide, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
3Q 2018 annual review: no significant change from previously approved policy; HIV specialist added as prescriber option, removed re-auth requirement for drug resistance testing if current HIV RNA is at least 500 copies/mL; initial: requirement for current HIV RNA at least 200 copies/mL added, continued: requirement for specific decrease in viral load/increase in CD4 count replaced by general positive response statement; continued approval durations modified from length of benefit to 6 months or renewal date and 12 months, respectively; continuity of care added; references reviewed and updated.	08/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	

References

1. Fuzeon Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; December 2016. Available at http://www.gene.com/. Accessed April 2, 2018.
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 March 27, 2018. Accessed May 3, 2018.
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.