Clinical Policy: Enfuvirtide (Fuzeon)

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

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®).

Policy/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. Prescribed by or in consultation with an infectious disease specialist;
2. Diagnosis of HIV-1 (human immunodeficiency virus-1);
3. Documented adherence to 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) for ≥ 12 weeks;
4. Current (within the past 30 days) HIV ribonucleic acid viral load of ≥ 200 copies/mL;
5. Antiretroviral regimen to be used concurrently with Fuzeon contains at least two antiretroviral agents, selected based on drug resistance testing;
6. Prescribed dose of Fuzeon does not exceed 90mg twice daily;
7. No known hypersensitivity to Fuzeon or any of its components.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

A. All Indications (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. If current (within the past 6 months) HIV ribonucleic acid is > 500 copies/ml, drug resistant testing result must confirm that Fuzeon will continue to be of benefit;
3. Antiretroviral regimen to be used concurrently with Fuzeon contains at least two antiretroviral agents, selected based on drug resistance testing;
4. Prescribed dose of Fuzeon does not exceed 90mg twice daily;
5. No known hypersensitivity to Fuzeon or any of its components.

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 CP.PHAR.57 - Global Biopharm Policy**.**

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.

Formulations:

Fuzeon is available as a lyophilized powder, 108mg/vial for subcutaneous injection.

FDA Approved Indication(s):

Fuzeon is an HIV-1 fusion inhibitor/subcutaneous injectable lyophilized powder indicated for

- HIV-1 infection in combination with other antiretroviral agents in treatment experienced patients with HIV-1 replication despite ongoing antiretroviral therapy

Appendices

Appendix A: Abbreviation Key

CD4: CD4 T lymphocyte
HIV: Human Immunodeficiency Virus
RNA: ribonucleic acid

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

References

1. Fuzeon Prescribing Information. South San Franciso, CA: Genentech USA, Inc.; December 2015. Available at http://www.gene.com/. Accessed July 13, 2016.
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. Accessed August 12, 2016.
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.