Medical Drug Clinical Criteria

Subject:	Fuzeon (enfuvirtide)		
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Overview

This document addresses the use of Fuzeon (enfuvirtide), a human immunodeficiency virus (HIV) gp41 fusion inhibitor approved by the Food and Drug Administration (FDA) for use in combination with other antiretroviral agents for the treatment of HIV infection in treatment-experienced adults and children 6 years of age and older with HIV replication despite ongoing antiretroviral therapy.

Fuzeon was studied in two randomized, controlled, open-label trials (TORO-1 and TORO-2) in 957 individuals with HIV infection. The study participants were treatment-experienced as defined: 1) Viremia despite 3 to 6 months prior therapy with a nucleoside reverse transcriptase inhibitor (NRTI), non-nucleoside reverse transcriptase inhibitor (NNRTI) and protease inhibitor (PI); or 2) Viremia and documented resistance or intolerance to at least one agent in each of the NRTI, NNRTI and PI classes. Participants received an individualized background regimen consisting of 3 to 5 antiretroviral agents selected based on the participants' prior treatment history and baseline viral resistance measurements. Participants were randomized at a 2:1 ratio to subcutaneous Fuzeon 90 mg given twice a day with background regimen or background regimen alone. At 48 weeks, 154 (23%) of subjects in the Fuzeon + background regimen and 27 (8%) in the background regimen alone had HIV-1 RNA levels <50 copies/mL.

The United States Public Health Service (USPHS) includes Fuzeon in their recommendations for postexposure prophylaxis (PEP) of HIV infection following occupational exposure in health-care personnel and other individuals exposed to blood, tissue or other body fluids that might contain HIV. The guidelines indicate the preferred regimen for PEP is Isentress in combination with Truvada. Fuzeon in combination with other antiretrovirals is one of several alternative regimens but should only be used with expert consultation.

The United States Centers for Disease Control and Prevention (CDC) includes Fuzeon in their recommendations for PEP of HIV infection following nonoccupational exposure to blood, genital secretions or other body fluids that might contain HIV when the exposure represents a substantial risk for HIV transmission. The CDC guidance states the preferred regimen in individuals 13 years of age or older with normal renal function is Isentress or Tivicay in combination with Truvada. Fuzeon in combination with other antiretrovirals is an alternative regimen but should only be used with expert consultation.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Fuzeon (enfuvirtide)

Requests for Fuzeon (enfuvirtide) may be approved if the following criteria are met:

I. Individual is using to treat human immunodeficiency virus (HIV) infection;
AND
II. Individual is using in combination with other antiretroviral agents;
AND
III. Individual has tried and failed at least three months of therapy with a regimen consisting of three or more antiretroviral agents; **OR**
IV. Individual has viremia and resistance or intolerance to at least one antiretroviral agent from three different classes;

OR
V. Individual is using for postexposure prophylaxis of HIV infection following exposure to blood, tissues or other body fluids associated with a risk for transmission of the HIV virus (AHFS, CDC, USPHS).

Fuzeon (enfuvirtide) may not be approved when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J1324	Injection, enfuvirtide, 1 mg [Fuzeon]

ICD-10 Diagnosis

B20	Human immunodeficiency virus [HIV] disease
Z20.6	Contact with and (suspected) exposure to human immunodeficiency virus [HIV]

Document History

Reviewed: 8/16/2024
Document History:

- 8/16/2024 – Annual Review: No changes. Coding Reviewed: No changes.
- 8/18/2023 – Annual Review: Wording and formatting changes. Coding Reviewed: No changes.
- 11/18/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 11/19/2021 – Annual Review: No changes. Coding reviewed: No changes.
- 11/20/2020 – Annual Review: No changes. Coding Reviewed: Added ICD-10-CM B20, Z20.6.
- 11/15/2019 – Annual Review: Wording and formatting changes. Coding Reviewed: no changes
- 11/16/2018 – Annual Review: Initial P&T review of ING-CC-0055 Fuzeon. Remove age criteria. Update wording in tried and failed criteria for clarity and add alternative for individuals with resistance or intolerance to reflect clinical trial inclusion parameters. Allow post-exposure prophylaxis use for non-occupational exposure as well as occupational exposure based on CDC guidelines and compendia. HCPCS and ICD-10 coding review: no changes.

References

1. Centers for Disease Control and Prevention. Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV – United States, 2016. Available at: https://stacks.cdc.gov/view/cdc/38856. Accessed: July 14, 2024.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 14, 2024.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Kuhar DT, Henderson DK, Struble KA, et al. Updated US Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis. *Infect Control Hosp Epidemiol*. 2013; 34:875-92.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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