Clinical Policy: Enfuvirtide (Fuzeon)

Reference Number: CP.PHAR.41
Effective Date: 06/10
Last Review Date: 10/16

Coding Implications
Revision Log

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

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

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® 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 Centene benefit or member has previously met all initial approval criteria;
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 Centene benefit and documentation supports positive response to therapy; 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
Converted to Centene clinical policy template	08/13	08/13
Added necessity for prior treatment to algorithm Updated background information	10/13	11/13
Replaced safety table with expanded adverse events description	09/14	11/14

Reviews, Revisions, and Approvals	Date	Approval Date
Updated background information Updated description section		
Converted policy to new format. Added abbreviation key In criteria: therapy initiation shortened to three months; specified HIV diagnosis as a diagnosis of HIV-1; added requirement that management be overseen by an HIV specialist; changed "experiencing continued HIV replication" to "failure to achieve or maintain"; added requirement that patient's new Fuzeon-based regimen be based on an assessment for drug resistance and medication intolerance, and that the regimen include at least a total of two antiretroviral agents. Added attestation that patient is not experiencing unacceptable toxicity due to Fuzeon therapy in the therapy continuation section.	09/15	11/15
Policy converted to new template. Added maximum dose and contraindications per PI; added antiretroviral therapy regimen per DHHS; Modified criteria so that virologic failure defined by > 200 copies/ml of HIV RNA per DHHS guideline; added requirement for resistant test for patients with > 500 copies of HIV RNA on renewal criteria; added the need for continued treatment with other ARV to renewal criteria; added maximum dose requirement. Modified approval duration to 6 months and 12 months for initial and reauthorization criteria respectively.	10/16	11/16

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.