Clinical Policy: Enfuvirtide (Fuzeon)

Reference Number: CP.PHAR.41
Effective Date: 06.01.10
Last Review Date: 08.20
Line of Business: Commercial, HIM, 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.

It is the policy of health plans affiliated with Centene Corporation® 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:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit, 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:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid 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)	Refer to prescribing information	Refer to prescribing information

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
(e.g., efavirenz, nevirapine, Edurant®, etc.)		
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 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 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 April 20, 2020.
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 December 18, 2019. Accessed April 20, 2020.
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 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
Converted to new template; references updated	09.17	11.17
3Q 2018 annual review: policies combined for Centene Medicaid, HIM (new), and Commercial lines of business; no significant change from previously approved corporate policy; Medicaid: HIV specialist added as prescriber option, removed re-auth requirement for drug resistance testing if current HIV RNA is at least 500 copies/mL; Commercial: age and prescriber requirement added, 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 (Commercial) and 6 months (Medicaid) to 6 months or renewal date and 12 months, respectively; 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

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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.

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.