Clinical Policy Title:	enfuvirtide
Policy Number:	RxA.125
Drug(s) Applied:	Fuzeon®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

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. Trial and failure of at least 12 weeks of antiretroviral therapy which includes at least two (2) nucleoside analogue reverse transcriptase inhibitors and at least one (1) drug from one of the following classes at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (a, b or c):
   a. Integrase strand transfer inhibitor;
   b. Nonnucleoside analogue reverse transcriptase inhibitor;
   c. 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 member is susceptible;
7. Dose does not exceed 180 mg per day.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria for the covered indications 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
Commercial: 6 months
Medicaid: 12 months

References

1. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. NIH's Office of AIDS Research. Updated September 21, 2022. Available at: https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-

guidelines-adult-and-adolescent-arv/whats-new-guidelines. Accessed October 13, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Policy was reviewed: • Continue Therapy II.A.1 was rephrased to " Currently receiving medication that has been authorized by RxAdvance…" • References were reviewed and updated	05/2020	05/21/2020
Policy was reviewed. 1. Clinical policy title was updated. 2. Removed HIM from initial and continued therapy criteria approval duration. 3. Continued therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria for the covered indications and has received this medication for at least 30 days". 4. References were reviewed and updated.	01/31/2021	03/09/2021
Policy was reviewed. 1. References were reviewed and updated.	11/26/2021	01/17/2021
Policy was reviewed: 1. References were reviewed and updated.	10/13/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023