

Title: enfuvirtide (Fuzeon)

Origination: 08/23/05	Revised: 02/27/08	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- Enfuvirtide is the first in a new class of HIV medications know as fusion inhibitors. Enfuvirtide interferes with the entry of HIV-1 into host cells by inhibiting the fusion of the virus and cell membranes. Enfuvirtide, in combination with other antiretroviral agents, is indicated for the treatment of HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy.
- Precaution: Fuzeon must be taken as part of a combination antiretroviral regimen. Use of Fuzeon alone may lead to rapid development of virus resistance to Fuzeon, and possibly other agents.

Reference Statement

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusions

- Member that is antiretroviral treatment naïve.
- Member less than 6 years of age, as safety and efficacy have not been established.

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Procedure:

1.0 Request for *initial therapy* with enfuvirtide requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

1.1 Member is diagnosed with HIV-1 infection; **AND**

1.2 Lab value indicating current CD4⁺ cell count; **AND**

1.3 Member has viremia (presence of virus in the blood with at least 5,000 copies of HIV-1 RNA per ml) despite at least three (3) months prior therapy with a nucleoside reverse transcriptase inhibitor (NRTI), non-nucleoside reverse transcriptase inhibitor (NNRTI), and protease inhibitor (PI):

1.3.1 Examples of NNRTIs:

1.3.1.1 Rescriptor (delavirdine [DLV]);

1.3.1.2 Sustiva (efavirenz [EFV]);

1.3.1.3 Viramune (nevirapine [NVP]);

1.3.1.4 Intelence (etravirivne [ETR]);

1.3.2 Examples of NRTIs, Protease inhibitors or triple therapy:

1.3.2.1 Ziagen (abacavir [ABC])	1.3.2.12 Retrovir (zidovudine [AZT or ZDV])
1.3.2.2 Epzicom (abacavir + lamivudine)	1.3.2.14 Reyataz (atazanavir [ATV])
1.3.2.3 Videx (didanosine [ddI])	1.3.2.15 Lexiva (fosamprenavir [f-APV])
1.3.2.4 Emtriva (emtricitabine [FTC])	1.3.2.16 Crixivan (indinavir)
1.3.2.5 Truvada (emtricitabine + tenofovir)	1.3.2.17 Kaletra (lopinavir + ritonavir [LPV/r])
1.3.2.6 Epivir (lamivudine [3TC])	1.3.2.18 Viracept (nelfinavir [NFV])
1.3.2.7 Combivir (lamivudine+zidovudine)	1.3.2.19 Norvir (ritonavir [RTV])
1.3.2.8 Trizivir (abacavir + lamivudine + zidovudine)	1.3.2.20 Prezista (darunavir [DRV])
1.3.2.9 Zerit (stavudine [d4T])	1.3.2.21 Invirase (saquinavir [SQV])
1.3.2.10 Viread (tenofovir disoproxil fumarate [TDF])	1.3.2.22 Aptivus (tipranavir [TPV])
1.3.2.11 Hivid (zalcitabine [ddC])	1.3.2.23 Atripla (Efavirenz [EFV], emtricitabine [FTC], tenofovir [TDF])

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Procedure, continued:

1.0 Request for *initial therapy* with enfuvirtide requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following, continued:

OR

1.3 Member has viremia and documented resistance or intolerance to at least one (1) agent in each of the NRTI, NNRTI, and PI classes; **AND**

1.4 Clinical documentation of concurrent medications, including doses; **AND**

1.5 Member is adherent to provider appointments and prescribed medications, and has a reliable prescription refill history;

1.6 If the Member meets all of the criteria, may approve for up to three (3) months.

2.0 Request for *continuation of therapy* beyond initial authorization period requires documentation from the requesting independent practitioner verifying the following:

2.1 Clinical notes indicating there is improvement in Member's CD4⁺ cell count, and a decrease (greater than 1 log₁₀ decline from baseline) in Member's viral load; **AND**

2.2 Member is adherent to provider appointments, their medication, and has a reliable prescription refill history;

2.3 If the Member meets both criteria, may approve for up to one (1) year.

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References:

1. Clotet, B. et al. Clinical Management of Treatment-Experienced, HIV Infected Patients With the Fusion Inhibitor Enfuvirtide: Consensus Recommendations. *AIDS* 2004; 18:1137-1146.
2. Lalezari, J. et al. Enfuvirtide, an HIV-1 Infusion Inhibitor, for Drug Resistance HIV Infection in North and South America. *NEJM* 2003; 348(22): 2175-2185.
3. Oldfield, V., Keating, G., and Plosker, G. Enfuvirtide: A Review of Its Use in the Management of HIV Infection. *Drugs*. 2005; 65 (8): 1139-1160.
4. The Panel on Clinical Practices for Treatment of HIV Infection convened by the Department of Health and Human Services. Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents. 2007. Accessed 01/23/2007.
5. Roche Laboratories, Inc. *Fuzeon* (Enfuvirtide) Full Prescribing Information. Nutley, NJ. Revised January 2007.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.