

Commercial/Healthcare Exchange PA Criteria *Effective: March 1, 2005*

Prior Authorization: Fuzeon

Products Affected: Fuzeon (enfuvirtide) injection

Medication Description: Fuzeon (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. Enfuvirtide has no activity against HIV-2. Enfuvirtide 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 conformational changes required for fusion of viral and cellular membranes. Enfuvirtide exhibited additive to synergistic effects in cell culture assays when combined with individual members of various antiretroviral classes, including zidovudine, lamivudine, nelfinavir, indinavir, and efavirenz.

Covered Uses:

1. For use 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

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. Medication history

Age Restrictions: 6 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, an infectious disease specialist

Coverage Duration: 12 months

Other Criteria:

Approve Fuzeon for 12 months if the patient meets the following criteria:

1. Patient has clinically diagnosed HIV-1 infection; **AND**
2. Fuzeon is being prescribed as part of an optimized antiretroviral regimen including at least two additional active antiretroviral agents
3. Patient has demonstrated virologic failure of medications in 3 or more classes of antiretroviral drug classes (nucleoside reverse transcriptase inhibitor, non-nucleoside reverse transcriptase inhibitor, and protease inhibitor), defined as:
 - a. Failure to suppress viral loads; **OR**
4. Patient has intolerance to 3 or more classes of antiretroviral therapy (nucleoside reverse transcriptase inhibitor, non-nucleoside reverse transcriptase inhibitor, and protease inhibitor), defined as:
 - a. Allergic reaction; **OR**
 - b. Adverse drug reaction

References:

1. FUZEON(R) subcutaneous injection, enfuvirtide subcutaneous injection. Genentech USA, Inc. (per FDA), South San Francisco, CA, 2015

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	3/2005
2	Update	<p>Updated template</p> <p>Added medication description</p> <p>Added other criteria: Fuzeon (enfuvirtide) is being prescribed as part of an optimized antiretroviral regimen including at least two additional active antiretroviral agents</p>	All	2/7/2020