



**Prior Authorization Approval Criteria**  
*Department of Pharmacy Services*

**Generic Name:** enfuvirtide

**Brand Name:** Fuzeon

**Medication Class:** Antiretroviral- fusion inhibitors

**FDA Approved Uses:** Approved for children ages 6 years and older, and adults for the treatment of HIV-1 infection in treatment experienced patients with evidence of HIV-1 replication despite ongoing retroviral therapy. Fuzeon must be used in combination with other antiretroviral agents, not as monotherapy.

**Usual Dose:** 90 mg subcutaneous BID

**Duration of Therapy:** Indefinite

**Criteria for Use:** *(bullet points below are all inclusive unless otherwise noted)*

- Clinically diagnosed HIV-1
- Clinically documented resistance to 3 or more medications
- Restricted to AIDs specialists
- Past use of at least 3 other classes of anti-HIV therapies for at least 6 months
- Failed/intolerant to other HIV therapies
- At least 5 log (10) copies of HIV-1 RNA per ml of plasma
- Patient must be compliant

**Not approved if:**

- Fuzeon is initial therapy
- Patient has acute bacterial pneumonia
- Patient is not resistant to other therapies
- Patient has not been compliant with medications in the past
- Patient has undetectable levels of virus

**Criteria for continuation of therapy:**

- Viral load reduction of at least 0.5 log (10) copies per ml after 28 days and a rise in CD4 count
- Continued or persistent viral load reduction or undetectable viral load
- Patient compliant with regimen

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_