



## PRIOR AUTHORIZATION CRITERIA

Generic/Brand: **Enfuvirtide (Fuzeon Injection)**

Therapeutic Class: Antiviral

### DESCRIPTION:

Enfuvirtide (Fuzeon) is the first of the newest class of anti-HIV drugs called fusion inhibitors - the first new class of drugs developed and approved for the treatment of HIV since 1996. Enfuvirtide interferes with the entry of HIV-1 into cells by inhibiting fusion of viral and cellular membranes. Enfuvirtide binds to the gp41 subunit of the viral envelope glycoprotein and prevents the conformational changes required for the fusion of viral and cellular membranes.

The use of enfuvirtide should be reserved as a salvage therapy for individuals who have advanced disease, are treatment-experienced, and continue to show evidence of ongoing viral replication (i.e., show resistance to current HIV treatments). Enfuvirtide should be used in combination with an individualized antiretroviral regimen.

This indication is based on analyses of plasma HIV-1 RNA levels and CD4 cell counts in controlled studies of FUZEON of 24 weeks duration. Subjects enrolled were treatment-experienced adults; many had advanced disease. Subjects were required to have either (1) viremia despite 3 to 6 months prior therapy with a nucleoside reverse transcriptase inhibitor (NRTI), non-nucleoside reverse transcriptase inhibitor (NNRTI), and protease inhibitor (PI) or (2) viremia and documented resistance or intolerance to at least one member in each of the NRTI, NNRTI, and PI classes. The study group, who received Fuzeon plus a standard combination anti-HIV drug regimen had a log decrease in HIV RNA viral load of  $-1.52$  compared to the control group's log change of  $-0.73$ . The Fuzeon group had an increase in CD4 cell count of  $+71$  cells/cc vs control group  $+35$ .

There are no studies of the overall clinical outcome or survival in patients treated with Fuzeon compared to standard regimens.

### CRITERIA FOR APPROVAL:

#### Indications:

Fuzeon is covered as salvage treatment for appropriate treatment-experienced HIV patients

#### Criteria:

FUZEON will be approved for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced patients:

1. with evidence of HIV-1 replication despite ongoing antiretroviral therapy and
2. with increasing HIV viral load, decreasing CD4 counts, persistent HIV viremia and/or progression/occurrence of opportunistic infections or tumors indicating depressed cellular immune function and
3. with history of failure of 3 to 6 months prior therapy with a nucleoside reverse transcriptase inhibitor (NRTI), non-nucleoside reverse transcriptase inhibitor (NNRTI), and protease inhibitor (PI)  
**or**
4. with documented resistance or intolerance to at least one member in each of the NRTI, NNRTI, and PI classes.
5. Members with prescription coverage via the Medicare Modernization Act (MMA, Medicare "Part D") benefit who are currently maintained on this medication will have their renewal request approved upon submission by a licensed physician.

### LENGTH OF APPROVAL:

The length of time requested by the prescriber, but no longer than 3 months. A new request for review would need to be made when approval expires and should include patient's clinical response documenting the presence and/or progression of infections and malignancies, the CD4 count, and viral load.

### REFERENCES:

Clinical Pharmacology, Version 2.14, Copyright 2004, Gold Standard Multimedia

Lippincott's Drug Facts and Comparisons, October 2004, © 2004 Wolters Kluwer Health, Inc.