# SPECIALTY GUIDELINE MANAGEMENT

## Use of Fuzeon (enfuvirtide) in Human Immunodeficiency Virus Infection

**POLICY**

**A. INDICATIONS**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Fuzeon 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.

This indication is based on results from two controlled studies of 48 weeks duration. Subjects enrolled were treatment-experienced adults; many had advanced disease. There are no studies of Fuzeon in antiretroviral naive subjects.

All other indications are considered experimental/investigational and are not a covered benefit.

**B. REQUIRED DOCUMENTATION**

The following information is necessary to initiate the prior authorization review:

- Initial therapy: baseline viral load (HIV RNA level) and CD4+ count
- Continuation of therapy: current viral load (HIV RNA level) and CD4+ count

**C. CRITERIA FOR APPROVAL**

Authorization of 6 months may be granted to members prescribed Fuzeon for the treatment of HIV infection when ALL of the following criteria are met:

a. The member has HIV-1 infection
b. The member is 6 years of age or older
c. There is evidence of HIV-1 replication despite ongoing antiretroviral therapy
d. Fuzeon is prescribed in combination with an optimized antiretroviral regimen

**D. CONTINUATION OF THERAPY**

Authorization of 24 months may be granted to members prescribed Fuzeon for the treatment of HIV infection when ALL of the following criteria are met:

a. The member has HIV-1 infection
b. The member is 6 years of age or older
c. The member has had a positive or stable virologic response to Fuzeon

**E. DOSAGE AND ADMINISTRATION**

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

**1. Dosing Limits**

The following dosing limits apply:

- 180 mg subcutaneous injection per day

**REFERENCES**


1. Fuzeon [package insert]. South San Francisco, CA: Genentech USA, Inc.; June 2014.
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Last updated November 13, 2014. http://aidsinfo.nih.gov/contentfiles/adultandadolescentgl.pdf. Accessed December 23, 2014.

3. Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children. Guidelines for the use of antiretroviral agents in pediatric HIV infection. Department of Health and Human Services. Last updated February 12, 2014. http://aidsinfo.nih.gov/contentfiles/lvguidelines/pediatricguidelines.pdf. Accessed December 23**,** 2014.