FUZEON (Enfuvirtide)

Effective Date: 7/28/05

Date Developed: 7/11/05 by C. Wilhelmy MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20, 2/2/21, 2/1/22, 1/31/23, 2/13/24, 2/18/25

Fuzeon is an Antiretroviral Agent, Fusion Protein Inhibitor. It inhibits the fusion of HIV-1 virus with CD4 cells by blocking the conformational change in gp41 required for membrane fusion and entry into CD4 cells.

Pre-Authorization Criteria: treatment of HIV-1 infection in combination with other antiretroviral agents in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy.

NOTE: VCHCP requires that it be prescribed by an Immunology Clinic physician.

DOSING: ADULTS — HIV Treatment: SubQ: 90 mg twice daily

DOSING: PEDIATRIC — HIV treatment: SubQ: Children 6 years: 2 mg/kg twice daily (maximum dose: 90 mg twice daily).

Authorization Limits:
Initial authorization for 6 months, continue therapy for length of benefit with **one** of the following:
1. Minimum 0.5 log decrease in viral load from baseline
2. Minimum increase of 25% in CD4+ count

WARNINGS / PRECAUTIONS — Monitor closely for signs/symptoms of pneumonia; associated with an increased incidence during clinical trials, particularly in patients with a low CD4 cell count, high initial viral load, I.V. drug use, smoking, or a history of lung disease. May cause hypersensitivity reactions (symptoms may include rash, fever, nausea, vomiting, hypotension, and elevated transaminases). ~~In addition,~~ Local injection site reactions may occur. Safety and efficacy have not been established in children <6 years of age.

DRUG INTERACTIONS — No interactions have been identified which would require alteration of other antiretroviral drugs.

PREGNANCY IMPLICATIONS — Teratogenic effects were not observed in animal studies, however there are no studies in pregnant women. An antiretroviral registry has been established to monitor maternal and fetal outcomes in women receiving antiretroviral drugs. Physicians are encouraged to register patients at 1-800-258-4263 or www.APRegistry.com.

LACTATION — Excretion in breast milk unknown/contraindicated

BREAST-FEEDING CONSIDERATIONS — HIV-infected mothers are discouraged from breast-feeding to decrease potential transmission of HIV.

REFERENCES

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4. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Bethesda (MD): Department of Health and Human Services (DHHS): 12-1-2009. 168p. Accessed at AIDSInfo.nih.gov/guidelines. Accessed June 6, 2010.
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7. Morris JL, Kraus DM. New antiretroviral therapies for pediatric HIV infection. J Pediatr Pharmacol Ther. 2005;10:215-247.
8. Hardy H, Skolnik PR. Enfuvirtide, a new fusion inhibitor for therapy of human immunodeficiency virus infection. Pharmacotherapy. 2004;24(2):198-211.

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1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
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2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Updated dosing information, added authorization limits and removed “Patient education” section