VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

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

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.

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).

DOSING: ELDERLY — See adults dosing.

DOSING: RENAL IMPAIRMENT — No dosage adjustment required.

Recommended Dosing Regimen and Authorization Limit:

Drug	Dosing Regimen	Authorization Limit
Fuzeon™ (enfuvirtide)	Patients 6 to 16 years old: 2 mg/kg BID up to a maximum of 90 mg BID Adult: 90 mg SQ BID	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

DOSAGE FORMS — Injection, powder for reconstitution [single-use vial]: 108 mg [90 mg/mL following reconstitution; available in convenience kit of 60 vials, SWFI, syringes, alcohol wipes, patient instructions]
ADMINISTRATION — Inject subcutaneously into upper arm, abdomen, or anterior thigh. Do not inject into moles, scar tissue, bruises, or the navel. Rotate injection site, give injections at a site different from the preceding injection site; do not inject into any site where an injection site reaction is evident.

CONTRAINDICATIONS — Hypersensitivity to enfuvirtide or any component of the formulation

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 RISK FACTOR — B

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.

PATIENT EDUCATION — Report any signs/symptoms of hypersensitivity or infection, including pneumonia (risk may be increased during therapy). Follow injection instructions closely. Rotate injection site, give injections at a site different from the preceding injection site; do not inject into any site where an injection site reaction is evident. Inject subcutaneously into upper arm, abdomen, or anterior thigh. Do not inject into moles, scar tissue, bruises, or the navel.

REFERENCES
1. Public Health Service Task Force Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States. June 23 2004. Available at: http://www.aidsinfo.nih.gov. Accessed July 1; 2004.
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3. Fuzeon. Prescribing information, Roche. February 2010.
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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