Prior Authorization Approval Criteria

Fuzeon (enfuvirtide)

Generic name: enfuvirtide
Brand name: Fuzeon
Medication class: Antiretroviral; fusion inhibitor
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 b.i.d.
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 (after first 2 months):
• Viral load reduction of at least 0.5 log (10) copies per ml after 28 days and a rise in CD4 count

Criteria for continuation of therapy (thereafter):
• Continued or persistent viral load reduction or undetectable viral load
• Patient compliant with regimen

FCHP Pharmacy and Therapeutics Committee approval: __________________________________________

Date: ______________________ Rev. 11/16/04