A Comprehensive Fuzeon (enfuvirtide) Administration Protocol

Pre-Qualification, Qualification, Initiation, and Discontinuation

Pre-Qualification

It is highly recommended that the healthcare Provider interested in initiating enfuvirtide should discuss the case with a specialist in antiretroviral management prior to discussion with the patient. A complete antiretroviral history of administration including CD4-lymphocyte counts and virologic response throughout the patient's treatment history and an up-to-date genotype are extremely important elements of this pre-qualification. As assessment of past and future adherence should be made also.

Qualification Criteria (all must be met)

1. Patient is willing to self-administer or have injected by a third-party two subcutaneous injections per day
2. Patient is willing to submit to educational efforts related to administration of enfuvirtide as well intensified laboratory monitoring for at least the first 3 months of therapy
3. In the opinion of an antiretroviral specialist, the patient has at least two potent antiretroviral drug options that may be combined with enfuvirtide. In certain cases one background drug may be sufficient (e.g. lopinavir/ritonavir, tipranavir/ritonavir)
4. Payment for enfuvirtide has been secured either via private insurance, Medicaid, or Patient Assistance
5. Patient is willing to adhere to the prescribed antiretroviral regimen and relatively intensive medical follow-up

Relative or Absolute Contraindications to enfuvirtide

1. Major previous nonadherence to medical care for which there has been little or no evidence of improvement
2. Uncontrolled moderate or severe mental health issues
3. Uncontrolled addiction to drugs (especially intravenous) or alcohol
4. Severe chronic staphylococcal skin disease
5. Hypersensitivity to enfuvirtide
6. Hypersensitivity or intolerance to components of required background antiretroviral regimen

Obtaining a Third-Party Payor for enfuvirtide Therapy

1. **Roche Patient Assistance Program:**

a. a basic medical qualification form is completed by the provider
b. a financial qualification form is completed by the patient

Both forms are faxed/mailed to Chronomed for consideration in this program.
Wait time: several weeks

2. **Louisiana ADAP:** 20 slots for indigent patients needing enfuvirtide are available. As patients initiate and discontinue enfuvirtide, the number of available slots will vary. Forms are completed by the Provider and Social Services and sent to Louisiana OPH for consideration by a panel of experts. Genotypic and other lab data are required for consideration in this program.
Wait time: usually 1-2 weeks

Initiation of Therapy with enfuvirtide

1. Prescription is written by Provider for one month of medication with maximum one refill plus any additional antiretrovirals that will be used with the enfuvirtide.
2. Prescription is delivered to pharmacy if applicable
3. Medication package is picked up by or delivered to patient:

   a. Instructional video
   b. 60 single dose vials
   c. 60 1.0 cc syringes for reconstitution
   d. 60 1.0 cc syringes for administration
   e. 60 1.0 cc vials of sterile water
   f. Alcohol wipes
   g. Large temperature-resistant storage container for all of the above supplies

4. Patient should receive instruction in administration of enfuvirtide by clinic RN prior to initiation of therapy. An appointment for this should be made with nursing. A patient information handout for enfuvirtide may be downloaded **HERE**.
5. Patient should begin therapy with enfuvirtide simultaneously with at least two other active antiretrovirals. Generally new antiretrovirals should not be begun on Fridays, weekends or while out of town.
6. Patient should be evaluated for efficacy and tolerance at 2, 4, and 8 weeks. Due to the relative complexity of this medication's administration, a follow-up visit at 1 week is also recommended.
7. HIV viral load testing should be performed no later than 4 weeks after initiation of therapy. If the viral load is not fully suppressed, it should be followed monthly until suppressed or until it is determined that virologic suppression will not be achieved. A viral load measurement at 2 weeks after initiation should also be considered
8. Refills of enfuvirtide should be written monthly or at a maximum every other month. Patient should call the pharmacy several days before each refill is required to ensure timely availability and minimize the chance of a break in therapy.

Criteria for Discontinuation of Therapy with enfuvirtide (only 1 needs to be met)

1. Lack of significant virologic suppression (>2 logs HIV RNA) after initiation
2. Loss of significant virologic suppression after initial response
3. Severe intolerance to enfuvirtide or to its administration
4. Nonadherence to enfuvirtide, other components of the antiretroviral regimen, or to follow-up medical or laboratory evaluations
5. Intolerance to an essential component of the antiretroviral regimen for which there is not an appropriate substitute
6. Desire by the patient to stop antiretroviral therapy for whatever reason