



Health Newsflash

Highlight on Fuzeon (enfuvirtide): A Novel therapy for HIV/AIDS



Redefining Health Claims Solutions

Approved use:	In combination with other HIV/AIDS drugs in patients with evidence of increasing HIV virus in the bloodstream despite ongoing therapy
NOC approval:	July 14, 2003
Availability:	Prescription only; availability late 4 th quarter 2003
Product supplied:	One-month supply kit of syringes, single-use vials with powder for reconstitution, sterile water for reconstitution and alcohol wipes. Kit includes syringes for reconstitution and administration with retractable needles for safety. Preservative-free
Dosing and administration:	Adult dose is 90 mg (1.0mL) twice daily injected under the skin of the upper arm, anterior thigh or abdomen. Pediatric dosing by weight available for patients 6-16 years of age. Once reconstituted, Fuzeon should be administered immediately. It may be kept in the vial refrigerated for 24 hr. Drug can be administered in the home setting.
Manufacturer:	Hoffmann-La Roche Limited
Therapeutic Class:	Antiretroviral agent
Cost:	Manufacturer's price for one-month kit \$2,385.60 Approximate yearly cost \$29,000 per patient

Fuzeon is the first in a new class of HIV drugs called fusion inhibitors. The major clinical trials, TORO-1 and TORO-2, were published in May of 2003 in the New England Journal of Medicine. These 2 trials showed that 24 weeks of continuous Fuzeon in combination with oral HIV therapy resulted in significant reduction of the HIV virus in the bloodstream of patients compared to patients on oral HIV therapy alone. Whether Fuzeon therapy results in increased patient survival remains to be seen.

Fuzeon represents a new therapy that will be added to existing treatment for HIV. It is an option for physicians with patients who have evidence of resistant HIV disease. Standard HIV therapy can include up to 3 oral drugs costing \$11,000 or more per patient per year. With the addition of Fuzeon to current HIV therapy, drug costs would increase to over \$40,000 per patient per year. In addition, drug therapy for co-existing HIV conditions, such as fungal and bacterial infections, will also be required. For plans currently covering HIV/AIDS drugs, there would be a significant increase in the cost of therapy.

Its adverse effects are significant and include injection site reactions in nearly all patients, as well as diarrhea, nausea and fatigue in over 16% of patients. Serious allergic reactions exhibited by rash, fever, chills, kidney problems and breathing trouble have also occurred. Increased incidence of bacterial pneumonia was seen in clinical trials in the Fuzeon treated patients. Nearly half of these patients were hospitalized and one death occurred. Due to the adverse effect profile, the use of this drug may be limited.

As treatment of HIV disease is both expensive and complex, it is difficult to estimate the number of patients who would be prescribed and then willing to use Fuzeon. The introduction of numerous combination oral products has improved patient compliance and outcomes over the past several years. Fuzeon's place in HIV therapy will be clarified as experience is gained with its use in clinical practice.

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