Reference number(s)
3099-A

SPECIALTY GUIDELINE MANAGEMENT

FUZEON (enfuviride)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication[1]
Fuzeon in combination with other antiretroviral agents is indicated for the treatment of human immunodeficiency virus (HIV)-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Human immunodeficiency virus (HIV)-1
Authorization of 12 months may be granted for treatment of HIV-1 infection when either of the following criteria is met:

A. The member has viremia despite 3 or more prior months of therapy with at least one appropriate regimen used to treat HIV.
B. The member has viremia and documented resistance or intolerance to at least one appropriate regimen used to treat HIV.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for treatment of human immunodeficiency virus type 1 (HIV-1) infection when the member has had a positive or stable virologic response to Fuzeon.

IV. REFERENCES

1. Fuzeon [package insert]. South San Francisco, CA: Genentech USA, Inc.; December 2019.