# 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

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 are 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 for continuation of therapy for 12 months may be granted for treatment of 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.

Fuzeon 3099-A SGM P2021.docx

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