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
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.; August 2019.
2. Micromedex Solutions [electronic version]. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com. Accessed December 11, 2019.
3. Clinical Pharmacology [database online]. Atlanta, GA: Elsevier, Inc.; 2019. https://www.clinicalkey.com/pharmacology. Accessed December 11, 2019.
4. Lexicomp Online®, AHFS® Drug Information, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; http://online.lexi.com Accessed December 11, 2019.