CVS Caremark®

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| Reference number(s) |
| 3099-A |

# Specialty Guideline Management Fuzeon

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Fuzeon | enfuviride |

## 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 Indications1

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.

## Coverage Criteria

### Human Immunodeficiency Virus Type 1 (HIV-1) Infection1

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

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

## 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.

## References

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