

Site of Care Criteria Sunlenca

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.

Brand Name	Generic Name	Dosage Form
Sunlenca	lenacapavir	subcutaneous

Criteria for Approval for Administration in Outpatient Hospital Setting

This policy provides coverage for administration of Sunlenca in an outpatient hospital setting for up to 45 days when a member is new to therapy or is reinitiating therapy after not being on therapy for at least 7 months.

This policy provides coverage for administration of Sunlenca in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

- The member has experienced an adverse reaction that did not respond to conventional interventions (e.g., acetaminophen, steroids, diphenhydramine, fluids or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after administration.
- The member is medically unstable (e.g., respiratory, cardiovascular, or renal conditions).
- The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of therapy AND the patient does not have access to a caregiver.
- Alternative administration sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home.
- The member is less than 14 years of age.

For situations where administration of Sunlenca does not meet the criteria for outpatient hospital administration, coverage for Sunlenca is provided when given in alternative sites such as; physician office, home, or ambulatory care.

Reference number(s)
7293-A

Required Documentation

The following information is necessary to initiate the site of care prior authorization review (where applicable):

- Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after administration
- Medical records supporting the member is medically unstable
- Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
- Records supporting alternative administration sites are greater than 30 miles from the member's home
- Medical records supporting the member is new to therapy

References

1. Sunlenca [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2024.

Document History

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