

<p>SUBJECT: CLINICAL POLICIES – INJECTABLE MEDICATIONS - LONG-ACTING ANTIRETROVIRAL AGENTS FOR HIV</p> <p>POLICY NUMBER: HS-CP-MA I3v</p> <p>EFFECTIVE DATE: September 24, 2025</p> <p>SERVICE/PRODUCT LINE: MEDICARE – MEDICAL</p>	<p>Product Line (check all that apply):</p> <p><input type="checkbox"/> All</p> <p><input type="checkbox"/> Group HMO</p> <p><input type="checkbox"/> Individual HMO</p> <p><input type="checkbox"/> PPO</p> <p><input type="checkbox"/> POS</p> <p><input checked="" type="checkbox"/> Medicare</p> <p><input type="checkbox"/> FEHB</p>
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These guidelines are used in conjunction with the independent judgment of a qualified licensed physician and do not constitute the practice of medicine or medical advice. This Clinical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This Clinical Policy is not intended to recommend treatment for members. Members should consult with their treating provider in connection with diagnosis and treatment decisions.

When coverage criteria are not fully established by Medicare including but not limited to National Coverage Decisions (NCD), Local Coverage Decisions (LCD), Medicare Manuals and National Coverage Articles, Sharp Health Plan develops Clinical Policies that serve as recommendations for medical necessity decisions. Sharp Health Plan utilizes evidence-based guidelines from nationally recognized professional organizations, peer reviewed medical and scientific literature and evidence-based consensus statements, which are all based on generally accepted standards of care.

I. BENEFIT STATEMENT: Any service reviewed and approved by this Sharp Health Plan Clinical Policy must be a covered benefit according to the member’s evidence of coverage (EOC). Since benefit plans vary in coverage and some plans may not provide coverage for certain services discussed in this clinical policy, decisions are subject to all terms and conditions of the applicable benefit plan. Benefit determinations should be based in all cases on the member’s contract benefits in effect at the time of service.

- A. All reviewers must first identify member eligibility and all decisions of this clinical policy are subject to current state and/or federal law. This Clinical policy does not constitute plan authorization, nor is it an explanation of benefits. In the event of a conflict, a member’s benefit plan, EOC, always supersedes the information in the Clinical Policies.

II. REGULATORY: N/A

III. DESCRIPTION

- A. This clinical policy should be utilized referencing the member’s specific Member Handbook to confirm the member’s coverage benefit(s).
- B. This policy defines the Sharp Health Plan (Plan) requirements for determination of medical necessity in order for Cabenuva (cabotegravir/rilpivirine) and Sunlenca (lenacapavir) to be covered.
- C. This policy is to be used when there is no CMS criteria (NCD,LCD, NCA, Medicare Manual) for the drug in question.
- D. This policy defines the Sharp Health Plan (Plan) criteria for coverage of medications with a parenteral (IM, SQ, IV, Intrathecal) route of administration. These are also referred to as a

“medical benefit” medication. A separate policy governs medications administered through the pharmacy benefit (Sharp Health Plan Pharmacy Procedure for Formulary and Pharmaceutical Management Procedures Development)

IV. DEFINITIONS

- A. A Qualified Individual is a Sharp Health Plan (Plan) member.
- B. Experimental and Investigational drugs and devices:
 - 1. Considered experimental if the FDA has not issued a specific indication or NDC number for the specific drug or device AND they are currently under investigation in a registered Clinical Trial.
 - 2. The Off-Label Use of an FDA approved prescription drug or device is not considered an experimental/investigational service if this off-label use is not currently being investigated in a registered Clinical Trial.
- C. Biosimilars: A biosimilar is a biologic that is highly similar to, and has no clinically meaningful differences from, another biologic that is already approved by the FDA (known as the original biologic or reference product). Biosimilars are made with the same types of natural sources as the original medication they were compared to; they are given the same way, have the same strength and dosage, and have the same potential side effects. A biosimilar provides the same treatment benefits as the original biologic.
- D. Injection: The introduction of a medicinal substance into the body; either subcutaneous, intramuscular, intravenous, intra-arterial or into other canals or cavities of the body. For purposes of this medical policy, a medication is provided either by a member (self-injectable) or by a medical provider. It is a “shot” or a dosage of medication given by way of a syringe and needle rather than over a period of time, though not to be given as part of a procedure.
- E. Infusion: The slow diagnostic, prophylactic, or therapeutic introduction of fluid or medicinal substance into a vein or tissue given over a period of time.
- F. Step Therapy: “Step therapy” is a process specifying the sequence in which different prescription drugs for a given medical condition and medically appropriate for a particular patient are prescribed. The health plan may require the enrollee to try one or more drugs to treat the enrollee's medical condition before the health plan will cover a particular drug for the condition pursuant to a step therapy request. If the enrollee's prescribing provider submits a request for step therapy exception, the health plans shall make exceptions to step therapy when the criteria is met.

V. MEDICAL NECESSITY

- A. To be eligible for coverage under this policy, the member must be a Qualified Individual with active Plan membership.
- B. The provision of physician samples does not guarantee coverage.
- C. Medications must be prescribed from a contracted Plan provider.
- D. Cabenuva (cabotegravir/rilpivirine) is considered medically necessary for members who meet all of the following criteria:
 - 1. Initial Criteria
 - a) Diagnosis of HIV-1 infection, and
 - b) Member is 12 years and older, and

- c) Member weighs at least 35 kilograms, and
 - d) Member is on a stable antiretroviral regimen for at least 3 months, and
 - e) Evidence of virological suppression (HIV-1 RNA < 50 copies/mL for at least 3 months), and
 - f) No history of treatment failure, and
 - g) No known or suspected resistance to cabotegravir or rilpivirine, and
 - h) Member is being treated by a contracted infectious disease specialist, and
 - i) Member is not a candidate for oral HIV medications as evidenced by either of the following:
 - (1) Significant intolerance or contraindications to oral HIV medications or
 - (2) Physician provides other reason indicating patient cannot take oral HIV medications.
 - j) Initial authorization for 12 months.
2. Reauthorization Criteria
- a) Member currently receiving Cabenuva and,
 - b) Evidence that patient has maintained virologic suppression (HIV-1 RNA < 50 copies/mL for at least 3 months) and,
 - c) Reauthorization for 12 months.
- E. Sunlenca (lenacapavir) is considered medically necessary for members who meet all of the following criteria:
1. Initial Criteria:
- a) Diagnosis of HIV-1 infection, and
 - b) Age 18 years and older, and
 - c) Used in combination with an optimized antiviral background regimen including at least one other antiretroviral agent, and
 - d) Documented resistance to at least 2 antiretroviral medications from at least 3 of the 4 following classes: NRTI, NNRTI, PI, and NSTI, and
 - e) Failing current antiretroviral regimen due to resistance, intolerance or safety concern, and
 - f) Member is being treated by a contracted infectious disease specialist.
 - g) Initial approval for 6 months.
2. Reauthorization Criteria
- a) Member is currently receiving Sunlenca, and
 - b) Medication will continue to be taken in combination with an optimized antiviral background regimen or at least one other antiretroviral medication, and
 - c) Member has responded to Sunlenca, as determine by infectious disease specialist.
 - d) Reauthorization for 12 months.

VI. NOT MEDICALLY NECESSARY

Any HIV-1 Pre-exposure Prophylaxis (PrEP) or HIV treatment that does not meet criteria of Section V. Medical Necessity in this policy is not medically necessary.

VII. PROCEDURE/ATTACHMENTS

A. Review and confirm the member’s coverage benefit for the member’s specific member.

VIII. CODES: N/A

IX. REFERENCES

- A. Apretude [package insert]. Durham, NC: GlaxoSmithKline; 2025.
- B. Cabenuva [package insert]. Durham, NC: GlaxoSmithKline; 2025.
- C. Sunlenca [package insert]. Foster City, CA: Gilead; 2025.
- D. Yeztugo [package insert]. Foster City, CA: Gilead; 2025.
- E. UpToDate, 2025. Fletcher CV. Overview of antiretroviral agents used to treat HIV. Retrieved online from:
- F. UpToDate 2024. Wood BR. Use of long-acting cabotegravir-rilpivirine in people with HIV. Retrieved online from
- G. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV. Department of Health and Human Services. Available at <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv>. Accessed 6/2/25

X. REVISION HISTORY

Date	Modification (Original, Reviewed or Revised)
09/24/25	Original

Approved by: (Signature of VP /CMO) 	Approval date: 9/24/25
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