Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Joenja (leniolisib)

Effective: November 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Joenja (leniolisib) is a kinase inhibitor indicated for the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adult and pediatric patients 4 years of age and older who weigh 27 kg or greater.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Joenja (leniolisib) for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of activated phosphoinositide 3-kinase delta syndrome (ADPS)

AND

2. Documented APDS-associated PIK3CD/PIK3RI mutation

AND

3. Documentation of one (1) of the following:
    a. Patient is at least 18 years of age or older
    b. Both of the following:
        i. Patient is 4 to 17 years of age
        ii. Patient is at least 27 kg

AND

4. Prescribed by or in consultation with a pediatrician, immunologist, hematologist, oncologist, or allergist

Reauthorization Criteria

1. Documented diagnosis of activated phosphoinositide 3-kinase delta syndrome (ADPS)

AND

2. Documented APDS-associated PIK3CD/PIK3RI mutation

AND

3. Documentation of one (1) of the following:
    a. Patient is at least 18 years of age or older
    b. Both of the following:
        i. Patient is 4 to 17 years of age
        ii. Patient is at least 27 kg

AND

4. Prescribed by or in consultation with a pediatrician, immunologist, hematologist, oncologist, or allergist

AND

5. Documentation the patient is responding positively to therapy based on provider attestation (i.e., lymph node size,

percentage of naïve B cells)

Limitations

1. Initial approval of Joenja will be authorized for six (6) months. Reauthorization of Joenja will be provided in 12-month intervals.
2. Members new to the plan stable on Joenja should be reviewed against Reauthorization Criteria.

Codes

None

References

1. Joenja (leniolisib) [package insert]. Quentin Fallavier, France: Skyepharma Production SAS; 2025 May.
2. Coulter TI, et al. The treatment of activated PI3Kδ syndrome. Front Immunol. 2018; 9:2043
3. Jamee M, et al. Clinical, immunological, and genetic features in patients with activated PI3Kδ syndrome (APDS): a systematic review. Clin Rev Allergy Immunol. 2020;59(3):323–333.
4. Rao VK, et al. A randomized, placebo-controlled, Phase 3 trial of PI3Kδ inhibitor leniolisib for activated PI3Kδ syndrome. Blood. 2023;141(9)971–983.
5. Rao VK, et al. A randomized, placebo-controlled, Phase 3 trial of PI3Kδ inhibitor leniolisib for activated PI3Kδ syndrome. Blood. 2023;141(9)971–983.
6. Singh A, et al. An updated review on activated PI3 kinase delta syndrome (APDS). Genes Dis. 2020;7(1):67–74.

Approval And Revision History

September 12, 2023: Reviewed by the Pharmacy & Therapeutics Committee.

- July 9, 2024: No changes (eff 7/9/24).
- May 13, 2025: No changes (eff 5/13/25).
- May 12, 2026: No changes. Administrative update to remove CareLink from the Medical Necessity Guideline template. (eff 5/12/26).
- October 13, 2026: Updated pediatric age requirements to at least 4 years of age and older who weigh 27 kg or greater. (eff 11/1/26)

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.