

Policy Name:	Joenja (leniolisib)	Policy#:	3204P
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Purpose of the Policy

The purpose of this policy is to define coverage criteria for Joenja (leniolisib).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Joenja (leniolisib) under the specialty pharmacy benefit if the following criteria are met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of activated phosphoinositide 3-kinase (PI3K) delta syndrome (APDS)
 - Diagnosis must be confirmed by gene testing to support APDS mutation variant in either PIK3CD or PIK3R1 genes
- 1.2 Documentation of clinical symptoms are consistent with APDS such as recurrent lung infections, enlarged lymph nodes, enlarged spleen, autoimmune low levels of blood cells and/or lung or liver dysfunction
- 1.3 Documentation of at least one measurable nodal lesion on a computerized tomography (CT) or magnetic resonance imaging (MRI) scan
- 1.4 Age 12-75 years
- 1.5 Prescribed by or in consultation with an immunologist (immune system doctor) or other specialist
- 1.6 Documentation to support previous trial and failure or contraindication to standard of care (such as antibiotics, immunoglobulin therapy, immunosuppressants (such as sirolimus)
- 1.7 Clinical review of documentation confirming that patient has met all of the above requirements for treatment completed by both a pharmacist and medical director

2. Exclusion Criteria

- 2.1 Pregnancy
- 2.2 Moderate to severe liver impairment

3. Managed Dose Limit

- 3.1 #60 tablets per 30 days

4. Approval Period

- 4.1 Initial: 12 months
- 4.2 Reauthorization: 12 months with documented benefit from therapy (such as reduced lymph node size, increased naïve B-cell percentage, decreased frequency or severity of infections, decreased frequency of hospitalizations)

CPT Codes

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HCPCS Codes

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References

1. Joenja (leniolisib) [prescribing information]. Fallavier, France: Skyepharma Production; March 2023.
2. Coulter TI, et al. The treatment of activated PI3K δ syndrome. *Front Immunol.* 2018; 9:2043.
3. Rao VK, Webster S, Šedivá A, et al. A randomized, placebo-controlled phase 3 trial of the PI3K δ inhibitor leniolisib for activated PI3K δ syndrome. *Blood.* 2023 Mar 2;141(9):971-983.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.