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| Clinical Policy Title: | Joenja |
| Policy Number: | RxA.803 |
| Drug(s) Applied: | Joenja |
| Original Policy Date: | 10/19/2023 |
| Last Review Date: | 12/19/2023 |
| Line of Business Policy Applies to: | All lines of business (except Medicare) |

Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Activated Phosphoinositide 3-Kinase Delta (PI3K δ) Syndrome (APDS) (must meet all):

1. Diagnosis of APDS;
2. Confirmation of genetic mutation in either PIK3CD (APDS1) or PIK3R1 (APDS2) gene;
3. Presence of clinical manifestations of APDS (e.g., nodal and/or extranodal lymphoproliferation, history of repeated oto-sino-pulmonary infections and/or organ dysfunction);
4. Prescribed by or in consultation with an immunologist or hematologist;

Approval duration

Commercial: 12 months

Medicaid: 12 months

II. Continued Therapy Approval

A. APDS

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

Approval duration

Commercial: 12 months

Medicaid: 12 months

References

1. 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;141(9):971-983. doi:10.1182/blood.2022018546
2. Rao VK, et al. Effective "activated PI3K δ syndrome"-targeted therapy with the PI3K δ inhibitor leniolisib. *Blood*. 2017;130(21):2307-2316. [doi:10.1182/blood-2017-08-801191][3]

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

| Review/Revision History | Review/Revision Date | P&T Approval Date |
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| Policy established. | 12/19/2023 | 10/19/2023 |
| Policy reviewed: Removed: 1. Age and weight restriction Added: 1. Continuation of treatment Changed: 1. Approval from 6 months to 12 months | 3/15/2024 | 10/19/2023 |