Joenja (leniolisib)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Joenja is indicated for the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adults and pediatric patients 12 years of age and older.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. For initial requests:
   1. Testing or analysis confirming a mutation of either *PIK3CD* or *PIK3R1* gene.
   2. Medical record documentation confirming the member demonstrates clinical manifestations of the disease (e.g., history of repeated oto-sino-pulmonary infections, lymphoproliferation, autoimmunity [e.g., cytopenia], enteropathy, organ dysfunction [e.g., lung, liver]).

B. For continuation requests:
   1. Documentation (e.g., chart notes) that the member has experienced improvement in one or more clinical manifestations of the disease (e.g., decrease in oto-sino-pulmonary infections, decrease in lymphoproliferation, improvement in autoimmunity [e.g., cytopenia], decrease in enteropathy, reduction of organ dysfunction [e.g., lung, liver]).

Prescriber Specialties

This medication must be prescribed by or in consultation with an immunologist or a physician who specializes in the treatment of APDS.

Criteria for Initial Approval

Activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS)

Authorization of 6 months may be granted when all of the following criteria are met:

A. Member's diagnosis is confirmed by detection of mutation of either *PIK3CD* or *PIK3R1* gene.
B. Member has clinical manifestations compatible with APDS (e.g., history of repeated oto-sino-pulmonary infections, lymphoproliferation, autoimmunity [e.g., cytopenia], enteropathy, organ dysfunction [e.g., lung, liver]).
C. Member is 12 years of age and older weighing greater than or equal to 45 kg.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in all members (including new members) who are currently receiving the requested medication and who are experiencing benefit from therapy as evidenced by improvement in clinical manifestations of disease (e.g., decrease in oto-sino-pulmonary infections, decrease in lymphoproliferation, improvement in autoimmunity [e.g., cytopenia], decrease in enteropathy, reduction of organ dysfunction [e.g., lung, liver]).

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Joenja is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Joenja – 60 tablets per 30 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

- Joenja [package insert]. Warren, NJ: Pharming Technologies B.V.; March 2023.
- Rao VK, Webster S, Šedivá A, et al. A randomized, placebo-controlled phase 3 trial of the PI3Kδ inhibitor leniolisib for activated PI3Kδ syndrome. *Blood*. 2023;141(9):971-983. doi:10.1182/blood.2022018546.

POLICY HISTORY

Policy #: 05.05.02
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