Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

leniolisib (Joenja)

Notes:

Quantity Limits: Yes

Initiation (new start) criteria and criteria for new members entering Kaiser

Permanente already taking the medication who have not been reviewed previously:

Non-formulary leniolisib (Joenja) will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by an Allergist/Immunologist
- Patient is at least 12 years of age and weighs at least 45 kg (99 lbs)
- Diagnosis of activated phosphoinositide 3-kinase delta syndrome (APDS) confirmed by an APDS-associated genetic variant in either PIK3CD or PIK3R1 gene.
- Documentation of clinical findings and manifestations consistent with APDS (e.g., recurrent respiratory tract infections, recurrent herpesvirus infections, lymphadenopathy, hepatosplenomegaly, autoimmune cytopenias).
- Patient has a history of trial and failure, intolerance or contraindication to current standard of care for APDS such as: antimicrobial prophylaxis, immunoglobulin replacement therapy, or immunosuppressive therapy.

<u>Continued use criteria (12 months after initiation)</u>: Non-formulary leniolisib (Joenja) will be covered on the prescription drug benefit when the following criteria are met:

- Continues to be prescribed by an Allergist/Immunologist
- Documentation of positive clinical response to therapy such as: reduced lymph node size, increased naïve B-cell percentage, decreased frequency or severity of infections, or decreased frequency of hospitalizations.
- Patient weighs at least 45 kg

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