SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Joenja® (leniolisib)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

Quantity Limit: 2 tablets per day

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Member is ≥ 12 years of age
- ❑ Member is ≥ 45 kg
- ❑ Provider is an immunologist, has been in consultation with one, or is a specialist in treating patients with activated phosphoinositide 3-kinase (PI3K) delta syndrome (APDS)
- ❑ Member has a diagnosis of activated phosphoinositide 3-kinase (PI3K) delta syndrome (APDS) confirmed by submission of laboratory results confirming the presence of an activated phosphoinositide 3-kinase delta syndrome (APDS)-associated genetic PI3Kδ mutation with a documented variant in either PIK3CD or PIK3R1

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- ❑ Provider must submit documentation of member's medical history which may note recurrent sinopulmonary infections, sinusitis, pneumonia, bronchitis, chronic Epstein-Barr virus and cytomegalovirus (CMV) viremia, autoimmune cytopenia, and/or lymphadenopathy/hepatomegaly
- ❑ For members with splenomegaly, the provider has submitted measured volume of spleen size using computed tomography (CT) or magnetic resonance imaging (MRI) scan
- ❑ For members with evidence of nodal lesions, the provider has submitted results from a computed tomography (CT) or magnetic resonance imaging (MRI) scan
- ❑ Member is **NOT** on concurrent immunosuppressive therapy (e.g., mTOR inhibitors, B-cell depleters, glucocorticoids [doses > 25 mg/day of prednisone equivalent], cyclophosphamide, mycophenolate)
- ❑ Provider must submit **BOTH** the following baseline objective clinical laboratory documentation prior to initiating treatment **(obtained within the past 30 days)**:
  - ❑ Results of a complete blood count with differential to include a T and B cell (lymphocytes) screening
  - ❑ Measurement of serum immunoglobulin M (IgM) level

Reauthorization: 12 months. All criteria that apply must be checked for approval. To support each line checked all documentation (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

- ❑ Member is **NOT** on concurrent immunosuppressive therapy (e.g., mTOR inhibitors, B-cell depleters, glucocorticoids [doses > 25 mg/day of prednisone equivalent], cyclophosphamide, mycophenolate)
- ❑ Member has been observed to have a positive clinical response since the beginning of therapy evidenced by disease stability, or mild progression, in any of the following **(check all that apply; submitted in documentation and charted in clinical notes)**:
  - ❑ Computed tomography (CT) or magnetic resonance imaging (MRI) scan observing the reduction in lymph node lesions if present at baseline
  - ❑ Follow-up complete blood count observing normalization in T and B cells
  - ❑ Computed tomography (CT) or magnetic resonance imaging (MRI) scan observing the reduction in spleen size if applicable
  - ❑ Follow-up serum immunoglobulin screening observing normalization in IgM levels
  - ❑ Submission of progress notes documenting frequency or severity of infections
- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., severe neutropenia (ANC <500 cells/µL), skin rash)

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan.
If a drug is non-formulary on a Plan, documentation of medical necessity will be required.
*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****
****Previous therapies will be verified through pharmacy paid claims or submitted chart notes***

***Approved by Pharmacy and Therapeutics Committee**: ~~5/25/2023;~~ **11/21/2024**
REVISED/UPDATED/REFORMATTED: ~~5/15/2023; 6/15/2023;~~ **12/17/2024**