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 information provided is not complete, correct, or legible, authorization may 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:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

Diagnosis: _____ **ICD Code:** _____

Weight: _____ **Date:** _____

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 **BOTH** the following:

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- ❑ 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
- ❑ Submission of clinical findings and manifestations compatible with APDS (e.g., history of recurrent sinopulmonary infections, sinusitis, pneumonia, bronchitis, chronic Epstein-Barr virus and cytomegalovirus (CMV) viremia, autoimmune cytopenia, and/or lymphadenopathy/hepatomegaly)

❑ 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 **ALL** the following objective clinical laboratory documentation prior to initiating treatment **(obtained within the past 30 days)**:

- ❑ Observation of at least **ONE** measurable nodal lesion using computed tomography (CT) or magnetic resonance imaging (MRI) scan
- ❑ Results of a complete blood count with differential to include a T and B cell (lymphocytes) screening
- ❑ Measured volume of spleen size using computed tomography (CT) or magnetic resonance imaging (MRI) scan
- ❑ 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 experienced a positive clinical response to treatment as evidenced by at least **ONE** of the following:

- ❑ Computed tomography (CT) or magnetic resonance imaging (MRI) scan observing the reduction in lymph node lesions
- ❑ 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
- ❑ Follow-up serum immunoglobulin screening observing normalization in IgM levels

❑ Member has experienced a decrease in the frequency of infections or severity of infections **(submission of progress notes to include patient-reported symptoms and treatment plan history)**

❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., severe neutropenia (ANC <500 cells/μL), skin rash)

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Medication being provided by Specialty Pharmacy - PropriumRx

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***