



## Commercial/Healthcare Exchange PA Criteria

**Effective: May 11, 2023**

**Prior Authorization:** Joenja (leniolisib phosphate)

**Products Affected:** Joenja (leniolisib phosphate) oral tablet

**Medication Description:** JOENJA is indicated for the treatment of activated phosphoinositide 3-kinase delta (PI3K $\delta$ ) syndrome (APDS) in adult and pediatric patients 12 years of age and older. Leniolisib inhibits PI3K-delta by blocking the active binding site of PI3K-delta. Leniolisib inhibits the signaling pathways that lead to increased production of PIP3, hyperactivity of the downstream mTOR/AKT pathway, and to the dysregulation of B and T cells.

**Covered Uses:** Treatment of activated phosphoinositide 3-kinase delta (PI3K $\delta$ ) syndrome (APDS) in adult and pediatric patients 12 years of age and older.

**Exclusion Criteria:** None

**Required Medical Information:**

1. Current medication list
2. Medication history
3. Patient Medical History

**Prescriber Restriction:** Medication must be prescribed by, or in consultation with, an immunologist, or a physician who specializes in the treatment of APDS.

**Age Restriction:** 12 years of age and older

**Coverage Duration:** 12 months

**Other Criteria:**

**Initial Approval Criteria**

**1. Activated Phosphoinositide 3-kinase delta (PI3K $\delta$ ) syndrome (APDS)**

- A. Patient is  $\geq$  12 years of age; **AND**
- B. Patient weighs  $\geq$  45 kg; **AND**
- C. Patient has a genetic phosphoinositide 3-kinase delta (PI3K $\delta$ ) mutation with a variant in *PIK3CD* and/or *PIK3R1* genes; **AND**
- D. Patient has at least one clinical finding or manifestation consistent with APDS; **AND**  
*Note: Examples of clinical findings or manifestations of APDS include recurrent sinopulmonary infections, recurrent herpesvirus infections, lymphadenopathy, hepatomegaly, splenomegaly, nodular lymphoid hyperplasia, autoimmunity, cytopenias, enteropathy, bronchiectasis, and organ dysfunction.*
- E. The medication is prescribed by or in consultation with an allergist, immunologist, otolaryngologist (ear, nose, and throat [ENT] physician), pulmonologist, an infectious diseases physician who treats patients with primary immune deficiencies, or a physician who specializes in genetic disorders.

April 2023



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**References:**

1. Product Information: JOENJA® oral tablets, leniolisib oral tablets. Pharming Healthcare, Inc (per FDA), Bridgewater, NJ, 2023.

**Policy Revision history**

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
1	New Policy	New Policy	All	05/11/2023