

POLICY NAME	Joenia (leniolisib)	POLICY #	3204P
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Criteria

Coverage Criteria

- ☐ **1.1** Diagnosis of activated phosphoinositide 3-kinase (PI3K) delta syndrome (APDS)
 - Diagnosis must be confirmed by gene testing to support APDS mutation variant in either PIK3CD or PIK3R1 genes
- ☐ **1.2** Documentation of clinical symptoms are consistent with APDS such as recurrent lung infections, enlarged lymph nodes, enlarged spleen, autoimmune low levels of blood cells and/or lung or liver dysfunction
- ☐ **1.3** Documentation of at least one measurable nodal lesion on a computerized tomography (CT) or magnetic resonance imaging (MRI) scan
- ☐ **1.4** Age 12-75 years
- ☐ **1.5** Prescribed by or in consultation with an immunologist (immune system doctor) or other specialist
- ☐ **1.6** Documentation to support previous trial and failure or contraindication to standard of care (such as antibiotics, immunoglobulin therapy, immunosuppressants (such as sirolimus)
- ☐ **1.7** Clinical review of documentation confirming that patient has met all of the above requirements for treatment completed by both a pharmacist and medical director

Exclusion Criteria – Any of the following prevents coverage

- ☐ **2.1** Pregnancy
- ☐ **2.2** Moderate to severe liver impairment