

**POLICY NAME**

Joenja (leniolisib)

**POLICY #**

## Criteria

### Exclusion Criteria – Any of the following prevents coverage

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

### 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