



**GEORGIA MEDICAID FEE-FOR-SERVICE
ENZYME INHIBITORS, SYSTEMIC PA SUMMARY**

Preferred	Non-Preferred
Aralast-NP (alpha-1 proteinase inhibitor [human] intravenous solution)	Joenja (leniolisib)
Glassia (alpha-1 proteinase inhibitor [human] intravenous solution)	
Prolastin-C (alpha-1 proteinase inhibitor [human] intravenous solution)	
Vijoice (alpelisib)	
Zemaira (alpha-1 proteinase inhibitor [human] intravenous solution)	
Zokinvy (lonafarnib)	

LENGTH OF AUTHORIZATION: Varies

NOTES:

- **The criteria details below are for the outpatient pharmacy program.** If a medication is being administered in a physician’s office or clinic, the medication must be billed through the physician services program and not the outpatient pharmacy program. Information regarding the DCH physician services program is located at www.mmis.georgia.gov.
- All agents require prior authorization (PA).

PA CRITERIA:

Aralast-NP, Glassia, Prolastin-C and Zemaira

- ❖ Approvable for members 18 years of age or older with a diagnosis of congenital deficiency of alpha-1 proteinase inhibitor (alpha-1 antitrypsin deficiency) confirmed by genetic testing of alleles associated with alpha-1 antitrypsin deficiency (AATD) with clinically evident emphysema; **AND**
- ❖ Members must have an alpha-1 antitrypsin (AAT) plasma level less than 11 umol/L and a forced expiratory volume in one second (FEV₁) of 30-65% of predicted or a documented rate of decline in FEV₁; **AND**
- ❖ Medication must be administered in member’s home or in a long-term care facility; **AND**
- ❖ Medication must be prescribed by or in consultation with a pulmonologist or specialist in alpha-1 antitrypsin deficiency.

Vijoice

- ❖ Approvable for members 2 years of age or older with a diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy **AND**
- ❖ Medication must be prescribed by or in consultation with a specialist in genetic disorders.

Zokinvy



- ❖ Approvable for members 1 year of age or older with a body surface area (BSA) of 0.39 m² or greater and a diagnosis of
 - Hutchinson-Gilford Progeria Syndrome (HGPS) confirmed by genetic testing of G608G (c.1824C>T[p.Gly608Gly]) pathogenic variant in the *LMNA* gene

OR

- Processing-deficient Progeroid Laminopathies confirmed by genetic testing of heterozygous *LMNA* mutation with progerin-like protein accumulation or homozygous or compound heterozygous ZMPSTE24 mutations

AND

- ❖ Member must have at least one of the following clinical characteristics
 - failure to thrive in the first year of life
 - characteristic facial appearance with micrognathia, prominent eyes and circumoral cyanosis
 - alopecia and prominent scalp veins
 - sclerotic skin changes with outpouching and dimpling/mottling especially on the abdomen
 - decreased joint range of motion and joint contracture

AND

- ❖ Medication must be prescribed by or in consultation with a geneticist, metabolic disorder specialist or progeria specialist.

Joenja

- ❖ Approvable for members 12 years of age or older who weigh 45 kg or more with a diagnosis of activated phosphoinositide 3-kinase delta syndrome (APDS) confirmed by an APDS-associated genetic PI3K δ mutation with a documented variant in either *PIK3CD* or *PIK3R1*;

AND

- ❖ Member must have presence of nodal or extranodal proliferation as well as clinical findings and manifestations consistent with APDS; **AND**
- ❖ Member must have a history of trial and failure, intolerance or contraindication to current standard of care for APDS; **AND**
- ❖ Medication must be prescribed by or in consultation with a hematologist, immunologist or other specialist in treating APDS.

EXCEPTIONS:

- Exceptions to these conditions of coverage are considered through the prior authorization process.
- The Prior Authorization process may be initiated by calling **OptumRx at 1-866-525-5827**.

PREFERRED DRUG LIST:

- For online access to the Preferred Drug List (PDL), please go to <http://dch.georgia.gov/preferred-drug-lists>.

PA AND APPEAL PROCESS:

- For online access to the PA process, please go to www.dch.georgia.gov/prior-authorization-process-and-criteria and click on Prior Authorization (PA) Request Process Guide.



QUANTITY LEVEL LIMITATIONS:

- For online access to the current Quantity Level Limits (QLL), please go to www.mmis.georgia.gov/portal, highlight Pharmacy and click on [Other Documents](#), then select the most recent quarters QLL list.