GEORGIA DEPARTMENT OF COMMUNITY HEALTH

GEORGIA MEDICAID FEE-FOR-SERVICE
COMPLEMENT INHIBITORS PA SUMMARY

Preferred	Non-Preferred
n/a	Empaveli (pegcetacoplan subcutaneous injection) Voydeya (danicopan)
n/a	Tavneos (avacopan)
n/a	Zilbrysq (zilucoplan subcutaneous injection)

LENGTH OF AUTHORIZATION: Varies

NOTE:

- If medication is being administered in a physician's office or clinic, then the medication must be billed through the DCH physician services program and not the outpatient pharmacy program. Information regarding the physician services program can be located at www.mmis.georgia.gov.

PA CRITERIA:

Empaveli

- Approvable for members 18 years of age or older with a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed with at least two independent flow cytometry reagents used on at least two cell lineages (e.g., granulocytes and red blood cells [RBCs]) demonstrating that the individual's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) – linked proteins *AND* member must have a hemoglobin (Hb) level <10.5 g/dL and have experienced an inadequate response, allergy, contraindication, drug-drug interaction or intolerable side effect to Soliris (eculizumab) or Ultomiris (ravulizumab).
- Approvable for members 12 years of age or older with a diagnosis of C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) with a urine protein-to-creatinine ratio (UPCR) ≥1 g/g, proteinuria level ≥1.5 g/day and estimated glomerular filtration rate (eGFR) ≥30 mL/min/1.73 m^2 *AND* member must have been on a stable and optimized doses of angiotensin-converting enzyme inhibitors, angiotensin receptor blockers and/or sodium-glucose cotransporter-2 inhibitors for at least 3 months and will remain on this therapy throughout the duration of treatment.
- Must be prescribed by or in consultation with a hematologist, nephrologist or other specialist.

Voydeya

- Approvable for members 18 years of age or older with a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed with at least two independent flow cytometry reagents used on at least two cell lineages (e.g., granulocytes and red blood cells [RBCs]) demonstrating that the individual's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) – linked proteins *AND*
- Member must be experiencing extravascular hemolysis (EVH), have a hemoglobin (Hb) level <10.5 g/dL and have experienced an inadequate response, allergy, contraindication, drug-drug interaction or intolerable side effect to Soliris (eculizumab) or Ultomiris (ravulizumab) *AND*
- Must be prescribed by or in consultation with a hematologist or other specialist in managing PNH.

Tavneos

- Approvable for members 18 years of age or older with a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) when used in combination with standard therapy (e.g., azathioprine, cyclophosphamide, methotrexate, mycophenolate, rituximab) including glucocorticoids (e.g., prednisone, methylprednisolone) *AND*
- Must be prescribed by or in consultation with a rheumatologist, nephrologist or immunologist.

Zilbrysq

- Approvable for members 18 years of age or older with a diagnosis of generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AchR) antibody positive, Myasthenia Gravis Foundation of America (MGFA) Clinical Classification II, III or IV at initiation of therapy and have tried two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) over the last 12 months and failed to achieve an adequate response or have tried at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/plasma exchanges and/or intravenous immune globulin over the last 12 months without symptom control *AND*
- Members have tried Soliris (eculizumab) and failed to achieve an adequate response or have an allergy, contraindication, drug-drug interaction or intolerable side effect to Soliris *AND*
- Must be prescribed by or in consultation with a neurologist or other specialist in managing myasthenia gravis.

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 Provider Information and click on Provider Manuals. Scroll to the page with Pharmacy Services and select that manual.