PROVIDER*ALERT*

AmeriHealth Caritas Louisiana

To: **AmeriHealth Caritas Louisiana Providers**

Date: **February 10, 2025**

Subject: **LDH Approved Medical Drug Policies**

Summary: Five Guidelines for Medical Drug Policies:
Chronic Inflammatory Demyelinating Polyneuropathy, Complement Inhibitors, Rytelo, Tecelra, and Veopoz

AmeriHealth Caritas Louisiana would like to make you aware of the attached policies that have been approved by the Louisiana Department of Health in accordance with La. R.S. 46:460.54. The guidelines will be located at the following link on our website:
https://www.amerihealthcaritasla.com/pdf/pharmacy/acla-non-pdl-prior-auth-criteria.pdf.

Reminder: If your practice is not registered with our website portal-NaviNet, we highly recommend registering.
To register, please visit www.navinet.net to sign up or contact your Provider Account Executive for details.

Questions: Thank you for your continued support and commitment to the care of our members. If you have questions about this communication, please contact AmeriHealth Caritas Louisiana Provider Services at 1-888-922-0007 or your Provider Network Management Account Executive.

Missed an alert? You can find a complete list of provider alerts on our website's Provider Newsletters and Updates page.

Need to update your provider information? Send full details to network@amerihealthcaritasla.com.

Field Name	Field Description
Prior Authorization Group Description	**Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Agents**
Drugs	Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA-approved labeling
Prescriber Restrictions	Prescriber must be a neurologist or neuromuscular specialist.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 3 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Date: 11/2024	**Drug is being requested through the member's medical benefit** Initial Authorization: • Diagnosis of CIDP confirmed by electrodiagnostic test results (e.g. electromyography or nerve conduction studies) • Patient has progressive or relapsing/remitting disease course for ≥2 months • Patient has an inadequate response, significant intolerance, or contraindication to intravenous immunoglobulin (IVIG) or subcutaneous immunoglobulin (SCIG) • Medication is prescribed at an FDA approved dose Re-Authorization: • Documentation or provider attestation of significant clinical improvement in neurologic symptoms or stabilization of disease • Medication is prescribed at an FDA approved dose If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	**Complement Inhibitors**
Drugs	Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Syfovre (pegcetacoplan injection), Fabhalta (iptacopan), Voydeya (danicopan), Izervay (avacincaptad pegol injection), PiaSky (crovalimab-akkz)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist, nephrologist, neurologist, oncologist, ophthalmologist, or other appropriate specialist.
Coverage Duration	If the criteria are met, criteria will be approved as follows: Initial Requests • 3 months: Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Voydeya (danicopan) • 6 months: Fabhalta (iptacopan), PiaSky (crovalimab-akkz) • 12 months: Syfovre (pegcetacoplan), Izervay (avacincaptad pegol) Reauthorization • 6 months: Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Voydeya (danicopan) • 12 months: Syfovre (pegcetacoplan), Fabhalta (iptacopan), PiaSky (crovalimab-akkz) No Reauthorization • Izervay (avacincaptad pegol)
Other Criteria	****Drug is being requested through the member's medical benefit**** **Initial Authorization:** • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient's diagnosis, age, body weight, and concomitant medical conditions; **AND** • For Fabhalta (iptacopan), Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), PiaSky (crovalimab-akkz), and Voydeya (danicopan) o Documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria. **Paroxysmal Nocturnal Hemoglobinuria (PNH):** • Documentation of diagnosis by high sensitivity flow cytometry • Hemoglobin (Hgb) < 10.5 g/dL for Empaveli (pegcetacoplan), or HgB < 10 g/dL for Fabhalta (iptacopan) • For Voydeya (danicopan): o Member has been receiving Soliris (eculizumab) or Ultomiris (ravulizumab) therapy for at least 6 months o Member has clinically evident extravascular hemolysis [defined as anemia (Hgb ≤9.5 gram/deciliter) with absolute reticulocyte count ≥120 x 10^9/liter] despite treatment with Soliris (eculizumab) or Ultomiris (ravulizumab)

Revision/Review Date 11/2024	o Voydeya (danicopan) will be used as add-on therapy to Soliris (eculizumab) or Ultomiris (ravulizumab) **Generalized Myasthenia Gravis (gMG):** • The request is for Soliris (eculizumab) or Ultomiris (ravulizumab) • Patient has a positive serologic test for anti-AChR antibodies; **AND** • Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV at initiation of therapy; **AND** • Patient has a Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score ≥ 6 at initiation of therapy; **AND** • One of the following: o Failed treatment over a total of 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; **OR** o Failed at least 1 IST and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin; **OR** o Has a documented history of contraindications or intolerance to ISTs **Neuromyelitis Optica Spectrum Disorder (NMOSD)** • Refer to the "Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents" policy **Atypical Hemolytic Uremic Syndrome (aHUS)/Complement-Mediated HUS)** • Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies; **OR** • Provider attestation treatment is being used empirically and delay in therapy will lead to unacceptable risk to the patient **Geographic Atrophy (GA):** • If the request is for Syfovre (pegcetacoplan injection), member must be ≥ 60 years of age • If the request is for Izervay (avacincaptad pegol injection), member must be ≥ 50 years of age • Diagnosis of GA secondary to age-related macular degeneration (AMD) • Absence of choroidal neovascularization (CNV) in treated eye • Best-corrected visual acuity (BCVA) ≥ 24 letters Early Treatment Diabetic Retinopathy Study (ETDRS) • GA lesion size > 2.5 and < 17.5 mm^2 with at least 1 lesion > 1.25 mm^2 **<u>Re-Authorization:</u>** • Re-authorization may be considered for all agents included in these criteria with the exception of Izervay (avacincaptad pegol injection), which is only indicated for a 12 month duration • Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality of life scores, increase in Hgb, reduced need for blood transfusions, slowing of growth rate of GA lessions, etc.); **AND** • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient's diagnosis, age, body weight, and concomitant medical condition; **AND** • If the request is for aHUS/Complement Mediated HUS o Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Rytelo**
Drugs	Rytelo (imetelstat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years of age and older
Prescriber Restrictions	Prescriber must be a hematologist or oncologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 6 months.
Other Criteria Revision/ Review Date: 11/2024	**Drug is being requested through the member's medical benefit** Initial Authorization: • Diagnosis of myelodysplastic syndromes (MDS) with transfusion-dependent anemia • Myelodysplastic Syndrome Revised International Prognostic Scoring System (IPSS-R) categorization as low or intermediate-1 risk of progression • Member has transfusion burden of 4 or more red blood cell (RBC) units within an 8-week period over the last 4 months • Prescriber attestation that complete blood cell count (CBC) will be obtained prior to initiation, weekly for first two cycles, and prior to each cycle thereafter • Member's weight has been provided with request • Medication is prescribed at an FDA approved dose Re-Authorization: • Documentation or provider attestation of reduction in RBC transfusion burden as compared with baseline • Provider attestation that patient is tolerating the medication and is not experiencing any serious adverse reactions • Member's weight has been provided with request • Medication is prescribed at an FDA approved dose If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	**Tecelra**
Drugs	Tecelra (afamitresgene autoleucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Homozygous or heterozygous for HLA-A*02:05P
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an oncologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria Date: 11/2024	**Drug is being requested through the member's medical benefit** Initial Authorization: • Diagnosis of unresectable or metastatic synovial sarcoma • Documentation that patient is HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive • Documentation that the tumor expresses the MAGE-A4 antigen • Documentation of treatment with prior chemotherapy • Member must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 • Medication is being prescribed at an FDA approved dose The safety and effectiveness of repeat administration of Tecelra has not been evaluated and will not be approved. If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	**Veopoz**
Drugs	Veopoz (pozelimab-bbfg)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Patients with unresolved Neisseria meningitidis infection • Concurrent use of another complement inhibitor (i.e. Soliris)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a physician with experience in managing complement related disorders (i.e., gastroenterologist, immunologist, cardiologist, etc.)
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 11/2024	**Drug is being requested through the member's medical benefit** Initial Authorization: • Medication is prescribed at an FDA approved dose • Diagnosis of CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease • Documentation of hypoalbuminemia (serum albumin <3.5 g/dL) • Documentation of patient weight Re-Authorization: • Documentation or provider attestation of positive clinical response (i.e. symptom improvement, normalization of labs such as serum albumin (3.5-5.5 g/dL) and IgG concentrations, reduced hospitalizations and severe adverse events, increased quality of life, etc.) • Documentation of patient weight • Medication is prescribed at an FDA approved dose If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.