PROVIDER*ALERT*

AmeriHealth Caritas Louisiana

To: **AmeriHealth Caritas Louisiana Providers**

Date: **July 25, 2025**

Subject: **LDH Approved Medical Policies**

Summary: Eight LDH Approved Medical Policies

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

1. Adzynma
2. Amtagvi (lifileucel)
3. Anti-CD19 CAR-T Immunotherapies
4. Blincyto
5. Complement Inhibitors
6. Dendritic Cell Tumor Peptide Immunotherapy
7. Hydroxyprogesterone caproate (generic Delalutin)
8. Kebilidi (eladocagene exuparvovec-tneq)

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	**Adzynma**
Drugs	Adzynma (ADAMTS13, recombinant-krhn)
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	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist, oncologist, intensive care specialist, or specialist in the treatment of rare genetic hematologic diseases
Coverage Duration	On-demand therapy: If all criteria are met, the request will be approved for 1 month. Prophylactic therapy: If all criteria are met, the initial request will be approved for 6 months. Reauthorization requests will be approved for 12 months.
Other Criteria Revision/Review Date: 4/2025	****Drug is being requested through the member's medical benefit**** **Initial Authorization** • Diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) as confirmed by BOTH of the following: o Molecular genetic testing o ADAMTS13 activity <10% • Prescriber attestation that member has not been diagnosed with any other TTP-like disorder (i.e., microangiopathic hemolytic anemia, immune-mediated thrombotic thrombocytopenic purpura [iTTP]) • If request is for prophylactic therapy, member must also have a history of at least one documented TTP event • Member's weight • Request is for an FDA-approved dose **Reauthorization** • Documentation of positive clinical response to therapy (i.e., improvement in acute and subacute TTP events, platelet counts, microangiopathic hemolytic anemia episodes, or clinical symptoms) • Member's weight • Request is for an FDA-approved dose **Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Amtagvi (lifileucel)**
Drugs	Amtagvi (lifileucel)
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	• Uncontrolled brain metastases • Melanoma of uveal or ocular origin • Systemic steroid therapy for any reason
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 Revision/Review Date: 4/2025	****Drug is being requested through the member's medical benefit**** **<u>Initial Authorization:</u>** • Diagnosis of unresectable or metastatic melanoma (Stage IIIc or Stage IV) • Member must have progressed through at least one prior systemic therapy including a PD-1/PD-L1 blocking antibody and, if BRAF V600 mutation–positive, a BRAF inhibitor or BRAF inhibitor in combination with a MEK inhibitor • Member must have at least one resectable lesion (or aggregate of lesions resected) of a minimum 1.5 cm in diameter post-resection • Eastern Cooperative Oncology Group (ECOG) score of 0 or 1 • Medication is prescribed at an FDA approved dose **The safety and effectiveness of repeat administration of Amtagvi has not been evaluated and will not be approved.** **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	**Anti-CD19 CAR-T Immunotherapies**

Drugs	Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel), Tecartus (brexucabtagene autoleucel), Breyanzi (lisocabtagene maraleucel)**, Aucatzyl (obecabtagene 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	Patients with primary central nervous system lymphoma
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescriber must be an oncologist, hematologist or other appropriate specialist
Coverage Duration	If all the criteria are met, the initial request will be approved for a **single treatment regimen**~~one – time infusion~~ per lifetime. • **Kymriah, Yescarta, Tecartus, Breyanzi :a one-time infusion** • **Aucatzyl: a split-dose infusion administered on day 1 and day 10 (± 2 days)**
Other Criteria	****Drug is being requested through the member's medical benefit**** **Initial authorization:** • Patient must not have received prior anti-CD19 CAR-T therapy. • Patient will be screened for HBV, HCV, and HIV in accordance with clinical guidelines. • Patient does not have an active infection or inflammatory disorder. • Patient has a life expectancy >12 weeks. • Patient will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment. • Use is supported by a labeled indication or NCCN guidelines **Leukemia**

	B-cell precursor Acute Lymphoblastic Leukemia (ALL):
	
	• If the request is for Kymriah
	  o Patient is 25 years of age or younger
	  o ALL that is refractory or in second or later relapse
	• If the request is for Tecartus **or Aucatzyl**
	  o Patient is 18 years of age or older
	  o ALL that is relapsed or refractory
	
	Chronic Lymphocytic Leukemia (CLL):
	
	• If the request is for Breyanzi
	  o Patient is 18 years of age or older
	  o Patient has relapsed/refractory disease defined as failure of two or more lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor AND a B-cell lymphoma 2 (BCL-2) inhibitor
	
	Non-Hodgkin's Lymphoma (NHL)
	
	Follicular Lymphoma (FL):
	
	• If the request is for Breyanzi, Kymriah, or Yescarta:
	  o Patient is 18 years of age or older
	  o Patient has relapsed/refractory disease defined as failure of two or more lines of systemic therapy
	
	Large B-cell Lymphoma (LBCL), Diffuse Large B-cell Lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, follicular lymphoma grade 3B, and DLBCL arising from follicular lymphoma or indolent lymphoma:
	
	• If the request is for Breyanzi, Kymriah, or Yescarta
	  o Patient is 18 years of age or older
	  o For Breyanzi ONE of the following:

Revision/Review Date: ~~4~~**7**/202**5**~~4~~	▪ Patient is refractory to first-line chemoimmunotherapy or relapsed within 12 months of first-line chemoimmunotherapy ▪ Patient is refractory to first-line chemoimmunotherapy or relapsed after first-line chemoimmunotherapy and is not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age ▪ Patient has **relapsed or refractory disease** **after**~~failed~~ two or more lines of systemic therapy o For Kymriah: Patient has relapsed/refractory disease defined as failure of two or more lines of systemic therapy o For Yescarta ONE of the following: ▪ Patient is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy or ▪ Patient has failed two or more lines of systemic therapy **Mantle Cell Lymphoma (MCL):** • **Patient is 18 years of age or older** • If the request is for Tecartus: o ~~Patient is 18 years of age or older~~ o Patient has relapsed/refractory disease defined as failure of **all**~~BOTH~~ the following~~lines of therapy~~: ▪ Chemoimmunotherapy such as an anti-CD20 monoclonal antibody (e.g. Rituxan) + any chemotherapeutic agent ▪ Bruton Tyrosine Kinase (BTK) Inhibitor (e.g. Calquence, Imbruvica, Brukinsa) • **If the request is for Breynazi:** o **Patient has relapsed or refractory disease who have received at least 2 prior lines of systemic therapy, including a BTK inhibitor** **Small Lymphocytic Lymphoma (SLL):** • If the request is for Breyanzi

	○ Patient is 18 years of age or older ○ Patient has received at least 2 prior lines of therapy including, a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor **<u>Re-authorization</u>:** • Treatment exceeding 1 **<u>single treatment regimen</u>**~~dose~~ per lifetime will not be authorized. ○ **<u>Kymriah, Yescarta, Tecartus, Breyanzi :a one-time infusion</u>** ○ **<u>Aucatzyl: a split-dose infusion administered on day 1 and day 10 (± 2 days)</u>** **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	**Blincyto**
Drugs	Blincyto (blinatumomab)
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 Restriction	N/A
Prescriber Restrictions	Prescriber must be an oncologist/hematologist
Coverage Duration	The request will be approved for up to a 12-month duration
Other Criteria	****Drug is being requested through the member's medical benefit**** **Initial Authorization:** • Patient has a diagnosis of one of the following forms of Acute Lymphoblastic Leukemia (ALL): a) Relapsed CD19-positive B-cell precursor ALL b) Refractory CD19-positive B-cell precursor ALL c) B-cell precursor CD-positive ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% **d) <u>CD19-positive Philadelphia chromosome-negative B-cell precursor ALL in the consolidation phase of multiphase chemotherapy</u>** • Provider attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities **Reauthorization:** • ~~Patient has a diagnosis of relapsed or refractory CD19-positive B-cell precursor ALL and has not exceeded 9 total cycles of Blincyto therapy~~ • Provider attests to treatment response or stabilization of disease • Prescriber attests to monitor patient for Cytokine Release Syndrome

Revision/Review Date 4/202**5**~~4~~	(CRS) and neurological toxicities ~~***For CD19-positive B-cell precursor ALL with MRD, reauthorization is not allowed***~~ **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	**Complement Inhibitors**
Drugs	**Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Syfovre (pegcetacoplan injection), Fabhalta (iptacopan), Voydeya (danicopan), Izervay (avacincaptad pegol injection), PiaSky (crovalimab-akkz) , BKEMV (eculizumab-aeeb), Epysqli (eculizumab-aagh)**
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 **(Soliris, BKEMV, Epysqli)**, 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**(Soliris, BKEMV, Epysqli)**, 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 **(Soliris, BKEMV, Epysqli)**, Ultomiris (ravulizumab), Empaveli (pegcetacoplan), PiaSky (crovalimab-akkz), and Voydeya (danicopan) o Documentation patient complies with the current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria. • **For Soliris or BKEMV, patient must have a documented trial and failure or intolerance to Epysqli or a medical reason why Epysqli cannot be used.** **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 **(Soliris, BKEMV, Epysqli)** 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 (Soliris, BKEMV, Epysqli)** or Ultomiris (ravulizumab) o Voydeya (danicopan) will be used as add-on therapy to ~~Soliris (~~eculizumab **(Soliris, BKEMV, Epysqli)** or Ultomiris (ravulizumab)

Revision/Review Date **4**~~11~~/202**5**~~4~~	**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:
	  ○ Failed treatment over a total of 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; **OR**
	  ○ Failed at least 1 IST and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin; **OR**
	  ○ 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	**Dendritic Cell Tumor Peptide Immunotherapy**
Drugs	Provenge (sipuleucel-T)
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	Small cell/neuroendocrine prostate cancer
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescriber must be an oncologist or urologist
Coverage Duration	3 doses per lifetime
Other Criteria	****Drug is being requested through the member's medical benefit**** **<u>Initial Authorization:</u>** • Metastatic castrate resistant (hormone-refractory) prostate cancer (mCRPC) (consistent with medical chart history) o Evidenced by soft tissue and/or bony metastases o Patient does NOT have ▪ M0CRPC (defined as CRPC whose only evidence of disseminated disease is an elevated serum PSA) is not authorized ▪ Visceral metastases (e.g. liver, lung, adrenal, peritoneal, brain)

Revision/Review Date 4/2025	• Patient is not currently being treated with systemic immunosuppressants (e.g. chemotherapy, corticosteroids) or, if the patient is being treated with immunosuppressants, the prescriber has provided a valid medical reason for combination therapy • Eastern Cooperative Oncology Group (ECOG) score 0-1 • Serum testosterone <50 ng/dL (e.g. castration levels of testosterone) • Predicted survival of at least six months **Reauthorization:** • Treatment exceeding 3 doses per lifetime will not be authorized **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	**Hydroxyprogesterone caproate (generic Delalutin)**
Drugs	Hydroxyprogesterone caproate (generic Delalutin)
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	Pregnancy
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a gynecologist or in consultation with a gynecologist
Coverage Duration	If all the criteria are met, the initial request will be approved for up to 6 months. For continuation of therapy, the request will be approved for up to 6 months.
Other Criteria	****Drug is being requested through the member's medical benefit****

Revision/Review
 	
Date: 4/2025
	Initial Authorization:
	
	• Medication is prescribed at an FDA approved dose
	• If request is for preterm birth, do not approve
	• Request is for one of the following indications:
	  o Amenorrhea or abnormal uterine bleeding due to hormonal imbalance
	  o Production of secretory endometrium and desquamation
	  o Test for endogenous estrogen production
	  o Advanced uterine adenocarcinoma
	
	Re-Authorization:
	
	• Documentation or provider attestation of clinical benefit
	• Medication is prescribed at an FDA approved dose
	
	If all 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	Kebilidi (eladocagene exuparvovec-tneq)
Drugs	Kebilidi (eladocagene exuparvovec-tneq)
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	Previous treatment with gene therapy
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a geneticist or neurologist.
Coverage Duration	If all the criteria are met, the request will be approved for one treatment per lifetime (4 infusions).
Other Criteria Review/Revision Date: 4/2025	**Drug is being requested through the member's medical benefit** Initial Authorization: • Medication is prescribed at an FDA approved dose • Documentation of genetically confirmed diagnosis of aromatic L-amino acid decarboxylase (AADC) deficiency evidenced by biallelic mutations in the *DDC* gene (copy of genetic test submitted with request) • Documentation of skull maturity confirmed by neuroimaging • Patient has classic clinical characteristics (e.g. oculogyric crises, hypotonia, developmental delay) of AADC deficiency that are not well-managed by symptomatic control drugs (i.e. dopamine agonists, monoamine oxidase inhibitor, pyridoxine, etc.)

	<u>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</u>