PROVIDER*ALERT*

AmeriHealth Caritas Louisiana

To: **AmeriHealth Caritas Louisiana Providers**

Date: **April 20, 2022**

Subject: **Pharmacy Policy Renewals**

Summary: Pharmacy policy renewals approved by the Louisiana Department of Health.

AmeriHealth Caritas Louisiana would like to make you aware of the attached policies that have been renewed by the Louisiana Department of Health in accordance with La. R.S. 46:460.54 and **will become effective May 20, 2022.**

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 listing of provider alerts on the Provider Newsletters and Updates page of our website.

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

Where can I find more information on COVID-19?
AmeriHealth Caritas Louisiana has updated its website to streamline communications and important notifications about COVID-19. Please visit http://amerihealthcaritasla.com/covid-19 for up-to-date information for both providers and members, including frequently asked questions, and important provider alerts from AmeriHealth Caritas Louisiana and the Louisiana Department of Health.

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; if all of the above criteria are not met, the request is referred to a Medical Director for medical necessity review.
Other Criteria Revision/Review Date ~~2/2021~~ **1/2022**	****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 • 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 (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	**Anti-CD19 CAR-T Immunotherapies**
Drugs	Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel), Tecartus (brexucabtagene autoleucel), Brevanzi (lisocabtagene maraleucel)
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 prescribers who specialize in the treatment of lymphoma.
Coverage Duration	If all the criteria are met, the initial request will be approved for a one – time infusion per lifetime.
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. **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** o **Patient is 18 years of age or older** o **ALL that is relapsed or refractory** **Non-Hodgkin's Lymphoma (NHL)** **Mantle Cell Lymphoma (MCL):**

Revision/Review Date: ~~5/2021~~ **1/2022**	• 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 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) **Other forms of NHL:** • If the request is for Breyanzi (lisocabtagene maraleucel), Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel) o Use is supported by a labeled indication or NCCN guidelines 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 **Re-authorization:** • Treatment exceeding 1 dose 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	Veklury (remdesivir) **/ remdesivir**
Drugs	Veklury (remdesivir), **remdesivir**
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), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	~~Labeled Use: 10 days~~ **Per FDA label**
Other Criteria Revision/Review Date ~~11/2020~~ **1/2022**	****Drug is being requested through the member's medical benefit**** Labeled Use: Veklury**/remdesivir** will be approved when all of the following criteria are met: • Diagnosis of COVID-19 • Patient is ≥12 years of age • Patient weighs at least 40kg • ~~Patient is hospitalized~~ • **Attestation that provider is not requesting reimbursement for ingredient cost of drug when drug is provided by U.S. government at no charge.** For uses related to the Emergency Use Authorization: Refer to the "Emergency Use Authorization (EUA) Drugs for COVID-19" policy **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	**Fabrazyme**
Drugs	Fabrazyme (agalsidase beta)
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), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Members should be greater than or equal to ~~8~~ **2** years of age
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease
Coverage Duration	Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.
Other Criteria	****Drug is being requested through the member's medical benefit**** **Initial Authorization:** • Male members must have a documented diagnosis of Fabry disease confirmed by one of the following: 1. An undetectable (<3%) alpha galactosidase A (alpha-Gal-A) activity level OR 2. A deficient (3-35%) alpha-Gal- activity level AND a documented detection of pathogenic mutations in the galactosidase alpha (*GLA*) gene by molecular genetic testing • Female members must have a documented diagnosis of Fabry disease confirmed by detection of pathogenic mutations in the *GLA* gene by molecular genetic testing **AND evidence of clinical manifestation of the disease (e.g. kidney, neurologic, cardiovascular, gastrointestinal)** • Member must not be using concurrently with Galafold (migalastat) • Documentation of the member's current weight • Request is for an FDA-approved dose

Revision/Review Date: 10/2020~~0~~**1**	**Re-Authorization:** • Documentation that member has experienced an improvement in symptoms from baseline including but not limited to: decreased pain, decreased gastrointestinal manifestations, decrease in proteinuria, stabilization of increase in eGFR, reduction of left ventricular hypertrophy (LVH) on echocardiogram, or improved myocardial function, or has remained asymptomatic • Member must not be using concurrently with Galafold (migalastat) • Documentation of the member's current weight • Request is for an FDA-approved dose If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review. **Physician/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	**Alpha-1 Proteinase Inhibitors (Human)**
Drugs	**Preferred:** Prolastin-C **Non-Preferred:** Aralast NP Glassia Zemaira Or any other newly marketed agent
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	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or specialist in the treatment of AAT
Coverage Duration	The request will be approved for up to a 12 month duration; if all of the above criteria are not met, the request is referred to a Medical Director for medical necessity review.
Other Criteria	****Drug is being requested through the member's medical benefit**** **Initial Authorization:** • Documented diagnosis of a congenital deficiency of alpha-1 antitrypsin (AAT) (serum AAT level < 11 micromol/L **[approximately 57 mg/dL using nephelometry** or 80mg/dl **by radial immunodiffusion]**). • Documentation was submitted indicating the member has undergone genetic testing for AAT deficiency and is classified as phenotype PiZZ, PiSZ, PiZ(null) or Pi(null)(null) [NOTE: phenotypes PiMZ or PiMS are not candidates for treatment with Alpha1-Proteinase Inhibitors] • Documentation was submitted (member's pulmonary function test results) indicating airflow obstruction by spirometry (forced expiratory volume in 1 second [FE_{V1}] ~~in the range of 35%-65%~~ **≤ 65%** of predicted), or provider has documented additional medical information demonstrating medical necessity • Documentation was submitted indicating member is a non-smoker or an ex-smoker (eg. smoking cessation treatment) • Documentation of the member's current weight

Revision/Review Date ~~6/2021~~ **1/2022**	• The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage • If the medication request is for an Alpha1-Proteinase Inhibitor (human) product other than Prolastin-C, the patient has a documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure, etc.) for not using Prolastin-C to treat their medical condition **Reauthorization:** • Documentation of the member's current weight • **Documentation was submitted indicating member is a non-smoker or an ex-smoker (e.g. smoking cessation treatment)** • Documentation was submitted indicating the member has clinically benefited from therapy (i.e. stable lung function, improved PFTs, alpha-1 antitrypsin serum level maintained above 11 micromol/L **[approximately 57 mg/dL** using or 80 mg/dL **by radial immunodiffusion],** improved quality of life) • The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage **Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Vascular Endothelial Growth Factor (VEGF) Inhibitors for Ophthalmic Conditions**
Drugs	Preferred Vascular Endothelial Growth Factor (VEGF) Inhibitor(s): • **Avastin, ~~Mvasi, Zirabev~~** (bevacizumab) • **Lucentis** (ranibizumab) Non-Preferred Vascular Endothelial Growth Factor (VEGF) Inhibitor(s): • **Beovu** (brolucizumab) • **Eylea** (afibercept) • **Macugen** (pegaptanib) • **Susvimo (ranibizumab)** • **Any newly marketed agent in this class** ****If the request is for an alternative indication please use the Specialty Drugs Criteria or Oncology Drugs Criteria as appropriate****
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	Approvable for adults 18 years of age and older only
Prescriber Restrictions	Ophthalmologist
Coverage Duration	If the above conditions are met, the request will be approved with a 3 month duration for initial and 12 months for renewal; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	****Drug is being requested through the member's medical benefit**** **Avastin, ~~Mvasi, Zirabev~~:** • Request is for compendia supported dosing for an ophthalmic indication **Lucentis:** • Request is for an FDA-approved dosing regimen **Non-Preferred VEGF Inhibitor:** • Request is for an FDA-approved dosing regimen; **AND**

Revision/Review Date ~~5/2021~~ **1/2022**	• Documented trial and failure with a preferred VEGF inhibitor for all FDA-approved indications OR: a medical justification for not using a preferred VEGF inhibitor (e.g. experienced a severe ADR such as hypersensitivity, arterial thromboembolism, cerebrovascular accident, raised intraocular pressure, retinal detachment). **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	**Specialty Drugs**
Drugs	Oral and injectable specialty drugs without drug or class specific prior authorization criteria *** The Oncology Drugs prior authorization criteria will be applied to oncology drugs without drug or class specific criteria***
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	N/A
Coverage Duration	If all of the conditions are met, requests will be approved for up to 6 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	**All of the following criteria must be met:** • The drug is requested through the medical benefit • The drug is requested for an appropriate use (per the references outlined in "Covered Uses" • The dose requested is appropriate for the requested use (per the references outlined in "Covered Uses") • Documentation has been provided of a trial and failure of an appropriate alternative first line therapy, if one exists, for the requested use (per the references outlined in "Covered Uses"**)** or has a medical reason why these drug(s) cannot be used (e.g. intolerance, contraindication) • If the request is for a reference biologic drug with either a biosimilar or interchangeable biologic drug currently available **documentation of one of the following:** o The provider has ~~either~~ verbally or in writing submitted a member specific reason why the reference biologic is required based on the member's condition or treatment history o **The currently available biosimilar product does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic drug being requested**

Revision/Review Date ~~5~~**10/2021**	**Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group	**Oncology Drugs**
Drugs	Oral and Injectable Oncology Medications (specialty or non-specialty) without medication specific criteria when requested for an oncology diagnosis
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) , and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is an oncologist, or specialist in type of cancer being treated
Coverage Duration	If the criteria are met, the request will be approved for up to 6 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	**All of the following criteria must be met:** • The drug is requested through the medical benefit • Requested use must be a labeled indication or be supported by NCCN Category 1 or 2A level of evidence. If the request is for an off-label use supported by NCCN as Category 2B recommendation then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication); **AND** • Documentation has been provided of the results of all required genetic testing where required per drug package insert; **AND** • Documentation has been provided of the results of all required laboratory values and patient specific information (e.g. weight, ALT/AST, Creatine Kinase, etc.) necessary to ensure the patient has no contraindications to therapy per drug package insert; **AND** • The medication is being prescribed at a dose that is within FDA approved/NCCN guidelines. • If the request is for a reference biologic drug with either a biosimilar or interchangeable biologic drug currently available**, documentation of one of the following:** o The provider has ~~either~~ verbally or in writing submitted a member specific reason why the ~~brand name~~ **reference**

Revision/Review ~~11/2020~~ **10/2021**	biologic is required based on the member's condition or treatment history; o **The currently available biosimilar product does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic drug being requested** • If the request is for **abiraterone** ~~brand~~ **(**Zytiga**)** 500 mg tablet, a documented medical reason why two tablets of generic abiraterone acetate 250 mg cannot be used **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**