

**To:** AmeriHealth Caritas Louisiana Providers

**Date:** November 11, 2021

**Subject:** New Drug Policy Approvals

**Summary:** New drug policies approved by the Louisiana Department of Health.

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 and **will become effective December 13, 2021.**

These drugs will no longer reimburse through retail pharmacy. Instead, claims will reimburse as provider-administered medications via medical benefits.

#### **Missed an alert?**

You can find a complete listing of provider alerts on the [Provider Newsletters and Updates](#) page of our website.

#### **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.

<u>Field Name</u>	<u>Field Description</u>
<u>Prior Authorization Group Description</u>	<u>Alpha-1 Proteinase Inhibitors (Human)</u>
<u>Drugs</u>	<u>Preferred:</u> <u>Prolastin-C</u> <u>Non-Preferred:</u> <u>Aralast NP</u> <u>Glassia</u> <u>Zemaira</u> <u>Or any other newly marketed agent</u>
<u>Covered Uses</u>	<u>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.</u>
<u>Exclusion Criteria</u>	<u>None</u>
<u>Required Medical Information</u>	<u>None</u>
<u>Age Restrictions</u>	<u>18 years of age or older</u>
<u>Prescriber Restrictions</u>	<u>Prescribed by or in consultation with a pulmonologist or specialist in the treatment of AAT</u>
<u>Coverage Duration</u>	<u>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.</u>
<u>Other Criteria</u>	<u>**Drug is being requested through the member's medical benefit**</u>  <u>Initial Authorization:</u> <ul style="list-style-type: none"> <li>• <u>Documented diagnosis of a congenital deficiency of alpha-1 antitrypsin (AAT) (serum AAT level &lt; 11 micromol/L or 80mg/dl).</u></li> <li>• <u>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]</u></li> <li>• <u>Documentation was submitted (member's pulmonary function test results) indicating airflow obstruction by spirometry (forced expiratory volume in 1 second [FEV<sub>1</sub>] in the range of 35%-65% of predicted), or provider has documented additional medical information demonstrating medical necessity</u></li> <li>• <u>Documentation was submitted indicating member is a non-smoker or an ex-smoker (eg. smoking cessation treatment)</u></li> <li>• <u>Documentation of the member's current weight</u></li> </ul>

<p><u>Revision/Review Date 6/2021</u></p>	<ul style="list-style-type: none"><li>• <u>The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage</u></li><li>• <u>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</u></li></ul> <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"><li>• <u>Documentation of the member's current weight</u></li><li>• <u>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 or 80 mg/dL, improved quality of life)</u></li><li>• <u>The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage</u></li></ul> <p><u>Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.</u></p>
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<u>Field Name</u>	<u>Field Description</u>
<u>Prior Authorization Group Description</u>	<u>Vascular Endothelial Growth Factor (VEGF) Inhibitors for Ophthalmic Conditions</u>
<u>Drugs</u>	<p><u>Preferred Vascular Endothelial Growth Factor (VEGF) Inhibitor(s):</u></p> <ul style="list-style-type: none"> <li>• <u>Avastin, Mvasi, Zirabev (bevacizumab)</u></li> <li>• <u>Lucentis (ranibizumab)</u></li> </ul> <p><u>Non-Preferred Vascular Endothelial Growth Factor (VEGF) Inhibitor(s):</u></p> <ul style="list-style-type: none"> <li>• <u>Beovu (brolucizumab)</u></li> <li>• <u>Eylea (afibercept)</u></li> <li>• <u>Macugen (pegaptanib)</u></li> <li>• <u>Any newly marketed agent in this class</u></li> </ul> <p><u>**If the request is for an alternative indication please use the Specialty Drugs Criteria or Oncology Drugs Criteria as appropriate**</u></p>
<u>Covered Uses</u>	<u>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.</u>
<u>Exclusion Criteria</u>	<u>N/A</u>
<u>Required Medical Information</u>	<u>See “other criteria”</u>
<u>Age Restrictions</u>	<u>Approvable for adults 18 years of age and older only</u>
<u>Prescriber Restrictions</u>	<u>Ophthalmologist</u>
<u>Coverage Duration</u>	<u>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.</u>
<u>Other Criteria</u>	<p><u>**Drug is being requested through the member’s medical benefit**</u></p> <p><u>Avastin, Mvasi, Zirabev:</u></p> <ul style="list-style-type: none"> <li>• <u>Request is for compendia supported dosing for an ophthalmic indication</u></li> </ul> <p><u>Lucentis:</u></p> <ul style="list-style-type: none"> <li>• <u>Request is for an FDA-approved dosing regimen</u></li> </ul> <p><u>Non-Preferred VEGF Inhibitor:</u></p> <ul style="list-style-type: none"> <li>• <u>Request is for an FDA-approved dosing regimen; AND</u></li> </ul>

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- 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.

<u>Field Name</u>	<u>Field Description</u>
<u>Prior Authorization Group Description</u>	<u>Primary Hemophagocytic Lymphohistiocytosis (HLH) Agents</u>
<u>Drugs</u>	<u>Gamifant (emapalumab-lzsg)</u>
<u>Covered Uses</u>	<u>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.</u>
<u>Exclusion Criteria</u>	<u>Members who have undergone hematopoietic stem cell transplantation (HSCT)</u>
<u>Required Medical Information</u>	<u>“See Other Criteria”</u>
<u>Age Restrictions</u>	<u>N/A</u>
<u>Prescriber Restrictions</u>	<u>Hematologist, Oncologist, Immunologist, Transplant Specialist, or other specialist experienced in the treatment of immunologic disorders</u>
<u>Coverage Duration</u>	<u>Initial Authorization: 1 month</u> <u>Reauthorization: 3 months</u>
<u>Other Criteria</u>	<p><u>*Gamifant will only be approved for members who have not yet received HSCT and will be discontinued at the initiation of HSCT*</u></p> <p><u>**Drug is being requested through the member’s medical benefit**</u></p> <p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> <li>• <u>Member has a diagnosis of Primary HLH</u></li> <li>• <u>Member does NOT have a diagnosis of Secondary HLH due to a proven rheumatic or neoplastic disease or an infection</u></li> <li>• <u>Prescriber attests that member has not achieved a satisfactory response to or is intolerant to conventional HLH therapy (e.g. etoposide, dexamethasone) or has recurrent disease</u></li> <li>• <u>Prescriber attests that the member is a candidate for hematopoietic stem cell transplant (HSCT)</u></li> <li>• <u>Member has been screened for latent tuberculosis infection</u></li> <li>• <u>Member has or will receive prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, <i>Pneumocystis jirovecii</i>, and other fungal infections</u></li> <li>• <u>Dosing is consistent with FDA approved labeling</u></li> </ul> <p><u>Reauthorization</u></p>

<p><b><u>Revision/Review</u></b> <b><u>Date 6/2021</u></b></p>	<ul style="list-style-type: none"><li>• <b><u>Member continues to meet initial authorization criteria</u></b></li><li>• <b><u>Member is receiving prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, <i>Pneumocystis jirovecii</i>, and other fungal infections</u></b></li><li>• <b><u>HSCT has not yet been initiated for member</u></b></li></ul> <p><b><u>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</u></b></p>
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<u>Field Name</u>	<u>Field Description</u>
<u>Prior Authorization Group Description</u>	<u>Insulin-Like Growth Factor-1 Receptor (Igf-1r) Antagonists For Thyroid Eye Disease</u>
<u>Drugs</u>	<u>Tepezza (teprotumumab-trbw)</u>
<u>Covered Uses</u>	<u>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.</u>
<u>Exclusion Criteria</u>	<u>N/A</u>
<u>Required Medical Information</u>	<u>See “Other Criteria”</u>
<u>Age Restrictions</u>	<u>Member must be 18 years age or older</u>
<u>Prescriber Restrictions</u>	<u>Ophthalmologist</u>
<u>Coverage Duration</u>	<u>If all of the criteria are met, the request will be approved for up to 24 weeks of treatment (8 total infusions). Retreatment requests will not be allowed beyond the 8 dose limit.</u>
<u>Other Criteria</u>	<p><u>**Drug is being requested through the member’s medical benefit**</u></p> <p><u>Initial Authorization:</u></p> <p><u>Tepezza is approved when all of the following are met:</u></p> <ul style="list-style-type: none"> <li>• <u>Dosing does not exceed dosing guidelines as outlined in the package insert</u></li> <li>• <u>Patient has a confirmed diagnosis of Graves’ disease</u></li> <li>• <u>Documentation of active moderate-severe thyroid eye disease as evidenced by one or more of the following:</u> <ul style="list-style-type: none"> <li>○ <u>Lid retraction of &gt;2mm</u></li> <li>○ <u>Moderate or severe soft-tissue involvement</u></li> <li>○ <u>Proptosis ≥3mm above normal values for race and sex</u></li> <li>○ <u>Periodic or constant diplopia</u></li> </ul> </li> <li>• <u>Patients Clinical Activity Score must be ≥4 (must be submitted with request)</u></li> <li>• <u>Patient must be euthyroid or thyroxine and free triiodothyronine levels are less than 50% above or below normal limits (submit laboratory results with request)</u></li> <li>• <u>Patients of reproductive potential: attestation the patient is not pregnant, and appropriate contraception methods will be used before, during, and 6 months after the last</u></li> </ul>

<p><u>Revision/Review Date</u> <u>6/2021</u></p>	<p><u>infusion</u></p> <ul style="list-style-type: none"><li>• <u>Patient has had a trial and therapy failure of, or contraindication to, oral or IV glucocorticoids to treat their condition</u></li></ul> <p><u>Re-authorization:</u></p> <ul style="list-style-type: none"><li>• <u>Retreatment or renewal requests beyond a total of 24 weeks of treatment (8 total infusions) will not be allowed.</u></li></ul> <p><u>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</u></p>
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<u>Field Name</u>	<u>Field Description</u>
<u>Prior Authorization Group Description</u>	<u>Fabrazyme</u>
<u>Drugs</u>	<u>Fabrazyme (agalsidase beta)</u>
<u>Covered Uses</u>	<u>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).</u>
<u>Exclusion Criteria</u>	<u>N/A</u>
<u>Required Medical Information</u>	<u>See “other criteria”</u>
<u>Age Restrictions</u>	<u>Members should be greater than or equal to 8 years of age</u>
<u>Prescriber Restrictions</u>	<u>Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease</u>
<u>Coverage Duration</u>	<u>Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration.</u> <u>Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.</u>
<u>Other Criteria</u>	<p><b><u>**Drug is being requested through the member’s medical benefit**</u></b></p> <p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• <b><u>Male members must have a documented diagnosis of Fabry disease confirmed by one of the following:</u></b> <ol style="list-style-type: none"> <li>1. <b><u>An undetectable (&lt;3%) alpha galactosidase A (alpha-Gal-A) activity level OR</u></b></li> <li>2. <b><u>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</u></b></li> </ol> </li> <li>• <b><u>Female members must have a documented diagnosis of Fabry disease confirmed by detection of pathogenic mutations in the GLA gene by molecular genetic testing</u></b></li> <li>• <b><u>Member must not be using concurrently with Galafold (migalastat)</u></b></li> <li>• <b><u>Documentation of the member’s current weight</u></b></li> <li>• <b><u>Request is for an FDA-approved dose</u></b></li> </ul> <p><b><u>Re-Authorization:</u></b></p>

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- **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.**

<u>Field Name</u>	<u>Field Description</u>
<u>Prior Authorization Group Description</u>	<u>Dendritic Cell Tumor Peptide Immunotherapy</u>
<u>Drugs</u>	<u>Provenge (sipuleucel-T)</u>
<u>Covered Uses</u>	<u>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.</u>
<u>Exclusion Criteria</u>	<u>Small cell/neuroendocrine prostate cancer</u>
<u>Required Medical Information</u>	<u>See "Other Criteria"</u>
<u>Age Restrictions</u>	<u>See "Other Criteria"</u>
<u>Prescriber Restrictions</u>	<u>Prescriber must be an oncologist or urologist</u>
<u>Coverage Duration</u>	<u>3 doses per lifetime</u>
<u>Other Criteria</u>	<p><b><u>**Drug is being requested through the member's medical benefit**</u></b></p> <p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• <b><u>Metastatic castrate resistant (hormone-refractory) prostate cancer (mCRPC) (consistent with medical chart history)</u></b> <ul style="list-style-type: none"> <li>○ <b><u>Evidenced by soft tissue and/or bony metastases</u></b></li> <li>○ <b><u>Patient does NOT have</u></b> <ul style="list-style-type: none"> <li>▪ <b><u>M0CRPC (defined as CRPC whose only evidence of disseminated disease is an elevated serum PSA) is not authorized</u></b></li> <li>▪ <b><u>Visceral metastases (e.g. liver, lung, adrenal, peritoneal, brain)</u></b></li> </ul> </li> </ul> </li> <li>• <b><u>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</u></b></li> <li>• <b><u>Eastern Cooperative Oncology Group (ECOG) score 0-1</u></b></li> <li>• <b><u>Serum testosterone &lt;50 ng/dL (e.g. castration levels of testosterone)</u></b></li> <li>• <b><u>Predicted survival of at least six months</u></b></li> </ul> <p><b><u>Reauthorization:</u></b></p> <ul style="list-style-type: none"> <li>• <b><u>Treatment exceeding 3 doses per lifetime will not be authorized</u></b></li> </ul>
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	<p><b><u>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</u></b></p>
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<u>Field Name</u>	<u>Field Description</u>
<u>Prior Authorization Group Description</u>	<u>Complement Inhibitors</u>
<u>Drugs</u>	<u>Soliris (eculizumab), Ultomiris (ravulizumab)</u>
<u>Covered Uses</u>	<u>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</u>
<u>Exclusion Criteria</u>	<u>N/A</u>
<u>Required Medical Information</u>	<u>See “other criteria”</u>
<u>Age Restrictions</u>	<u>N/A</u>
<u>Prescriber Restrictions</u>	<u>Prescriber must be a hematologist, nephrologist, neurologist, oncologist, or other appropriate specialist.</u>
<u>Coverage Duration</u>	<u>If the criteria are met, the initial request will be approved for up to 3 month duration; reauthorization requests will be approved for up to 6 months. If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.</u>
<u>Other Criteria</u>	<p><b><u>**Drug is being requested through the member’s medical benefit**</u></b></p> <p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• <b><u>The patient has a confirmed diagnosis that is indicated in the FDA approved package insert OR is a medically-accepted indication; AND</u></b></li> <li>• <b><u>The request is age appropriate according to FDA approved package labeling or nationally recognized compendia; AND</u></b></li> <li>• <b><u>The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient’s diagnosis, age and concomitant medical conditions; AND</u></b></li> <li>• <b><u>Documentation of vaccination against meningococcal disease or a documented medical reason why the patient cannot receive vaccination or vaccination needs to be delayed; AND</u></b></li> <li>• <b><u>Antimicrobial prophylaxis with oral antibiotics for two weeks will be administered if vaccine is administered less than two weeks before starting Soliris/Ultomiris therapy or a documented medical reason why the patient cannot receive oral antibiotic prophylaxis.</u></b></li> </ul> <p><b><u>Generalized Myasthenia Gravis (gMG):</u></b></p>

- The request is for Soliris (eculizumab)
  - If the request is for Ultomiris (ravulizumab), do not approve, not indicated for gMG
- 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  $\geq 6$  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)

- If the request is for Soliris (eculizumab)
  - Refer to the “Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents” policy
- If the request is for Ultomiris (ravulizumab), do not approve; not indicated for NMOSD

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

Re-Authorization:

- Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality of life scores, reduced need for blood transfusions); AND
- The request is for an FDA approved dose; AND
- If the request is for aHUS/Complement Mediated HUS

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|  | <ul style="list-style-type: none"><li>○ <b><u>Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies</u></b></li></ul> |
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**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

<u>Field Name</u>	<u>Field Description</u>
<u>Prior Authorization Group Description</u>	<u>Brineura (cerliponase alfa)</u>
<u>Drugs</u>	<u>Brineura (cerliponase alfa)</u>
<u>Covered Uses</u>	<u>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)</u>
<u>Exclusion Criteria</u>	<u>N/A</u>
<u>Required Medical Information</u>	<u>See “other criteria”</u>
<u>Age Restrictions</u>	<u>Member must be 3 years of age or older</u>
<u>Prescriber Restrictions</u>	<u>Prescriber must be a neurologist</u>
<u>Coverage Duration</u>	<u>If the criteria are met, the request will be approved for 6 months.</u>
<u>Other Criteria</u>	<p><b><u>**Drug is being requested through the member’s medical benefit**</u></b></p> <p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• <b><u>Documentation of confirmed diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) with one of the following:</u></b> <ul style="list-style-type: none"> <li>○ <b><u>Lab results demonstrating deficient TPP1 enzyme activity</u></b></li> <li>○ <b><u>Identification of causative mutations in the TPP1/CLN2 gene</u></b></li> </ul> </li> <li>• <b><u>Prescribed dose is consistent with FDA-approved labeling</u></b></li> <li>• <b><u>Documentation of baseline CLN2 Clinical Rating Scale motor +language score. Baseline CLN2 score must be &gt; 0.</u></b></li> </ul> <p><b><u>Re-authorization:</u></b></p> <ul style="list-style-type: none"> <li>• <b><u>Prescribed dose is consistent with FDA-approved labeling</u></b></li> <li>• <b><u>Documentation of CLN2 Clinical Rating Scale motor +language score has remained &gt; 0</u></b></li> </ul> <p><b><u>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</u></b></p>
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Field Name	Field Description
<b><u>Prior Authorization Group Description</u></b>	<b><u>Blincyto</u></b>
<b><u>Drugs</u></b>	<b><u>Blincyto (blinatumomab)</u></b>
<b><u>Covered Uses</u></b>	<b><u>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.</u></b>
<b><u>Exclusion Criteria</u></b>	<b><u>N/A</u></b>
<b><u>Required Medical Information</u></b>	<b><u>See “Other Criteria”</u></b>
<b><u>Age Restriction</u></b>	<b><u>N/A</u></b>
<b><u>Prescriber Restrictions</u></b>	<b><u>Prescriber must be an oncologist/hematologist</u></b>
<b><u>Coverage Duration</u></b>	<b><u>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.</u></b>
<b><u>Other Criteria</u></b>	<p><b><u>**Drug is being requested through the member’s medical benefit**</u></b></p> <p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• <b><u>Patient has a diagnosis of one of the following forms of Acute Lymphoblastic Leukemia (ALL):</u></b> <ol style="list-style-type: none"> <li>a) <b><u>Relapsed B-cell precursor ALL</u></b></li> <li>b) <b><u>Refractory B-cell precursor ALL</u></b></li> <li>c) <b><u>B-cell precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1</u></b></li> </ol> </li> <li>• <b><u>Provider attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities</u></b></li> </ul> <p><b><u>Reauthorization:</u></b></p> <ul style="list-style-type: none"> <li>• <b><u>Patient has a diagnosis of relapsed or refractory B-cell precursor ALL and has not exceeded 9 total cycles of Blincyto therapy</u></b></li> <li>• <b><u>Provider attests to treatment response or stabilization of disease</u></b></li> <li>• <b><u>Prescriber attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities</u></b></li> </ul> <p><b><u>***For B-cell precursor ALL with MRD, reauthorization is not allowed***</u></b></p> <p><b><u>Medical Director/clinical reviewer must override criteria when,</u></b></p>
<b><u>Revision/Review Date</u></b> <b><u>6/2021</u></b>	

	<p><b><u>in his/her professional judgement, the requested item is medically necessary.</u></b></p>
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Field Name	Field Description
<b><u>Prior Authorization Group Description</u></b>	<b><u>Anti-CD19 CAR-T Immunotherapies</u></b>
<b><u>Drugs</u></b>	<b><u>Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel), Tecartus (brexucabtagene autoleucel), Breyanzi (lisocabtagene maraleucel)</u></b>
<b><u>Covered Uses</u></b>	<b><u>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.</u></b>
<b><u>Exclusion Criteria</u></b>	<b><u>Patients with primary central nervous system lymphoma</u></b>
<b><u>Required Medical Information</u></b>	<b><u>See “Other Criteria”</u></b>
<b><u>Age Restrictions</u></b>	<b><u>See “Other Criteria”</u></b>
<b><u>Prescriber Restrictions</u></b>	<b><u>Prescriber must be an oncologist, hematologist or other prescribers who specialize in the treatment of lymphoma.</u></b>
<b><u>Coverage Duration</u></b>	<b><u>If all the criteria are met, the initial request will be approved for a one – time infusion per lifetime.</u></b>
<b><u>Other Criteria</u></b>	<p data-bbox="570 999 1349 1073"><b><u>**Drug is being requested through the member’s medical benefit**</u></b></p> <p data-bbox="500 1073 789 1108"><b><u>Initial authorization:</u></b></p> <ul data-bbox="548 1108 1390 1476" style="list-style-type: none"> <li data-bbox="548 1108 1354 1182">• <b><u>Patient must not have received prior anti-CD19 CAR-T therapy.</u></b></li> <li data-bbox="548 1182 1304 1255">• <b><u>Patient will be screened for HBV, HCV, and HIV in accordance with clinical guidelines.</u></b></li> <li data-bbox="548 1255 1377 1329">• <b><u>Patient does not have an active infection or inflammatory disorder.</u></b></li> <li data-bbox="548 1329 1138 1360">• <b><u>Patient has a life expectancy &gt;12 weeks.</u></b></li> <li data-bbox="548 1360 1390 1476">• <b><u>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.</u></b></li> </ul> <p data-bbox="500 1514 639 1545"><b><u>Leukemia</u></b></p> <p data-bbox="500 1583 1273 1619"><b><u>B-cell precursor Acute Lymphoblastic Leukemia (ALL):</u></b></p> <ul data-bbox="548 1619 1390 1734" style="list-style-type: none"> <li data-bbox="548 1619 992 1654">• <b><u>If the request is for Kymriah</u></b> <ul data-bbox="646 1654 1390 1734" style="list-style-type: none"> <li data-bbox="646 1654 1187 1692">○ <b><u>Patient is 25 years of age or younger</u></b></li> <li data-bbox="646 1692 1390 1734">○ <b><u>ALL that is refractory or in second or later relapse</u></b></li> </ul> </li> </ul> <p data-bbox="500 1801 976 1839"><b><u>Non-Hodgkin’s Lymphoma (NHL)</u></b></p>

<p><u>Revision/Review</u> <u>Date: 6/2021</u></p>	<p><b><u>Mantle Cell Lymphoma (MCL):</u></b></p> <ul style="list-style-type: none"><li>• <b><u>If the request is for Tecartus:</u></b><ul style="list-style-type: none"><li>○ <b><u>Patient is 18 years of age or older</u></b></li><li>○ <b><u>Patient has relapsed/refractory disease defined as failure of BOTH the following lines of therapy:</u></b><ul style="list-style-type: none"><li>▪ <b><u>Chemoimmunotherapy such as an anti-CD20 monoclonal antibody (e.g. Rituxan) + any chemotherapeutic agent</u></b></li><li>▪ <b><u>Bruton Tyrosine Kinase (BTK) Inhibitor (e.g. Calquence, Imbruvica, Brukinsa)</u></b></li></ul></li></ul></li></ul> <p><b><u>Other forms of NHL:</u></b></p> <ul style="list-style-type: none"><li>• <b><u>If the request is for Brevanzi (lisocabtagene maraleucel), Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel)</u></b><ul style="list-style-type: none"><li>○ <b><u>Use is supported by a labeled indication or NCCN guidelines</u></b></li><li>○ <b><u>Patient is 18 years of age or older</u></b></li><li>○ <b><u>Patient has relapsed/refractory disease defined as failure of two or more lines of systemic therapy</u></b></li></ul></li></ul> <p><b><u>Re-authorization:</u></b></p> <ul style="list-style-type: none"><li>• <b><u>Treatment exceeding 1 dose per lifetime will not be authorized.</u></b></li></ul> <p><b><u>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</u></b></p>
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<b><u>Field Name</u></b>	<b><u>Field Description</u></b>
<b><u>Prior Authorization Group Description</u></b>	<b><u>B-Cell Maturation Antigen (BCMA) Directed Chimeric Antigen Receptor (CAR) T-Cell Therapy</u></b>
<b><u>Drugs</u></b>	<b><u>Abecma (idecabtagene vicleucel)</u></b>
<b><u>Covered Uses</u></b>	<b><u>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).</u></b>
<b><u>Exclusion Criteria</u></b>	<b><u>N/A</u></b>
<b><u>Required Medical Information</u></b>	<b><u>See “Other Criteria”</u></b>
<b><u>Age Restrictions</u></b>	<b><u>Member must be 18 years or older</u></b>
<b><u>Prescriber Restrictions</u></b>	<b><u>Prescriber must be a hematologist, an oncologist, or other appropriate specialist</u></b>
<b><u>Coverage Duration</u></b>	<b><u>If all the criteria are met, the initial request will be approved for a one – time infusion per lifetime.</u></b>
<b><u>Other Criteria</u></b>	<p><b><u>**Drug is being requested through the member’s medical benefit**</u></b></p> <p><b><u>Initial Authorization</u></b></p> <ul style="list-style-type: none"> <li>• <b><u>Member has a diagnosis of relapsed or refractory multiple myeloma (RRMM)</u></b></li> <li>• <b><u>Member must have received at least 4 prior lines of therapy, which must include ALL of the following:</u></b> <ul style="list-style-type: none"> <li>○ <b><u>An immunomodulatory agent (e.g. lenalidomide, pomalidomide, thalidomide)</u></b></li> <li>○ <b><u>A proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib)</u></b></li> <li>○ <b><u>An anti-CD38 monoclonal antibody (e.g. daratumumab, isatuximab)</u></b></li> </ul> </li> <li>• <b><u>Member does not have an active infection</u></b></li> <li>• <b><u>Member will be screened for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines</u></b></li> <li>• <b><u>Member will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment</u></b></li> </ul> <p><b><u>Re-authorization:</u></b></p> <ul style="list-style-type: none"> <li>• <b><u>Treatment exceeding 1 dose per lifetime will not be authorized.</u></b></li> </ul> <p><b><u>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</u></b></p>
<b><u>Revision/Review Date 6/2021</u></b>	