United Healthcare Community Plan

UnitedHealthcare Community Plan of Louisiana
Medical Policy Update Bulletin: April 2022

In This Issue

Take Note

Page

Quarterly CPT® and HCPCS Code Updates

Medical Policy Updates

New

Revised

Replaced

Medical Benefit Drug Policy Updates

New

Revised

Quarterly CPT® and HCPCS Code Updates

Effective Apr. 1, 2022, the following Medical Policies and Medical Benefit Drug Policies have been updated to reflect the quarterly Current Procedural Terminology (CPT®) and Healthcare Common Procedure Coding System (HCPCS) code additions, revisions, and deletions. Refer to the following sources for information on the code updates:

- American Medical Association. Current Procedural Terminology: CPT®
- Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System: HCPCS Level II

Policy Title	Policy Type	Summary of Changes
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for Louisiana Only)	Medical Policy	• Added A4238 and E2102
Medical Therapies for Enzyme Deficiencies (for Louisiana Only)	Medical Benefit Drug Policy	Nexviazyme • Replaced C9085, J3490, and J3590 with J0219
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for Louisiana Only)	Medical Policy	• Added 0306U, 0307U, 0313U, 0314U, and 0315U • Revised description for 0022U
Ryplazim® (Plasminogen, Human-Tvmh) (for Louisiana Only)	Medical Benefit Drug Policy	• Replaced C9399 with C9090
Saphnelo™ (Anifrolumab-Fnia) (for Louisiana Only)	Medical Benefit Drug Policy	• Replaced C9086, J3490, and J3590 with J0491

Medical Policy Updates

New		
Policy Title	**Effective Date**	**Coverage Rationale**
Percutaneous Patent Foramen Ovale (PFO) Closure (for Louisiana Only)	Jun. 1, 2022	Note: This policy does not apply to individuals < 18 years of age. Percutaneous patent foramen ovale closure for the prevention of recurrent ischemic stroke is proven and medically necessary when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions and all of the following criteria are met: • History of cryptogenic stroke confirmed by imaging; and • A cardiologist and a neurologist agree that the stroke is likely embolic in nature; and • Other causes of ischemic stroke have been ruled out including, but not limited to, carotid disease, hypercoagulable states or atrial fibrillation; and • Individual is 18–60 years of age Due to insufficient evidence of efficacy, percutaneous patent foramen ovale closure is unproven and not medically necessary for all other stroke or related neurological indications including, but not limited to, primary prevention of stroke, transient ischemic attacks, and migraine prevention.
Percutaneous Vertebroplasty and Kyphoplasty (for Louisiana Only)	Jun. 1, 2022	Percutaneous vertebroplasty and kyphoplasty are proven and medically necessary for treating pain causing Functional or Physical Impairment in cervical, thoracic or lumbar vertebral bodies within 4 months of pain onset that has failed to respond to optimal medical therapy for the following indications: • Osteoporotic vertebral compression fracture (VCF) • Steroid-induced vertebral fracture • Osteolytic metastatic disease involving a vertebral body • Multiple myeloma involving a vertebral body • Vertebral hemangioma with aggressive features • Unstable fractures due to osteonecrosis (e.g., Kummel disease) and Computed tomography (CT) or magnetic resonance imaging (MRI) has ruled out other causes of spinal pain, including but not limited to: • Foraminal stenosis • Facet arthropathy • Herniated intervertebral disk • Other spinal degenerative disease • Other significant coexistent spinal or bony pain generators and The following are not present:

Medical Policy Updates

New

Policy Title	Effective Date	Coverage Rationale
Percutaneous Vertebroplasty and Kyphoplasty (for Louisiana Only) (continued)	Jun. 1, 2022	• Clinical evidence of spinal cord compression as confirmed by CT or MRI; or • Significant vertebral collapse or destruction (e.g., vertebra reduced to less than one-third of its original height) as confirmed by CT or MRI; or • Healed VCF as confirmed by CT or MRI; or • Lesions of the sacrum or coccyx (see the Medical Policy titled *Surgical Treatment for Spine Pain* for additional information on percutaneous sacral augmentation); or • Asymptomatic vertebral compression fractures (VCFs); or • VCFs responding appropriately to conservative therapy Percutaneous vertebroplasty and kyphoplasty are unproven and not medically necessary for treating indications other than those listed above due to insufficient evidence of efficacy.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Sinus Procedures (for Louisiana Only)	Mar. 9, 2022	**Title Change**
		• Previously titled *Balloon Sinus Ostial Dilation (for Louisiana Only)*
		Coverage Rationale
		• Revised language to indicate:
		  ○ The *Coverage Rationale* contained in this policy represents Louisiana Medicaid coverage policy and is set forth below in accordance with State requirements
		  ○ Balloon ostial dilation and functional endoscopic sinus surgery are considered medically necessary for the treatment of chronic rhinosinusitis when all of the following criteria are met:
		  ▪ Uncomplicated chronic
			The coverage rationale contained in this policy represents Louisiana Medicaid coverage policy and is set forth below in accordance with State requirements.
			
			Balloon ostial dilation and functional endoscopic sinus surgery are considered medically necessary for the treatment of chronic rhinosinusitis when all of the following criteria are met:
			• Uncomplicated chronic rhinosinusitis limited to the paranasal sinuses without the involvement of adjacent neurological, soft tissue, or bony structures that has persisted for at least 12 weeks with at least two of the following sinonasal symptoms:
			  ○ Facial pain/pressure;
			  ○ Hyposmia/anosmia;
			  ○ Nasal obstruction;
			  ○ Mucopurulent nasal discharge; and
			• Sinonasal symptoms that are persistent after maximal medical therapy has been attempted, as defined by all of the following, either sequentially or overlapping:
			  ○ Saline nasal irrigation for at least six weeks;
			  ○ Nasal corticosteroids for at least six weeks;
			  ○ Approved biologics, if applicable, for at least six weeks;

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Sinus Procedures (for Louisiana Only) (continued)	Mar. 9, 2022	rhinosinusitis limited to the paranasal sinuses without the involvement of adjacent neurological, soft tissue, or bony structures that has persisted for at least 12 weeks with at least two of the following sinonasal symptoms: – Facial pain/pressure – Hyposmia/anosmia – Nasal obstruction – Mucopurulent nasal discharge ▪ Sinonasal symptoms that are persistent after maximal medical therapy has been attempted, as defined by all of the following, either sequentially or overlapping: – Saline nasal irrigation for at least six weeks – Nasal corticosteroids for at least six weeks – Approved biologics, if applicable, for at least six weeks – A complete course of antibiotic therapy when an acute bacterial infection is	○ A complete course of antibiotic therapy when an acute bacterial infection is suspected; ○ Treatment of concomitant allergic rhinitis, if present; and • Objective evidence of sinonasal inflammation as determined by one of the following: ○ Nasal endoscopy; or ○ Computed tomography Balloon ostial dilation and functional endoscopic sinus surgery are not covered and not considered medically necessary in the following situations: • Presence of sinonasal symptoms but no objective evidence of sinonasal disease by nasal endoscopy or computed tomography; • For the treatment of obstructive sleep apnea and/or snoring when the above criteria are not met; • For the treatment of headaches when the above criteria are not met; and • For balloon ostial dilation only, when sinonasal polyps are present

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Sinus Procedures (for Louisiana Only) (continued)	Mar. 9, 2022	suspected – Treatment of concomitant allergic rhinitis, if present ▪ Objective evidence of sinonasal inflammation as determined by one of the following: – Nasal endoscopy – Computed tomography ○ Balloon ostial dilation and functional endoscopic sinus surgery are not covered and not considered medically necessary in the following situations: ▪ Presence of sinonasal symptoms but no objective evidence of sinonasal disease by nasal endoscopy or computed tomography ▪ For the treatment of obstructive sleep apnea and/or snoring when the above criteria are not met ▪ For the treatment of headaches when the above criteria are not met ▪ For balloon ostial dilation only, when sinonasal polyps are present	

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Sinus Procedures (for Louisiana Only) (continued)	Mar. 9, 2022	**Applicable Codes** • Added CPT codes 31240, 31253, 31254, 31255, 31256, 31257, 31259, 31267, 31276, 31287, 31288, and 31299 **Supporting Information** • Updated *References* section to reflect the most current information • Removed *Definitions*, *Description of Services*, *Clinical Evidence*, and *FDA* sections	

Replaced

Policy Title	Effective Date	Summary of Changes
Functional Endoscopic Sinus Surgery (FESS) (for Louisiana Only)	Mar. 9, 2022	Policy replaced; refer to the Medical Policy titled Sinus Procedures (for Louisiana Only)

Medical Benefit Drug Policy Updates

New		
Policy Title	**Effective Date**	**Coverage Rationale**
Tezspire™ (Tezepelumab) (for Louisiana Only)	May 1, 2022	Tezspire is proven and medically necessary when all of the following criteria is met: • For initial therapy, all of the following: ○ Diagnosis of severe asthma; and ○ Classification of asthma as uncontrolled or inadequately controlled as defined by at least one of the following: ▪ Poor symptom control (e.g., ACQ score consistently greater than 1.5 or ACT score consistently less than 20); or ▪ Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months; or ▪ Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment); or ▪ Airflow limitation (e.g., after appropriate bronchodilator withhold FEV1 less than 80% predicted (in the face of reduced FEV1/FVC defined as less than the lower limit of normal); or ▪ Patient is currently dependent on maintenance therapy with oral corticosteroids for the treatment of asthma and ○ Used in combination with one of the following: ▪ One maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) product [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]; or ▪ Combination therapy including both of the following: – One high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco®), mometasone furoate (Asmanex®), beclomethasone dipropionate (QVAR®)]; and – One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi®) or indacaterol (Arcapta®), leukotriene receptor antagonist – montelukast (Singulair®), theophylline] and ○ Patient is not receiving Tezspire in combination with any of the following: ▪ Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab] ▪ Anti-IgE therapy [e.g., Xolair (omalizumab)] ▪ Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] ○ Tezspire dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Tezspire is prescribed by a pulmonologist or allergist/immunologist; and ○ Initial authorization will be for no more than 6 months. • For continuation of therapy, all of the following: ○ Documentation of a positive clinical response as demonstrated by at least one of the following: ▪ Reduction in the frequency of exacerbations

Medical Benefit Drug Policy Updates

New

Policy Title	Effective Date	Coverage Rationale
Tezspire™ (Tezepelumab) (for Louisiana Only) (continued)	May 1, 2022	▪ Decreased utilization of rescue medications ▪ Increase in percent predicted FEV1 from pretreatment baseline ▪ Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.) and ○ Used in combination with an ICS-containing controller medication; and ○ Patient is not receiving Tezspire in combination with any of the following: ▪ Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab] ▪ Anti-IgE therapy [e.g., Xolair (omalizumab)] ▪ Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] and ○ Tezspire dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Reauthorization will be for no more than 12 months.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Benlysta® (Belimumab) (for Louisiana Only)	May 1, 2022	**Coverage Rationale** • Revised coverage criteria; added criterion requiring the patient is not receiving Benlysta in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab-fnia) **Supporting Information** • Updated *References* section to reflect the most current information	This policy refers only to Benlysta (belimumab) injection for intravenous infusion for the treatment of systemic lupus erythematosus (SLE) and active lupus nephritis (LN). Benlysta (belimumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit and is indicated for systemic lupus erythematosus and active lupus nephritis. Benlysta (belimumab) is proven and medically necessary for the treatment of systemic lupus erythematosus when all of the following criteria are met: • For initial therapy, all of the following: ○ Diagnosis of active systemic lupus erythematosus, without severe active central nervous system lupus; and ○ Laboratory testing has documented the presence of autoantibodies [e.g., ANA, Anti-dsDNA, Anti-Sm, Anti-Ro/SSA, Anti-La/SSB]; and ○ Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants); that is not a biologic; and ○ Patient is not receiving Benlysta in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab-fnia); and

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Benlysta® (Belimumab) (for Louisiana Only) (continued)	May 1, 2022		○ Benlysta is initiated and titrated according to U.S. Food and Drug Administration labeled dosing for SLE; and ○ Initial authorization is for no more than 12 months • For continuation of therapy, all of the following: ○ Patient has previously received Benlysta injection for intravenous infusion; and ○ Documentation of positive clinical response; and ○ Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants); that is not a biologic; and ○ Patient is not receiving Benlysta in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab-fnia); and ○ Benlysta is dosed according to U.S. Food and Drug Administration labeled dosing for SLE; and ○ Authorization is for no more than 12 months Benlysta (belimumab) is proven and medically necessary for the treatment of active lupus nephritis when all of the following criteria are met: • For initial therapy, all of the following: ○ Diagnosis of active lupus nephritis, without severe active central nervous system lupus; and ○ Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic; and ○ Patient is not receiving Benlysta in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab-fnia); and ○ Benlysta is initiated and titrated according to US Food and Drug Administration labeled dosing; and ○ Initial authorization is for no more than 12 months • For continuation of therapy, all of the following: ○ Patient has previously received Benlysta injection for intravenous infusion; and ○ Documentation of positive clinical response; and

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Benlysta® (Belimumab) (for Louisiana Only) (continued)	May 1, 2022		○ Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants; that is not a biologic; and ○ Patient is not receiving Benlysta in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab-fnia); and ○ Benlysta is dosed according to US Food and Drug Administration labeled dosing; and ○ Authorization is for no more than 12 months Benlysta is unproven and not medically necessary for: • Antineutrophil cytoplasmic antibody-associated vasculitis • Rheumatoid arthritis • Severe active central nervous system (CNS) lupus • Sjögren's syndrome • Use in combination with other biologics • Waldenström macroglobulinemia
Intravenous Iron Replacement Therapy (Feraheme®, Injectafer® & Monoferric®) (for Louisiana Only)	May 1, 2022	Coverage Rationale *Iron Deficiency Anemia (IDA) Without Chronic Kidney Disease (CKD)* • Revised medical necessity criteria for Infed® and Venofer®; added criterion to allow coverage if the patient has one of the following: ○ Severe iron deficiency in late-stage pregnancy ○ Impaired absorption due to prior gastric surgery or inflammatory bowel disease ○ Blood loss that exceeds the ability to replete iron orally Definitions • Updated definition of “Iron	This policy refers to the following intravenous iron replacements: • Feraheme® (ferumoxytol) • Injectafer® (ferric carboxymaltose) • Monoferric® (ferric derisomaltose) The following intravenous iron replacements are not subject to the coverage criteria in this section: • Ferrlecit (sodium ferric gluconate complex) • Infed® (iron dextran) • Venofer® (iron sucrose) Feraheme (ferumoxytol), Injectafer (ferric carboxymaltose), and Monoferric (ferric derisomaltose) are proven for the following indications: *Iron Deficiency Anemia (IDA) without Chronic Kidney Disease (CKD)* Feraheme, Injectafer, and Monoferric are medically necessary when the following criteria are met: • For initial therapy, all of the following:

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) (for Louisiana Only) (continued)	May 1, 2022	Deficiency Anemia (IDA) Without Chronic Kidney Disease (CKD) or Acute or Chronic Inflammatory Conditions" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	○ Submission of medical records (e.g., lab values, chart notes, etc.) supporting the diagnosis of IDA; and ○ Patient does not have CKD; and ○ One of the following: ▪ History of failure, contraindication, or intolerance, to oral iron therapy; or ▪ One of the following: – Patient has severe iron deficiency in late stage pregnancy – Patient has impaired absorption due to prior gastric surgery or inflammatory bowel disease – Blood loss exceed the ability to replete iron orally; and ○ One of the following: ▪ Both of the following: – Submission of laboratory values demonstrating treatment failure after at least 3 weeks of therapy, to at least two of the following intravenous iron therapies each (Note: Laboratory values should be obtained within 1 to 3 weeks following the last dose of intravenous iron in a treatment course): • Infed® (iron dextran) • Ferrlecit (sodium ferric gluconate complex) • Venofer® (iron sucrose); and – Physician attests that in their clinical opinion, the clinical response would be expected to be superior with Feraheme, Injectafer, or Monoferric than experienced with the other products; or ▪ Both of the following: – History of intolerance, contraindication, or severe adverse event, to all of the following intravenous iron therapies not previously tried and experienced treatment failure:

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) (for Louisiana Only) (continued)	May 1, 2022		• Infed® (iron dextran) • Ferrlecit (sodium ferric gluconate complex) • Venofer® (iron sucrose); and – Physician attests that in their clinical opinion, the same intolerance, contraindication, or severe adverse event would not be expected to occur with Feraheme, Injectafer, or Monoferric than experienced with the other products; and ○ One of the following: ▪ Feraheme dose does not exceed 510 mg elemental iron per dose and 2.04g elemental iron per course ▪ Injectafer dose does not exceed 750 mg elemental iron per dose and 1500mg elemental iron per course ▪ Monoferric dose does not exceed 1000 mg elemental iron per dose/course; and ○ Initial authorization will be for no longer than 3 months. • For continuation of therapy, all of the following: ○ Coverage has previously been provided by UnitedHealthcare for Feraheme, Injectafer, or Monoferric for the treatment of IDA; and ○ Submission of recent laboratory results (within the past 4 weeks) since the last Feraheme, Injectafer, or Monoferric administration to demonstrate need for additional therapy; and ○ Patient does not have CKD; and ○ One of the following: ▪ Feraheme dose does not exceed 510 mg elemental iron per dose and 2.04g elemental iron per course ▪ Injectafer dose does not exceed 750 mg elemental iron per dose and 1500mg elemental iron per course ▪ Monoferric dose does not exceed 1000 mg elemental iron per dose/course; and

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) (for Louisiana Only) (continued)	May 1, 2022		○ Continuation authorization will be for no longer than 3 months. *Iron Deficiency Anemia (IDA) associated with Chronic Kidney Disease (CKD), without end stage renal disease (ESRD)* Feraheme, Injectafer, and Monoferric are medically necessary when the following criteria are met: • For initial therapy, all of the following: ○ Diagnosis of IDA and CKD; and ○ Submission of medical records (e.g., lab values, chart notes, etc.) supporting the diagnosis of IDA; and ○ Patient does not have ESRD; and ○ One of the following: ▪ Patient's CKD requires hemodialysis or peritoneal dialysis treatment; or ▪ Both of the following: – Patient's CKD does not require hemodialysis or peritoneal dialysis treatment; and – History of failure, contraindication, or intolerance, to oral iron therapy; and ○ One of the following: ▪ Both of the following: – Submission of laboratory values demonstrating treatment failure after at least 3 weeks of therapy, to at least two of the following intravenous iron therapies each (Note: Laboratory values should be obtained within 1 to 3 weeks following the last dose of intravenous iron in a treatment course): • Infed® (iron dextran) • Ferrlecit (sodium ferric gluconate complex) • Venofer® (iron sucrose); and – Physician attests that in their clinical opinion, the clinical response would be expected to be superior with Feraheme, Injectafer, or Monoferric than experienced with the other

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) (for Louisiana Only) (continued)	May 1, 2022		products; or ▪ Both of the following: – History of intolerance, contraindication, or severe adverse event, to all of the following intravenous iron therapies not previously tried and experienced treatment failure: • Infed® (iron dextran) • Ferrlecit (sodium ferric gluconate complex) • Venofer® (iron sucrose); and – Physician attests that in their clinical opinion, the same intolerance, contraindication, or severe adverse event would not be expected to occur with Feraheme, Injectafer, or Monoferric than experienced with the other products; and ○ One of the following: ▪ Feraheme dose does not exceed 510 mg elemental iron per dose and 2.04g elemental iron per course ▪ Injectafer dose does not exceed 750 mg elemental iron per dose and 1500mg elemental iron per course ▪ Monoferric dose does not exceed 1000 mg elemental iron per dose/course; and ○ Initial authorization will be for no longer than 3 months. • For continuation of therapy, all of the following: ○ Coverage has previously been provided by UnitedHealthcare for Feraheme, Injectafer, or Monoferric for the treatment of IDA with CKD; and ○ Patient does not have ESRD; and ○ Submission of recent laboratory results (within the past 4 weeks) since the last Feraheme, Injectafer, or Monoferric administration to demonstrate need for additional therapy; and ○ One of the following:

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) (for Louisiana Only) (continued)	May 1, 2022		▪ Feraheme dose does not exceed 510 mg elemental iron per dose and 2.04g elemental iron per course ▪ Injectafer dose does not exceed 750 mg elemental iron per dose and 1500mg elemental iron per course ▪ Monoferric dose does not exceed 1000 mg elemental iron per dose/course; and ○ Continuation authorization will be for no longer than 3 months.
Ryplazim® (Plasminogen, Human-Tvmh) (for Louisiana Only)	May 1, 2022	Coverage Rationale • Revised coverage criteria for: *Initial Therapy* ○ Added criterion requiring Ryplazim is prescribed by or in consultation with a hematologist ○ Changed timeframe for initial authorization from "no more than *12* months" to "no more than *6* months" *Continuation Therapy* ○ Added criterion requiring Ryplazim is prescribed by or in consultation with a hematologist ○ Replaced criterion requiring "patient has experienced a positive clinical response to Ryplazim therapy [e.g., improved (reduction) in lesion number/size, improvement in wound-healing, etc.]" with "patient has experienced a positive clinical response to	Ryplazim (plasminogen, human-tvmh) is proven and medically necessary for the treatment of plasminogen deficiency type 1 (hypoplasminogenemia) when the following criteria are met: • For initial therapy, all of the following: ○ Diagnosis of hypoplasminogenemia as measured by plasminogen activity level ≤ 45% of laboratory standard; and ○ Presence of clinical signs and symptoms of the disease (e.g., ligneous conjunctivitis, gingivitis, tonsillitis, abnormal wound healing, etc.); and ○ Prescribed by or in consultation with a hematologist; and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Initial authorization will be for no more than 6 months. • For continuation therapy, all of the following: ○ Patient has previously received treatment with Ryplazim therapy; and ○ Patient has experienced a positive clinical response to Ryplazim therapy (e.g., improved (reduction) in lesion number/size, improvement in wound-healing, plasminogen activity trough level has increased by at least 10 percentage points from baseline, etc.); and ○ Prescribed by or in consultation with a hematologist; and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Reauthorization will be for no more than 12 months. Ryplazim is unproven and not medically necessary for the treatment of idiopathic pulmonary fibrosis.

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ryplazim® (Plasminogen, Human-Tvmh) (for Louisiana Only) (continued)	May 1, 2022	Ryplazim therapy [e.g., improved (reduction) in lesion number/size, improvement in wound-healing, *plasminogen activity trough level has increased by at least 10 percentage points from baseline*, etc.]"	
Saphnelo™ (Anifrolumab-Fnia) (for Louisiana Only)	May 1, 2022	Coverage Rationale • Revised coverage criteria for initial therapy; added criterion requiring history of failure, contraindication, or intolerance to Benlysta intravenous (IV) or subcutaneous (SQ) Supporting Information • Updated *References* section to reflect the most current information	Saphnelo™ (anifrolumab-fnia) is proven and medically necessary for the treatment of moderate to severe systemic lupus erythematosus (SLE) when all of the following criteria are met: • For initial therapy, all of the following: ○ Diagnosis of moderate to severe systemic lupus erythematosus, without severe active central nervous system lupus or severe active lupus nephritis; and ○ Laboratory testing has documented the presence of autoantibodies [e.g., ANA, Anti-dsDNA, Anti-Sm, Anti-Ro/SSA, Anti-La/SSB]; and ○ Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic; and ○ History of failure, contraindication, or intolerance to Benlysta intravenous (IV) or subcutaneous (SQ); and ○ Patient is not receiving Saphnelo™ in combination with a biologic agent or Benlysta; and ○ Saphnelo™ is dosed according to US Food and Drug Administration labeled dosing for SLE; and ○ Initial authorization is for no more than 6 months. • For continuation of therapy, all of the following: ○ Patient has previously received Saphnelo™ injection for intravenous infusion; and ○ Documentation of positive clinical response; and ○ Patient is without severe active central nervous system lupus or severe active lupus nephritis; and

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Saphnelo™ (Anifrolumab-Fnia) (for Louisiana Only) (continued)	May 1, 2022		○ Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic; and ○ Patient is not receiving Saphnelo™ in combination with a biologic agent or Benlysta; and ○ Saphnelo™ is dosed according to US Food and Drug Administration labeled dosing for SLE; and ○ Authorization is for no more than 12 months. Saphnelo™ is unproven and not medically necessary for: ● Severe active lupus nephritis ● Severe active central nervous system (CNS) lupus ● Use in combination with other biologics

General Information

The inclusion of a health service (e.g., test, drug, device or procedure) in this bulletin indicates only that UnitedHealthcare is adopting a new policy and/or updated, revised, replaced or retired an existing policy; it does not imply that UnitedHealthcare provides coverage for the health service. Note that most benefit plan documents exclude from benefit coverage health services identified as investigational or unproven/not medically necessary. Physicians and other health care professionals may not seek or collect payment from a member for services not covered by the applicable benefit plan unless first obtaining the member's written consent, acknowledging that the service is not covered by the benefit plan and that they will be billed directly for the service.

Note: The absence of a policy does not automatically indicate or imply coverage. As always, coverage for a health service must be determined in accordance with the member's benefit plan and any applicable federal or state regulatory requirements. Additionally, UnitedHealthcare reserves the right to review the clinical evidence supporting the safety and effectiveness of a medical technology prior to rendering a coverage determination.

UnitedHealthcare respects the expertise of the physicians, health care professionals, and their staff who participate in our network. Our goal is to support you and your patients in making the most informed decisions regarding the choice of quality and cost-effective care, and to support practice staff with a simple and predictable administrative experience. The Medical Policy Update Bulletin was developed to share important information regarding UnitedHealthcare Community Plan of Louisiana Medical Policy, Medical Benefit Drug Policy, Coverage Determination Guideline, and Utilization Review Guideline updates. When information in this bulletin conflicts with applicable state and/or federal law, UnitedHealthcare follows such applicable federal and/or state law.

Policy Update Classifications

New

New clinical coverage criteria have been adopted for a health service (e.g., test, drug, device or procedure)

Updated

An existing policy has been reviewed and changes have not been made to the clinical coverage criteria; however, items such as the clinical evidence, FDA information, and/or list(s) of applicable codes may have been updated

Revised

An existing policy has been reviewed and revisions have been made to the clinical coverage criteria

Replaced

An existing policy has been replaced with a new or different policy

Retired

The health service(s) addressed in the policy are no longer being managed or are considered to be proven/medically necessary and are therefore not excluded as unproven/not medically necessary services, unless coverage guidelines or criteria are otherwise documented in another policy

The complete library of UnitedHealthcare Community Plan of Louisiana Medical Policies, Medical Benefit Drug Policies, Coverage Determination Guidelines, and Utilization Review Guidelines is available at UHCprovider.com/Louisiana > Medicaid (Community Plan) > Current Policies and Clinical Guidelines > UnitedHealthcare Community Plan of Louisiana Medical & Drug Policies and Coverage Determination Guidelines.