United Healthcare Community Plan

UnitedHealthcare Community Plan of Mississippi
Medical Policy Update Bulletin: July 2022

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Take Note

Community Plan of Mississippi to Use National Policy Versions

Effective Jul. 1, 2022, Community Plan of Mississippi will no longer maintain state-specific Medical Policies for the following services; coverage guidelines for the state of Mississippi will now be provided in the Community Plan National policy versions listed below:

- Ablative Treatment for Spinal Pain
- Abnormal Uterine Bleeding and Uterine Fibroids
- Articular Cartilage Defect Repairs
- Computed Tomographic Colonography
- Core Decompression for Avascular Necrosis
- Discogenic Pain Treatment
- Embolization of the Ovarian and Iliac Veins for Pelvic Congestion Syndrome
- Functional Endoscopic Sinus Surgery (FESS)
- Home Hemodialysis
- Inhaled Nitric Oxide Therapy
- Intensity-Modulated Radiation Therapy
- Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions
- Motorized Spinal Traction
- Nerve Graft to Restore Erectile Function During Radical Prostatectomy
- Neurophysiologic Testing and Monitoring
- Pectus Deformity Repair
- Percutaneous Vertebroplasty and Kyphoplasty
- Plagiocephaly and Craniosynostosis Treatment
- Prosthetic Devices, Specialized, Microprocessor or Myoelectric Limbs
- Sensory Integration Therapy and Auditory Integration Training
- Surgery of the Elbow
- Surgery of the Hip
- Surgery of the Knee
- Surgery of the Shoulder
- Temporomandibular Joint Disorders
- Unicondylar Spacer Devices for Treatment of Pain or Disability
- Vagus and External Trigeminal Nerve Stimulation
- Virtual Upper Gastrointestinal Endoscopy
- Whole Exome and Whole Genome Sequencing

Quarterly CPT® and HCPCS Code Updates

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 Mississippi Only)	Medical Policy	• Added HCPCS codes G0308 and G0309
Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation (for Mississippi Only)	Medical Policy	• Added CPT code 0720T
Immune Globulin (IVIG and SCIG) (for Mississippi Only)	Medical Benefit Drug Policy	• Added HCPCS code J1551

Take Note

Policy Title	Policy Type	Summary of Changes
Long-Acting Injectable Antiretroviral Agents for HIV	Medical Benefit Drug Policy	• Replaced HCPCS codes C9399 and J3490 with J0739
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions	Medical Policy	• Added CPT codes 0326U, 0329U, and 0331U • Revised description for CPT code 0016M
Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF)	Medical Benefit Drug Policy	• Replaced HCPCS code C9399 with C9097
Ryplazim® (Plasminogen, Human-Tvmh) (for Mississippi Only)	Medical Benefit Drug Policy	• Replaced J3490 and J3590 with J2998 • Removed C9090
Surgical Treatment for Spine Pain (for Mississippi Only)	Medical Policy	• Added CPT code 0719T

Medical Policy Updates

New

Policy Title	Effective Date	Coverage Rationale
Gastrointestinal Pathogen Nucleic Acid Detection Panel Testing for Infectious Diarrhea (for Mississippi Only)	Aug. 1, 2022	The following are proven and medically necessary: • Multiplex polymerase chain reaction (PCR) panel testing of gastrointestinal pathogens of up to 5 targets when performed as part of an evaluation that includes blood cultures for an individual with any of the following: ○ Diarrhea for more than 7 days with any of the following: ▪ Fever; or ▪ Bloody or mucoid stools; or ▪ Severe abdominal cramping or tenderness; or ▪ Signs of sepsis ○ Suspected enteric fever (i.e., typhoid or paratyphoid) in an individual with a history of recent travel to an endemic region (e.g., south-central Asia, Southeast Asia, and southern Africa) or who has consumed foods prepared by people with recent endemic exposure • Multiplex PCR panel testing of gastrointestinal pathogens of up to 11 targets for the evaluation of persistent diarrhea in an individual with any of the following: ○ At risk for Clostridium difficile (C. difficile) colitis and has had diarrhea for more than 7 days with any of the following; ▪ Fever; or ▪ Bloody or mucoid stools; or ▪ Severe abdominal cramping or tenderness; or ▪ Signs of sepsis ○ Acquired Immune Deficiency Syndrome (AIDS) ○ On immunosuppressive medications either following an organ transplant or when used for treatment of an auto-immune disease ○ Other condition causing immunosuppression and other stool diagnostic studies have failed to yield a pathogenic organism Due to insufficient evidence of efficacy, multiplex PCR panel testing of gastrointestinal pathogens is unproven and not medically necessary for evaluating all other indications not listed above as proven and medically necessary.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Negative Pressure Wound Therapy (for Mississippi Only)	Aug. 1, 2022	Coverage Rationale • Revised list of indications and devices that are unproven and not medically necessary:	• The proven and medically necessary coverage statements in this policy apply to the use of negative pressure wound therapy (NPWT) in the outpatient setting. • The unproven and not medically necessary coverage statements in this

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Negative Pressure Wound Therapy (for Mississippi Only) (continued)	Aug. 1, 2022	○ Added "negative pressure wound therapy (NPWT) systems with instillation" ○ Replaced "NPWT for treating closed surgical *wounds*" with "NPWT for treating closed surgical *incisions*" **Definitions** • Updated definition of "National Pressure Injury Advisory Panel (NPIAP) Staging System" **Applicable Codes** • Removed instruction to refer to the Coverage Determination Guideline titled *Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements* (for Mississippi Only) for use of HCPCS codes K0743-K0746 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	policy apply to all settings. NPWT, in an outpatient setting or upon discharge from an inpatient setting, is proven and medically necessary for treating individuals who have undergone a complete wound therapy program and meet indication-specific criteria as noted below. A complete wound therapy program, meeting the following criteria, must have been tried or considered and ruled out prior to initiation of NPWT: • Documentation of evaluation, care and wound measurements; and • Application of dressings to maintain a moist wound environment; and • Debridement of necrotic tissue, if present; and • Evaluation of and provision for adequate nutritional status; and • Documentation, by provider, of indication for NPWT; and • Documentation that open wound has not responded to conventional treatment after 30 days **Indications** • Pressure ulcer (Stage III or IV) with documentation of the following: ○ Complete wound therapy program, as outlined above; and ○ Appropriate turning and positioning; and ○ Use of a pressure-reducing support surface; and ○ Moisture and incontinence management • Neuropathic ulcer (e.g., Diabetic ulcer) with documentation of the following: ○ Complete wound therapy program, as outlined above; and ○ Comprehensive diabetic management program; and ○ Reduction in pressure on ulcer • Venous insufficiency ulcer with documentation of the following: ○ Complete wound therapy program, as outlined above; and ○ Compression bandages and/or garments have been used consistently, for at least 30 days; and ○ Leg elevation and ambulation • Open surgical wound with documentation of the following:

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Negative Pressure Wound Therapy (for Mississippi Only) (continued)	Aug. 1, 2022		○ Post-operative dehiscence (separation of a previously closed surgical incision) with documentation of a complete wound therapy program, as outlined above; or ○ Open, non-healing amputation site in diabetics; or ○ Post-sternotomy infection (mediastinitis); or ○ Delayed healing or non-healing of skin graft is likely due to irregularly contoured or inadequate blood flow of the graft bed • High-risk open fracture (Gustilo Grade III) The following indications and devices are unproven and not medically necessary due to insufficient evidence of efficacy: • NPWT for treating all other indications, including but not limited to: ○ Closed surgical incisions ○ Pilonidal disease • Disposable/single-use NPWT systems • NPWT systems with instillation **Contraindications to NPWT** • Active bleeding or exposed vasculature in wound • Eschar or necrotic tissue present in wound • Exposed bone, nerves or organs in vicinity of wound • Malignancy present in wound • Uncontrolled soft tissue infection or osteomyelitis within vicinity of wound • Presence of an open fistula to body organs or cavities within vicinity of wound NPWT should be discontinued when any of the following criteria are present: • Documentation of weekly assessment of the wound's dimensions and characteristics by the provider indicate failure of progressive wound healing (i.e., wound is not diminishing in size [either surface area or depth] within 30 days); or • The depth of the wound is 1 mm or less; or • Uniform granulation tissue has been obtained

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Pneumatic Compression Devices (for Mississippi Only)	Aug. 1, 2022	**Coverage Rationale** • Replaced language indicating "pneumatic compression devices are proven and medically necessary in certain circumstances" with "pneumatic compression devices are proven and medically necessary in certain circumstances *for the treatment of lymphedema or chronic venous insufficiency with edema and non-healing lower extremity ulcers*" • Added language to indicate intermittent limb compression devices are proven and medically necessary in an outpatient setting or upon discharge from an inpatient setting for the prevention of deep venous thrombosis (DVT) when all the following criteria are met: ○ Immobility (i.e., not able to get up from a chair/out of bed and walk to the toilet without the help of another person) ○ Contraindication to pharmaceutical anti-coagulation ○ None of the following contraindications are present: ▪ Active infection ▪ Pulmonary edema ▪ Severe arteriosclerosis	Pneumatic compression devices are proven and medically necessary in certain circumstances for the treatment of lymphedema or chronic venous insufficiency with edema and non-healing lower extremity ulcers. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Pneumatic Compression Devices. Click here to view the InterQual® criteria. Intermittent limb compression devices are proven and medically necessary in an outpatient setting or upon discharge from an inpatient setting for the prevention of deep venous thrombosis (DVT) when all the following criteria are met: • Immobility (i.e. not able to get up from a chair / out of bed and walk to the toilet without the help of another person) • Contraindication to pharmaceutical anti-coagulation • None of the following contraindications are present: ○ Active infection ○ Pulmonary edema ○ Severe arteriosclerosis ○ Severe congestive heart failure ○ Skin or tissue condition that may be negatively impacted by the use of garments ○ Suspected or known DVT Note: The InterQual® criteria does not apply to HCPCS codes E0652 and E0675. For E0652 and E0675, use available criteria from the CMS.gov website in LCD L33829.

Medical Policy Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Pneumatic Compression Devices (for Mississippi Only) (continued)	Aug. 1, 2022	▪ Severe congestive heart failure ▪ Skin or tissue condition that may be negatively impacted by the use of garments ▪ Suspected or known DVT • Updated notation to indicate the InterQual® criteria [listed in the policy] does not apply to HCPCS codes E0652 and E0675; use available criteria from the CMS.gov website in LCD L33829 **Supporting Information** • Added *Description of Services* and *Clinical Evidence* sections • Updated *References* section to reflect the most current information	
Skin and Soft Tissue Substitutes (for Mississippi Only)	Aug. 1, 2022	**Coverage Rationale** • Revised list of skin and soft tissue substitutes that are unproven and not medically necessary for any indication; added: ○ Apis ○ Cygnus matrix ○ InnovaMatrix AC ○ Microlyte Matrix ○ Mirragen Advanced Wound Matrix ○ NovoSorb SynPath ○ Restrata ○ Symphony ○ TheraGenesis	Refer to the policy for complete details.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Skin and Soft Tissue Substitutes (for Mississippi Only) (continued)	Aug. 1, 2022	○ XCelliStem Applicable Codes ● Added HCPCS codes A2001, A2002, A2004, A2005, A2006, A2007, A2008, A2009, A2010, and Q4199 Supporting Information ● Updated *Clinical Evidence* and *References* sections to reflect the most current information	
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Mississippi Only)	Aug. 1, 2022	Coverage Rationale *Documentation Requirements* ● Revised list of clinical information/items to be documented in the medical notes, when applicable, to reflect/include: ○ Diagnosis ○ History of the medical condition(s) requiring treatment or surgical intervention ○ Documentation of signs and symptoms; including onset, duration, frequency, and which extremity (right, left, or both) ○ Relevant medical history, including: ▪ DVT (deep vein thrombosis) ▪ Aneurysm ▪ Tortuosity ○ Physical exam, including: ▪ Which extremity (right, left,	**Varicose Vein Ablative and Stripping Procedures** The initial and subsequent radiofrequency ablation, endovenous laser ablation, Stripping, Ligation and excision of the Great Saphenous Vein (GSV) and Small Saphenous Veins (SSV) are considered reconstructive, proven and medically necessary when all of the following criteria are present: ● Junctional Reflux: ○ Ablative therapy for the GSV or SSV only if Junctional Reflux is demonstrated in these veins; or ○ Ablative therapy for Accessory Veins only if anatomically related persistent Junctional Reflux is demonstrated after the GSV or SSV have been removed or ablated ● Individual must have one of the following Functional or Physical Impairments: ○ Skin ulceration; or ○ Documented episode(s) of frank bleeding of the Varicose Vein due to erosion of/or trauma to the skin; or ○ Documented Superficial Thrombophlebitis; or ○ Documented Venous Stasis Dermatitis causing Functional or Physical Impairment; or ○ Moderate to Severe Pain causing Functional or Physical Impairment ● Venous Size: ○ The GSV must be 5.5 mm or greater when measured at the proximal thigh immediately below the sapheno-femoral junction via Duplex

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Mississippi Only) (continued)	Aug. 1, 2022	or both) ▪ Vein(s) that will be treated [e.g., great saphenous vein (GSV) and small saphenous vein (SSV), etc.] ▪ Vein diameter including the specific anatomic location where the measurement was taken (e.g., proximal thigh, proximal calf, etc.) ▪ Duration of reflux including the position of member at the time of measurement and the anatomic location where the measurement was taken [e.g., standing, saphenofemoral junction (SFJ)] ○ Severity of pain or other symptoms that interfere with activities of daily living related to vein disease ○ Functional disability(ies), as documented on a validated functional disability scale, (interfering with the ability to stand or sit for long periods of time, such as, preparing meals, performing work functions, driving, walking, etc.) ○ Diagnostic study/imaging	Ultrasonography. (Navarro et al. 2002) ○ The SSV or Accessory Veins must measure 5 mm or greater in diameter immediately below the sapheno-popliteal junction • Duration of reflux, in the standing or reverse Trendelenburg position that meets the following parameters: ○ Greater than or equal to 500 milliseconds (ms) for the GSV, SSV Veins or principal tributaries ○ Perforating veins > 350ms ○ Some Duplex Ultrasound readings will describe this as moderate to severe reflux which will be acceptable See *Coding Clarification* section of the policy. Adherence to American Medical Association (AMA) coding guidance is required when requesting coverage of endovenous ablation procedures. Note that only one primary code may be requested for the initial vein treated, and only one add-on code per extremity may be requested for any subsequent vein(s) treated. Ablation of perforator veins is considered reconstructive, proven and medically necessary when the following criteria are present: • Evidence of perforator Venous Insufficiency measured by recent Duplex Ultrasonography report (see criteria above); and • Perforator vein size is 3.5 mm or greater; and • Perforating vein lies beneath a healed or active venous stasis ulcer Endovenous mechanochemical ablation (MOCA) of Varicose Veins is unproven and not medically necessary due to insufficient evidence of efficacy. **Ligation Procedures** The following procedure is proven and medically necessary: • Ligation at the saphenofemoral junction, as a stand-alone procedure, when used to prevent the propagation of an active clot to the deep venous system in individuals with ascending Superficial Thrombophlebitis who fail or are

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Mississippi Only) (continued)	Aug. 1, 2022	reports ○ Pulses ○ Prior conservative treatments tried, failed, or contraindicated. Include the dates and reason for discontinuation ○ Proposed treatment plan with procedure code, including specific vein(s) that will be treated (e.g., great saphenous vein (GSV) and small saphenous vein (SSV), etc.), which extremity (left, right, or both) and date of procedure for each vein to be treated ○ In addition to the above, additional documentation requirements may apply for CPT codes 37761, 37765, 37766, and 37785; refer to the Utilization Review Guideline titled *Outpatient Surgical Procedures – Site of Service (for Mississippi Only)* **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	intolerant of anticoagulation therapy The following procedure is proven and medically necessary in certain circumstances: • Ligation, subfascial, endoscopic surgery for treatment of perforating veins associated with chronic Venous Insufficiency. For medical necessity clinical coverage criteria, refer to the InterQual®CP: Procedures, Ligation, Subfascial, Endoscopic, Perforating Vein. Click here to view the InterQual® criteria. The following procedures are unproven and not medically necessary for treating Venous Reflux due to insufficient evidence of efficacy: • Ligation of the GSV at the saphenofemoral junction, as a stand-alone procedure • Ligation of the SSV at the saphenopopliteal junction, as a stand-alone procedure • Ligation at the saphenofemoral junction, as an adjunct to radiofrequency ablation or endovenous laser ablation of the main saphenous veins **Ambulatory Phlebectomy** Ambulatory phlebectomy for treating varicose veins is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual®CP: Procedures, Ambulatory Phlebectomy, Varicose Vein for: • Hook Phlebectomy • Microphlebectomy • Mini Phlebectomy • Stab Avulsion • Stab Phlebectomy Click here to view the InterQual® criteria.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**

Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Mississippi Only) (continued)	Aug. 1, 2022		**Other Procedures**
			The following procedures are unproven and not medically necessary for treating Venous Reflux due to insufficient evidence of efficacy:
			• Endovascular embolization of Varicose Veins using cyanoacrylate-based adhesive
			• Endovenous low-nitrogen foam sclerotherapy of incompetent GSV, lesser saphenous veins, and accessory saphenous veins
			
			Documentation Requirements
			Medical notes documenting the following, when applicable:
			• Diagnosis
			• History of the medical condition(s) requiring treatment or surgical intervention
			• Documentation of signs and symptoms; including onset, duration, frequency, and which extremity (right, left, or both)
			• Relevant medical history, including:
			  ○ DVT (deep vein thrombosis)
			  ○ Aneurysm
			  ○ Tortuosity
			• Physical exam, including:
			  ○ Which extremity (right, left, or both)
			  ○ Vein(s) that will be treated [e.g., great saphenous vein (GSV) and small saphenous vein (SSV), etc.]
			  ○ Vein diameter including the specific anatomic location where the measurement was taken (e.g., proximal thigh, proximal calf, etc.)
			  ○ Duration of reflux including the position of member at the time of measurement and the anatomic location where the measurement was taken [e.g., standing, saphenofemoral junction (SFJ)]
			• Severity of pain or other symptoms that interfere with activities of daily living related to vein disease
			• Functional disability(ies), as documented on a validated functional disability scale, (interfering with the ability to stand or sit for long periods of time, such as, preparing meals, performing work functions, driving, walking, etc.)

Medical Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Mississippi Only) (continued)	Aug. 1, 2022		• Diagnostic study/imaging reports • Pulses • Prior conservative treatments tried, failed, or contraindicated. Include the dates and reason for discontinuation • Proposed treatment plan with procedure code, including specific vein(s) that will be treated (e.g., great saphenous vein (GSV) and small saphenous vein (SSV), etc.), which extremity (left, right, or both) and date of procedure for each vein to be treated In addition to the above, additional documentation requirements may apply for the following codes. Review the below listed policy in conjunction with the guidelines in this policy. • For CPT codes 37761, 37765, 37766, and 37785, refer to the Utilization Review Guideline titled Outpatient Surgical Procedures – Site of Service.
Transcatheter Heart Valve Procedures (for Mississippi Only)	Aug. 1, 2022	Coverage Rationale • Added instruction to refer to the following sources for additional information pertaining to Volume Requirements consistent with the Centers for Medicare and Medicaid Services (CMS): ○ CMS National Coverage Determination 20.32: *Transcatheter Aortic Valve Replacement (TAVR)* ○ Society of Thoracic Surgeons/American College of Cardiology (STS/ACC) *Transcatheter Valve Therapy (TVT) Registry* • Added language to indicate transcatheter pulmonary heart valve replacement using the	**Aortic** Transcatheter aortic heart valve replacement is proven and medically necessary when performed according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions and all of the following criteria are met: • Diagnosis of severe calcific native aortic valve stenosis as indicated by one of the following: ○ Mean aortic valve gradient ≥ 40 mmHg; or ○ Peak aortic jet velocity ≥ 4.0 m/s; or ○ Aortic valve area of ≤ 0.8 cm^2 • Individual is symptomatic (New York Heart Association [NYHA] class II or greater) and symptoms are due to aortic valve stenosis • Individual does not have a congenitally bicuspid aortic valve • An interventional cardiologist and an experienced cardiothoracic surgeon have determined that the procedure is appropriate • Individual has engaged in a Shared Decision Making conversation with an interventional cardiologist and an experienced cardiothoracic surgeon • Procedure is performed in a center that meets all of the following criteria: ○ On-site heart valve surgery and interventional cardiology programs; and

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Transcatheter Heart Valve Procedures (for Mississippi Only) (continued)	Aug. 1, 2022	Harmony™ valve is unproven and not medically necessary **Definitions** • Added definition of "CMS Volume Requirements for Transcatheter Aortic Heart Valve Replacement (TAVR)" **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	○ Post-procedure intensive care unit with personnel experienced in managing individuals who have undergone open-heart valve procedures; and ○ Volume Requirements consistent with the Centers for Medicare and Medicaid Services (CMS); for additional information, see corresponding CMS National Coverage Determination and the Society of Thoracic Surgeons/American College of Cardiology (STS/ACC) Transcatheter Valve Therapy (TVT) Registry. Transcatheter valve-in-valve (ViV) replacement within a failed bioprosthetic aortic valve is proven and medically necessary for individuals at high or prohibitive surgical risk (Predicted Risk of Mortality [PROM] score of ≥ 8%) when performed according to FDA labeled indications, contraindications, warnings and precautions. Note: Requests for transcatheter aortic heart valve replacement for low-flow/low-gradient aortic stenosis will be evaluated on a case-by-case basis. **Mitral** Transcatheter mitral valve repair is proven and medically necessary when used according to FDA labeled indications, contraindications, warnings and precautions in individuals with one of the following clinical indications for intervention: • Primary (degenerative) mitral regurgitation (MR) when all of the following criteria are met: ○ Moderate-to-severe or severe MR (grade ≥ 3); and ○ Symptomatic NYHA class III or IV; and ○ Prohibitive surgical risk as defined by ONE of the following: ▪ PROM score of ≥ 8% for individuals deemed likely to undergo mitral valve replacement; or ▪ PROM score of ≥ 6% for individuals deemed likely to undergo mitral valve repair; or ▪ Predicted risk of death or major morbidity at 1 year of over 50%;

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Transcatheter Heart Valve Procedures (for Mississippi Only) (continued)	Aug. 1, 2022		and ○ Care directed by a multidisciplinary heart team which includes a heart failure specialist, interventional cardiologist and cardiothoracic surgeon experienced in the evaluation and treatment of heart failure and mitral valve disease. • Secondary (functional) MR when all of the following criteria are met: ○ Moderate-to-severe or severe MR (grade ≥ 3) with left ventricular ejection fraction (LVEF) ≥ 20 and ≤50; and ○ Symptomatic NYHA class II –IV (ambulatory); and ○ Optimal evidence-based management which includes pharmacologic therapy plus cardiac resynchronization therapy as indicated; and ○ High surgical risk (PROM score of ≥ 8%); and ○ Care directed by a multidisciplinary heart team which includes a heart failure specialist, interventional cardiologist and cardiothoracic surgeon experienced in the evaluation and treatment of heart failure and mitral valve disease. **Pulmonary** Transcatheter pulmonary heart valve replacement, using the Melody™ or Sapien valves, is proven and medically necessary, when used according to FDA labeled indications, contraindications, warnings and precautions, in individuals with right ventricular outflow tract (RVOT) dysfunction with one of the following clinical indications for intervention: • Moderate or greater pulmonary regurgitation; and/or • Pulmonary stenosis with a mean RVOT gradient ≥ 35 mmHg The following transcatheter heart valve devices and/or procedures are unproven and not medically necessary due to insufficient evidence of efficacy: • Cerebral protection devices (e.g., Sentinel™) • Mitral valve repair, reconstruction or replacement, except where noted above • Tricuspid valve repair, reconstruction or replacement

Medical Policy Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Transcatheter Heart Valve Procedures (for Mississippi Only) (continued)	Aug. 1, 2022		• Valve-in-Valve (ViV) replacement within a failed bioprosthesis for mitral, pulmonary, or tricuspid valves • Transcatheter pulmonary heart valve replacement using the Harmony™ valve

Medical Benefit Drug Policy Updates

New		
Policy Title	**Effective Date**	**Coverage Rationale**
Enjaymo™ (Sutimlimab-Jome)	Aug. 1, 2022	Enjaymo is medically necessary for the treatment of CAD in patients who meet all of the following criteria: ● For initial therapy, all of the following: ○ Diagnosis of CAD by, or in consultation with, a hematologist with expertise in the diagnosis of CAD; and ○ Confirmation of the CAD diagnosis based on all of the following: ▪ Evidence of chronic hemolysis (e.g., elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased indirect bilirubin, increased reticulocyte count); and ▪ Positive polyspecific direct antiglobin test (DAT); and ▪ Positive monospecific DAT specific for C3d; and ▪ Immunoglubulin G (IgG) DAT ≤ 1+; and ▪ Cold agglutinin titer ≥ 64 at 4°C and ○ Cold agglutinin syndrome secondary to other factors has been ruled out (e.g., infection, rheumatologic disease, systemic lupus erythematosus, overt hematologic malignancy, other autoimmune disorders); and ○ Patient has a baseline hemoglobin level ≤ 10 g/dL; and ○ Enjaymo is prescribed by a hematologist; and ○ Enjaymo dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Patient is not receiving Enjaymo in combination with a complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravilizumab-cwzb), Empaveli (pegcetacoplan)]; and ○ Initial authorization will be for no more than 6 months. ● For continuation of therapy, all of the following: ○ Documentation of positive clinical response to therapy (e.g., increase in hemoglobin, decreased transfusion requirements, decreased markers of hemolysis, improvement in anemia-related symptoms); and ○ Enjaymo is prescribed by, or in consultation with, a hematologist; and ○ Enjaymo dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Patient is not receiving Enjaymo in combination with a complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravilizumab-cwzb), Empaveli (pegcetacoplan)]; and ○ Reauthorization will be for no more than 12 months. Requests outside of this criteria will be reviewed for medical necessity on a case by case basis.
Korsuva™ (Difelikefalin)	Aug. 1, 2022	**Initial Therapy** Korsuva (Difelikefalin) is proven and medically necessary for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis when the following criteria are met: ● Diagnosis of moderate-to-severe pruritus associated with chronic kidney disease; and

New		
Policy Title	**Effective Date**	**Coverage Rationale**
Korsuva™ (Difelikefalin) (continued)	Aug. 1, 2022	• Patient is on hemodialysis; and • Pruritus is not attributed to a cause other than end stage renal disease or its complications (e.g., pruritic dermatological disease, cholestatic liver disease); and • Pruritus is not limited to occurring only during the dialysis session; and • Pruritis is not localized to just the palms of the hands, and • History of failure, contraindication, or intolerance to other pruritis treatments (e.g., antihistamines, corticosteroids, gabapentin, pregabalin, capsaicin); and • Prescribed by or in consultation with a nephrologist; and • Dosing is in accordance with the United States Food and Drug Administration approved labeling; and • Initial authorization will be for no longer than 3 months. **Continuation Therapy** Korsuva (Difelikefalin) will be reauthorized based on all of the following criteria: • Documentation of a positive clinical response (i.e., reduction in itch from baseline); and • Prescribed by or in consultation with a nephrologist; and • Dosing is in accordance with the United States Food and Drug Administration approved labeling; and • Reauthorization will be for no longer than 12 months.
Leqvio® (Inclisiran)	Aug. 1, 2022	Leqvio (inclisiran) is proven and medically necessary for the treatment of heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) in patients who meet all of the following criteria: • For initial therapy, all of the following: ○ Diagnosis of one of the following: ▪ Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following*: – Both of the following: • Pre-treatment LDL-C greater than or equal to 190 mg/dL (greater than or equal to 155 mg/dL if less than 16 years of age); and • One of the following: ○ Family history of myocardial infarction in first-degree relative < 60 years of age; or ○ Family history of myocardial infarction in second-degree relative < 50 years of age; or ○ Family history of LDL-C greater than or equal to 190 mg/dL in first- or second-degree relative; or ○ Family history of heterozygous or homozygous familial hypercholesterolemia in first; or second degree relative; or ○ Family history of tendinous xanthomata and/or arcus cornealis in first- or second degree relative or

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Policy Title	Effective Date	Coverage Rationale
Leqvio® (Inclisiran) (continued)	Aug. 1, 2022	– Both of the following: • Pre-treatment LDL-C greater than or equal to 190 mg/dL (greater than or equal to 155 mg/dL if less than 16 years of age); and • One of the following: ○ Functional mutation in LDL, apoB, or PCSK9 gene*; or ○ Tendinous xanthomata; or ○ Arcus cornealis before age 45 or ▪ Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: – Acute coronary syndromes; or – History of myocardial infarction; or – Coronary or other arterial revascularization; or – Stroke; or – Transient ischemic attack; or – Peripheral arterial disease presumed to be of atherosclerotic origin and ○ Prescribed by, a lipid specialist (e.g., cardiologist, endocrinologist, lipid specialist/lipidologist); and ○ One of the following: ▪ Despite adherence to PCSK9 therapy (defined by at least 12 consecutive weeks of use), one of the following: – Both of the following: • Patient has clinical ASCVD; and • Patient failed to achieve LDL-C goal of < 70 mg/dL or – Both of the following: • Patient has severe primary hypercholesterolemia (HeFH) (pre-treatment LDL-C ≥ 190 mg/dL); and • Patient failed to achieve LDL-C goal of < 100 mg/dL or ▪ Patient has a history of intolerance or contraindication to PCSK9 therapy and ○ Patient will continue other traditional low-density lipoprotein-cholesterol (LDL-C) lowering therapies (e.g., maximally tolerated statins, ezetimibe) in combination with Leqvio; and ○ Leqvio will not be used in combination with PCSK9 inhibitor therapy; and ○ Leqvio dosing is in accordance with the United States Food and Drug Administration approved labeling; and

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Policy Title	**Effective Date**	**Coverage Rationale**
Leqvio® (Inclisiran) (continued)	Aug. 1, 2022	○ Initial authorization will be for no more than 12 months ● For continuation of therapy, all of the following: ○ Documentation of a positive clinical response to therapy from pre-treatment baseline (e.g., achieved LDL-C goal of < 100 mg/dL or achieved a 50% reduction in LDL-C levels); and ○ Patient continues treatment with other traditional low-density lipoprotein-cholesterol (LDL-C) lowering therapies (e.g., statin, ezetimibe) in combination with Leqvio; and ○ Leqvio will not be used in combination with PCSK9 therapy; and ○ Leqvio dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Reauthorization will be for no more than 12 months. *Results of prior genetic testing can be submitted as confirmation of diagnosis of HeFH, however please note that UnitedHealthcare does not currently cover genetic testing for evidence of an LDL-receptor mutation, familial defective apo B-100 or a PCSK9 mutation.
Tezspire™ (Tezepelumab-Ekko)	Aug. 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 beta$_2$ 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

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Policy Title	Effective Date	Coverage Rationale
Tezspire™ (Tezepelumab-Ekko) (continued)	Aug. 1, 2022	– One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi®) or indacaterol (Arcapta®), leukotriene receptor antagonist – montelukast (Singulair®), theophylline] and ○ One of the following: ▪ History of failure, contraindication, or intolerance to a 4 month trial of an anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Fasenra (benralizumab)]; or ▪ Patient's asthma is not of the eosinophilic phenotype; or ▪ Patient is currently on Tezspire 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 ▪ 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.

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Policy Title	Effective Date	Coverage Rationale
Vyvgart™ (Efgartigimod Alfa-Fcab)	Aug. 1, 2022	**Myasthenia Gravis** Vyvgart™ is proven and medically necessary when the following criteria are met: • Initial Therapy: ○ Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of generalized myasthenia gravis (gMG) by a neurologist or in consultation with a neurologist confirming all of the following: ▪ Patient has not failed a previous course of Vyvgart™ therapy; and ▪ Positive serologic test for anti-AChR antibodies; and ▪ One of the following: – History of abnormal neuromuscular transmission test demonstrated by single-fiber electromyography (SFEMG) or repetitive nerve stimulation – History of positive anticholinesterase test, e.g., edrophonium chloride test – Patient has demonstrated improvement in MG signs on oral cholinesterase inhibitors as assessed by the treating neurologist 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 ≥ 5 at initiation of therapy and ○ Both of the following: ▪ History of failure of at least two immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, methotrexate, cyclosporine, mycophenylate, etc.); and ▪ Patient has required 2 or more courses of plasmapheresis/plasma exchanges and/or intravenous immune globulin for at least 12 months without symptom control and ○ Patient is currently on a stable dose (at least 2 months) of immunosuppressive therapy; and ○ Patient is not receiving Vyvgart™ in combination with Soliris (eculizumab); and ○ Vyvgart™ is initiated and titrated according to the U.S. FDA labeled dosing for gMG, up to a maximum of 1200 mg per dose; and ○ Prescribed by or in consultation with a neurologist; and ○ Initial authorization will be for no more than 6 months. • Continuation of Therapy:

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Policy Title	Effective Date	Coverage Rationale
Vyvgart™ (Efgartigimod Alfa-Fcab) (continued)	Aug. 1, 2022	○ Patient has previously been treated with Vyvgart™; and ○ Submission of medical records (e.g., chart notes, laboratory tests) to demonstrate a positive clinical response from baseline as demonstrated by all of the following: ▪ Improvement and/or maintenance of at least a 2-point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline. ▪ Reduction in signs and symptoms of myasthenia gravis ▪ Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Vyvgart™. Note: add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on Vyvgart™ therapy will be considered as treatment failure. and ○ Patient is not receiving Vyvgart™ in combination with Soliris (eculizumab); and ○ Vyvgart™ is dosed according to the U.S. FDA labeled dosing for gMG: up to a maximum of 1200 mg per dose; and ○ Prescribed by or in consultation with a neurologist; and ○ Reauthorization will be for no more than 12 months.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gonadotropin Releasing Hormone Analogs	Aug. 1, 2022	Coverage Rationale ● Revised list of applicable gonadotropin releasing hormone analog (GnRH analog) drug products; added Camcevi™ (leuprolide mesylate) Applicable Codes ● Added HCPCS code J1952 Supporting Information ● Updated *Background*, *FDA*, and *References* sections to reflect the most current information	Refer to the policy for complete details.
Long-Acting Injectable Antiretroviral Agents for HIV	Aug. 1, 2022	Coverage Rationale *Cabenuva* ● Revised coverage criteria for initial	This policy refers to the following long-acting injectable antiretroviral products: ● Apretude (cabotegravir) ● Cabenuva (cabotegravir/rilpivirine)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Long-Acting Injectable Antiretroviral Agents for HIV (continued)	Aug. 1, 2022	therapy; removed criterion requiring the provider confirms that tolerability will be assessed using a 28-day oral lead-in of Vocabria (cabotegravir) and Edurant® (rilpivirine) tablets prior to the first injection of Cabenuva **Supporting Information** • Updated *References* section to reflect the most current information	Apretude (cabotegravir) is proven to reduce the risk of sexually acquired HIV-1 infection in at-risk adults and adolescents weighing at least 35kg. Apretude is medically necessary when the following additional criteria are met: For initial therapy, all of the following: ○ Used for HIV-1 pre-exposure prophylaxis (PrEP); and ○ Patient has a negative HIV-1 test; and ○ Provider confirms that the patient will be tested for HIV-1 infection with each subsequent injection; and ○ Patient is not an appropriate candidate for oral PrEP (e.g. difficulty with adherence to prior oral PrEP, significant renal disease); and ○ Provider attests that patient demonstrates treatment readiness by both of the following: ▪ Patient understands the risks of missed doses of Apretude ▪ Patient has the ability to adhere to the required every 2 months injection and testing appointments; and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Initial authorization is for no more than 12 months. • For continuation therapy, all of the following: ○ Patient has previously received treatment with Apretude; and ○ Patient has a negative HIV-1 test; and ○ Provider confirms that the patient will be tested for HIV-1 infection with each subsequent injection; and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Authorization is for no more than 12 months. Apretude is unproven and not medically necessary for the treatment of human immunodeficiency virus type-1 (HIV-1). Cabenuva (cabotegravir/rilpivirine) is proven for the treatment of a human

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Long-Acting Injectable Antiretroviral Agents for HIV (continued)	Aug. 1, 2022		immunodeficiency virus type-1 (HIV-1) in patients who are virologically suppressed (HIV-1 RNA less than 50 copies per mL). Cabenuva is medically necessary when the following additional criteria are met: For initial therapy, all of the following: ○ Diagnosis of HIV-1 infection; and ○ Patient has no prior virologic failures or baseline resistance to either cabotegravir or rilpivirine; and ○ Patient is currently on a stable antiretroviral regimen; and ○ Submission of medical records (e.g., chart notes, laboratory results) showing viral suppression (HIV-1 RNA less than 50 copies per mL) for at least 6 months prior to initiation of Cabenuva; and ○ Provider attests that patient demonstrates treatment readiness by both of the following: ▪ Patient understands the risks of missed doses of Cabenuva ▪ Patient has the ability to adhere to the required monthly or every 2 months injection appointments and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Initial authorization is for no more than 12 months • For continuation therapy, all of the following: ○ Patient has previously received treatment with Cabenuva; and ○ Provider confirms that the patient has achieved and maintained viral suppression (HIV-1 RNA less than 50 copies per mL) while on Cabenuva therapy; and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Authorization is for no more than 12 months Cabenuva is unproven and not medically necessary for the treatment of Human immunodeficiency virus type-1 (HIV-1) in patients who are not currently virally suppressed (HIV-1 RNA less than 50 copies per mL)

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Off-Label/Unproven Specialty Drug Treatment	Aug. 1, 2022	**Coverage Rationale**
		• Replaced reference(s) to:
		  ○ "*Injectable* specialty drug" with "specialty drug"
		  ○ "*Injectable* oncology medications" with "oncology medications"
		• Added language to indicate this policy provides parameters for coverage of off-label and unproven indications of FDA-approved medications covered under the medical benefit for patient self-administered specialty drugs covered under the medical benefit
		Supporting Information
		• Updated *References* section to reflect the most current information
			Description
			This policy provides parameters for coverage of off-label and unproven indications of FDA-approved medications covered under the medical benefit for one of the following:
			• Provider administered or supervised specialty drug or patient self-administered specialty drug covered under the medical benefit with a corresponding UnitedHealthcare policy that does not address the requested indication
			• Provider administered or supervised specialty drug or patient self-administered specialty drug covered under the medical benefit with a corresponding UnitedHealthcare policy that lists the drug as unproven for the requested indication
			• Provider administered or supervised specialty drug or patient self-administered specialty drug covered under the medical benefit without a UnitedHealthcare drug policy
			
			This policy does not address coverage for self-administered medications covered under the pharmacy benefit. Please refer to pharmacy benefit coverage.
			
			This policy does not address coverage of oncology medications (including, but not limited to octreotide acetate, leuprolide acetate, leucovorin and levoleucovorin), including therapeutic radiopharmaceuticals, covered under the medical benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®). Refer to the Medical Benefit Drug Policy titled Oncology Medication Clinical Coverage for more information.
			This policy does not address coverage of vaccines.
			
			Indications of Coverage
			A specialty drug may be determined medically necessary for the requested off-label or unproven indication when all of the criteria are met:
			• The drug is approved by the U.S. Food and Drug Administration (FDA); and
			• The requested drug is a covered benefit by the member's state Medicaid

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Off-Label/Unproven Specialty Drug Treatment (continued)	Aug. 1, 2022		agency; and
			• One of the following:
			  ○ The requested drug is considered 'unproven' per UnitedHealthcare drug policy, where applicable
			  ○ The indication for the requested drug is not addressed by a UnitedHealthcare drug policy, where applicable
			  ○ A UnitedHealthcare drug policy does not exist for the requested drug; and
			• The requested drug is intended to treat a chronic and seriously debilitating, or Serious Rare Disease; and
			• The patient has not failed a previous course or trial of the requested drug; and
			• The patient is not currently in an eligible clinical trial; and
			• Documented history of failure, contraindication, or intolerance to standard, conventional therapies to treat or manage the disease or condition, where available; and
			• Diagnosis is clinically supported as a use by at least one of the following:
			  ○ One of the following compendia:
			  ▪ The American Hospital Formulary Service Drug Information (AHFS - DI) under the Therapeutic Uses section
			  ▪ The Elsevier Gold Standard's Clinical Pharmacology under the Indications section
			  ▪ DRUGDEX System by Micromedex® has a Strength of Recommendation rating of Class I, Class IIa, or Class IIb under the Therapeutic Uses section;
			  or
			  ○ Clinical indications supported by InterQual® Specialty Rx; or
			  ○ Two (2) articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is validated, and uncontested contradictory evidence presented in a major peer-reviewed medical journal. (Examples of accepted journals include, but are not limited to, Journal of American Medical Association, New England Journal of Medicine,

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Off-Label/Unproven Specialty Drug Treatment (continued)	Aug. 1, 2022		and Lancet. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. Evidence limited to case studies or case series is not sufficient to meet the standard of this criterion.)
Oncology Medication Clinical Coverage Policy	Aug. 1, 2022	**Related Policies** • Added reference link to the Medical Benefit Drug Policy titled *Antiemetics for Oncology* **Coverage Rationale** • Revised list of UnitedHealthcare non-preferred oncology products; added Alymsys (bevacizumab-maly)	This policy provides parameters for coverage of injectable oncology medications (including, but not limited to, octreotide acetate, leuprolide acetate, leucovorin, and levoleucovorin), including therapeutic radiopharmaceuticals, covered under the medical benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®). The Compendium lists the appropriate drugs and biologics for specific cancers using US Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category. Coverage of White Blood Cell Colony Stimulating Factors and Erythropoiesis-Stimulating Agents are addressed in separate policies. This policy does not provide coverage criteria for Chimeric Antigen Receptor (CAR)-T Cell products. Coverage determinations are based on the member's benefits and the OptumHealth Transplant Solutions criteria for covered transplants in the Clinical Guideline titled Chimeric Antigen Receptor T-cell Therapy. **Coverage Rationale** The Oncology Products table below lists the UnitedHealthcare preferred oncology products and respective non-preferred products. Coverage will be provided for the UnitedHealthcare preferred oncology product contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Coverage for any respective non-preferred oncology product will be provided contingent on the criteria in the Preferred Product Criteria and the Diagnosis-Specific Criteria sections. ***Preferred Product Criteria*** Treatment with the respective non-preferred product specified in the Oncology Products table below is medically necessary for oncology

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Oncology Medication Clinical Coverage Policy (continued)	Aug. 1, 2022		indications when both of the following are met: • History of intolerance or contraindication to one of UnitedHealthcare's preferred oncology products; and • Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with the respective non-preferred product **Oncology Products** Below are UnitedHealthcare preferred oncology products with therapeutically equivalent and/or biosimilar* non-preferred products as determined by the UnitedHealthcare P&T Committee:

Preferred Oncology Product	Non-Preferred Oncology Product
Mvasi (bevacizumab-awwb)	Avastin (bevacizumab) Zirabev (bevacizumab-bvzr) Alymsys (bevacizumab-maly)
Kanjinti (trastuzumab-anns)	Herceptin (trastuzumab) Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) Herzuma (trastuzumab-pkrb) Ogivri (trastuzumab-dkst) Ontruzant (trastuzumab-dttb) Trazimera (trastuzumab-qyyp)
Gemcitabine	Infugem (gemcitabine in sodium chloride injection)
Leucovorin	Levoleucovorin
Ruxience (rituximab-pvvr) Truxima (rituximab-abbs)	Riabni (rituximab-arrx) Rituxan (rituximab) Rituxan Hycela (rituximab/hyaluronidase human, recombinant)

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Oncology Medication Clinical Coverage Policy (continued)	Aug. 1, 2022		Eligard, Lupron Depot 7.5mg (J9217) / Lupron Depot 3.75mg (J1950) *Biosimilar means that the biological product is FDA-approved based on data demonstrating that it is highly similar to an already FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. ***Diagnosis-Specific Criteria*** Injectable Oncology Medications UnitedHealthcare recognizes indications and uses of injectable oncology medications, including therapeutic radiopharmaceuticals, in the NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and Categories of Evidence and Consensus of 3 as unproven and not medically necessary. (However, refer to the Benefit *Considerations* section of the policy.) UnitedHealthcare will cover all chemotherapy agents for individuals under the age of 19 years for oncology indications. The majority of pediatric patients receive treatments on national pediatric protocols that are quite similar in concept to the NCCN patient care guidelines. Refer to Preferred Product Criteria for the UnitedHealthcare preferred oncology products that have therapeutically equivalent and/or biosimilar products available.
White Blood Cell Colony Stimulating Factors	Jul. 1, 2022	Notice of Revision: The following summary of changes has been modified. Revisions to the previous policy update announcement are outlined in red below. Please take note of the additional updates to be applied on Jul. 1, 2022.	his policy refers to the following white blood cell colony stimulating factors (CSFs): • Long-acting pegfilgrastim agents: ○ Fulphila® (pegfilgrastim-jmdb) ○ Neulasta® (pegfilgrastim) ○ Nyvepria™ (pegfilgrastim-apgf) ○ Udenyca® (pegfilgrastim-cbqv)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	**Coverage Rationale** • Revised list of applicable short-acting filgrastim agents; added Releuko® (filgrastim-ayow) • Added language to indicate: ○ Coverage for Releuko will be provided contingent on the criteria in the *Preferred Product Criteria* section and the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ Treatment with Releuko is medically necessary for the indications specified in the policy when one of the following is met: ▪ Both of the following: – History of a trial of adequate dose and duration of Zarxio, resulting in minimal clinical response; and – Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Releuko than experienced with Zarxio ▪ Both of the following: – History of intolerance,	○ Ziextenzo® (pegfilgrastim-bmez) • Short-acting filgrastim agents: ○ Granix® (tbo-filgrastim) ○ Neupogen® (filgrastim) ○ Nivestym® (filgrastim-aafi) ○ Releuko® (filgrastim-ayow) ○ Zarxio® (filgrastim-sndz) • Leukine® (sargramostim) (refer to the Diagnosis-Specific Criteria) • Any FDA-approved white blood cell colony stimulating factor product not listed here* *Any U.S. Food and Drug Administration (FDA) approved white blood cell colony stimulating factor product not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare. **Long-Acting Pegfilgrastim Agents (Fulphila®, Neulasta®, Nyvepria™, Udenyca®, Ziextenzo®): Preferred Product** The long-acting preferred product criteria in this section applies to the following states: CA, HI, KY, MD, MI, MN, NE, NJ, NY, OH, RI, TN, VA. For all other states, coverage will be provided contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Neulasta® and Ziextenzo® are the preferred pegfilgrastim products. Coverage will be provided for Neulasta® and Ziextenzo® contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Coverage for Fulphila®, Nyvepria™, or Udenyca® will be provided contingent on the criteria in this section and the coverage criteria in the Diagnosis-Specific Criteria section. ***Preferred Product Criteria*** Treatment with Fulphila®, Nyvepria™, Udenyca®, or other pegfilgrastim biosimilar is medically necessary for the indications specified in the policy

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	contraindication, or adverse event to Zarxio; and – Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with Releuko ○ Releuko is medically necessary for the following indications when the criteria listed in policy are met: ▪ Bone marrow/stem cell transplant ▪ Acute myeloid leukemia (AML) induction or consolidation therapy ▪ Primary prophylaxis of chemotherapy-induced febrile neutropenia (FN) ▪ Secondary prophylaxis of febrile neutropenia (FN) ▪ Treatment of febrile neutropenia ▪ Severe chronic neutropenia (SCN) ▪ Hematopoietic syndrome of acute radiation syndrome • Revised coverage criteria for:	when one of the following is met: • Both of the following: ○ History of a trial of adequate dose and duration of Neulasta® or Ziextenzo®, resulting in minimal clinical response; and ○ Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Fulphila®, Nyvepria™, Udenyca®, or other pegfilgrastim biosimilar product than experienced with Neulasta® or Ziextenzo®; or • Both of the following: ○ History of intolerance, contraindication, or adverse event to Neulasta® or Ziextenzo®; and ○ Physician attests that, in their clinical opinion, the same intolerance, contraindication or adverse event would not be expected to occur with Fulphila, Nyvepria, Udenyca, or other pegfilgrastim biosimilar product **Short-Acting Filgrastim Agents (Granix®, Neupogen®, Nivestym®, Releuko, & Zarxio®): Preferred Product** The short-acting preferred product criteria in this section applies to the following states: CA, HI, KY, MD, MI, MN, NE, NJ, NY, OH, RI, TN, VA. For all other states, coverage will be provided contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Zarxio® is the preferred filgrastim product. Coverage will be provided for Zarxio® contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Coverage for Granix®, Neupogen®, Nivestym®, or Releuko will be provided contingent on the criteria in this section and the coverage criteria in the Diagnosis-Specific Criteria section. ***Preferred Product Criteria*** Treatment with Granix, Neupogen, Nivestym, Releuko, or other filgrastim

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	*Bone Marrow/Stem Cell Transplant* ○ Removed criterion requiring medication is: ▪ Dosed in accordance with the U.S. Food and Drug Administration (FDA) approved labeling ▪ Prescribed by or in consultation with a hematologist or oncologist *Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia* ○ Added criterion to allow coverage for the applicable products when the patient is receiving myelosuppressive anticancer drugs given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting) or the patient is receiving myelosuppressive anticancer drugs for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease) ○ Updated list of risk factors for chemotherapy-induced febrile neutropenia; replaced	biosimilar is medically necessary for the indications specified in the policy when one of the following is met: • Both of the following: ○ History of a trial of adequate dose and duration of Zarxio, resulting in minimal clinical response; and ○ Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Granix, Neupogen, Nivestym, Releuko or other filgrastim biosimilar product, than experienced with Zarxio; or • Both of the following: ○ History of intolerance, contraindication, or adverse event to Zarxio; and ○ Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with Granix, Neupogen, Nivestym, Releuko or other filgrastim biosimilar product **Diagnosis-Specific Criteria** For the coverage criteria below, in absence of specified drug products, the term "colony stimulating factors" or "CSFs" will be used in this policy where the coverage criteria apply to all products listed above. • Bone Marrow/Stem Cell Transplant (Leukine, Neupogen, Nivestym, Releuko, Zarxio) Leukine, Neupogen, Nivestym, Releuko, and Zarxio are proven and medically necessary when all of the following criteria are met: ○ One of the following: ▪ Patient has non-myeloid malignancies and is undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT); or ▪ Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; or ▪ Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy;

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White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	persistent neutropenia due to prior chemotherapy, radiation therapy, or bone marrow involvement by tumor measure of "ANC < 1500 neutrophils/mcL" with "< 500 neutrophils/mcL or < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours" ○ Replaced language indicating "chemotherapy regimen associated incidence of febrile neutropenia (FN) will be based on the clinical trial(s) with the highest level of evidence *according to the GRADE criteria*" with "chemotherapy regimen associated incidence of FN will be based on the clinical trial(s) with the highest level of evidence" ○ Added language to indicate: ▪ Chemotherapy regimens and associated incidence of FN based on the clinical trial(s) according to the grade based on Common Terminology Criteria for Adverse Events (CTCAE) by the National Cancer Institute (NCI) criteria are	• Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy (Leukine, Neupogen, Nivestym, Releuko, Zarxio) Leukine, Neupogen, Nivestym, Releuko and Zarxio are proven and medically necessary when the following criteria are met: Both of the following: ▪ Diagnosis of AML; and ▪ Patient has completed either induction or consolidation chemotherapy • Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (FN) (Fulphila, Granix, Leukine, Neulasta, Neupogen, Nivestym, Nyvepria, Releuko, Udenyca, Zarxio, Ziextenzo) White blood cell colony stimulating factors are proven and medically necessary when the following criteria are met: ○ One of the following: ▪ Patient is receiving myelosuppressive anticancer drugs given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting); or ▪ Patient is receiving myelosuppressive anticancer drugs for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease); and ○ One of the following: ▪ Patient is receiving dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin) for bladder cancer; or ▪ Patient is receiving dose dense AC (doxorubicin, cyclophosphamide) followed by dose-dense paclitaxel for breast cancer; or ▪ Patient is receiving chemotherapy regimen(s) associated with > 20% incidence of FN; or ○ Both of the following: ▪ Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN; and

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White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	available for reference at uhcprovider.com ▪ The reference document is not a substitute for the experience and judgment of a physician or other health care professional; any clinician must use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment *Secondary Prophylaxis of Febrile Neutropenia* ○ Added criterion to allow coverage for the applicable products: ▪ When the patient is receiving myelosuppressive anticancer drugs given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting) or the patient is receiving myelosuppressive anticancer drugs for definitive therapy (bridge to stem cell transplant,	▪ Patient has one or more risk factors for chemotherapy-induced febrile neutropenia such as: – Persistent neutropenia due to prior chemotherapy, radiation therapy or bone marrow involvement by tumor (< 500 neutrophils/mcL or < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours) – Liver dysfunction (bilirubin > 2.0) – Renal dysfunction (creatinine clearance < 50) – Age > 65 years receiving full chemotherapy dose intensity *Note: Chemotherapy regimen associated incidence of FN will be based on the clinical trial(s) with the highest level of evidence. Chemotherapy regimens and associated incidence of FN based on the clinical trial(s) according to the grade based on Common Terminology Criteria for Adverse Events (CTCAE) by the National Cancer Institute (NCI) criteria are available for reference at uhcprovider.com. The reference document is not a substitute for the experience and judgment of a physician or other health care professional. Any clinician must use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment. • Secondary Prophylaxis of Febrile Neutropenia (FN) (Fulphila, Granix, Leukine, Neulasta, Neupogen, Nivestym, Nyvepria, Releuko, Udenyca, Zarxio, Ziextenzo) White blood cell colony stimulating factors are proven and medically necessary when the following criteria are met: ○ One of the following: ▪ Patient is receiving myelosuppressive anticancer drugs given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting); or ▪ Patient is receiving myelosuppressive anticancer drugs for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease); and

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White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	organ transplant, definitive surgery for oligometastatic disease) ▪ Patient has a documented history of a neutropenic event (febrile neutropenia or low neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen at full dose for which primary prophylaxis was not received ○ Removed criterion allowing coverage for the applicable products when the patient is receiving myelosuppressive anticancer drugs associated with neutropenia (ANC ≤ 1500 neutrophils/mcL) *Treatment of Febrile Neutropenia* ○ Added criterion requiring the patient has not received long-acting prophylactic pegfilgrastim in the last 14 days ○ Removed criterion requiring the score of < 21 on the *Multinational Association of Supportive Care in Cancer (MASCC)* scoring system in	○ One of the following: ▪ Patient has a documented history of a neutropenic event (febrile neutropenia or low neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen at full dose for which primary prophylaxis was not received; or ▪ Patient has a documented history of neutropenic event from a previous course of chemotherapy • Treatment of Febrile Neutropenia (FN) (Fulphila, Leukine, Neulasta, Neupogen, Nivestym, Nyvepria, Releuko, Udenyca, Zarxio, Ziextenzo) (Off-Label) Fulphila, Leukine, Neulasta, Neupogen, Nivestym, Nyvepria, Releuko, Udenyca, Zarxio, and Ziextenzo are proven and medically necessary when the following criteria are met: ○ All of the following: ▪ Diagnosis of febrile neutropenia; and ▪ Patient has not received long-acting prophylactic pegfilgrastim in the last 14 days; and ▪ Patient has one or more risk factors for an infection-associated complication such as: – Sepsis syndrome – Age > 65 years – Absolute Neutrophil Count (ANC) < 100/mcL – Neutropenia expected to be > 10 days in duration – Pneumonia – Clinically documented infections including invasive fungal infection – Hospitalization at the time of fever – Prior episode(s) of FN • Severe Chronic Neutropenia (SCN) (Neupogen, Nivestym, Releuko, Zarxio) Neupogen®, Nivestym®, Releuko, and Zarxio® are proven and medically necessary when the following criteria are met: ○ All of the following: ▪ Diagnosis of SCN (i.e., congenital, cyclic, and idiopathic

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White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	patients with cancer and febrile neutropenia ○ Revised list of examples of risk factors for an infection-associated complication: ▪ Added: – Sepsis syndrome – Age > 65 years – Absolute Neutrophil Count (ANC) < 100/mcL – Neutropenia expected to be > 10 days in duration – Pneumonia – Clinically documented infections including invasive fungal infection – Hospitalization at the time of fever – Prior episode(s) of FN ▪ Removed: – Hypotension – Acute renal failure – Acute respiratory failure – Acute heart failure **Definitions** ● Updated definition of “Febrile Neutropenia” **Applicable Codes** ● Added HCPCS codes C9096,	neutropenias with chronic ANC ≤ 500 neutrophils/mcL); and ▪ Medication is dosed in accordance with the U.S. Food and Drug Administration (FDA) approved labeling; and ▪ Prescribed by or in consultation with a hematologist or oncologist ● Hematopoietic Syndrome of Acute Radiation Syndrome (Fulphila®, Leukine®, Neulasta®, Neupogen®, Nivestym®, Nyvepria™, Udenyca®, Releuko, Zarxio®, Ziextenzo®) Fulphila®, Leukine®, Neulasta®, Neupogen®, Nivestym®, Nyvepria™, Releuko, Udenyca®, Zarxio®, and Ziextenzo® are proven and medically necessary when all of the following criteria are met: ○ All of the following: ▪ Patient has been acutely exposed to myelosuppressive doses of radiation; and ▪ Medication is dosed in accordance with the U.S. Food and Drug Administration (FDA) approved labeling; and ▪ Prescribed by or in consultation with a hematologist or oncologist

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	C9399, J3490, and J3590 Supporting Information • Updated *FDA* and *References* sections to reflect the most current information	

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