United Healthcare Community Plan

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

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InterQual® Release Dates Removed

Effective Jun. 1, 2022, all references to specific InterQual® release dates will be removed from the Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines which contain language pertaining to InterQual® criteria; refer to the most current version of the InterQual® criteria, when applicable.

Community Plan of Mississippi to Use National Policy Versions

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

Policy Title	Policy Type
Apheresis	Medical Policy
Athletic Pubalgia Surgery	Medical Policy
Autologous Cellular Therapy	Medical Policy
Balloon Sinus Ostial Dilation	Medical Policy
Bariatric Surgery	Medical Policy
Breast Imaging for Screening and Diagnosing Cancer	Medical Policy
Bronchial Thermoplasty	Medical Policy
Cardiac Event Monitoring)	Medical Policy
Carrier Testing for Genetic Diseases	Medical Policy
Catheter Ablation for Atrial Fibrillation	Medical Policy
Chromosome Microarray Testing (Non-Oncology Conditions)	Medical Policy
Cognitive Rehabilitation	Medical Policy
Collagen Crosslinks and Biochemical Markers of Bone Turnover	Medical Policy
Computer-Assisted Surgical Navigation for Musculoskeletal Procedures	Medical Policy
Computerized Dynamic Posturography	Medical Policy
Corneal Hysteresis and Intraocular Pressure Measurement	Medical Policy
Cytological Examination of Breast Fluids for Cancer Screening or Diagnosis	Medical Policy
Deep Brain and Cortical Stimulation	Medical Policy
Diagnostic Spinal Ultrasonography)	Medical Policy
Electric Tumor Treatment Field Therapy	Medical Policy
Electrical and Ultrasound Bone Growth Stimulators	Medical Policy

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Policy Title	Policy Type
Electrical Bioimpedance for Cardiac Output Measurement	Medical Policy
Electrical Stimulation and Electromagnetic Therapy for Wounds	Medical Policy
Epiduroscopy, Epidural Lysis of Adhesions and Discography	Medical Policy
Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds	Medical Policy
Fecal Calprotectin Testing	Medical Policy
Gender Dysphoria Treatment	Medical Policy
Genetic Testing for Cardiac Disease	Medical Policy
Genetic Testing for Hereditary Cancer	Medical Policy
Genetic Testing for Neuromuscular Disorders	Medical Policy
Glaucoma Surgical Treatments	Medical Policy
Hearing Aids and Devices Including Wearable, Bone-Anchored and Semi-Implantable	Medical Policy
Hepatitis Screening	Medical Policy
Hysterectomy	Medical Policy
Implantable Beta-Emitting Microspheres for Treatment of Malignant Tumors	Medical Policy
Intraoperative Hyperthermic Intraperitoneal Chemotherapy (HIPEC)	Medical Policy
Intrauterine Fetal Surgery	Medical Policy
Laser Interstitial Thermal Therapy	Medical Policy
Light and Laser Therapy	Medical Policy
Lithotripsy for Salivary Stones	Medical Policy
Macular Degeneration Treatment Procedures	Medical Policy
Mechanical Stretching Devices	Medical Policy
Meniscus Implant and Allograft	Medical Policy
Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) and Achalasia	Medical Policy
Neuropsychological Testing Under the Medical Benefit	Medical Policy
Occipital Neuralgia and Headache Treatment	Medical Policy
Outpatient Surgical Procedures – Site of Service	Utilization Review Guideline
Percutaneous Patent Foramen Ovale (PFO) Closure	Medical Policy

Take Note

Policy Title	Policy Type
Pharmacogenetic Testing	Medical Policy
Preimplantation Genetic Testing	Medical Policy
Prolotherapy and Platelet Rich Plasma Therapies	Medical Policy
Prostate Surgeries and Interventions	Medical Policy
Radiation Therapy: Fractionation, Image-Guidance, and Special Services	Medical Policy
Rhinoplasty and Other Nasal Surgeries	Coverage Determination Guideline
Stereotactic Body Radiation Therapy and Stereotactic Radiosurgery	Medical Policy
Surgery of the Foot	Medical Policy
Surgery of the Hand or Wrist	Medical Policy
Thermography	Medical Policy
Total Artificial Disc Replacement for the Spine	Medical Policy
Transcranial Magnetic Stimulation	Medical Policy
Transpupillary Thermotherapy	Medical Policy
Umbilical Cord Blood Harvesting and Storage for Future Use	Medical Policy
Vertebral Body Tethering for Scoliosis)	Medical Policy
Warming Therapy and Ultrasound Therapy for Wounds)	Medical Policy

Medical Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes

Percutaneous Vertebroplasty and Kyphoplasty (for Mississippi Only)	Jun. 1, 2022	**Related Policies**
		• Removed list of related policies
		Definitions
		• Added definition of:
		  ○ Osteonecrosis
		  ○ Vertebral Hemangiomas
		Supporting Information
		• Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information

Proton Beam Radiation Therapy (for Mississippi Only)	Jul. 1, 2022	**Applicable Codes** • Added ICD-10 diagnosis codes C69.0, C69.00, C69.01, C69.02, C69.1, C69.10, C69.11, C69.12, C69.20, C69.21, C69.22, C69.50, C69.51, C69.52, C69.6, C69.60, C69.61, C69.62, C69.8, C69.80, C69.81, C69.82, C69.9, C69.90, C69.91, and C69.92 • Replaced ICD-10 diagnosis code C61.0 with C61 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Spinal Fusion Enhancement Products (for Mississippi Only)	Jul. 1, 2022	**Coverage Rationale**
		• Updated list of products that are proven and medically necessary for the enhancement of spinal fusion; replaced "Autografts" with "Autografts *(including bone marrow aspirate used for bone grafting)*"
		Applicable Codes
		• Added CPT code 20939
		Supporting Information
		• Updated *Description of Services*, *Clinical Evidence*, and *References* section to reflect the most current
			The following are proven and medically necessary for the enhancement of spinal fusion:
			• Autografts (including bone marrow aspirate used for bone grafting)
			• Demineralized bone matrix (DBM) without added products listed below as unproven and not medically necessary
			• Allograft-based products not listed below as unproven and not medically necessary
			• Infuse® Bone Graft (Recombinant human bone morphogenetic protein-2 (rhBMP-2)) of the lumbar spine when the following criteria are met:
			  ○ The approach is anterior or oblique and used in conjunction with an FDA-approved interbody fusion device
			  ○ Skeletally mature individual (18 years of age or older or radiographic evidence of epiphyseal closure) with degenerative disc disease (DDD)
			  ○ The fusion involves vertebral bodies L2-S1, without or with spondylolisthesis of no more than grade 1 (25% displacement) at the

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Spinal Fusion Enhancement Products (for Mississippi Only) (continued)	Jul. 1, 2022	information	involved level ○ The fusion is single-level • The InFUSE/MASTERGRAFT™ Posterolateral Revision Device System (or InFUSE BMP used with MASTERGRAFT) when used according to U.S. Food and Drug Administration (FDA) indications in individuals who meet all the following criteria: ○ Implanted via a posterolateral approach ○ Presence of symptomatic posterolateral lumbar spine pseudoarthrosis ○ Skeletally mature patient (older than 21 years of age or radiographic evidence of epiphyseal closure) ○ Autologous bone and/or bone marrow harvest is not feasible or is not expected to promote fusion. The following are unproven and not medically necessary for the enhancement of spinal fusion due to insufficient evidence of efficacy: • Allograft based products ○ Cell-based [e.g., mesenchymal stem cells (MSC)] ○ Ceramic-based products [e.g., beta tricalcium phosphate (b-TCP), calcium phosphate, calcium sulfate and bioactive glass] used alone or in combination with other grafts including bone marrow aspirate ○ Human amniotic tissue materials, including amniotic fluid stem cell substitutes for the treatment of spine disease or in spine surgery • Recombinant human bone morphogenetic protein-2 (e.g., rhBMP-2, InFUSE) and the InFUSE/MASTERGRAFT™ (or InFUSE BMP used with Mastergraft or Mastergraft alone) Posterolateral Revision Device for all other indications not included above • The OptiMesh® Expandable Interbody Fusion System
Surgical Treatment for Spine Pain (for Mississippi Only)	Jul. 1, 2022	Applicable Codes • Removed CPT code 20939; refer to the Medical Policy titled *Spinal Fusion Enhancement Products (for Mississippi Only)*	Spinal procedures for the treatment of spine pain are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures: • Decompression +/- Fusion, Cervical • Decompression +/- Fusion, Lumbar

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical Treatment for Spine Pain (for Mississippi Only) (continued)	Jul. 1, 2022		• Decompression +/- Fusion, Thoracic • Fusion, Cervical Spine • Fusion, Lumbar Spine • Fusion, Thoracic Spine Click here to view the InterQual® criteria. The following techniques for lumbar interbody fusion (LIF) are proven and medically necessary: • Anterior LIF(ALIF) including lateral approaches, e.g., extreme lateral interbody fusion (XLIF®), Direct lateral interbody fusion (DLIF) • Posterior LIF (PLIF), including transforaminal lumbar interbody fusion (TLIF) The following indications for a surgical spine procedure that is performed to alleviate symptoms or prevent clinical deterioration are considered proven and medically necessary if not addressed in the above criteria: • Congenital or idiopathic deformity or bone disease other than scoliosis • Muscular dystrophy • Laminectomy procedure to provide surgical exposure to treat lesions within the spinal canal Interspinous process fusion devices is proven and medically necessary when used in conjunction with any of the following procedures: • Open laminar and/or facet decortication and fusion • Autograft inter-and extra-spinous process decortication and fusion • Interbody fusion of the same motion segment The following spinal procedures are unproven and not medically necessary due to insufficient evidence of efficacy (this includes procedures that utilize interbody cages, screws, and pedicle screw fixation devices): • Laparoscopic anterior lumbar interbody fusion (LALIF) • Transforaminal lumbar interbody fusion (TLIF) which utilizes only endoscopy visualization (such as a percutaneous incision with video visualization) • Axial lumbar interbody fusion (AxiaLIF®)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Surgical Treatment for Spine Pain (for Mississippi Only) (continued)	Jul. 1, 2022		• Spinal decompression and interspinous process decompression systems for the treatment of lumbar spinal stenosis (e.g., Interspinous process decompression (IPD), Minimally invasive lumbar decompression (mild®)
			• Dividing treatment of symptomatic, multi-site spinal pathology via anterior or posterior approach into serial, multiple, or staged sessions when one session can address all sites
			• Spinal stabilization systems
			  ○ Stabilization systems for the treatment of degenerative spondylolisthesis
			  ○ Total facet joint arthroplasty, including facetectomy, laminectomy, foraminotomy, vertebral column fixation
			  ○ Percutaneous sacral augmentation (sacroplasty) with or without a balloon or bone cement for the treatment of back pain
			• Stand-alone facet fusion without an accompanying decompressive procedures; this includes procedures performed with or without bone grafting and/or the use of posterior intrafacet implants such as fixation systems, facet screw systems or anti-migration dowels
			
			For information on vertebral body tethering, refer to the Medical policy titled *Vertebral Body Tethering for Scoliosis*.
			
			Documentation Requirements
			Medical notes documenting the following, when applicable:
			• Condition requiring procedure
			• History and co-morbid medical condition(s)
			  ○ Smoking history/ status, including date of last smoking cessation
			• Member's symptoms, pain, location, and severity including functional impairment that is interfering with activities of daily living (meals, walking, getting dressed, driving)
			• Failure of Conservative Therapy through lack of clinically significant improvement between at least two measurements, on a validated pain or function scale or quantifiable symptoms despite concurrent Conservative Therapies (see definition), if applicable
			• Progressive deficits with clinically significant worsening based on at least two measurements over time, if applicable

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Surgical Treatment for Spine Pain (for Mississippi Only) (continued)	Jul. 1, 2022		• Disabling Symptoms, if applicable
			• Upon request, we may request the specific diagnostic image(s) that shows the abnormality for which surgery is being requested which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting surgeon may be needed to select the optimal image(s)
			  ○ Note: When requested, diagnostic images must be labeled with the:
			  ▪ Date taken
			  ▪ Applicable case number obtained at time of notification, or the member's name and ID number on the image(s)
			  ○ Upon request, diagnostic imaging must be submitted via the external portal at www.uhcprovider.com/paan; faxes will not be accepted
			• Diagnostic image(s) report(s), including presence or absence of:
			  ○ Segment (s) instability
			  ○ Spinal cord compression
			  ○ Disc herniation
			  ○ Nerve root compression
			  ○ Quantification of subluxation, translation by flexion, angulation when appropriate
			  ○ Discitis
			  ○ Epidural abscess
			• Physical exam, including neurologic exam, including degree and progression of curvature (for scoliosis), if applicable
			  ○ Degree and progression of curvature (for scoliosis)
			  ○ Quantification of relevant muscle strength
			• Whether the surgery will be performed with direct visualization or only with endoscopic visualization
			• Complete report(s) of diagnostic tests
			  ○ Results of biopsy(ies)
			  ○ Results of bone aspirate
			• Describe the surgical technique(s) planned [e.g., AxiaLIF®, XLIF, ILIF, OLIF, LALIF, image-guided minimally invasive lumbar decompression (mild®), percutaneous endoscopic discectomy with or without laser, etc.]

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Botulinum Toxins A and B	Aug. 1, 2022	**Coverage Rationale** • Replaced instruction to refer to the current release of the [listed] InterQual® guideline with Diagnosis-Specific Criteria • Added language to indicate: ○ The following are General Requirements (applicable to all medical necessity requests): ▪ For initial therapy, both of the following: – Diagnosis – Medical records documenting both of the following: • History and physical examination documenting the severity of the condition; and • Laboratory results or diagnostic evidence supporting the indication for which botulinum toxin is requested – Botulinum toxin administration is no more frequent than every 12 weeks, regardless of	This policy refers to the following Botulinum toxin type A and B drug products: • Dysport® (abobotulinumtoxinA) • Xeomin® (incobotulinumtoxinA) • Botox® (onabotulinumtoxinA) • Myobloc® (rimabotulinumtoxinB) The following information pertains to medical necessity review: **General Requirements (applicable to all medical necessity requests)** • For initial therapy, both of the following: ○ Diagnosis; and ○ Medical records documenting both of the following: ▪ History and physical examination documenting the severity of the condition; and ▪ Laboratory results or diagnostic evidence supporting the indication for which botulinum toxin is requested and ○ Botulinum toxin administration is no more frequent than every 12 weeks, regardless of diagnosis. ○ Initial authorization will be for no more than 6 months. • For continuation of therapy, both of the following: ○ Documentation of positive clinical response to botulinum toxin therapy; and ○ Statement of expected frequency and duration of proposed botulinum toxin treatment; and ○ Botulinum toxin administration is no more frequent than every 12 weeks, regardless of diagnosis. ○ Reauthorization will be for no more than 12 months. **Diagnosis-Specific Requirements** The information below indicates additional requirements for those indications

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Botulinum Toxins A and B (continued)	Aug. 1, 2022	diagnosis ▪ For continuation of therapy, both of the following: – Documentation of positive clinical response to botulinum toxin therapy – Statement of expected frequency and duration of proposed botulinum toxin treatment – Botulinum toxin administration is no more frequent than every 12 weeks, regardless of diagnosis ○ Dysport (abobotulinumtoxinA) is proven and medically necessary for the treatment of the following indications when the criteria listed in the policy are met: ▪ Achalasia ▪ Anal fissures, chronic ▪ Blepharospasm associated with dystonia ▪ Cervical dystonia (also known as spasmodic torticollis) ▪ Detrusor overactivity (also	having specific medical necessity criteria in the list of proven indications. Dysport (abobotulinumtoxinA) is medically necessary in the treatment of the following conditions: • Achalasia Dysport is medically necessary for the treatment of achalasia when all of the following criteria are met: ○ Diagnosis of achalasia as confirmed by esophageal manometry; and ○ Patient has failed or is not a candidate for pneumatic dilation or myotomy; and ○ History of failure, contraindication, or intolerance to one of the following: ▪ Calcium channel blocker ▪ Long-acting nitrate and ○ Other causes of dysphagia (e.g., peptic stricture, carcinoma, extrinsic compression) ruled out by upper gastrointestinal endoscopy • Anal fissures, chronic Dysport is medically necessary for the treatment of chronic anal fissures when all of the following criteria are met: ○ Diagnosis of chronic anal fissure; and ○ At least 2 months of symptoms including one of the following: ▪ Nocturnal pain and bleeding ▪ Post-defecation pain and ○ History of failure, contraindication, or intolerance to one of the following conventional therapies: ▪ Topical nitrate ▪ Topical calcium channel blocker (e.g., diltiazem, nifedipine) • Blepharospasm associated with dystonia • Cervical dystonia (also known as spasmodic torticollis) Dysport is medically necessary for the treatment of cervical dystonia when both of the following criteria are met: ○ Diagnosis of cervical dystonia; and

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Botulinum Toxins A and B (continued)	Aug. 1, 2022	known as detrusor hyperreflexia) or detrusor-sphincter dyssynergia due to spinal cord injury or disease ▪ Hand dystonia (writer's, musician's or typist's cramp) ▪ Hand tremor ▪ Hemifacial spasm (seventh cranial nerve disorders) ▪ Hyperhidrosis including gustatory sweating (Frey's Syndrome) ▪ Oromandibular dystonia ▪ Sialorrhea ▪ Spasmodic dysphonia (laryngeal dystonia) ▪ Spasticity associated with: – Cerebral palsy – Multiple sclerosis – Neuromyelitis optica (NMO) – Stroke – Other injury, disease, or tumor of the brain or spinal cord ▪ Strabismus ▪ Tongue dystonia ▪ Torsion dystonia ▪ Voice tremor ○ Xeomin (incobotulinumtoxinA) is proven and medically	○ Symptoms including both of the following: ▪ Sustained head tilt or abnormal posturing resulting in pain and/or functional impairment ▪ Recurrent involuntary contraction of one or more muscles of the neck (e.g., sternocleidomastoid, splenius, trapezius, posterior cervical) • Detrusor overactivity (also known as detrusor hyperreflexia) or detrusor-sphincter dyssynergia due to spinal cord injury or disease Dysport is medically necessary when both of the following criteria are met: ○ One of the following: ▪ Diagnosis of detrusor overactivity ▪ Diagnosis of detrusor-sphincter dyssynergia due to spinal cord injury or disease and ○ History of failure, contraindication, or intolerance to two anticholinergic medications (e.g., oxybutynin, trospium, darifenacin, tolterodine) • Hand dystonia (writer's, musician's or typist's cramp) • Hand tremor • Hemifacial spasm (seventh cranial nerve disorders) • Hyperhidrosis including gustatory sweating (Frey's Syndrome) • Oromandibular dystonia • Sialorrhea • Spasmodic dysphonia (laryngeal dystonia) • Spasticity associated with: ○ Cerebral palsy ○ Multiple sclerosis ○ Neuromyelitis optica (NMO) ○ Stroke ○ Other injury, disease, or tumor of the brain or spinal cord • Strabismus • Tongue dystonia • Torsion dystonia

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Botulinum Toxins A and B (continued)	Aug. 1, 2022	necessary for the treatment of the following indications when the criteria listed in the policy are met: ▪ Blepharospasm associated with dystonia ▪ Cervical dystonia (spasmodic torticollis) ▪ Sialorrhea ▪ Spasticity associated with: – Cerebral palsy – Multiple sclerosis – Neuromyelitis optica (NMO) – Stroke – Other injury, disease, or tumor of the brain or spinal cord ○ Botox (onabotulinumtoxinA) is proven and medically necessary for the treatment of the following indications when the criteria listed in the policy are met: ▪ Achalasia ▪ Anal fissures, chronic ▪ Blepharospasm associated with dystonia ▪ Cervical dystonia (also known as spasmodic torticollis) ▪ Detrusor overactivity (also known as detrusor	• Voice tremor Xeomin (incobotulinumtoxinA) is medically necessary in the treatment of the following conditions: • Blepharospasm associated with dystonia • Cervical dystonia (spasmodic torticollis) • Xeomin is medically necessary for the treatment of cervical dystonia (spasmodic torticollis) when both of the following criteria are met: ○ Diagnosis of cervical dystonia; and ○ Symptoms including both of the following: ▪ Sustained head tilt or abnormal posturing resulting in pain and/or functional impairment ▪ Recurrent involuntary contraction of one or more muscles of the neck (e.g., sternocleidomastoid, splenius, trapezius, posterior cervical) • Sialorrhea • Spasticity associated with: ○ Cerebral palsy ○ Multiple sclerosis ○ Neuromyelitis optica (NMO) ○ Stroke ○ Other injury, disease, or tumor of the brain or spinal cord Botox (onabotulinumtoxinA) is medically necessary in the treatment of the following conditions: • Achalasia Botox is medically necessary for the treatment of achalasia when all of the following criteria are met: ○ Diagnosis of achalasia as confirmed by esophageal manometry; and ○ Patient has failed or is not a candidate for pneumatic dilation or myotomy; and ○ History of failure, contraindication, or intolerance to one of the following: ▪ Calcium channel blocker

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Botulinum Toxins A and B (continued)	Aug. 1, 2022	hyperreflexia) or detrusor-sphincter dyssynergia due to spinal cord injury or disease ▪ Hand dystonia (writer's, musician's or typist's cramp) ▪ Hand tremor ▪ Hemifacial spasm (seventh cranial nerve disorders) ▪ Hyperhidrosis including gustatory sweating (Frey's Syndrome) ▪ Migraine headache, chronic ▪ Oromandibular dystonia ▪ Overactive bladder ▪ Sialorrhea ▪ Spasmodic dysphonia (laryngeal dystonia) ▪ Spasticity associated with: – Cerebral palsy – Multiple sclerosis – Neuromyelitis optica (NMO) – Stroke – Other injury, disease, or tumor of the brain or spinal cord ▪ Strabismus ▪ Tongue dystonia ▪ Torsion dystonia ▪ Voice tremor	▪ Long-acting nitrate and ○ Other causes of dysphagia (e.g., peptic stricture, carcinoma, extrinsic compression) ruled out by upper gastrointestinal endoscopy • Anal fissures, chronic Botox is medically necessary for the treatment of chronic anal fissures when all of the following criteria are met: ○ Diagnosis of chronic anal fissure; and ○ At least 2 months of symptoms including one of the following: ▪ Nocturnal pain and bleeding ▪ Post defecation pain and ○ History of failure, contraindication, or intolerance to one of the following conventional therapies: ▪ Topical nitrates ▪ Topical calcium channel blockers (e.g., diltiazem, nifedipine) • Blepharospasm associated with dystonia • Cervical dystonia (also known as spasmodic torticollis) Botox is medically necessary for the treatment of cervical dystonia when both of the following criteria are met: ○ Diagnosis of cervical dystonia; and ○ Symptoms including both of the following: ▪ Sustained head tilt or abnormal posturing resulting in pain and/or functional impairment ▪ Recurrent involuntary contraction of one or more muscles of the neck (e.g., sternocleidomastoid, splenius, trapezius, posterior cervical) • Detrusor overactivity (also known as detrusor hyperreflexia) or detrusor-sphincter dyssynergia due to spinal cord injury or disease Botox is medically necessary when both of the following criteria are met: ○ One of the following: ▪ Diagnosis of detrusor overactivity

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Botulinum Toxins A and B (continued)	Aug. 1, 2022	○ Myobloc (rimabotulinumtoxinB) is proven and medically necessary for the treatment of the following indications when the criteria listed in the policy are met: ▪ Cervical dystonia (also known as spasmodic torticollis) ▪ Detrusor overactivity (also known as detrusor hyperreflexia) ▪ Sialorrhea ▪ Spasticity associated with: – Cerebral palsy – Multiple sclerosis – Neuromyelitis optica (NMO) – Stroke – Other injury, disease, or tumor of the brain or spinal cord ○ Dysport, Myobloc, and Xeomin are unproven and not medically necessary for the treatment of chronic migraine headache ○ Botox, Dysport, Myobloc, and Xeomin are unproven and not medically necessary for the treatment of the following conditions:	▪ Diagnosis of detrusor-sphincter dyssynergia due to spinal cord injury or disease and ○ History of failure, contraindication, or intolerance to two anticholinergic medications (e.g., oxybutynin, trospium, darifenacin, tolterodine) • Hand dystonia (writer's, musician's or typist's cramp) • Hand tremor • Hemifacial spasm (seventh cranial nerve disorders) • Hyperhidrosis including gustatory sweating (Frey's Syndrome) • Migraine headache, chronic Botox is medically necessary for the prophylaxis of chronic migraine when all of the following criteria are met: ○ Diagnosis of chronic migraine, defined by all of the following: ▪ Greater than or equal to 15 headache days per month ▪ Greater than or equal to 8 migraine days per month ▪ Headaches last 4 hours per day or longer and ○ History of failure (after a trial of at least two months), contraindication, or intolerance to prophylactic therapy with one agent from two of the following therapeutic classes: ▪ Antidepressant [i.e., Elavil (amitriptyline), Effexor (venlafaxine)] ▪ Antiepileptic drug [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)] ▪ Beta blocker [i.e., atenolol, Inderal (propranolol), nadolol, timolol, Toprol XL (metoprolol extended-release)] and ○ Botox dose does not exceed 155 units administered intramuscularly divided over 31 injection sites divided across 7 head and neck muscles every 12 weeks • Oromandibular dystonia • Overactive bladder Botox is medically necessary for the treatment of overactive bladder when all of the following criteria are met:

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Botulinum Toxins A and B (continued)	Aug. 1, 2022	▪ Acquired nystagmus ▪ Anismus (pelvic floor dyssynergia) ▪ Benign prostatic hyperplasia ▪ Brachial plexus palsy ▪ Chronic daily headache ▪ Chronic low back pain ▪ Chronic prostatic pain ▪ Cricopharyngeal dysphagia ▪ Epiphora following salivary gland transplantation ▪ Esophageal spasm ▪ Gastroparesis (including diabetic gastroparesis) ▪ Gustatory epiphora (Crocodile tears) ▪ Head tremor ▪ Lateral epicondylitis (tennis elbow) ▪ Lichen simplex ▪ Lower urinary tract (voiding) dysfunction ▪ Motor tics ▪ Myofascial pain syndrome ▪ Nasal hypersecretion ▪ Pain and/or wound healing after hemorrhoidectomy ▪ Pancreas divisum ▪ Pelvic floor spasticity (and associated pain conditions)	○ Diagnosis of overactive bladder; and ○ One of the following symptoms: ▪ Urge urinary incontinence ▪ Urgency ▪ Frequency and ○ History of failure, contraindication, or intolerance to two anticholinergic medications (e.g., oxybutynin, trospium, darifenacin, tolterodine); and ○ Botox dose does not exceed 100 units divided over 20 injection sites every 12 weeks • Sialorrhea • Spasmodic dysphonia (laryngeal dystonia) • Spasticity associated with: ○ Cerebral palsy ○ Multiple sclerosis ○ Neuromyelitis optica (NMO) ○ Stroke ○ Other injury, disease, or tumor of the brain or spinal cord • Strabismus • Tongue dystonia • Torsion dystonia • Voice tremor Myobloc (rimabotulinumtoxinB) is medically necessary in the treatment of the following conditions: • Cervical dystonia (also known as spasmodic torticollis) Myobloc is medically necessary for the treatment of cervical dystonia when both of the following criteria are met: ○ Diagnosis of cervical dystonia; and ○ Symptoms including both of the following: ▪ Sustained head tilt or abnormal posturing resulting in pain and/or functional impairment ▪ Recurrent involuntary contraction of one or more muscles of the

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Botulinum Toxins A and B (continued)	Aug. 1, 2022	▪ Piriformis syndrome ▪ Post-parotidectomy sialoceles ▪ Post-thoracotomy pseudoangina ▪ Proctalgia fugax ▪ Severe bruxism ▪ Severe paradoxical vocal cord movement ▪ Sphincter of Oddi dysfunction ▪ Stiff-person syndrome ▪ Temporomandibular disorders ▪ Tension headache ▪ Thyroid associated ophthalmopathy ▪ Tourette's syndrome ▪ Traumatic sixth nerve palsy ▪ Trigeminal neuralgia ▪ Trismus and stridor in amyotrophic lateral sclerosis Applicable Codes • Added list of applicable ICD-10 diagnosis codes: G04.1, G11.4, G24.09, G24.1, G24.2, G24.3, G24.4, G24.5, G24.8, G24.9, G25.89, G36.0, G43.7, G43.70, G43.701, G43.709, G43.71, G43.711, G43.719, G51.0, G51.1, G51.2, G51.31, G51.32, G51.33,	neck (e.g., sternocleidomastoid, splenius, trapezius, posterior cervical) • Detrusor overactivity (also known as detrusor hyperreflexia) Myobloc is medically necessary when both of the following criteria are met: ○ Diagnosis of neurogenic detrusor overactivity; and ○ History of failure, contraindication, or intolerance to two anticholinergic medications (e.g., oxybutynin, trospium, darifenacin, tolterodine) • Sialorrhea • Spasticity associated with: ○ Cerebral palsy ○ Multiple sclerosis ○ Neuromyelitis optica (NMO) ○ Stroke ○ Other injury, disease, or tumor of the brain or spinal cord **Unproven** Dysport, Myobloc, and Xeomin are unproven and not medically necessary for the treatment of chronic migraine headache. Botox, Dysport, Myobloc, and Xeomin are unproven and not medically necessary for the treatment of the following conditions: • Acquired nystagmus • Anismus (pelvic floor dyssynergia) • Benign prostatic hyperplasia • Brachial plexus palsy • Chronic daily headache • Chronic low back pain • Chronic prostatic pain • Cricopharyngeal dysphagia • Epiphora following salivary gland transplantation • Esophageal spasm • Gastroparesis (including diabetic gastroparesis)

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Botulinum Toxins A and B (continued)	Aug. 1, 2022	G51.39, G51.4, G51.8, G51.9, G80.0, G80.1, G80.2, G80.3, G80.4, G80.8, G80.9, G81.10, G81.11, G81.12, G81.13, G81.14, G83.4, H50.89, H51.0, J38.5, K11.7, K22.0, K59.4, K60.1, K60.2, L74.510, L74.511, L74.512, L74.513, L74.519, L74.52, N31.0, N31.1, N31.9, N32.81, N36.44, N39.41, N39.46, R25.0, R25.1, R25.2, R25.3, R25.8, R25.9, R29.891, R49.0, R49.9, S04.50XA, S04.51XA, and S04.52XA **Supporting Information** • Added *Background*, *Clinical Evidence*, *FDA*, and *References* sections	• Gustatory epiphora (Crocodile tears) • Head tremor • Lateral epicondylitis (tennis elbow) • Lichen simplex • Lower urinary tract (voiding) dysfunction • Motor tics • Myofascial pain syndrome • Nasal hypersecretion • Pain and/or wound healing after hemorrhoidectomy • Pancreas divisum • Pelvic floor spasticity (and associated pain conditions) • Piriformis syndrome • Post-parotidectomy sialoceles • Post-thoracotomy pseudoangina • Proctalgia fugax • Severe bruxism • Severe paradoxical vocal cord movement • Sphincter of Oddi dysfunction • Stiff-person syndrome • Temporomandibular disorders • Tension headache • Thyroid associated ophthalmopathy • Tourette's syndrome • Traumatic sixth nerve palsy • Trigeminal neuralgia • Trismus and stridor in amyotrophic lateral sclerosis
Complement Inhibitors (Soliris & Ultomiris®) (for Mississippi Only)	Jul. 1, 2022	**Coverage Rationale** • Removed language indicating Soliris is proven and medically necessary for initial therapy for treatment of generalized Myasthenia Gravis when the patient is currently on a stable dose	• Refer to the policy for complete details.

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Complement Inhibitors (Soliris® & Ultomiris®) (for Mississippi Only)	Jul. 1, 2022	(at least two months) of immunosuppressive therapy	
Entyvio® (Vedolizumab)	Aug. 1, 2022	**Coverage Rationale** • Removed instruction to refer to the current release of the [listed] InterQual® guideline for medical necessity clinical coverage criteria • Added language to indicate Entyvio (vedolizumab) is proven and medically necessary for the treatment of the following indications when the criteria listed in the policy are met: ○ Crohn's disease ○ Ulcerative colitis ○ Immune checkpoint inhibitor-related toxicities **Applicable Codes** • Added list of applicable ICD-10 diagnosis codes: K50.00, K50.011, K50.012, K50.013, K50.014, K50.018, K50.019, K50.10, K50.111, K50.112, K50.113, K50.114, K50.118, K50.119, K50.80, K50.811, K50.812, K50.813, K50.814, K50.818, K50.819, K50.90, K50.911, K50.912, K50.913, K50.914, K50.918, K50.919, K51.00, K51.011, K51.012, K51.013, K51.014, K51.018, K51.019, K51.20, K51.211, K51.212,	Entyvio (vedolizumab) is proven and medically necessary for the treatment of: • Crohn's disease when all of the following criteria are met: ○ For initial therapy, all of the following: ▪ Diagnosis of moderately to severely active Crohn's disease (CD); and ▪ One of the following: – History of failure, contraindication, or intolerance to at least one of the following conventional therapies: • Tumor necrosis factor (TNF) blocker [e.g., Humira (adalimumab), Cimzia (certolizumab)] • Immunomodulator (e.g., azathioprine, 6-mercaptopurine) • Corticosteroid – Corticosteroid dependent (e.g., unable to successfully taper corticosteroids without a return of the symptoms of CD); and ▪ Entyvio is initiated and titrated according to US Food and Drug Administration (FDA) labeled dosing for Crohn's disease; and ▪ Patient is not receiving Entyvio in combination with either of the following: – Biologic DMARD [e.g., infliximab, Humira (adalimumab), Cimzia (certolizumab), Stelara (ustekinumab)] – Janus kinase inhibitor [e.g., Xeljanz/Xeljanz XR (tofacitinib)] – Tysabri (natalizumab) and ▪ Initial authorization will be for no more than 14 weeks. ○ For continuation of therapy, all of the following: ▪ Documentation of positive clinical response to Entyvio; and ▪ Entyvio dosing for Crohn's disease is in accordance with the FDA labeled dosing; and

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Entyvio® (Vedolizumab) (continued)	Aug. 1, 2022	K51.213, K51.214, K51.218, K51.219, K51.30, K51.311, K51.312, K51.313, K51.314, K51.318, K51.319, K51.40, K51.411, K51.412, K51.413, K51.414, K51.418, K51.419, K51.50, K51.511, K51.512, K51.513, K51.514, K51.518, K51.519, K51.80, K51.811, K51.812, K51.813, K51.814, K51.818, K51.819, K51.90, K51.911, K51.912, K51.913, K51.914, K51.918, K51.919, T45.1X5A, T45.1X5D, and T45.1X5S • Added maximum dosage requirements for Entyvio **Supporting Information** • Added *Background*, *Clinical Evidence*, *FDA*, and *References* sections	▪ Reauthorization will be for no more than 12 months. • Ulcerative colitis when all of the following criteria are met: ○ For initial therapy, all of the following: ▪ Diagnosis of moderately to severely active ulcerative colitis (UC); and ▪ One of the following: – History of failure, contraindication, or intolerance to at least one of the following conventional therapies: • Tumor necrosis factor (TNF) blocker [e.g., Humira (adalimumab), Simponi (golimumab)] • Immunomodulator (e.g., azathioprine, 6-mercaptopurine) • Corticosteroid – Corticosteroid dependent (e.g., unable to successfully taper corticosteroids without a return of the symptoms of UC) and ▪ Entyvio is initiated and titrated according to US Food and Drug Administration labeled dosing for ulcerative colitis; and ▪ Patient is not receiving Entyvio in combination with either of the following: – Biologic DMARD [e.g., infliximab, Humira (adalimumab), Simponi (golimumab), Stelara (ustekinumab)] – Janus kinase inhibitor [e.g., Xeljanz/Xeljanz XR (tofacitinib)] – Tysabri (natalizumab) and ▪ Initial authorization will be for no more than 14 weeks. ○ For continuation of therapy, all of the following: ▪ Documentation of positive clinical response to Entyvio; and ▪ Entyvio dosing for ulcerative colitis is in accordance with the FDA labeled dosing; and ▪ Reauthorization will be for no more than 12 months. • Immune checkpoint inhibitor-related toxicities when all of the following criteria are met for initial and continuation of therapy: ○ Diagnosis of severe (G3-4) immunotherapy-related diarrhea or colitis;

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Entyvio® (Vedolizumab) (continued)	Aug. 1, 2022		and ○ Patient is receiving a checkpoint inhibitor [e.g., Keytruda (Pembrolizumab), Opdivo (Nivolumab)]; and ○ One of the following: ▪ History of failure, contraindication, or intolerance to infliximab ▪ Patient has immune-related hepatitis and ○ Authorization will be for no more than 3 doses of Entyvio.
Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®)	Aug. 1, 2022	Coverage Rationale • Removed instruction to refer to the current release of the [listed] InterQual® guideline for medical necessity clinical coverage criteria • Added language to indicate Feraheme® (ferumoxytol), Injectafer® (ferric carboxymaltose), and Monoferric® (ferric derisomaltose) are proven and medically necessary for the treatment of the following indications when the criteria listed in the policy are met: ○ Iron Deficiency Anemia (IDA) without chronic kidney disease (CKD) ○ Iron Deficiency Anemia (IDA) associated with chronic kidney disease (CKD), without end stage renal disease (ESRD) ○ Iron Deficiency Anemia (IDA) associated with chronic kidney disease (CKD), with end stage renal disease (ESRD)	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: ▪ 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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) (continued)	Aug. 1, 2022	**Definitions** • Added definition of: ○ Iron Deficiency Anemia (IDA) Without Chronic Kidney Disease (CKD) or Acute or Chronic Inflammatory Conditions ○ Iron Deficiency Anemia (IDA) With CKD or Acute or Chronic Inflammatory Conditions **Applicable Codes** • Added ICD-10 diagnosis codes D50.0, D50.1, D50.8, D50.9, D63.1, I12.9, I13.0, I13.10, N18.1, N18.2, N18.30, N18.31, N18.32, N18.4, and N18.5 **Supporting Information** • Added *Background*, *Clinical Evidence*, *FDA*, and *References* sections	• Patient has impaired absorption due to prior gastric surgery or inflammatory bowel disease • Blood loss exceeds 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: ○ 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

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Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) (continued)	Aug. 1, 2022		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 based on documented history of one of the following: – Intolerance, contraindication, or severe adverse event to all three preferred intravenous iron products; or – Treatment failure of at least two of the three preferred intravenous iron products 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 ▪ Continuation authorization will be for no longer than 3 months

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Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) (continued)	Aug. 1, 2022		• 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

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Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) (continued)	Aug. 1, 2022		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: ○ 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 based on documented history of one of the following: – Intolerance, contraindication, or severe adverse event to all three preferred intravenous iron products; or – Treatment failure of at least two of the three preferred intravenous iron products and

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Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) (continued)	Aug. 1, 2022		▪ 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: – 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
Ocrevus® (Ocrelizumab)	Aug. 1, 2022	Coverage Rationale ● Removed instruction to refer to the current release of the [listed] InterQual® guideline for medical necessity clinical coverage criteria ● Added language to indicate: ○ Ocrevus is proven and medically necessary for the treatment of the following indications when the criteria listed in the policy are met: ▪ Primary progressive multiple sclerosis (PPMS) ▪ Relapsing forms of multiple sclerosis (MS) ○ Ocrevus is unproven and not medically necessary for the treatment of: ▪ Lupus nephritis ▪ Rheumatoid arthritis	**Primary Progressive Multiple Sclerosis** Ocrevus is proven and medically necessary for the treatment of primary progressive multiple sclerosis (PPMS) when all of the following criteria are met: ● Diagnosis of primary progressive multiple sclerosis (PPMS); and ● One of the following: ○ Initial therapy for ocrelizumab when meeting all of the following: ▪ Patient is not receiving ocrelizumab in combination with any of the following: – Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide) – B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab) – Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) and ▪ Initial dosing: One time 300 mg intravenous course of doses on days 1 and 15; and ▪ Initial authorization is for no more than 6 months;

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Ocrevus® (Ocrelizumab) (continued)	Aug. 1, 2022	▪ Systemic lupus erythematosus **Applicable Codes** ● Added ICD-10 diagnosis code G35 **Supporting Information** ● Added *Background*, *Clinical Evidence*, *FDA*, and *References* sections	or ○ Continuation of therapy for ocrelizumab when meeting all of the following: ▪ Patient has previously received treatment with ocrelizumab; and ▪ Documentation of positive clinical response to ocrelizumab therapy; and ▪ Patient is not receiving ocrelizumab in combination with any of the following: – Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide) – B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab) – Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) and ▪ Continued dosing: One 600 mg intravenous dose every 6 months; and ▪ Authorization is for no more than 12 months **Relapsing Forms of Multiple Sclerosis** Ocrevus is proven and medically necessary for the treatment of relapsing forms of multiple sclerosis (MS) when both of the following criteria are met: ● Diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses); and ● One of the following: ○ Initial therapy for ocrelizumab meeting all of the following: ○ Both of the following:* – Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting either a history of intolerance or severe adverse event to rituximab or a contraindication to rituximab that would not be applicable to

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Ocrevus® (Ocrelizumab) (continued)	Aug. 1, 2022		ocrelizumab; and – Physician attests that, in their clinical opinion, the same intolerance or severe adverse event would not be expected to occur with ocrelizumab – Rituximab Step Therapy only applies to the following states: AZ, MI, NJ, NY, OH, RI, and TN) ▪ Patient is not receiving ocrelizumab in combination with any of the following: – Disease modifying therapy (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide) – B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab) – Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) and ▪ Initial dosing: One time 300 mg intravenous course of doses on days 1 and 15; and ▪ Initial authorization is for no more than 6 months; or ○ Continuation of therapy for ocrelizumab when meeting all of the following: ▪ Patient has previously received treatment with ocrelizumab; and ▪ Documentation of positive clinical response to ocrelizumab therapy; and ▪ Patient is not receiving ocrelizumab in combination with any of the following: – Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide) – B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ocrevus® (Ocrelizumab) (continued)	Aug. 1, 2022		– Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) and ▪ Continued dosing: One 600 mg intravenous dose every 6 months; and ▪ Authorization is for no more than 12 months Ocrevus is unproven and not medically necessary for the treatment of: • Lupus nephritis • Rheumatoid arthritis • Systemic lupus erythematosus
Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors	Jul. 1, 2022	Coverage Rationale • Revised list of applicable vascular endothelial growth factor (VEGF) inhibitors and dual VEGF/angiopoietin-2 (Ang-2) inhibitors; added Byooviz™ (ranibizumab-nuna) and Vabysmo™ (faricimab-svoa) • Added language to indicate: ○ Dual VEGF/Ang-2 inhibitor administration is no more than 12 doses per year per eye, regardless of diagnosis ○ Byooviz (ranibizumab-nuna) is proven and medically necessary for the treatment of: ▪ Neovascular age - related macular degeneration (AMD) ▪ Macular Edema Following Retinal Vein Occlusion (RVO)	This policy provides information about the use of certain specialty pharmacy medications administered by the intravitreal route for ophthalmologic conditions. This policy refers to the following vascular endothelial growth factor (VEGF) inhibitors and dual VEGF/angiopoietin-2 (Ang-2) inhibitors: • Avastin® (bevacizumab) • Beovu® (brolucizumab-dbll) • Byooviz™ (ranibizumab-nuna) • Eylea™ (aflibercept) • Lucentis® (ranibizumab) • Macugen® (pegaptanib) • Vabysmo™ (faricimab-svoa) The following information pertains to medical necessity review: **General Requirements (applicable to all medical necessity requests)** • For initial therapy, both of the following: ○ Diagnosis; and ○ Intravitreal VEGF or dual VEGF/Ang-2 inhibitor administration is no more than 12 doses per year per eye, regardless of diagnosis • For continuation of therapy, both of the following:

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Jul. 1, 2022	▪ Myopic Choroidal Neovascularization (mCNV) ○ Vabysmo (faricimab-svoa) is proven and medically necessary for the treatment of: ▪ Neovascular age-related macular degeneration (AMD) ▪ Diabetic macular edema (DME) **Applicable Codes** ● Added HCPCS codes C9399, J3490, J3590, and Q5124 ● Added Maximum Allowed Frequencies for: *Byooviz (Ranibizumab-Nuna)* ○ Neovascular age-related macular degeneration: The recommended dose is 0.5 mg (0.05 ML) administered by intravitreal injection once a month (approximately 28 days) ▪ Patients may be treated with 3 monthly doses followed by less frequent dosing ▪ Patients may also be treated with one dose every 3 months after 4 monthly doses ▪ Maximum of 12 doses per year per eye	○ Documentation of positive clinical response to anti - VEGF therapy; and ○ Intravitreal VEGF or dual VEGF/Ang-2 inhibitor administration is no more than 12 doses per year per eye, regardless of diagnosis **Diagnosis-Specific Requirements** The information below indicates the list of proven and medically necessary indications. Beovu (brolucizumab) is proven and medically necessary for the treatment of: ● Neovascular age-related macular degeneration (AMD) Avastin (bevacizumab) is proven and medically necessary for the treatment of: ● Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome (OHS) ● Diabetic macular edema (DME) ● Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) ● Neovascular age-related macular degeneration (AMD) ● Neovascular glaucoma ● Neovascularization of the iris (NVI) (rubeosis iridis) ● Proliferative diabetic retinopathy ● Type I retinopathy of prematurity Byooviz (ranibizumab-nuna) is proven and medically necessary for the treatment of: ● Neovascular age - related macular degeneration (AMD) ● Macular Edema Following Retinal Vein Occlusion (RVO) ● Myopic Choroidal Neovascularization (mCNV) Eylea (aflibercept) is proven and medically necessary for the treatment of:

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Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Jul. 1, 2022	○ Macular edema following retinal vein occlusion (RVO): The recommended dose is 0.5 mg (0.05 ML) administered by intravitreal injection once a month (approximately 28 days); maximum of 12 doses per year per eye ○ Myopic choroidal neovascularization (mCNV): The recommended dose is 0.5 mg (0.05 ML) administered by intravitreal injection once a month (approximately 28 days) for up to 3 months *Vabysmo (Faricimab)* ○ Diabetic macular edema: ▪ The recommended dose is 6 mg by intravitreal injection every 4 weeks for the first 4 doses, followed by one of the following three regimens: – Weeks 28 and 44 – Weeks 24, 36, and 48 – Weeks 20, 28, 36 and 44 ▪ Although most patients require dosing every 8 weeks, some patients may need dosing every 4 weeks ▪ Maximum of 12 doses per	• Diabetic macular edema (DME) • Diabetic retinopathy • Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) • Neovascular age - related macular degeneration (AMD) Lucentis (ranibizumab) is proven and medically necessary for the treatment of: • Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome (OHS) • Diabetic macular edema (DME) • Diabetic retinopathy • Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) • Neovascular age - related macular degeneration (AMD) Macugen (pegaptanib) is proven and medically necessary for the treatment of: • Diabetic macular edema • Neovascular age - related macular degeneration (AMD) Vabysmo (faricimab-svoa) is proven and medically necessary for the treatment of: • Neovascular age-related macular degeneration (AMD) • Diabetic macular edema (DME) **Additional Information** Avastin (bevacizumab) is supplied in sterile vials containing a solution of 25 mg/mL. Doses utilized in ophthalmic conditions generally range from 6.2 mcg to 2.5 mg. Therefore, bevacizumab in vials is often divided into single-dose, prefilled syringes for intravitreal use by compounding pharmacies. Compounding pharmacies must comply with United States Pharmacopeia (USP)

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Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Jul. 1, 2022	year per eye ○ Neovascular age-related macular degeneration: ▪ The recommended dose is one of the following regimens: – 6 mg administered by intravitreal injection every 4 weeks for at least 4 doses, followed by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on response – 6 mg administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injections at intervals of every 8 weeks over the next 28 weeks ▪ Although most patients require dosing every 8 weeks, some patients may need dosing every 4 weeks ▪ Maximum of 12 doses per year per eye Supporting Information	Chapter 797, which sets standards for the compounding, transportation, and storage of compounded sterile products (CSP). The Pharmacy Compounding Accreditation Board can verify that the pharmacy is adhering to these standards. The American Society of Retinal Specialists (ASRS) is committed to ensuring that retina specialists have access to compounded drugs (such as Avastin) that are prepared with high - quality material following good quality controls and sound engineering design by appropriately trained personnel. Refer to their information page at https://www.asrs.org/advocacy-practice/access-to-safe-compounded-agents for resources pertaining to access of safe compounded agents. Refer to the *U.S. Food and Drug Administration (FDA)* section of the policy for information related to contamination of compounded bevacizumab. In an effort to guard against contamination during the compounding process, the United States Veterans Health Administration (USVHA) requires that only USVHA pharmacies may dispense bevacizumab for intravitreal administration to Veterans Administration beneficiaries. The medication must be dispensed directly to the VA ophthalmologist, who will then be responsible for preparing and administering the bevacizumab dose for each patient. In addition to strict labeling and storage requirements, the ophthalmologist is required to prepare only one dose of medication from each vial; if both eyes are to be treated, a separate vial and syringe must be utilized.

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Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Jul. 1, 2022	• Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Orencia® (Abatacept) Injection for Intravenous Infusion	Aug. 1, 2022	Coverage Rationale • Removed instruction to refer to the current release of the [listed] InterQual® guideline for medical necessity clinical coverage criteria • Removed language indicating the prescriber attestation that the patient or caregiver is not able to be trained or is physically unable to administer Orencia FDA labeled for self-administration; the prescriber must submit an explanation • Added language to indicate Orencia is: ○ Proven and medically necessary for the treatment of the following indications when the criteria listed in the policy are met: ▪ Polyarticular juvenile idiopathic arthritis ▪ Rheumatoid arthritis ▪ Psoriatic arthritis ▪ Chronic graft-versus-host disease (GVHD) ▪ Acute graft-versus-host disease (aGVHD)	This policy refers to Orencia (abatacept) injection for intravenous infusion. Orencia (abatacept) for self-administered subcutaneous injection is obtained under the pharmacy benefit. Orencia is proven and medically necessary for the treatment of: • Polyarticular juvenile idiopathic arthritis when all of the following criteria are met: ○ For initial therapy, all of the following: ▪ Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA); and Orencia is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for polyarticular juvenile idiopathic arthritis; and ▪ Patient is not receiving Orencia in combination with either of the following: – Biologic disease-modifying antirheumatic drug (DMARD) *[e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]* – Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] and ▪ Prescribed by or in consultation with a rheumatologist; and ▪ Initial authorization is for no more than 12 months ○ For continuation of therapy, all of the following: ▪ Patient has previously received Orencia injection for intravenous infusion; and

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Orencia® (Abatacept) Injection for Intravenous Infusion (continued)	Aug. 1, 2022	▪ Immune checkpoint inhibitor-related toxicities ○ Unproven and not medically necessary for the treatment of: ▪ Multiple sclerosis ▪ Systemic lupus erythematosus ▪ Uveitis associated with Behçet's disease **Applicable Codes** ● Added list of applicable ICD-10 diagnosis codes **Supporting Information** ● Added *Background*, *Clinical Evidence*, *FDA*, and *References* sections	▪ Documentation of a positive clinical response; and ▪ Orencia is dosed according to FDA labeled dosing for polyarticular juvenile idiopathic arthritis; and ▪ Patient is not receiving Orencia in combination with either of the following: – Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] – Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] and ▪ Authorization is for no more than 12 months ● Rheumatoid arthritis when all of the following criteria are met: ○ For initial therapy, all of the following: ▪ Diagnosis of moderately to severely active rheumatoid arthritis (RA); and ▪ One of the following: – History of failure or intolerance to a 3-month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) at maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced; or – Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of rheumatoid arthritis [e.g., Cimzia (certolizumab), Humira (adalimumab), Simponi (golimumab), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib)]; or – Patient is currently on Orencia; and ▪ Orencia is initiated and titrated according to FDA labeled dosing for rheumatoid arthritis; and ▪ Patient is not receiving Orencia in combination with either of the

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Orencia® (Abatacept) Injection for Intravenous Infusion (continued)	Aug. 1, 2022		following: – Biologic DMARD *[e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]* – Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] and ▪ Prescribed by or in consultation with a rheumatologist; and ▪ Initial authorization is for no more than 12 months ○ For continuation of therapy, all of the following: ▪ Patient has previously received Orencia injection for intravenous infusion; and ▪ Documentation of a positive clinical response; and ▪ Orencia is dosed according to FDA labeled dosing for rheumatoid arthritis; and ▪ Patient is not receiving Orencia in combination with either of the following: – Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] – Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] and ▪ Authorization is for no more than 12 months • Psoriatic arthritis when all of the following criteria are met: ○ For initial therapy, all of the following: ▪ Diagnosis of active psoriatic arthritis (PsA); and ▪ One of the following: – History of failure to a 3 month trial of methotrexate at the maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced; or – Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of psoriatic arthritis [e.g., Cimzia (certolizumab), Humira (adalimumab),

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Orencia® (Abatacept) Injection for Intravenous Infusion (continued)	Aug. 1, 2022		Simponi (golimumab), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz (tofacitinib), Otezla (apremilast)]; or – Patient is currently on Orencia and ▪ Orencia is initiated and titrated according to FDA labeled dosing for psoriatic arthritis; and ▪ Patient is not receiving Orencia in combination with any of the following: – Biologic DMARD *[e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]* – Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] – Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] and ▪ Prescribed by or in consultation with one of the following: – Rheumatologist – Dermatologist and ▪ Initial authorization is for no more than 12 months ○ For continuation of therapy, all of the following: ▪ Patient has previously received Orencia injection for intravenous infusion; and ▪ Documentation of a positive clinical response; and ▪ Orencia is dosed according to FDA labeled dosing for psoriatic arthritis; and ▪ Patient is not receiving Orencia in combination with any of the following: – Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] – Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] – Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] and

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Orencia® (Abatacept) Injection for Intravenous Infusion (continued)	Aug. 1, 2022		▪ Authorization is for no more than 12 months • Chronic graft-versus-host disease (GVHD) when all of the following criteria are met: ○ For initial therapy, all of the following: ▪ Diagnosis of steroid-refractory chronic GVHD; and ▪ One of the following: – Patient is receiving Orencia in combination with systemic corticosteroids – Patient is intolerant to systemic corticosteroid therapy and ▪ Initial authorization is for no more than 12 months ○ For continuation of therapy, all of the following: ▪ Documentation of positive clinical response; and ▪ Patient continues to experience chronic GVHD; and ▪ One of the following: – Patient is receiving Orencia in combination with systemic corticosteroids – Patient is intolerant to systemic corticosteroid therapy – Patient has been successfully tapered off of corticosteroid therapy and ▪ Authorization is for no more than 12 months • Acute graft-versus-host disease (aGVHD) when all of the following criteria are met: ○ Patient is at least 2 years old; and ○ One of the following: ▪ Patient is undergoing hematopoietic stem cell transplantation (HSCT) from a matched donor ▪ Patient is undergoing HSCT from a 1 allele-mismatched unrelated donor and

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Orencia® (Abatacept) Injection for Intravenous Infusion (continued)	Aug. 1, 2022		○ Patient is receiving Orencia in combination with a calcineurin inhibitor; and ○ Patient is receiving Orencia in combination with methotrexate ○ Authorization is for no more than 4 doses • Immune checkpoint inhibitor-related toxicities when all of the following criteria are met: ○ Patient has recently received checkpoint inhibitor therapy [e.g., Keytruda (Pembrolizumab), Opdivo (Nivolumab)]; and ○ Diagnosis of severe (G3) or life threatening (G4) immunotherapy-related myocarditis, pericarditis, arrhythmias, or impaired ventricular function, or conduction abnormalities; and ○ No improvement of toxicity within 24 hours of starting pulse-dose methylprednisolone; and ○ History of failure, contraindication, or intolerance to infliximab (e.g., Inflectra, Remicade); and ○ Authorization is for no more than 4 doses Orencia is unproven and not medically necessary for the treatment of: • Multiple sclerosis • Systemic lupus erythematosus • Uveitis associated with Behçet's disease
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®)	Aug. 1, 2022	Coverage Rationale • Removed instruction to refer to the current release of the [listed] InterQual® guideline for medical necessity clinical coverage criteria • Added language to indicate: ○ Nucala is proven and medically necessary for the treatment of the following indications when the criteria listed in the policy are met:	• Refer to the policy for complete details.

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Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Aug. 1, 2022	▪ Eosinophilic granulomatosis with polyangiitis (EGPA) ▪ Hypereosinophilic syndrome (HES) ▪ Chronic rhinosinusitis with nasal polyps (CRSwNP) ○ Cinqair, Fasenra, and Nucala are proven and medically necessary for the treatment of severe asthma when the criteria listed in the policy are met ○ Cinqair, Fasenra, and Nucala are unproven and not medically necessary for the treatment of: ▪ Other eosinophilic conditions ▪ Acute bronchospasm ▪ Status asthmaticus ▪ Chronic obstructive pulmonary disease (COPD) ▪ Granulomatosis with polyangiitis (Wegener's) ▪ Microscopic polyangiitis ▪ Organ or life-threatening EGPA **Applicable Codes** ● Added list of applicable ICD-10 diagnosis codes: D72.11, J31.0, J32.0, J32.1, J32.2, J32.3, J32.4,	

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Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Aug. 1, 2022	J32.8, J32.9, J33.0, J33.1, J33.8, J33.9, J45.50, J45.51, J45.52, J82.81, J82.82, J82.83, J82.89, and M30.1 **Supporting Information** • Added *Background*, *Clinical Evidence*, *FDA*, and *References* sections	
Sodium Hyaluronate	Aug. 1, 2022	**Coverage Rationale** • Replaced instruction to refer to the current release of the [listed] InterQual® guideline with Diagnosis-Specific Criteria • Added language to indicate: ○ Intra-articular injections of sodium hyaluronate are proven and medically necessary for the treatment of knee osteoarthritis when the criteria listed in the policy are met ○ Repeated courses of intra-articular hyaluronan injections may be considered for the treatment of knee osteoarthritis when the criteria listed in the policy are met ○ Intra-articular injections of sodium hyaluronate are unproven and not medically necessary for treating any other indication due to insufficient evidence of efficacy including but not limited to the	Coverage for Durolane, Euflexxa, and Gelsyn-3 is contingent on criteria in the *Diagnosis-Specific Criteria* section. Coverage for GenVisc 850, Hyalgan, Supartz, Visco-3, Hymovis, Orthovisc, Synvisc or Synvisc-One, Gel-One, Monovisc, Triluron, TriVisc, or Synojoynt is contingent on *Medical Necessity Criteria* and *Diagnosis-Specific Criteria*. • In order to continue coverage, members already on these products will be required to change therapy to Durolane, Euflexxa, or Gelsyn-3 unless they meet the criteria below. **Medical Necessity Criteria** Treatment with GenVisc 850, Hyalgan, Supartz, Visco-3, Hymovis, Orthovisc, Synvisc or Synvisc-One, Gel-One, Monovisc, Triluron, TriVisc, or Synojoynt is medically necessary for the indications specified in this policy when one of the criteria below are met: • Both of the following: ○ History of a trial of adequate dose and duration of Durolane, Euflexxa, and Gelsyn-3, resulting in minimal clinical response; and ○ Physician attests that, in their clinical opinion, the clinical response would be expected to be superior than experienced with Durolane, Euflexxa, and Gelsyn-3; or • Both of the following: ○ History of failure, contraindication, or intolerance to Durolane, Euflexxa, and Gelsyn-3; and

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Sodium Hyaluronate (continued)	Aug. 1, 2022	following: ▪ Hip osteoarthritis ▪ Temporomandibular joint osteoarthritis ▪ Temporomandibular joint disc displacement ○ Hyaluronic acid gel preparations to improve the skin's appearance, contour and/or reduce depressions due to acne, scars, injury or wrinkles are considered cosmetic and are not covered **Applicable Codes** • Added list of applicable ICD-10 diagnosis codes: M13.0, M17.0, M17.10, M17.11, M17.12, M17.2, M17.30, M17.31, M17.32, M17.4, M17.5, and M17.9 **Supporting Information** • Added *Background*, *Clinical Evidence*, *FDA*, and *References* sections	○ Physician attests that, in their clinical opinion, the same failure, contraindication, or intolerance would not be expected to occur with GenVisc 850, Hyalgan, Supartz, Visco-3, Hymovis, Orthovisc, Synvisc or Synvisc-One, Gel-One, Monovisc, Triluron, TriVisc, or Synojoynt **Diagnosis-Specific Criteria** ***Initial Authorization (Sodium Hyaluronate Naïve Patients)*** Intra-articular injections of sodium hyaluronate are proven and medically necessary when all of the following are met: • Diagnosis of knee osteoarthritis; and • The member has not responded adequately to conservative therapy which may include physical therapy or pharmacotherapy (e.g., non-steroidal anti-inflammatory drugs [NSAIDs], acetaminophen and/or topical capsaicin cream) or injection of intra-articular steroids and such therapy has not resulted in functional improvement after at least 3 months, or the member is unable to tolerate conservative therapy because of adverse side effects; and • The member reports pain which interferes with functional activities (e.g., ambulation, prolonged standing); and • The pain is attributed to degenerative joint disease/primary osteoarthritis of the knee; and • There are no contraindications to the injections (e.g., active joint infection, bleeding disorder); and • Dosing is in accordance with the U.S. FDA approved labeling as shown in the table below; and • Initial authorization is for a single injection course once per joint for 6 months ***Reauthorization/Continuation*** Repeated courses of intra-articular hyaluronan injections may be considered when all of the following are met: • Diagnosis of knee osteoarthritis; and • Documentation of positive clinical response to therapy (e.g., significant pain

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Sodium Hyaluronate (continued)	Aug. 1, 2022		relief was achieved with the prior course of injections); and • Pain has recurred; and • At least 6 months have passed since the prior course of treatment for the respective joint; and • Dosing is in accordance with the U.S. FDA approved labeling as shown in the table below; and • Continuing authorization is for a single injection course once per joint for 6 months The table below shows the FDA approved sodium hyaluronate products and their respective FDA labeled dosage per treatment course per joint:

Sodium Hyaluronate Product	Course of Treatment per Joint
Durolane	1 injection
Euflexxa	3 injections
Gel One	1 injection
Gelsyn-3	3 injections
GenVisc 850	3 to 5 injections
Hyalgan	5 injections
Hymovis	2 injections
Monovisc	1 injection
Orthovisc	3 to 4 injections
Supartz	3 to 5 injections
Synojoynt	3 injections
Synvisc	3 injections
Synvisc One	1 injection
Triluron	3 injections

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Sodium Hyaluronate (continued)	Aug. 1, 2022		TriVisc: 3 injections Visco-3: 3 injections Intra-articular injections of sodium hyaluronate are unproven and not medically necessary for treating any other indication due to insufficient evidence of efficacy including but not limited to the following: • Hip osteoarthritis • Temporomandibular joint osteoarthritis • Temporomandibular joint disc displacement Hyaluronic acid gel preparations to improve the skin's appearance, contour and/or reduce depressions due to acne, scars, injury or wrinkles are considered cosmetic and are not covered.
White Blood Cell Colony Stimulating Factors	Jul. 1, 2022	Coverage Rationale • Revised list of applicable short-acting filgrastim agents; added Releuko® (filgrastim-ayow) • Added langauge 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	This 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) ○ 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

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White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	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, 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	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 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

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White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	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: *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	○ 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 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

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White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	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 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	○ 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 nonmyeloid 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; • 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)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	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 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:	(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 ▪ 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)

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	▪ 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) ▪ 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	– 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 ○ 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

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	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 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	• 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 neutropenias with chronic ANC ≤ 500 neutrophils/mcL[50]); 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®,

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	– 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 and J3590 **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information	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
Xolair® (Omalizumab)	Aug. 1, 2022	**Coverage Rationale** • Removed instruction to refer to the current release of the [listed] InterQual® guideline for medical necessity clinical coverage criteria • Added language to indicate Xolair for provider administration is: ○ Proven and medically necessary for treatment of the following indications when the criteria listed in the policy are met:	• Refer to the policy for complete details.

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Xolair® (Omalizumab) (continued)	Aug. 1, 2022	▪ Moderate to severe persistent asthma ▪ Chronic urticaria ▪ Nasal polyps ○ Unproven and not medically necessary for: ▪ Seasonal allergic rhinitis ▪ Perennial allergic rhinitis ▪ Atopic dermatitis ▪ Peanut allergy ▪ Acute bronchospasm or status asthmaticus **Applicable Codes** ● Added list of applicable ICD-10 diagnosis codes: J33.0, J33.1, J33.8, J33.9, J44.1, J44.9, J45.40, J45.41, J45.50, J45.51, J45.909, J45.998, L50.0, L50.1, and L50.8 ● Added maximum dosage requirements for Xolair **Supporting Information** ● Added *Background*, *Clinical Evidence*, *FDA*, and *References* sections	

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.