United Healthcare Community Plan

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

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Take Note

Omnibus Codes: Policy Revisions Delayed

The Medical Policy titled *Omnibus Codes (for Mississippi Only)* will not be revised on May 1, 2022, as previously announced; details on upcoming changes to this policy will be provided in a future edition of the Medical Policy Update Bulletin.

InterQual® 2022 Clinical Criteria: Apr. 2022 Release

Effective May 1, 2022, the following Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines have been updated to reflect the applicable InterQual® clinical criteria reference(s) associated with the Apr. 2022 Release:

Policy Title	Policy Type
Abnormal Uterine Bleeding and Uterine Fibroids (for Mississippi Only)	Medical Policy
Airway Clearance Devices (for Mississippi Only)	Medical Policy
Articular Cartilage Defect Repairs (for Mississippi Only)	Medical Policy
Attended Polysomnography for Evaluation of Sleep Disorders (for Mississippi Only)	Medical Policy
Beds and Mattresses (for Mississippi Only)	Coverage Determination Guideline
Catheter Ablation for Atrial Fibrillation (for Mississippi Only)	Medical Policy
Chemotherapy Observation or Inpatient Hospitalization (for Mississippi Only)	Utilization Review Guideline
Cosmetic and Reconstructive Procedures (for Mississippi Only)	Coverage Determination Guideline
Deep Brain and Cortical Stimulation (for Mississippi Only)	Medical Policy
Hysterectomy (for Mississippi Only)	Medical Policy
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Manual Wheelchairs (for Mississippi Only)	Coverage Determination Guideline
Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) and Achalasia (for Mississippi Only)	Medical Policy
Obstructive and Central Sleep Apnea Treatment (for Mississippi Only)	Medical Policy
Orthognathic (Jaw) Surgery (for Mississippi Only)	Coverage Determination Guideline
Patient Lifts (for Mississippi Only)	Coverage Determination Guideline
Plagiocephaly and Craniosynostosis Treatment (for Mississippi Only)	Medical Policy
Pneumatic Compression Devices (for Mississippi Only)	Medical Policy
Power Mobility Devices (for Mississippi Only)	Coverage Determination Guideline
Rhinoplasty and Other Nasal Surgeries (for Mississippi Only)	Coverage Determination Guideline

Take Note

Policy Title	Policy Type
Surgery of the Elbow (for Mississippi Only)	Medical Policy
Surgery of the Foot (for Mississippi Only)	Medical Policy
Surgery of the Hand and Wrist (for Mississippi Only)	Medical Policy
Surgery of the Hip (for Mississippi Only)	Medical Policy
Surgery of the Knee (for Mississippi Only)	Medical Policy
Surgery of the Shoulder (for Mississippi Only)	Medical Policy
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Mississippi Only)	Medical Policy
Surgical Treatment for Spine Pain (for Mississippi Only)	Medical Policy
Temporomandibular Joint Disorders (for Mississippi Only)	Medical Policy
Total Artificial Disc Replacement for the Spine (for Mississippi Only)	Medical Policy
Wheelchair Options and Accessories (for Mississippi Only)	Coverage Determination Guideline
Wheelchair Seating (for Mississippi Only)	Coverage Determination Guideline

Medical Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Cardiovascular Disease Risk Tests (for Mississippi Only)	Jun. 1, 2022	**Applicable Codes** ● Added CPT code 84999 **Supporting Information** ● Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information ● Removed *CMS* section
Plagiocephaly and Craniosynostosis Treatment (for Mississippi Only)	Jun. 1, 2022	**Coverage Rationale** ● Revised documentation requirements for cranial orthosis (HCPCS code S1040): *Initial Request* ○ Added requirement of medical notes documenting (when applicable): ▪ Presence or absence of torticollis ▪ At least one of the following (for more details about the definition of these measurements, refer to the InterQual® criteria informational notes): – Cranial vault asymmetry index (CVAI) – Cephalic index (CI) – Transcranial diameter difference (TDD) – Cranial vault asymmetry (CVA) Children's Healthcare of Atlanta (CHOA) level ▪ Treatments tried, failed, contraindicated. Include the dates and reason for discontinuation, including: – Repositioning – Physical or occupational therapy ▪ Plan to treat torticollis with cranial orthosis (when applicable) ○ Removed requirement of medical notes documenting cephalic index in orthotist notes *Replacement Request* ○ Added requirement of medical notes documenting: ▪ Adjustments/modifications to current cranial helmet if applicable ▪ Compliance with wear

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ablative Treatment for Spinal Pain (for Mississippi Only)	Jun. 1, 2022	**Coverage Rationale** ● Replaced reference to "Thermal Radiofrequency Ablation" with "*Conventional* (Thermal) Radiofrequency Ablation"	Conventional (Thermal) Radiofrequency Ablation of facet joint nerves is proven and medically necessary for the following: ● Initial treatment of Chronic cervical (C3-4 joint and below), thoracic and lumbar pain when: ○ Clinical documentation shows a Functional Impairment due to facet

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ablative Treatment for Spinal Pain (for Mississippi Only) (continued)	Jun. 1, 2022	• Removed language pertaining to documentation requirements *Unproven and Not Medically Necessary* • Replaced language indicating: ○ "Thermal Radiofrequency Ablation of facet joint nerves is unproven and not medically necessary for spinal segments that have been surgically fused" with "*Conventional* (Thermal) Radiofrequency Ablation of facet joint nerves is unproven and not medically necessary for spinal segments that have been *successfully* surgically fused" ○ "*Thermal Radiofrequency Ablation, including cooled* radiofrequency ablation, is unproven and not medically necessary for treating sacroiliac pain" with "*all forms of* radiofrequency ablation are unproven and not medically necessary for treating sacroiliac pain" • Updated list of examples of other pain indications; removed "sacroiliac pain" Definitions • Updated definition of: ○ Conventional (Thermal)	pain; and ○ Clinical documentation of a diagnostic Facet Joint Injection and/or Facet Nerve Block (i.e., Medial Branch Block) to localize the source of spinal pain to the facet joint confirms the following: ▪ At least a 50% reduction in pain from baseline at the specific side and level of the proposed ablation; and ▪ The reduction in pain is sufficient to allow a measurable functional improvement; and ○ The diagnostic procedure is not performed on the same day as the ablation procedure • Repeat treatment of Chronic cervical (C3 and below), thoracic and lumbar pain when: ○ History and physical examination confirm that the facet joint is the source of pain; and ○ Clinical documentation shows a Functional Impairment due to facet pain; and ○ Performed at a frequency of six months or longer (maximum of 2 times over a 12-month period per side and level); and ○ There has been a 50% or greater documented reduction in pain for at least 10 weeks following the previous ablation, as substantiated by a validated pain scale Conventional (Thermal) Radiofrequency Ablation of facet joint nerves is unproven and not medically necessary in the following circumstances due to insufficient evidence of efficacy: • The source of back pain at the proposed ablation level is from a cause other than facet joint syndrome that requires a different treatment approach. Examples include disc herniation, spinal stenosis, foraminal narrowing, vertebral fracture radiculopathy and spondylolisthesis; or • Spinal segments that have been successfully surgically fused; or • All other pain indications. Examples include, but are not limited to, occipital neuralgia, headache, or Complex Regional Pain Syndrome. All forms of radiofrequency ablation, are unproven and not medically

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ablative Treatment for Spinal Pain (for Mississippi Only) (continued)	Jun. 1, 2022	Radiofrequency Ablation ○ Cooled Radiofrequency Ablation ○ Pulsed Radiofrequency Ablation **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	necessary for treating sacroiliac pain. The following facet joint nerve ablation techniques are unproven and not medically necessary due to insufficient evidence of efficacy: • Pulsed Radiofrequency Ablation of the facet nerves of the cervical, thoracic or lumbar region, sacral nerve root or dorsal root ganglion • Endoscopic radiofrequency ablation/endoscopic rhizotomy • Cryoablation (cryodenervation, cryoneurolysis, cryosurgery or cryoanesthesia) • Cooled Radiofrequency Ablation • Chemical ablation (including, but not limited to, alcohol, phenol or sodium morrhuate) • Laser ablation (including pulsed, continuous or low level) • Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept®)
Airway Clearance Devices (for Mississippi Only)	Jun. 1, 2022	**Coverage Rationale** • Revised language to indicate: ○ A two-month rental trial of a high-frequency chest wall oscillation system is proven and medically necessary in the management of neuromuscular diseases, when all of the following criteria have been met: ▪ A confirmed diagnosis of one of the following neuromuscular diseases: – Quadriplegia – Muscular dystrophy – Multiple sclerosis – Polio or post-polio syndrome	A two-month rental trial of a high-frequency chest wall oscillation system is proven and medically necessary in the management of neuromuscular diseases, when all of the following criteria have been met: • A confirmed diagnosis of one of the following neuromuscular diseases: ○ Quadriplegia ○ Muscular dystrophy ○ Multiple sclerosis ○ Polio or post-polio syndrome ○ Other anterior horn cell disease ○ Myotonic disorder or other myopathy ○ Paralysis of the diaphragm ○ Acid maltase deficiency ○ Amyotrophic lateral sclerosis (ALS) ○ Spinal muscular atrophy (SMA) and • Frequent pulmonary symptom exacerbations requiring antibiotic therapy (> 2 per year); and • Failure of standard treatments to adequately mobilize retained secretions

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Airway Clearance Devices (for Mississippi Only) (continued)	Jun. 1, 2022	– Other anterior horn cell disease – Myotonic disorder or other myopathy – Paralysis of the diaphragm – Acid maltase deficiency – Amyotrophic lateral sclerosis (ALS) – Spinal muscular atrophy (SMA) ▪ Frequent pulmonary symptom exacerbations requiring antibiotic therapy (> 2 per year) ▪ Failure of standard treatments to adequately mobilize retained secretions ○ A two-month rental trial of a high-frequency chest wall oscillation system is proven and Medically Necessary in the management of bronchiectasis and cystic fibrosis, which are characterized by the production of excessive airway secretions, infection, and inadequate airway clearance, when criteria have been met; for additional medical necessity clinical coverage	A two-month rental trial of a high-frequency chest wall oscillation system is proven and medically necessary in the management of bronchiectasis and, cystic fibrosis, which are characterized by the production of excessive airway secretions, infection and inadequate airway clearance, when criteria have been met. For additional medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release CP: Durable Medical Equipment, Secretion Clearance Devices. Click here to view the InterQual® criteria. For all indications for a high-frequency chest wall oscillation system, an initial two-month rental trial must confirm individual tolerance and efficacy in using the device before ongoing medical necessity can be determined. For Medical Necessity determination to address ongoing use, refer to the InterQual Criteria. Intrapulmonary percussive ventilation (IPV) devices for home use are considered unproven and not Medically Necessary. Combination Positive Expiratory Pressure, Airway Oscillation, and Intermittent Flow Acceleration Device is considered medically necessary under certain circumstances. For medical necessity clinical coverage criteria, refer to the *Mississippi Division of Medicaid Administrative Code: Title 23: Medicaid Part 209 Durable Medical Equipment And Medical Supplies.*

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Airway Clearance Devices (for Mississippi Only) (continued)	Jun. 1, 2022	criteria, refer to the InterQual® 2022, Apr. 2022 Release CP: Durable Medical Equipment, Secretion Clearance Devices ○ For all indications for a high-frequency chest wall oscillation system, an initial two-month rental trial must confirm individual tolerance and efficacy in using the device before ongoing medical necessity can be determined; for Medical Necessity determination to address ongoing use, refer to the InterQual® criteria ○ Intrapulmonary percussive ventilation (IPV) devices for home use are considered unproven and not Medically Necessary ○ A combination positive expiratory pressure, airway oscillation, and intermittent flow acceleration device is considered medically necessary under certain circumstances; for medical necessity clinical coverage criteria, refer to the Mississippi Division of Medicaid Administrative Code: *Title 23: Medicaid Part 209 Durable*	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Airway Clearance Devices (for Mississippi Only) (continued)	Jun. 1, 2022	*Medical Equipment and Medical Supplies* Definitions • Added definition of "Bronchiectasis" Applicable Codes • Removed HCPCS code E1399 • Added ICD-10 diagnosis codes G71.8, G72.41, G72.89, G73.1, G73.3, G73.7, J98.6, M33.02, M33.12, M33.22, M33.92, M34.82, and M35.03 Supporting Information • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Articular Cartilage Defect Repairs (for Mississippi Only)	Jun. 1, 2022	Related Policies • Added reference link to the Utilization Review Guideline titled *Outpatient Surgical Procedures – Site of Service (for Mississippi Only)* Coverage Rationale *Autologous Chondrocyte Transplantation (ACT) and Microfracture* • Revised language pertaining to medical necessity clinical coverage criteria: ○ Removed reference to the InterQual® Client Defined 2022, CP: Procedures, Articular	**ACT and Microfracture** Autologous chondrocyte transplantation (ACT) is proven and medically necessary for treating individuals with symptomatic full-thickness articular cartilage defects when all of the following criteria are met. • The lesion is: ○ Greater than or equal to 2 squared centimeters ○ A result of acute or repetitive trauma ○ Single or multiple full thickness (Outerbridge Classification of grade III or IV) articular cartilage defect of the femoral condyle (medial, lateral or trochlea) and/or patella • Knee is stable with intact menisci and ligaments • Normal joint space and alignment confirmed by X-ray • No active inflammatory or other arthritis, clinically and by X-ray • Failed non-surgical conservative management (e.g., physical therapy, braces, and/or nonsteroidal anti-inflammatory drugs)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Articular Cartilage Defect Repairs (for Mississippi Only) (continued)	Jun. 1, 2022	Cartilage Defect Repairs (Custom) – UHG ○ Added criteria requiring all of the following: Autologous Chondrocyte Transplantation (ACT) ▪ The lesion is: – Greater than or equal to 2 squared centimeters – A result of acute or repetitive trauma – Single or multiple full thickness (Outerbridge Classification of grade III or IV) articular cartilage defect of the Femoral Condyle (medial, lateral or trochlea) and/or patella ▪ Knee is stable with intact menisci and ligaments ▪ Normal joint space and alignment confirmed by X-ray ▪ No active inflammatory or other arthritis, clinically and by X-ray ▪ Failed non-surgical conservative management (e.g., physical therapy,	• Inadequate response to a prior arthroscopic or other surgical repair procedure (e.g., debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft) • Individual is less than 55 years of age. ACT is unproven and not medically necessary for treating individuals with the following indications due to insufficient evidence of efficacy: • Treatment of joints other than the knee • Growth plates have not closed • History of partial-thickness defects • Osteochondritis dissecans (OCD) • Malignancy in the bone, cartilage, fat or muscle of the treated limb • Active infection in the affected knee • Instability of the knee • History of total meniscectomy • Repeat ACT • Active inflammatory degenerative, rheumatoid or osteoarthritis • As initial or first line of surgical therapy Microfracture repair to treat full and partial thickness chondral defects of the knee is proven and medically necessary when all of the following criteria are met. • Symptomatic focal cartilage defects of the weight-bearing femoral condyles, tibial plateau, trochlea, and patella • Defect has been identified by Magnetic resonance imaging (*MRI), arthrogram or arthroscopy • Outerbridge Grade 3-4 cartilage lesions • Measure less than or equal to 4 square centimeters **Osteochondral Autograft and Allograft Transplantation** Osteochondral Autograft and Allograft transplantation is proven and medically necessary for treating individuals with cartilage defects of the knee. For medical necessity clinical coverage criteria for Osteochondral

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Articular Cartilage Defect Repairs (for Mississippi Only) (continued)	Jun. 1, 2022	braces, and/or nonsteroidal anti-inflammatory drugs) ▪ Inadequate response to a prior arthroscopic or other surgical repair procedure (e.g., debridement, Microfracture, drilling/ abrasion arthroplasty, or Osteochondral Allograft/ Autograft) ▪ Individual is less than 55 years of age **Microfracture** ▪ Symptomatic Focal cartilage Defects of the weight-bearing Femoral Condyles, tibial plateau, trochlea, and patella ▪ Defect has been identified by magnetic resonance imaging (MRI), arthrogram or arthroscopy ▪ Outerbridge Grade 3-4 cartilage lesions ▪ Measure less than or equal to 4 square centimeters **Definitions** • Added definition of "Focal Defect" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	Autograft and Allograft Transplantation, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures: • Arthroscopy or Arthroscopically Assisted Surgery, Knee • Arthroscopy or Arthroscopically Assisted Surgery, Knee (Pediatric) • Arthrotomy, Knee Click here to view the InterQual® criteria. **Focal Articular Cartilage Repair** Focal articular cartilage repair is unproven and not medically necessary for treating individuals with any of the following due to insufficient evidence of efficacy: • Osteochondral Autograft and Allograft transplantation for all other indications than those listed above • Use of minced articular cartilage repair (whether synthetic, allograft or autograft) for treating osteochondral defects of the knee • Use of cryopreserved viable Osteochondral Allograft products (e.g., Cartiform) • Microfracture repair of the knee with any of the following indications: ○ Misalignment of the knee ○ Osteoarthritis ○ Systemic immune-mediated disease, disease-induced arthritis, or cartilage disease ○ Unwilling or unable to participate in post-operative physical rehabilitation program

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Discogenic Pain Treatment (for Mississippi Only)	Jun. 1, 2022	**Coverage Rationale**
		• Revised list of unproven and not medically necessary procedures:
		  ○ Added:
		  ▪ Annular closure devices (ACDs)
		  ▪ Percutaneous injection of allogeneic cellular/tissue-based products
		  ○ Removed:
		  ▪ Annulus fibrosus repair following spinal surgery
		Applicable Codes
		• Added CPT codes 0627T, 0628T, 0629T, and 0630T
		Supporting Information
		• Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
			The following procedures are unproven and not medically necessary due to insufficient evidence of efficacy:
			• Annular Closure Devices (ACDs)
			• Percutaneous discectomy and decompression procedures for treating discogenic pain
			• Percutaneous injection of allogeneic cellular/tissue based products
			• Thermal intradiscal procedures (TIPs) for treating discogenic pain

Functional Endoscopic Sinus Surgery (FESS) (for Mississippi Only)	Jun. 1, 2022	**Coverage Rationale**
		• Revised coverage criteria for Chronic Rhinosinusitis (CRS) with or without polyps; replaced criterion requiring:
		  ○ "Intranasal corticosteroids" with "intranasal corticosteroids *(and/or oral corticosteroids when appropriate)*"
		  ○ "Nasal lavage" with "nasal lavage/ *irrigation if appropriate*"
		Supporting Information
			Functional Endoscopic Sinus Surgery (FESS) is proven and medically necessary when one or more of the following conditions are present:
			• Chronic Rhinosinusitis (CRS) with or without polyps which has all of the following:
			  ○ Lasted longer than 12 weeks
			  ○ Persistence of symptoms despite administration of full courses of all of the following treatments:
			  ▪ Intranasal corticosteroids (and/or oral corticosteroids when appropriate), and
			  ▪ Antibiotic therapy if bacterial infection is suspected; and
			  ▪ Nasal lavage/irrigation if appropriate
			  ○ Confirmation of Chronic Rhinosinusitis on a computed tomography (CT) scan for each sinus to be treated meeting all of the following criteria:

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Functional Endoscopic Sinus Surgery (FESS) (for Mississippi Only) (continued)	Jun. 1, 2022	• Updated *References* section to reflect the most current information	▪ CT images are obtained after completion of medical management; and ▪ Documentation of which sinus disease and the extent of disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring System; and ▪ CT findings include one or more of the following: – Bony remodeling – Bony thickening – Opacified sinus – Ostial obstruction (outflow tract obstruction) and mucosal thickening ○ Sinonasal symptoms such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis • Recurrent Acute Rhinosinusitis (RARS) with all of the following: ○ Four or more episodes per year with distinct symptom free intervals between episodes; and Sinonasal symptoms such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis; and ○ CT scan evidence of one of the following: ▪ For the maxillary, frontal, or sphenoid sinuses, both of the following are present: – Ostial obstruction (outflow tract obstruction) in the sinus to be treated – Mucosal thickening in the sinus to be treated ▪ For the ethmoid sinus, mucosal thickening is present • Any of the following conditions confirmed on CT : ○ Complications of sinusitis such as abscess ○ Symptomatic concha bullosa ○ Symptomatic mucocele ○ Polyposis with obstructive symptoms (for Chronic Rhinosinusitis with polyps, refer to the above criteria) ○ Sinonasal tumor Functional Endoscopic Sinus Surgery (FESS) is unproven and not medically

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Functional Endoscopic Sinus Surgery (FESS) (for Mississippi Only) (continued)	Jun. 1, 2022		necessary for any condition other than those listed above due to insufficient evidence of efficacy.
			
			Documentation Requirements
			Medical notes documenting the following, when applicable:
			• Chronic Rhinosinusitis (CRS) with the following:
			  ○ Signs and symptoms
			  ○ Treatments tried and failed including duration of treatments/medical therapies
			  ○ Post medical management CT scan images:
			  ▪ That show the abnormality for which surgery is being requested
			  ▪ Are the optimal image to show the abnormality of the affected area with use of the Modified Lund-Mackay Scoring System to define the severity of Chronic Rhinosinusitis
			  ▪ Note: Upon request, CT images may be required and 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 images
			  – Whether the imaging was taken pre-or post-medical therapy
			  ▪ CT images can be submitted via the external portal at www.uhcprovider.com/paan; faxes will not be accepted
			  ○ CT scan report documents all of the following:
			  ▪ Which sinus has the disease
			  ▪ The extent of disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring System
			• Recurrent Acute Rhinosinusitis with the following:
			  ○ Number of episodes per year of Acute Rhinosinusitis
			  ○ Signs and symptoms
			  ○ CT scan images:
			  ▪ That show the abnormality for which surgery is being requested
			  ▪ Are the optimal image to show the abnormality of the affected area
			  ▪ Note: Upon request, CT images may be required and must be

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Functional Endoscopic Sinus Surgery (FESS) (for Mississippi Only) (continued)	Jun. 1, 2022		labeled with the: – Date taken – Applicable case number obtained at time of notification, or the member's name and ID number on the images – Whether the images were taken pre- or post-medical therapy ▪ CT images can be submitted via the external portal at www.uhcprovider.com/paan; faxes will not be accepted ○ CT scan report documents all of the following: ▪ Which sinus has the disease ▪ The extent of disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring System
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for Mississippi Only)	Jun. 1, 2022	Coverage Rationale ● Updated list of examples of liquid biopsy tumor tests for genetic analysis or tumor screening: ○ Added "Foundation One Liquid CDx" ○ Replaced "Guardant" with "Guardant*360*" ● Added language to indicate multi-cancer early detection tests (e.g., Galleri) are unproven and not medically necessary ● Replaced language indicating "molecular *profiling using* gene expression profiling, Chromosome Microarray multi-gene cancer panels are unproven and not medically necessary for all other indications [not listed as proven in the policy]" with "molecular *testing such as* gene expression profiling, Chromosome Microarray *Analysis,*	**Breast Cancer** The use of one of the following Gene Expression Tests – MammaPrint, Oncotype Dx Breast, Prosigna PAM-50 Breast Cancer Prognostic Gene Signature Assay, Breast Cancer Index (BCI) and EndoPredict – is proven and medically necessary to make a treatment decision regarding adjuvant chemotherapy in females or males with invasive breast cancer in the following situations: ● Newly diagnosed (within the last 6 months) when all of the following criteria are met: ○ Lymph node negative or 1-3 positive ipsilateral axillary lymph nodes; and ○ No distant metastases; and ○ Hormone receptor-positive (estrogen receptor positive, progesterone receptor positive or both); and ○ HER2 receptor negative; and ○ Adjuvant chemotherapy is not precluded due to any other factor (e.g., advanced age and/or significant co-morbidities) or ● Currently receiving adjuvant hormonal therapy (e.g., Tamoxifen or an aromatase inhibitor) for a breast cancer when all of the following criteria are met: ○ Hormone receptor-positive (estrogen receptor positive, progesterone

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Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for Mississippi Only) (continued)	Jun. 1, 2022	*and* multi-gene cancer panels are unproven and not medically necessary for all other indications [not listed as proven in the policy]" • Revised list of indications for which molecular testing is unproven and not medically necessary: ○ Added: ▪ Pancreatic cancer (e.g., PancraGen) ▪ Tumor-informed assays (Signatera) ○ Replaced "Leukemia other than Chromosome Microarray" with "Leukemia other than Chromosome Microarray *Analysis*" ○ Updated list of examples of molecular tests for: ▪ Cancers of unknown primary site: Removed "PancraGen" ▪ Colorectal cancer: Added "ColoPrint®" and "ColDx" ▪ Melanoma: Removed "DecisionDx-UM) *Breast Cancer* • Replaced language indicating: ○ "[The listed] Gene Expression Tests are proven and medically necessary to make a treatment decision regarding adjuvant chemotherapy in females or	receptor positive or both); and ○ HER2 receptor negative; and ○ Individual and treating physician have had a discussion prior to testing regarding the potential results of the test and determined to use the results to guide a decision regarding extended adjuvant hormonal therapy Use of more than one predictive Gene Expression Test for the same tumor in an individual with breast cancer is unproven and not medically necessary due to insufficient evidence of efficacy. *Note: This does not apply to BCI testing. Gene Expression Tests for breast cancer are unproven and not medically necessary for all other indications, including ductal carcinoma in situ (DCIS), due to insufficient evidence of efficacy. Due to insufficient evidence of efficacy, gene expression profiling assays for breast cancer treatment other than those previously described as covered are unproven and not medically necessary, including but not limited to: • BluePrint (also referred to as "80-gene profile") • Breast Cancer Gene Expression Ratio (also known as Theros H/I) • DCISionRT • Oncotype DX DCIS • The 41-gene signature assay • The 76-gene "Rotterdam signature" assay **Thyroid Cancer** Molecular profiling of thyroid nodules with indeterminate cytology (e.g., Afirma GSC, ThyroSeq V3, ThyGeNEXT/ThyraMIR is proven and medically necessary when all the following criteria are met: • Follicular pathology on fine needle aspiration is indeterminate (Bethesda III/IV) • The results of the test will be used for making decisions about further

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Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for Mississippi Only) (continued)	Jun. 1, 2022	males with breast cancer in the [listed] situations" with "[the listed] Gene Expression Tests are proven and medically necessary to make a treatment decision regarding adjuvant chemotherapy in females or males with *invasive* breast cancer in the [listed] situations" ○ "Use of more than one Gene Expression Test for the same tumor in an individual with breast cancer is unproven and not medically necessary" with "use of more than one *predictive* Gene Expression Test for the same tumor in an individual with breast cancer is unproven and not medically necessary *(this does not apply to BCI testing)*" • Revised coverage criteria: ○ Replaced criterion requiring: ▪ "Lymph node negative or 1-3 positive axillary lymph nodes" with "lymph node negative or 1-3 positive *ipsilateral* axillary lymph nodes" ▪ "[Individual is] currently receiving adjuvant hormonal therapy for a breast cancer *diagnosed*	surgery Molecular profiling of confirmed thyroid cancer (except anaplastic thyroid cancer) with genes or gene panels (NTRK, ALK, MMR, MSI, RAS, HRAS, NRAS, RET/PTC1, RET/PTC3, PAX8/PPAR$_{\gamma}$) is unproven and not medically necessary for all indications due to insufficient evidence of efficacy. Use of more than one molecular profile test in an individual with a thyroid nodule is unproven and not medically necessary due to insufficient evidence of efficacy. **Hematological Cancer** Molecular profiling using chromosomal microarray Analysis (e.g., Oncoscan, Reveal SNP-Oncology, CGH or SNP array) is proven and medically necessary for individuals with acute leukemia. Use of a Next Generation Sequencing profile test to assess minimal residual disease (e.g., ClonoSeq, MyMRD) is proven and medically necessary when the following criteria are met: • Individual has acute myeloid leukemia (AML) or acute lymphoblastic leukemia (ALL) and testing is being performed within 3 months of completing a course of therapy and there is no clinical evidence of disease; or • Individual has multiple myeloma and testing is being performed within three months of an allogenic or autologous bone marrow transplant; and there is no clinical evidence of disease All other multigene, gene expression or microarray molecular profiling for hematological malignancies is unproven and not medically necessary due to insufficient evidence of efficacy. This includes, but is not limited to the following: • Assessment of minimal residual disease by Next Generation Sequencing for acute myeloid leukemia

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for Mississippi Only) (continued)	Jun. 1, 2022	*within the prior six years* when criteria are met" with "[Individual is] currently receiving adjuvant hormonal therapy for a breast cancer when criteria are met" ○ Removed criterion requiring the individual [is currently receiving adjuvant hormonal therapy and] has not had prior Gene Expression Testing • Revised list of unproven and not medically necessary gene expression profiling assays for breast cancer treatment; added "DCISionRT" *Thyroid Cancer* • Replaced language indicating "molecular profiling of thyroid nodules (e.g., Afirma GSC, ThyroSeq V3, ThyGeNEXT/ ThyraMIR, *or the gene and gene fusion panel BRAF V600E, RET fusions, NTRK, ALK, MMR,* MSI*RAS, HRAS, NRAS, RET/PTC1, RET/PTC3, PAX8/ PPARγ*) is proven and medically necessary when all of the [listed] criteria are met" with "molecular profiling of thyroid nodules *with indeterminate cytology* (e.g., Afirma GSC, ThyroSeq V3, ThyGeNEXT/	• Use of multi-gene Next Generation Sequencing gene panels for predicting prognosis **Lung Cancer** Multigene molecular profiling of metastatic non-small cell lung cancer is proven and medically necessary when all of the following criteria are met: • The panel selected has no more than 50 genes; and • No prior molecular profiling has been performed on the same tumor Liquid biopsy (circulating tumor cell free DNA) molecular profiling tests of non-small cell lung cancer are proven and medically necessary when the following criteria is met: • The test selected has no more than 50 genes; and • No prior molecular profiling has been performed on the same tumor; and • The individual is not medically fit for invasive biopsy; or • Non-small cell lung cancer has been pathologically confirmed, but there is insufficient material available for molecular testing; and • Individual and treating physician have had a discussion prior to testing regarding the potential results of the test and determined to use the results to guide therapy **Uveal Melanoma** Gene expression profile testing (e.g., DecisionDx-UM) is considered proven and medically necessary when used to assist with predicting disease severity and making treatment decisions in the following situations: • Individual has primary, localized uveal melanoma; and • There is no evidence of metastatic disease; and • Has not previously had DecisionDx-UM testing for current diagnosis Liquid biopsy (circulating tumor cell free DNA or circulating tumor cells) for any other tumor genetic analysis or tumor screening (e.g., Guardant360, ColoSentry, epi ProColon, OncoCEE CTC, Foundation One Liquid CDx) or multi-cancer early detection tests (e.g., Galleri) are unproven and not

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for Mississippi Only) (continued)	Jun. 1, 2022	ThyraMIR) is proven and medically necessary when all of the [listed] criteria are met" • Updated coverage criteria; replaced criterion requiring "follicular pathology on fine needle aspiration is indeterminate" with "follicular pathology on fine needle aspiration is indeterminate *(Bethesda III/IV)*" • Removed language indicating molecular profiling of thyroid nodules or thyroid cancers is unproven and not medically necessary for all other indications [not listed as proven in the policy] • Added language to indicate molecular profiling of confirmed thyroid cancer (except anaplastic thyroid cancer) with genes or gene panels (NTRK, ALK, MMR, MSI, RAS, HRAS, NRAS, RET/PTC1, RET/PTC3, PAX8/PPAR$_{\gamma}$) is unproven and not medically necessary for *all indications* due to insufficient evidence of efficacy *Hematological Cancer* • Updated list of examples of Next Generation Sequencing profile tests; added "MyMRD" *Uveal Melanoma* • Added language to indicate gene expression profile testing (e.g.,	medically necessary due to insufficient evidence of efficacy. Due to insufficient evidence of efficacy, molecular testing such as gene expression profiling, Chromosome Microarray Analysis and multi-gene cancer panels are unproven and not medically necessary for all other indications, including but not limited to: • Bladder Cancer (e.g., Decipher Bladder) (NCCN, Bladder 2021) • Cancers of unknown primary site (e.g., Response Dx, CancerTYPE ID, Rosetta Cancer Origin, ProOnc, SourceDX) • Pancreatic Cancer (e.g., PancraGen) • Colorectal Cancer (e.g., Oncotype DX®Colon Cancer Assay, Colorectal Cancer DSA™, Genefx Colon® [also known as ColDx], OncoDefender™-CRC, ColoPrint®, ColDx) • Gene panels of > 50 genes • Leukemia other than Chromosome Microarray Analysis (e.g., *FoundationOne®* Heme) • Melanoma (e.g., DecisionDx–Melanoma, DermTech PLA) • Multiple myeloma (e.g., MyPRS/MyPRS Plus) • Prostate cancer [e.g., Oncotype DX Prostate Cancer Assay, TMPRSS2 fusion gene, Prolaris Prostate Cancer Test, Decipher Prostate Cancer Classifier, ExoDX Prostate IntelliScore (EPI)] • Tumor-informed assays (Signatera) • Whole Exome Sequencing (WES) and Whole Genome Sequencing (WGS) of tumors

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for Mississippi Only) (continued)	Jun. 1, 2022	DecisionDx-UM) is considered proven and medically necessary when used to assist with predicting disease severity and making treatment decisions in the following situations: ○ Individual has primary, localized uveal melanoma; and ○ There is no evidence of metastatic disease; and ○ Has not previously had DecisionDx-UM testing for current diagnosis ● Removed language indicating molecular profiling using gene expression profiling, Chromosome Microarray, and multi-gene cancer panels is unproven and not medically necessary for uveal melanoma (e.g., DecisionDx-UM) **Definitions** ● Added definition of: ○ Predictive Molecular Markers ○ Prognostic Molecular Markers ● Updated definition of: ○ Comparative Genome Hybridization (CGH) ○ Chromosome Microarray Analysis **Supporting Information** ● Updated *Clinical Evidence* and *References* sections to reflect the most current information	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgery of the Elbow (for Mississippi Only)	Jun. 1, 2022	Coverage Rationale *Documentation Requirements* • Added language to indicate medical notes documenting the following are required, when applicable: ○ Upon request, we may require the specific diagnostic image(s) that show 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 of benefit to select the optimal images ▪ Diagnostic images must be labeled with: – The date taken – Applicable case number obtained at time of notification, or member's name and ID number on the image(s) ▪ Submission of diagnostic imaging is required via the external portal at uhcprovider.com/paan; faxes will not be accepted ○ Reports of all recent imaging studies and applicable diagnostic tests)	Surgery of the elbow is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures: • Arthroscopy, Diagnostic, +/- Synovial Biopsy, Elbow • Arthroscopy, Surgical, Elbow • Joint Replacement, Elbow • Removal or Revision, Arthroplasty, Elbow Click here to view the InterQual® criteria. **Documentation Requirements** Medical notes documenting the following, when applicable: • Upon request, we may require the specific diagnostic image(s) that show 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 of benefit to select the optimal images ○ Note: Diagnostic images must be labeled with: ▪ The date taken ▪ Applicable case number obtained at time of notification, or member's name and ID number on the image(s) ○ Submission of diagnostic imaging is required via the external portal at www.uhcprovider.com/paan; faxes will not be accepted • Reports of all recent imaging studies and applicable diagnostic tests) ○ Microbiological findings ○ Synovial fluid exam ○ Erythrocyte sedimentation rate (ESR) ○ C-reactive protein (CRP) • Condition requiring procedure • Pertinent physical examination of the relevant joint • Pain severity, circadian patterns of pain, location of pain, and details of functional disability(ies) interfering with activities of daily living (preparing meals, dressing, driving)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgery of the Elbow (for Mississippi Only) (continued)	Jun. 1, 2022	▪ Microbiological findings ▪ Synovial fluid exam ▪ Erythrocyte sedimentation rate (ESR) ▪ C-reactive protein (CRP) ○ Condition requiring procedure ○ Pertinent physical examination of the relevant joint ○ Pain severity, circadian patterns of pain, location of pain, and details of functional disability(ies) interfering with activities of daily living (preparing meals, dressing, driving) ○ Prior therapies/ treatments tried, failed, or contraindicated. Include the dates and reason for discontinuation ○ Date of previous failed surgery to the same joint, if applicable ○ Physician's treatment plan, including pre-op discussion ○ For revision surgery, also include: ▪ Details of complication ▪ Complete (staged) surgical plan	• Prior therapies/ treatments tried, failed, or contraindicated. Include the dates and reason for discontinuation • Date of previous failed surgery to the same joint, if applicable • Physician's treatment plan, including pre-op discussion • For revision surgery, also include: ○ Details of complication ○ Complete (staged) surgical plan
Surgery of the Hip (for Mississippi Only)	Jun. 1, 2022	Coverage Rationale • Revised language pertaining to medical necessity clinical coverage criteria: ○ Added reference to the	Surgery of the hip and surgical treatment for femoroacetabular impingement (FAI) syndrome is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures: • Arthroscopy, Diagnostic, +/- Synovial Biopsy, Hip

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgery of the Hip (for Mississippi Only) (continued)	Jun. 1, 2022	InterQual® 2022, Apr. 2022 Release, CP: Procedures, Arthroscopy, Surgical, Hip (Pediatric) ○ Replaced reference to the "InterQual® 2022, Apr. 2022 Release, CP: Procedures, Arthroscopy, Surgical, Hip *(includes FAI)*" with "InterQual® 2022, Apr. 2022 Release, CP: Procedures, Arthroscopy, Surgical, Hip" • Added language to indicate surgical treatment for femoroacetabular impingement (FAI) syndrome is unproven and not medically necessary in the presence of advanced osteoarthritis (i.e., Tönnis Grade 2 or 3) and/or severe cartilage damage (i.e., Outerbridge Grade III or IV) *Documentation Requirements* • Added language to indicate specific diagnostic images may be required when requested • Revised list of clinical information to be documented in the medical notes, when applicable; added: ○ Date of previous hip fracture fixation, if applicable ○ Prior therapies/treatments tried, failed, or contraindicated;	• Arthroscopy, Surgical, Hip • Arthroscopy, Surgical, Hip (Pediatric) • Arthrotomy, Hip • Hemiarthroplasty, Hip • Removal and Replacement, Total Joint Replacement (TJR), Hip • Total Joint Replacement (TJR), Hip Click here to view the InterQual® criteria. Surgical treatment for femoroacetabular impingement (FAI) syndrome is unproven and not medically necessary in the presence of advanced osteoarthritis (i.e., Tönnis Grade 2 or 3) and/or severe cartilage damage (i.e., Outerbridge Grade III or IV). **Documentation Requirements** Medical notes documenting the following, when applicable: • Upon request, we may require 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 of benefit 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 imaging report(s) • Condition requiring procedure • Severity of pain and details of functional disability(ies) interfering with activities of daily living (preparing meals, dressing, driving, walking) using a standard scale; such as the: ○ Western Ontario and McMaster Universities Arthritis Index (WOMAC) or ○ Hip Dysfunction and Osteoarthritis Outcome Score (HOOS)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgery of the Hip (for Mississippi Only) (continued)	Jun. 1, 2022	include the dates and reason for discontinuation ○ For femoroacetabular impingement (FAI) syndrome (CPT codes 29914, 29915, and 29916), include radiographic reports of presence and severity of cartilage damage using Tönnis or Outerbridge grading ● Removed list of examples of therapies tried and failed ● Added list of examples of co-morbid medical conditions: cardiovascular diseases, hypertension, diabetes, cancer, pulmonary diseases, neurodegenerative diseases **Definitions** ● Added definition of: ○ Outerbridge Grades ○ Tönnis Classification of Osteoarthritis by Radiographic Changes **Applicable Codes** ● Removed CPT code 27122 **Supporting Information** ● Added *Clinical Evidence* section ● Updated *References* section to reflect the most current information	● Physician's treatment plan, including pre-op discussion ● Pertinent physical examination of the relevant joint ● Co-morbid medical conditions (cardiovascular diseases, hypertension, diabetes, cancer, pulmonary diseases, neurodegenerative diseases) ● Prior therapies/treatments tried, failed, or contraindicated; include the dates and reason for discontinuation ● Date of previous hip fracture fixation, if applicable ● If the location is being requested as an inpatient stay, provide medical notes to support at least one of the following: ○ Surgery is bilateral ○ Member has significant co-morbidities; include the list of comorbidities and current treatment ▪ Member does not have appropriate resources to support post-operative care after an outpatient procedure; include the barriers to care as an outpatient In addition to the above, for femoroacetabular impingement (FAI) syndrome (29914 29915 29916), also include radiographic reports of presence and severity of cartilage damage using Tönnis or Outerbridge grading.
Surgery of the Knee (for Mississippi Only)	Jun. 1, 2022	**Coverage Rationale** ● Revised language pertaining to medical necessity clinical coverage	Surgery of the knee is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures:

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgery of the Knee (for Mississippi Only) (continued)	Jun. 1, 2022	criteria; added reference to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Arthroscopy or Arthroscopically Assisted Surgery, Knee (Pediatric) *Documentation Requirements* • Updated list of report findings for recent imaging studies and appliable diagnostic tests; added "documented closure of skeletal plates (pediatric patients)" Applicable Codes • Removed CPT codes 29850, 29851, 29855, and 29856	• Arthroscopy or Arthroscopically Assisted Surgery, Knee • Arthroscopy, Diagnostic, +/- Synovial Biopsy, Knee • Arthrotomy, Knee • Removal and Replacement, Total Joint Replacement (TJR), Knee • Total Joint Replacement (TJR), Knee • Unicondylar or Patellofemoral Knee Replacement Click here to view the InterQual® criteria **Documentation Requirements** Medical notes documenting the following, when applicable: • Upon request, we may require the specific diagnostic image(s) that show 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 of benefit to select the optimal images ○ 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 • Reports of all recent imaging studies and applicable diagnostic tests, including: ○ Microbiological findings ○ Synovial exam ○ Erythrocyte sedimentation rate (ESR) ○ C-reactive protein (CRP) ○ Documented closure of skeletal plates (pediatric patients) • Condition requiring procedure • Severity of pain and details of functional disability(ies) interfering with activities of daily living (preparing meals, dressing, driving, walking) using a standard scale, such as the *Western Ontario and McMaster Universities Arthritis Index (WOMAC) or the Knee injury and Osteoarthritis Outcome*

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Surgery of the Knee (for Mississippi Only) (continued)	Jun. 1, 2022		*Score (KOOS)*
			• Pertinent physical examination of the relevant joint
			• Consideration of arthroscopic approach
			• Co-morbid medical condition(s)
			  ○ Prior therapies/treatments tried, failed, or contraindicated; include the dates and reason for discontinuation
			• Date of failed previous surgery to the same joint (proximal tibial or distal femoral osteotomy, if applicable)
			• Physician's treatment plan including pre-op discussion
			• For revision surgery, also include:
			  ○ Details of complication
			  ○ Complete (staged) surgical plan
			• If the location is being requested as an inpatient stay, provide medical notes to support the following, when applicable:
			  ○ Surgery is bilateral
			  ○ Member has significant co-morbidities; include the list of comorbidities and current treatment
			  ○ Member does not have appropriate resources to support post-operative care after an outpatient procedure; include the barriers to care as an outpatient

Surgery of the Shoulder (for Mississippi Only)	Jun. 1, 2022	Coverage Rationale
		• Revised language pertaining to medical necessity clinical coverage criteria; added reference to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Removal and Replacement, Total Joint Replacement (TJR), Shoulder
		Documentation Requirements
		• Added language to indicate specific diagnostic images may be required when requested
		• Revised list of clinical information
			Surgery of the shoulder is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the:
			• InterQual® 2022, Apr. 2022 Release, CP: Procedures:
			  ○ Arthroscopy or Arthroscopically Assisted Surgery, Shoulder
			  ○ Arthroscopy or Arthroscopically Assisted Surgery, Shoulder (Adolescent)
			  ○ Arthroscopy, Diagnostic, +/- Synovial Biopsy, Shoulder
			  ○ Arthrotomy, Shoulder
			  ○ Joint Replacement, Shoulder
			  ○ Removal and Replacement, Total Joint Replacement (TJR), Shoulder
			• InterQual® Client Defined 2022, CP: Procedures, Arthroplasty, Removal or Revision, Shoulder (Custom) - UHG
			
			Click here to view the InterQual® criteria.

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Surgery of the Shoulder (for Mississippi Only) (continued)	Jun. 1, 2022	to be documented in the medical notes, when applicable: ○ Added: ▪ Reports of all recent imaging studies and applicable diagnostic tests, including when applicable: – Microbiological findings – Synovial fluid cytology – Erythrocyte sedimentation rate (ESR) – C-reactive protein (CRP) ▪ Feasibility of arthroscopic approach ▪ Member has the ability to participate in post-surgical rehabilitation ▪ For revision surgery, also include: – Details of complication – Complete (staged) surgical plan ▪ If the location is being requested as an inpatient stay, provide medical notes to support at least one of the following: – Surgery is bilateral	**Documentation Requirements** Medical notes documenting the following, when applicable: • Pertinent physical examination of the relevant joint • Severity of pain as documented on a validated pain scale • Functional disability(ies) as documented on a validated functional disability scale or described as interfering with activities of daily living (preparing meals, dressing, driving, walking) • Upon request, we may require the specific diagnostic image(s) that documents the severity of joint disease using a validated scale (e.g., Walch classification of primary glenohumeral osteoarthritis) and 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 of benefit 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 • Advanced joint disease using a validated scale (e.g., Walch classification of primary glenohumeral osteoarthritis) • Reports of all recent imaging studies and applicable diagnostic tests, including when applicable: ○ Microbiological findings ○ Synovial fluid cytology ○ Erythrocyte sedimentation rate (ESR) ○ C-reactive protein (CRP) • Condition requiring procedure, including relevant past history with dates • Physician's treatment plan including pre-op discussion • Feasibility of arthroscopic approach • Co-morbid medical condition(s) • Therapies tried (including dates) and failed as documented by a lack of clinically significant improvement between at least two measurements

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Surgery of the Shoulder (for Mississippi Only) (continued)	Jun. 1, 2022	– Member has significant co-morbidities; include the list of comorbidities and current treatment – Member does not have appropriate resources to support post-operative care after an outpatient procedure; include the barriers to care as an outpatient ○ Removed "diagnostic image(s) report(s)" ○ Replaced "condition requiring procedure" with "condition requiring procedure, *including relevant past history with dates*" **Applicable Codes** • Removed CPT code 23412	concurrent to the therapy, on validated pain or functional disability scale(s) or quantifiable symptoms; these therapies could include: ○ Nonoperative Therapy (i.e., orthotics, medications/injections, physical therapy, other pain management procedures, etc.) ○ Surgery • Member has the ability to participate in post-surgical rehabilitation • For revision surgery, also include: ○ Details of complication ○ Complete (staged) surgical plan • If the location is being requested as an inpatient stay, provide medical notes to support at least one of the following: ○ Surgery is bilateral ○ Member has significant co-morbidities; include the list of comorbidities and current treatment ○ Member does not have appropriate resources to support post-operative care after an outpatient procedure; include the barriers to care as an outpatient
Surgical Treatment for Spine Pain (for Mississippi Only)	Jun. 1, 2022	**Coverage Rationale** • Replaced language indicating "a surgical spine procedure that is performed to alleviate symptoms or prevent clinical deterioration of a congenital or idiopathic deformity or bone disease is proven and medically necessary if not addressed in the [InterQual® criteria listed in the policy]" with "a surgical	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® 2022, Apr.2022 Release, CP: Procedures: • Decompression +/- Fusion, Cervical • Decompression +/- Fusion, Lumbar • Decompression +/- Fusion, Thoracic • Fusion, Cervical Spine • Fusion, Lumbar Spine • Fusion, Thoracic Spine

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical Treatment for Spine Pain (for Mississippi Only) (continued)	Jun. 1, 2022	spine procedure that is performed to alleviate symptoms or prevent clinical deterioration of a congenital or idiopathic deformity or bone disease *other than scoliosis* is proven and medically necessary if not addressed in the [InterQual® criteria listed in the policy]" • Added language to indicate: ○ Interspinous process fusion devices are 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 ○ 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 is unproven and not medically necessary • Removed language indicating interlaminar lumbar instrumented fusion (ILIF) utilizing an interspinous process fusion device is unproven	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®) • 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

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Surgical Treatment for Spine Pain (for Mississippi Only) (continued)	Jun. 1, 2022	and not medically necessary Documentation Requirements • Added language to indicate specific diagnostic images may be required when requested • Revised list of clinical information to be documented in the medical notes, when applicable; added: ○ Smoking history/status, including date of last smoking cessation ○ Degree and progression of curvature (for scoliosis) ○ Quantification of relevant muscle strength ○ Results of biopsy(ies) ○ Results of bone aspirate ○ List of conditions included in diagnostic image reports (when applicable): ▪ Disc herniation ▪ Discitis ▪ Epidural abscess ▪ Nerve root compression ▪ Quantification of subluxation, translation by flexion, angulation when appropriate ▪ Segment (s) instability ▪ Spinal cord compression Definitions • Added definition of “Staged Multi-Session”	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 (for Mississippi Only)*. **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 • 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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical Treatment for Spine Pain (for Mississippi Only) (continued)	Jun. 1, 2022	Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information	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.]
Temporomandibular Joint Disorders (for Mississippi Only)	Jun. 1, 2022	Coverage Rationale • Revised language pertaining to medical necessity clinical coverage criteria:	The following services are proven and medically necessary for treating disorders of the temporomandibular joint (TMJ): • Arthrocentesis • Arthroscopy • Intra-articular Injections of corticosteroids

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Temporomandibular Joint Disorders (for Mississippi Only) (continued)	Jun. 1, 2022	○ Added reference to the InterQual® Client Defined 2022, CP: Procedures, Arthroplasty, Temporomandibular Joint (TMJ) (Custom) - UHG ○ Removed reference to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Arthroplasty, Temporomandibular Joint (TMJ) ● Added language to indicate multiple occlusal splints (i.e., daytime and nighttime splints, maxillary and mandibular splints) are unproven and not medically necessary for treating disorders of the temporomandibular joint (TMJ) ● Added reference link to the Medical Benefit Drug Policy titled *Botulinum Toxins A and B* for information regarding botulinum toxin injections for temporomandibular joint disorders **Supporting Information** ● Updated *Clinical Evidence* and *References* sections to reflect the most current information	● Trigger point injections ● Physical therapy ● Occlusal splints (stabilization and repositioning splints) ● Partial or total joint replacement For medical necessity clinical coverage criteria for the following services, refer to the: ● InterQual® 2022, Apr. 2022 Release, CP: Procedures: ○ Arthroscopy, Temporomandibular Joint (TMJ) ○ Discectomy, Temporomandibular Joint (TMJ) ○ Reconstruction, Temporomandibular Joint (TMJ) ● InterQual® Client Defined 2022, CP: Procedures, Arthroplasty, Temporomandibular Joint (TMJ) (Custom) – UHG Click here to view the InterQual® criteria. The following services are unproven and not medically necessary for treating disorders of the temporomandibular joint (TMJ) due to insufficient evidence of efficacy (this list is not all-inclusive): ● Biofeedback ● Craniosacral manipulation/therapy ● Passive rehabilitation therapy ● Low-load prolonged-duration stretch (LLPS) devices ● Multiple occlusal splints (i.e., daytime, and nighttime splints; maxillary and mandibular splints) For information regarding intra-articular injections of sodium hyaluronate for temporomandibular joint disorders, refer to the Medical Benefit Drug Policy titled *Sodium Hyaluronate*. For information regarding botulinum toxin injections for temporomandibular joint disorders, refer to the Medical Benefit Drug Policy titled *Botulinum Toxins A and B.*

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Vagus and External Trigeminal Nerve Stimulation (for Mississippi Only)	Jun. 1, 2022	**Coverage Rationale**
		• Replaced language indicating "implantable vagus nerve stimulators are proven and medically necessary for treating *focal or partial seizure disorder or generalized seizure disorder*" with "implantable vagus nerve stimulators are proven and medically necessary for treating *epilepsy in certain circumstances*"
		• Revised list of conditions for which implantable vagus nerve stimulators are unproven and not medically necessary; added:
		  ○ Autoimmune disorders
		  ○ Musculoskeletal disorders
		  ○ Upper limb impairment related to stroke
		• Removed language indicating vagus nerve stimulation implants that allow detection and stimulation of increased heart rate (e.g., AspireSR™ Model 106, SenTiva™ Model 1000) are unproven and not medically necessary for treating epilepsy
		Definitions
		• Removed definition of "Shared Decision Making"
		Applicable Codes
		• Added CPT/HCPCS codes 61886, K1016, K1017, and K1020
			Conventional implantable vagus nerve stimulators, also known as non-responsive or open loop stimulators are proven and medically necessary for treating epilepsy in individuals with all of the following:
			• Medically refractory epileptic seizures with failure of two or more trials of single or combination antiepileptic drug therapy or intolerable side effects of antiepileptic drug therapy; and
			• The individual is not a candidate for epilepsy surgery, has failed epilepsy surgery, or refuses epilepsy surgery after Shared Decision Making discussion; and
			• No history of left or bilateral cervical vagotomy. The U.S. Food and Drug Administration (FDA) identifies a history of left or bilateral cervical vagotomy as a contraindication to vagus nerve stimulation.
			
			Implantable vagus nerve stimulators are unproven and not medically necessary for treating all other conditions due to insufficient evidence of efficacy. These conditions include but are not limited to:
			• Alzheimer's disease
			• Anxiety disorder
			• Autism spectrum disorder
			• Autoimmune disorders
			• Back and neck pain
			• Bipolar disorder
			• Bulimia
			• Cerebral palsy
			• Chronic pain syndrome
			• Cluster headaches
			• Depression
			• Fibromyalgia
			• Heart failure
			• Migraines
			• Morbid obesity
			• Musculoskeletal disorders
			• Narcolepsy

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Vagus and External Trigeminal Nerve Stimulation (for Mississippi Only) (continued)	Jun. 1, 2022	**Supporting Information**
		• Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
			• Obsessive-compulsive disorder
			• Paralysis agitans
			• Sleep disorders
			• Tourette's syndrome
			• Upper limb impairment related to stroke
			
			The following devices are unproven and not medically necessary due to insufficient evidence of efficacy:
			• Responsive vagus nerve stimulation implants (closed loop technology) that allow detection and stimulation based upon increased heart rate (e.g., AspireSR™ Model 106, SenTiva™ Model 1000) for treating epilepsy
			• Transcutaneous (non-implantable) vagus nerve stimulation (e.g., gammaCore® for headaches) for preventing or treating all indications
			• External or transcutaneous (non-implantable) trigeminal nerve stimulation devices (e.g., Monarch® eTNS System, Cefaly®) for preventing or treating all conditions including but not limited to:
			  ○ Attention deficit hyperactivity disorder (ADHD)
			  ○ Depression
			  ○ Epilepsy
			  ○ Headache
			Note: For vagus nerve blocking for the treatment of obesity, refer to the Medical Policy titled *Bariatric Surgery (for Mississippi Only)*.

Whole Exome and Whole Genome Sequencing (for Mississippi Only)	Jun. 1, 2022	**Coverage Rationale**
		• Added language to indicate this policy applies to genetic testing in an outpatient setting or upon discharge from an inpatient setting
		• Revised coverage criteria for Whole Exome Sequencing (WES):
		  ○ Replaced criterion requiring:
		  ▪ "WES is ordered by a board-certified medical geneticist, neonatologist,
			Whole Exome Sequencing (WES)
			Whole Exome Sequencing (WES) is proven and medically necessary for the following:
			• Diagnosing or evaluating a genetic disorder when the results are expected to directly influence medical management and clinical outcomes and all of the following criteria are met:
			  ○ Clinical presentation is nonspecific and does not fit a well-defined syndrome for which a specific or targeted gene test is available. If a specific genetic syndrome is suspected, a single gene or targeted gene panel should be performed prior to determining if WES is necessary; and

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Whole Exome and Whole Genome Sequencing (for Mississippi Only) (continued)	Jun. 1, 2022	neurologist, or developmental *and behavioral* pediatrician" with "WES is ordered by a board-certified medical geneticist, neonatologist, neurologist, or developmental pediatrician" ▪ "*There is a clinical diagnosis of a genetic condition that can be caused by multiple genes and* WES is a more practical approach to identifying the underlying genetic cause than are individual tests of multiple genes" with "WES is a more practical approach to identifying the underlying genetic cause than are individual tests of multiple genes" ○ Removed criterion requiring "there is likely a genetic disorder and multiple targeted gene tests have failed to identify the underlying cause" **Supporting Information** ● Updated *Clinical Evidence* and *References* sections to reflect the most current information	○ WES is ordered by a board-certified medical geneticist, neonatologist, neurologist, or developmental pediatrician; and ○ One of the following: ▪ Clinical and/or family history strongly suggest a genetic cause for which a specific clinical diagnosis cannot be made with any clinically available targeted genetic tests; or ▪ WES is a more practical approach to identifying the underlying genetic cause than are individual tests of multiple genes ● Comparator (e.g., parents or siblings) WES for evaluating a genetic disorder when the above criteria have been met and WES is performed concurrently or has been previously performed on the individual Due to insufficient evidence of efficacy, WES is unproven and not medically necessary for all other indications, including but not limited to the following: ● Evaluation of fetal demise ● Molecular profiling of tumors for the diagnosis, prognosis or management of cancer ● Preimplantation Genetic Testing (PGT) in embryos ● Prenatal genetic diagnosis or screening ● Screening and evaluating disorders in individuals when the above criteria are not met **Whole Genome Sequencing (WGS)** Whole Genome Sequencing (WGS) is not medically necessary for evaluating any genetic disorder due to the availability of clinically equivalent diagnostic tests. *This policy applies to genetic testing in an outpatient setting or upon discharge from an inpatient setting.

Medical Benefit Drug Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Rituximab (Riabni™, Rituxan®, Ruxience®, & Truxima®)	Jun. 1, 2022	**Applicable Codes** ● Revised description for HCPCS code Q5115
Zolgensma® (Onasemnogene Abeparvovec-Xioi)	Jun. 1, 2022	**Applicable Codes** ● Added ICD-10 diagnosis code G12.8 **Supporting Information** ● Updated *References* section to reflect the most current information

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Actemra® (Tocilizumab) Injection for Intravenous Infusion	Jun. 1, 2022	**Coverage Rationale** ● Added language to indicate: ○ Actemra is proven and medically necessary for the treatment of giant cell arteritis when all of the following criteria are met: *Initial Therapy* ▪ Diagnosis of giant cell arteritis (GCA) ▪ Actemra is dosed according to U.S. Food and Drug Administration (FDA) labeled dosing for giant cell arteritis ▪ Patient is not receiving Actemra in combination with either of the following: – Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira	Refer to the Medical Benefit Drug Policy titled *Oncology Medication Clinical Coverage* for updated information based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®) for oncology indications. This policy refers only to Actemra (tocilizumab) injection for intravenous infusion. Actemra (tocilizumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit. Actemra is proven and medically necessary for the treatment of: **Polyarticular Juvenile Idiopathic Arthritis** Actemra 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 polyarticular juvenile idiopathic arthritis (PJIA); and ○ Actemra is dosed according to U.S. Food and Drug Administration (FDA) labeled dosing for polyarticular juvenile idiopathic arthritis; and ○ Patient is not receiving Actemra in combination with either of the following: ▪ Biologic disease-modifying antirheumatic drug (DMARD) *[e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]*

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Actemra® (Tocilizumab) Injection for Intravenous Infusion (continued)	Jun. 1, 2022	(adalimumab), Cimzia (certolizumab), Simponi (golimumab)] – Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] ▪ Prescribed by or in consultation with a rheumatologist ▪ Initial authorization is for no more than 12 months *Continuation of Therapy* ▪ Patient has previously received Actemra injection for intravenous infusion ▪ Documentation of positive clinical response to Actemra ▪ Actemra is dosed according to FDA labeled dosing for giant cell arteritis ▪ Patient is not receiving Actemra 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 Actemra injection for intravenous infusion; and ○ Documentation of positive clinical response to Actemra; and ○ Actemra is dosed according to FDA labeled dosing for polyarticular juvenile idiopathic arthritis; and ○ Patient is not receiving Actemra 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** Actemra is proven and medically necessary for the treatment of 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 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

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Actemra® (Tocilizumab) Injection for Intravenous Infusion (continued)	Jun. 1, 2022	– Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] ▪ Authorization is for no more than 12 months **Applicable Codes** • Added ICD-10 diagnosis codes M31.5 and M31.6 **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	synthetic DMARD FDA-approved for the treatment of rheumatoid arthritis [e.g., Humira (adalimumab), Simponi (golimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)]; or ▪ Patient is currently on Actemra and ○ Actemra is dosed according to FDA labeled dosing for rheumatoid arthritis; and ○ Patient is not receiving Actemra 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 ○ 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 Actemra injection for intravenous infusion; and ○ Documentation of positive clinical response; and ○ Actemra is dosed according to FDA labeled dosing for rheumatoid arthritis; and ○ Patient is not receiving Actemra 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 **Systemic Juvenile Idiopathic Arthritis** Actemra is proven and medically necessary for the treatment of systemic

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Actemra® (Tocilizumab) Injection for Intravenous Infusion (continued)	Jun. 1, 2022		juvenile idiopathic arthritis when all of the following criteria are met: ● For initial therapy, all of the following: ○ Diagnosis of systemic juvenile idiopathic arthritis (SJIA); and ○ Actemra is dosed according to FDA labeled dosing for systemic juvenile idiopathic arthritis; and ○ Patient is not receiving Actemra 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 ○ 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 Actemra injection for intravenous infusion; and ○ Documentation of positive clinical response; and ○ Actemra is dosed according to FDA labeled dosing for systemic juvenile idiopathic arthritis; and ○ Patient is not receiving Actemra in combination with either of the following:1 ▪ 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 **Giant Cell Arteritis** Actemra is proven and medically necessary for the treatment of giant cell arteritis when all of the following criteria are met: ● For initial therapy, all of the following:

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Actemra® (Tocilizumab) Injection for Intravenous Infusion (continued)	Jun. 1, 2022		○ Diagnosis of giant cell arteritis (GCA) and ○ Actemra is dosed according to U.S. Food and Drug Administration (FDA) labeled dosing for giant cell arteritis; and ○ Patient is not receiving Actemra 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 Actemra injection for intravenous infusion; and ○ Documentation of positive clinical response to Actemra; and ○ Actemra is dosed according to FDA labeled dosing for giant cell arteritis; and ○ Patient is not receiving Actemra 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 **Cytokine Release Syndrome** Actemra is proven and medically necessary for the treatment of cytokine release syndrome when all of the following criteria are met: ● For initial therapy, all of the following:

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Actemra® (Tocilizumab) Injection for Intravenous Infusion (continued)	Jun. 1, 2022		○ Diagnosis of cytokine release syndrome (CRS); and ○ Patient has received treatment with one of the following: ▪ Chimeric antigen receptor (CAR) T cell therapy [e.g., Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel)] ▪ Blincyto (blinatumomab) and ○ Actemra is dosed according to FDA labeled dosing for CRS; and ○ Initial authorization is for no more than 4 doses ● For continuation of therapy, all of the following: ○ Documentation of positive clinical response; and ○ Patient continues to experience signs and symptoms of CRS; and ○ Actemra is dosed according to FDA labeled dosing for CRS; and ○ Authorization is for no more than 4 doses **Acute Graft-Versus-Host Disease (GVHD)** Actemra is proven and medically necessary for the treatment of acute graft-versus-host disease (GVHD) when all of the following criteria are met: ● For initial therapy, all of the following: ○ Diagnosis of steroid refractory acute GVHD; and ○ One of the following: ▪ Patient is receiving Actemra in combination with systemic corticosteroids ▪ Patient is intolerant to systemic corticosteroid therapy and ○ Initial authorization is for no more than 4 doses ● For continuation of therapy, all of the following: ○ Documentation of positive clinical response; and ○ Patient continues to experience acute GVHD; and ○ One of the following: ▪ Patient is receiving Actemra in combination with systemic corticosteroids ▪ Patient is intolerant to systemic corticosteroid therapy and

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Actemra® (Tocilizumab) Injection for Intravenous Infusion (continued)	Jun. 1, 2022		○ Authorization is for no more than 4 doses **Immune Checkpoint Inhibitor-Related Toxicities** Actemra is proven and medically necessary for the treatment of 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 immunotherapy-related inflammatory arthritis; and ● No symptom improvement after 7 days of starting high-dose corticosteroids; and ● History of failure, contraindication, or intolerance to infliximab (e.g., Inflectra, Remicade); and ● One of the following: ○ Patient is receiving Actemra in combination with systemic corticosteroids ○ Patient is intolerant to systemic corticosteroid therapy and ● Authorization is for no more than 4 doses
Denosumab (Prolia® & Xgeva®)	Jun. 1, 2022	Coverage Rationale *Prolia (Denosumab)* ● Revised coverage guidelines; replaced reference to InterQual® criteria with language indicating: ○ Prolia is proven and medically necessary for the treatment of postmenopausal patients with osteoporosis or to increase bone mass in patients with osteoporosis at high risk for fracture, when all of the following criteria are met: Initial Therapy ▪ Diagnosis of osteoporosis;	This policy refers to the following denosumab products: ● Prolia ● Xgeva **Prolia (Denosumab)** Prolia is proven and medically necessary for the treatment of postmenopausal patients with osteoporosis, or to increase bone mass in patients with osteoporosis at high risk for fracture, who meet all of the following criteria: ● Initial Therapy ○ Diagnosis of osteoporosis; and ○ One of the following: ▪ BMD T-score ≤-2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); or

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Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	and ▪ One of the following: – BMD T-score ≤-2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); or – History of one of the following resulting from minimal trauma: ● Vertebral compression fracture ● Fracture of the hip ● Fracture of the distal radius ● Fracture of the pelvis ● Fracture of the proximal humerus or – Both of the following: ● BMD T-score between -1 and -2.5 (BMD T-score greater than-2.5 and less than or equal to -1) based on BMD measurements	▪ History of one of the following resulting from minimal trauma: – Vertebral compression fracture – Fracture of the hip – Fracture of the distal radius – Fracture of the pelvis – Fracture of the proximal humerus or ▪ Both of the following: – BMD T-score between -1 and -2.5 (BMD T-score greater than-2.5 and less than or equal to -1) based on BMD measurements from lumber spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) – One of the following: ● FRAX 10-year fracture probabilities: major osteoporotic fracture at 20% or more ● FRAX 10-year fracture probabilities: hip fracture at 3% or more and ○ One of the following: ▪ Both of the following: – History of intolerance to oral bisphosphonate therapy; and – History of failure, contraindication, or intolerance to intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid) or ▪ History of failure or contraindication to oral bisphosphonate therapy; or ▪ History of failure, contraindication, or intolerance to IV bisphosphonate therapy and ○ Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; and

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Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	from lumber spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) • One of the following: ○ FRAX 10-year fracture probabilities: major osteoporotic fracture at 20% or more ○ FRAX 10-year fracture probabilities: hip fracture at 3% or more and ▪ One of the following: – Both of the following: • History of intolerance to oral bisphosphonate therapy; and • History of failure, contraindication, or intolerance to intravenous bisphosphonate	○ Authorization is for no more than 12 months. • Reauthorization/Continuation of Care Criteria For patients currently on Prolia for the treatment of postmenopausal patients with osteoporosis, or to increase bone mass in patients with osteoporosis at high risk for fracture, continued use will be approved based on the following criteria: ○ Provider attests to a positive clinical response; and ○ Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; and ○ Authorization is for no more than 12 months. Prolia is proven and medically necessary to increase bone mass in patients at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer in patients who meet all of the following criteria: • Initial Therapy ○ Diagnosis of non-metastatic prostate cancer; and ○ Patient is receiving androgen deprivation therapy; and ○ One of the following: ▪ Both of the following: – History of intolerance to oral bisphosphonate therapy; and – History of failure, contraindication, or intolerance to intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid) or ▪ History of failure or contraindication to oral bisphosphonate therapy; or ▪ History of failure, contraindication, or intolerance to IV bisphosphonate therapy and ○ Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; and

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Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	therapy (e.g., pamidronate, zoledronic acid) or – History of failure or contraindication to oral bisphosphonate therapy; or – History of failure, contraindication, or intolerance to IV bisphosphonate therapy and ▪ Prolia dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling: maximum dosing of 60 mg every 6 months; and ▪ Authorization is for no more than 12 months Reauthorization/Continuation of Care Criteria ▪ Treatment of postmenopausal patients with osteoporosis or to increase bone mass in patients with osteoporosis at high risk for fracture, continued use of Prolia will be approved based on the	○ Authorization is for no more than 12 months. • Reauthorization/Continuation of Care Criteria For patients currently on Prolia to increase bone mass in patients at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer, continued use will be approved based on the following criteria: ○ Patient is receiving androgen deprivation therapy; and ○ Provider attests to a positive clinical response; and ○ Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; and ○ Authorization is for no more than 12 months. Prolia is proven and medically necessary to treat patients at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer in patients who meet all of the following criteria: • Initial Therapy ○ Diagnosis of breast cancer; and ○ Patient is receiving aromatase inhibitor therapy; and ○ One of the following: ▪ Both of the following: – History of intolerance to oral bisphosphonate therapy; and – History of failure, contraindication, or intolerance to intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid) or ▪ History of failure or contraindication to oral bisphosphonate therapy; or ▪ History of failure, contraindication, or intolerance to IV bisphosphonate therapy and ○ Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6

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Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	following criteria: – Provider attests to a positive clinical response; and – Prolia dosing is in accordance with the FDA approved labeling: maximum dosing of 60 mg every 6 months; and – Authorization is for no more than 12 months ○ Prolia is proven and medically necessary to increase bone mass in patients at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer when all of the following criteria are met: Initial Therapy ▪ Diagnosis of non-metastatic prostate cancer; and ▪ Patient is receiving androgen deprivation therapy; and ▪ One of the following: – Both of the following: ● History of intolerance to oral bisphosphonate therapy; and ● History of failure,	months; and ○ Authorization is for no more than 12 months. ● Reauthorization/Continuation of Care Criteria For patients currently on Prolia to treat patients at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer, continued use will be approved based on the following criteria: ○ Patient is receiving aromatase inhibitor therapy; and ○ Provider attests to a positive clinical response; and ○ Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; and ○ Authorization is for no more than 12 months. Prolia is proven and medically necessary to treat glucocorticoid-induced osteoporosis in patients at high risk for fracture when all of the following criteria are met: ● Initial Therapy ○ Diagnosis of glucocorticoid-induced osteoporosis; and ○ History of prednisone or its equivalent at a dose ≥ 5 mg/day for ≥ 3 months; and ○ One of the following: ▪ BMD T-score ≤-2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); or ▪ History of one of the following resulting from minimal trauma: – Vertebral compression fracture – Fracture of the hip – Fracture of the distal radius – Fracture of the pelvis – Fracture of the proximal humerus or ▪ One of the following: – FRAX 10-year fracture probabilities: major osteoporotic

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Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	contraindication, or intolerance to intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid) or – History of failure or contraindication to oral bisphosphonate therapy; or – History of failure, contraindication, or intolerance to IV bisphosphonate therapy and ▪ Prolia dosing is in accordance with the FDA approved labeling: maximum dosing of 60 mg every 6 months; and ▪ Authorization is for no more than 12 months Reauthorization/Continuation of Care Criteria ▪ To increase bone mass in patients at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer, continued use of Prolia will	fracture at 20% or more – FRAX 10-year fracture probabilities: hip fracture at 3% or more and ○ One of the following: ▪ Both of the following: – History of intolerance to oral bisphosphonate therapy; and – History of failure, contraindication, or intolerance to intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid) or ▪ History of failure or contraindication to oral bisphosphonate therapy; or ▪ History of failure, contraindication, or intolerance to IV bisphosphonate therapy and ○ Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; and ○ Authorization is for no more than 12 months. • Reauthorization/Continuation of Care Criteria For patients currently on Prolia to treat glucocorticoid-induced osteoporosis in patients at high risk for fracture, continued use will be approved based on the following criteria: ○ Provider attests to a positive clinical response; and ○ Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; and ○ Authorization is for no more than 12 months. **Xgeva (Denosumab)** Xgeva is proven and medically necessary for the prevention of skeletal-related events in patients with multiple myeloma and with bone metastases from solid tumors when all of the following criteria are met:

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Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	be approved based on the following criteria: – Patient is receiving androgen deprivation therapy; and – Provider attests to a positive clinical response; and – Prolia dosing is in accordance with the FDA approved labeling: maximum dosing of 60 mg every 6 months; and – Authorization is for no more than 12 months ○ Prolia is proven and medically necessary to treat patients at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer when all of the following criteria are met: Initial Therapy ▪ Diagnosis of breast cancer; and ▪ Patient is receiving aromatase inhibitor therapy; and ▪ One of the following: – Both of the following: ● History of intolerance to oral	● Initial Therapy ○ Patient is one of the following: ▪ Patient is ≥ 18 years of age ▪ Patient is a skeletally mature adolescent as defined by having at least 1 mature long bone (e.g., closed epiphyseal growth plate of the humerus) and ○ One of the following: ▪ Diagnosis of multiple myeloma ▪ Presence of metastatic disease secondary to a solid tumor (e.g., bladder, breast, kidney, lung, ovarian, thyroid, etc.) and ○ Individual has an expected survival of 3 months or greater; and ○ Refractory (within the past 30 days), contraindication (including renal insufficiency), or intolerance to treatment with intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid); and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ○ Authorization is for no more than 12 months ● Reauthorization/Continuation of Care Criteria For patients currently on Xgeva for the prevention of skeletal-related events in patients with multiple myeloma and with bone metastases from solid tumors, continued use will be approved based on the following criteria: ○ Individual has an expected survival of 3 months or greater; and ○ Provider attests to a positive clinical response; and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ○ Authorization is for no more than 12 months Xgeva is proven and medically necessary for the treatment of giant cell tumor of the bone when all of the following criteria are met:

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Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	bisphosphonate therapy; and ● History of failure, contraindication, or intolerance to intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid) or – History of failure or contraindication to oral bisphosphonate therapy; or – History of failure, contraindication, or intolerance to IV bisphosphonate therapy and ▪ Prolia dosing is in accordance with the FDA approved labeling: maximum dosing of 60 mg every 6 months; and ▪ Authorization is for no more than 12 months Reauthorization/Continuation of Care Criteria ▪ To treat patients at high risk for fracture receiving adjuvant aromatase	● Initial Therapy ○ Patient is one of the following: ▪ Patient is ≥ 18 years of age ▪ Patient is a skeletally mature adolescent as defined by having at least 1 mature long bone (e.g., closed epiphyseal growth plate of the humerus) and ○ Diagnosis of localized or metastatic giant cell tumor of the bone; and ○ Disease is one of the following: ▪ Unresectable ▪ Surgical resection is likely to result in severe morbidity and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks (additional 120 mg doses allowed on Day 8 and 15 in the first month of therapy); and ○ Authorization is for no more than 12 months ● Reauthorization/Continuation of Care Criteria For patients currently on Xgeva for the treatment of giant cell tumor of the bone, continued use will be approved based on the following criteria: ○ Provider attests to a positive clinical response; and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ○ Authorization is for no more than 12 months Xgeva is proven and medically necessary for the treatment of hypercalcemia of malignancy when all of the following criteria are met: ● Initial Therapy ○ Patient is one of the following: ▪ Patient is ≥ 18 years of age ▪ Patient is a skeletally mature adolescent as defined by having at least 1 mature long bone (e.g., closed epiphyseal growth plate of

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	inhibitor therapy for breast cancer, continued use of Prolia will be approved based on the following criteria: – Patient is receiving aromatase inhibitor therapy; and – Provider attests to a positive clinical response; and – Prolia dosing is in accordance with the FDA approved labeling: maximum dosing of 60 mg every 6 months; and – Authorization is for no more than 12 months ○ Prolia is proven and medically necessary to treat glucocorticoid-induced osteoporosis in patients at high risk for fracture when all of the following criteria are met: Initial Therapy ▪ Diagnosis of glucocorticoid-induced osteoporosis; and ▪ History of prednisone or its equivalent at a dose ≥ 5 mg/day for ≥ 3 months; and ▪ One of the following: – BMD T-score ≤ -2.5	the humerus); and ○ Diagnosis of hypercalcemia of malignancy as defined as albumin-corrected serum calcium level greater than 12.5 mg/dL (3.1 mmol/L); and ○ No pre-existing hypocalcemia (i.e., serum calcium or corrected calcium within normal limits per laboratory reference); and ○ Refractory (within the past 30 days), contraindication (including renal insufficiency), or intolerance to treatment with intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid); and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks (additional 120 mg doses allowed on Day 8 and 15 in the first month of therapy); and ○ Authorization is for no more than 12 months ● Reauthorization/Continuation of Care Criteria For patients currently on Xgeva for the treatment of hypercalcemia of malignancy, continued use will be approved based on the following criteria: ○ Provider attests to a positive clinical response; and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ○ Authorization is for no more than 12 months Xgeva is proven and medically necessary for the prevention of skeletal-related events in men with castration-resistant prostate cancer who have bone metastases when all of the following criteria are met: ● Initial Therapy ○ Diagnosis of castration-resistant prostate cancer; and ○ Presence of metastatic disease; and ○ Refractory (within the past 30 days), contraindication (including renal insufficiency), or intolerance to treatment with intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid); and

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); or – History of one of the following resulting from minimal trauma: • Vertebral compression fracture • Fracture of the hip • Fracture of the distal radius • Fracture of the pelvis • Fracture of the proximal humerus or – One of the following: • FRAX 10-year fracture probabilities: major osteoporotic fracture at 20% or more • FRAX 10-year fracture probabilities: hip fracture at 3% or more	○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ○ Authorization is for no more than 12 months • Reauthorization/Continuation of Care Criteria For patients currently on Xgeva for the prevention of skeletal-related events in men with castration-resistant prostate cancer who have bone metastases, continued use will be approved based on the following criteria: ○ Provider attests to a positive clinical response; and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ○ Authorization is for no more than 12 months Xgeva is proven and medically necessary for the treatment of osteopenia/osteoporosis in patients with systemic mastocytosis with bone pain not responding to bisphosphonates when all of the following criteria are met: • Initial Therapy ○ Diagnosis of systemic mastocytosis; and ○ Patient has bone pain; and ○ Diagnosis of osteoporosis or osteopenia based on one of the following: ▪ BMD T-score ≤-1 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); or ▪ History of one of the following resulting from minimal trauma: – Vertebral compression fracture – Fracture of the hip – Fracture of the distal radius – Fracture of the pelvis – Fracture of the proximal humerus; and ○ Refractory (within the past 30 days), contraindication (including renal

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	and ▪ One of the following: – Both of the following: ● History of intolerance to oral bisphosphonate therapy; and ● History of failure, contraindication, or intolerance to intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid) or – History of failure or contraindication to oral bisphosphonate therapy; or – History of failure, contraindication, or intolerance to IV bisphosphonate therapy and ▪ Prolia dosing is in accordance with the FDA approved labeling: maximum dosing of 60 mg every 6 months; and ▪ Authorization is for no more than 12 months	insufficiency), or intolerance to treatment with intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid); and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ○ Authorization for no more than 12 months ● Reauthorization/Continuation of Care Criteria For patients currently on Xgeva for the treatment of osteopenia/osteoporosis in patients with systemic mastocytosis with bone pain not responding to bisphosphonates, continued use will be approved based on the following criteria: ○ Provider attests to a positive clinical response; and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ○ Authorization is for no more than 12 months **Unproven and Not Medically Necessary** Denosumab is unproven and not medically necessary for the following indications: ● Combination therapy of denosumab and intravenous bisphosphonates ● Bone loss associated with hormone-ablation therapy (other than aromatase inhibitors) in breast cancer ● Cancer pain ● Central giant cell granuloma ● Hyper-parathyroidism ● Immobilization hypercalcemia ● Osteogenesis imperfecta ● Osteopenia

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	Reauthorization/Continuation of Care Criteria ▪ To treat glucocorticoid-induced osteoporosis in patients at high risk for fracture, continued use of Prolia will be approved based on the following criteria: – Provider attests to a positive clinical response; and – Prolia dosing is in accordance with the FDA approved labeling: maximum dosing of 60 mg every 6 months; and – Authorization is for no more than 12 months Applicable Codes *Prolia* • Added list of applicable ICD-10 diagnosis codes • Added maximum dosage requirements: ○ HCPCS code: J0897 ○ National drug code (NDC): 55513-0710-01 ○ Maximum dosage per administration: 60 mg ○ How supplied: 60 mg/1 ml vial ○ Maximum allowed: 60 HCPCS	

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	units (1 mg per unit); 1 vial/1 ml Supporting Information • Updated *Clinical Evidence* and *FDA* sections to reflect the most current information	

Coverage Determination Guideline Updates

Updated

Policy Title	Effective Date	Summary of Changes
Ambulance Services (for Mississippi Only)	Jun. 1, 2022	**Definitions** • Added definition of "Air Ambulance" **Supporting Information** • Updated *References* section to reflect the most current information
Private Duty Nursing (PDN) Services (for Mississippi Only)	May 1, 2022	**Additional State Considerations** • Replaced reference to "MCG™ Care Guidelines, [*25th* edition, *2021*], Private Duty Nursing" with "MCG™ Care Guidelines, [*26th* edition, *2022*], Private Duty Nursing"
Prosthetic Devices, Specialized, Microprocessor or Myoelectric Limbs (for Mississippi Only)	Jun. 1, 2022	**Applicable Codes** • Removed HCPCS code L5990

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (for Mississippi Only)	Jun. 1, 2022	**Coverage Rationale**
		• Removed language pertaining to:
		  ○ Safety enclosure with beds; refer to the Coverage Determination Guideline titled *Beds and Mattresses (for Mississippi Only)*
		  ○ Speech generating devices; refer to the Coverage Determination Guideline titled *Speech Generating Devices (for Mississippi Only)*
		Breast Pumps* and *Mobility Devices
		• Replaced coverage guidelines with instruction to refer to the *Mississippi Administrative Code*
			Refer to the policy for complete details.

Coverage Determination Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (for Mississippi Only) (continued)	Jun. 1, 2022	*Title 23: Medicaid, Part 209, Durable Medical Equipment and Medical Supplies* for medical necessity clinical coverage criteria	
Pectus Deformity Repair (for Mississippi Only)	Jun. 1, 2022	Coverage Rationale *Documentation Requirements* • Revised list of clinical information to be documented in the medical notes, when applicable, to reflect/include: ○ Diagnosis ○ History of the medical condition(s) requiring treatment or surgical intervention ○ Functional limitation/impairment ○ Results of all recent imaging studies and applicable diagnostics, including results of: ▪ CT scan confirming Haller Index calculation ▪ Pulmonary function test ▪ Echocardiogram including ejection fraction ▪ Stress test including cardiopulmonary values ○ Physician treatment plan	**Indications for Coverage** Surgical repair of Pectus Excavatum is considered reconstructive and medically necessary when the following criteria has been met: • Imaging studies confirm Haller Index greater than 3.25; and • A Functional Impairment defined in physician office notes; and ○ For restrictive lung capacity the total lung capacity is documented in the physician office notes as < 80% of the predicted value; or ○ There is cardiac compromise as demonstrated by decreased cardiac output on the echocardiogram; or ○ There is objective evidence of exercise intolerance as documented by cardiopulmonary exercise testing that is below the predicted values Surgical repair of Pectus Carinatum may be considered reconstructive and medically necessary. Requests for coverage of repair of Pectus Carinatum will be reviewed by a UnitedHealthcare Medical Director on a case-by-case basis. **Documentation Requirements** Medical notes documenting the following, when applicable: • Diagnosis • History of the medical condition(s) requiring treatment or surgical intervention • Documentation of functional limitation/impairment • Results of all recent imaging studies and applicable diagnostics, including results of: ○ CT scan confirming Haller Index calculation ○ Pulmonary function test Echocardiogram including ejection fraction

Coverage Determination Guideline Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Pectus Deformity Repair (for Mississippi Only) (continued)	Jun. 1, 2022		○ Stress test including cardiopulmonary values ● Physician treatment plan **Coverage Limitations and Exclusions** UnitedHealthcare excludes Cosmetic Procedures from coverage including but not limited to the following: ● Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures. The fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure. ● Procedures that do not meet the reconstructive criteria in the *Indications for Coverage* section.

Utilization Review Guideline Updates

Updated

Policy Title	Effective Date	Summary of Changes
Chemotherapy Observation or Inpatient Hospitalization (for Mississippi Only)	Jun. 1, 2022	**Coverage Rationale** • Updated list of clinical conditions or complications of cancer chemotherapy which may require an observation stay; replaced "comorbidities *that require an observation or overnight stay*" with "comorbidities" **Supporting Information** • Updated *References* section to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Elective Inpatient Services (for Mississippi Only)	Jul. 1, 2022	**Coverage Rationale**
		• Updated list of procedure-related factors that may increase risk of anesthetic complications; removed "class III obesity (body mass index greater than 40) with hemodynamic or respiratory problems" (duplicative of "American Society of Anesthesiologists class III or greater")
		Definitions
		• Added definition of "Hemodynamic Instability"
		• Updated definition of "Acute Kidney Injury"
		Supporting Information
		• Updated *References* section to reflect the most current information
			A planned elective inpatient admission for certain surgeries or procedures is considered medically necessary when any of the following criteria is met:
			• Medical conditions increasing the risk of major post-operative complications:
			  ○ Advanced liver disease (MELD Score > 8)
			  ○ Cognitive status that warrants inpatient stay
			  ○ Severe renal disease (GFR < or = 30 mL/min)
			  ○ Severe valvular heart disease
			  ○ Stroke or TIA within last 3 months
			  ○ Symptomatic chronic lung disease (e.g., asthma, COPD)
			  ○ Symptomatic coronary artery disease or heart failure
			  ○ Unstable medical condition (e.g., poorly controlled diabetes)
			• Procedure related factors that may increase the risk of complications:
			  ○ Anesthetic risk
			  ▪ American Society of Anesthesiologists class III or greater
			  ▪ Age 85 years or older
			  ▪ High risk for thromboembolism
			  ▪ Moderate (AHI 15-30) to severe (AHI > 30) sleep apnea
			  ▪ Persistent electrolyte abnormalities unresponsive to treatment (e.g., hyperkalemia, hyponatremia)
			  ▪ Risk of post-operative airway compromise (e.g., open neck procedure, airway surgery)
			  ○ Complexity of surgical procedure
			  ▪ Complex surgical approach (e.g., unusually extensive dissection needed)

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Elective Inpatient Services (for Mississippi Only) (continued)	Jul. 1, 2022		▪ Complex post-operative wound care (e.g., complex drain management, open wound, previous local tissue injury resulting from factors such as, radiation, previous surgery, impaired circulation, sustained pressure) ▪ Difficult approach because of previous operation ▪ Extensive or prolonged (longer than the usual time frame) surgery ● The need for preoperative diagnostic studies that cannot be performed as an outpatient ● Advance surgical planning determines an individual requires inpatient recovery and care following a surgical procedure: ○ Individual's residence is distant to medical facility and there is a potential for urgent complications and no other nearby temporary residence is available and not appropriate for ambulatory or observation level of care ○ Pre- or post-operative inpatient monitoring or treatment related to need to discontinue drugs or other therapies ● Procedural related event that may require an inpatient stay as indicated by any of the following: ○ Acute Kidney Injury ○ Altered mental status that is severe or persistent ○ Ambulatory or appropriate activity level status is not achieved ○ Conversion to open or complex procedure that requires inpatient care ○ Excessive drainage or bleeding from the operative site ○ Hemodynamic Instability ○ Longer postoperative monitoring or treatment is needed due to preoperative use of drugs (e.g., cocaine, amphetamines) ○ Pain, fever, or vomiting not appropriate for ambulatory or observation level of care ○ Severe complications of procedure (e.g., bowel injury, airway compromise, vascular injury) ○ Unstable clinical status Note: This policy does not apply to an obstetric member during pregnancy, childbirth, or the post-partum period.

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.