United Healthcare Community Plan

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

Take Note

InterQual® Release Dates Removed

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

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Policy Title	**Effective Date**	**Summary of Changes**
Catheter Ablation for Atrial Fibrillation (for Tennessee Only)	Jun. 1, 2022	Application • Added language to indicate this Medical Policy applies to CoverKids Coverage Rationale • Removed reference to specific InterQual® release date; refer to the most current InterQual® criteria
Computed Tomographic Colonography (for Tennessee Only)	Jun. 1, 2022	Application • Added language to indicate this Medical Policy applies to CoverKids Supporting Information • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information • Removed *CMS* section
Gastrointestinal Pathogen Nucleic Acid Detection Panel Testing for Infectious Diarrhea (for Tennessee Only)	Jun. 1, 2022	Application • Added language to indicate this Medical Policy applies to CoverKids Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information
Hearing Aids and Devices Including Wearable, Bone-Anchored and Semi-Implantable (for Tennessee Only)	Jun. 1, 2022	Application • Added language to indicate this Medical Policy applies to CoverKids Applicable Codes • Changed service type classification for HCPCS code L8692 from “Bone Anchored Hearing Aid (BAHA)” to “Wearable Hearing Aid” Supporting Information • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information
Mechanical Stretching Devices (for Tennessee Only)	Jun. 1, 2022	Application • Added language to indicate this Medical Policy applies to CoverKids Supporting Information • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Removed *CMS* section
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Tennessee Only)	Jun. 1, 2022	Application • Added language to indicate this Medical Policy applies to CoverKids Coverage Rationale *Documentation Requirements* • Updated list of clinical information to be documented in the medical notes, when applicable, to reflect/include:

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Policy Title	Effective Date	Summary of Changes
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Tennessee Only) (continued)	Jun. 1, 2022	○ Diagnosis ○ History of the medical condition(s) requiring treatment or surgical intervention ○ Documentation of signs and symptoms; including onset, duration, frequency, and which extremity (right, left, or both) ○ Relevant medical history, including: ▪ DVT (deep vein thrombosis) ▪ Aneurysm ▪ Tortuosity ○ Physical exam, including: ▪ Which extremity (right, left, or both) ▪ Vein(s) that will be treated [e.g., great saphenous vein (GSV) and small saphenous vein (SSV), etc.] ▪ Vein diameter including the specific anatomic location where the measurement was taken (e.g., proximal thigh, proximal calf, etc.) ▪ Duration of reflux including the position of member at the time of measurement and the anatomic location where the measurement was taken [e.g., standing, saphenofemoral junction (SFJ)] ○ Severity of pain or other symptoms that interfere with activities of daily living related to vein disease ○ Functional disability(ies), as documented on a validated functional disability scale, (interfering with the ability to stand or sit for long periods of time, such as, preparing meals, performing work functions, driving, walking, etc.) ○ Diagnostic study/imaging reports ○ Pulses ○ Prior conservative treatments tried, failed, or contraindicated; include the dates and reason for discontinuation ○ Proposed treatment plan with procedure code, including specific vein(s) that will be treated (e.g., great saphenous vein (GSV) and small saphenous vein (SSV), etc.), which extremity (left, right, or both) and date of procedure for each vein to be treated ○ In addition to the above, additional documentation requirements may apply for CPT codes 37761, 37765, 37766, and 37785; refer to the Utilization Review Guideline titled *Outpatient Surgical Procedures – Site of Service (for Tennessee Only)* **Supporting Information** ● Updated *Clinical Evidence* and *References* sections to reflect the most current information ● Removed *CMS* section
Visual Information Processing Evaluation and Orthoptic and Vision	Jul. 1, 2022	**Application** ● Added language to indicate this Medical Policy applies to CoverKids

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Policy Title	Effective Date	Summary of Changes
Therapy (for Tennessee Only)	Jul. 1, 2022	**Coverage Rationale** • Revised language to indicate visual information processing evaluation and orthoptic and vision therapy is proven and medically necessary under certain circumstances; refer to the *Rules of Tennessee Department of Finance and Administration, Bureau of TennCare, Chapter 1200-13-13* for clinical coverage criteria • Supporting Information • Updated *References* section to reflect the most current information • Removed Definitions, Description of Services, Clinical Evidence, and FDA sections
Warming Therapy and Ultrasound Therapy for Wounds (for Tennessee Only)	Jun. 1, 2022	**Application** • Added language to indicate this Medical Policy applies to CoverKids **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Removed *CMS* section

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ablative Treatment for Spinal Pain (for Tennessee Only)	Jul. 1, 2022	**Application** • Added language to indicate this Medical Policy applies to CoverKids **Coverage Rationale** • Replaced reference to "Thermal Radiofrequency Ablation" with "*Conventional* (Thermal) Radiofrequency Ablation" • 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"	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 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

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Ablative Treatment for Spinal Pain (for Tennessee Only) (continued)	Jul. 1, 2022	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) 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 ● Removed *CMS* section	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 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)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ablative Treatment for Spinal Pain (for Tennessee Only) (continued)	Jul. 1, 2022		• Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept®)
Articular Cartilage Defect Repairs (for Tennessee Only)	Jul. 1, 2022	Coverage Rationale *Autologous Chondrocyte Transplantation (ACT) and Microfracture* • Revised language pertaining to medical necessity clinical coverage criteria: ○ Removed reference to the InterQual® Client Defined, CP: Procedures, Articular 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	**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) • 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

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Articular Cartilage Defect Repairs (for Tennessee Only) (continued)	Jul. 1, 2022	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) ▪ 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	● 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 Autograft and Allograft Transplantation, refer to the InterQual® 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

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Articular Cartilage Defect Repairs (for Tennessee Only) (continued)	Jul. 1, 2022	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	• 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
Discogenic Pain Treatment (for Tennessee Only)	Jul. 1, 2022	**Application** • Added language to indicate this Medical Policy applies to CoverKids **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	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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Discogenic Pain Treatment (for Tennessee Only) (continued)	Jul. 1, 2022	most current information • Removed *CMS* section	
Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation (for Tennessee Only)	Jul. 1, 2022	Coverage Rationale • Added language to indicate neuromuscular electrical stimulation (NMES) is proven and medically necessary when used as part of a comprehensive lower limb rehabilitation program following total knee arthroplasty • Replaced language indicating "NMES is proven and medically necessary to improve *wrist and finger* function *and prevent or correct shoulder subluxation* in persons with partial paralysis following stroke" with "NMES is proven and medically necessary to improve *upper extremity* function in persons with partial paralysis following stroke *when used as part of a comprehensive rehabilitation program*" • Revised list of unproven and not medically necessary indications: ○ Added "translingual stimulation (TS) for gait rehabilitation" ○ Removed "dorsal root ganglion (DRG) stimulation" • Added reference link to the Medical Policy titled *Implanted Electrical Stimulator for Spinal Cord* for	For specific guidelines for functional electrical stimulation (FES), refer to the coverage statements and criteria in the *Rules of Tennessee Department of Finance and Administration Bureau of Tenncare, Chapter 1200-1313 Tenncare Medicaid*. Neuromuscular electrical stimulation (NMES) is proven and medically necessary for treating the following indications: • Disuse muscle atrophy if: ○ The nerve supply to the muscle is intact; and ○ The disuse muscle atrophy is not of neurological origin but results from other conditions including but not limited to casting, splinting or contractures • When used as part of a comprehensive lower limb rehabilitation program following total knee arthroplasty • To improve upper extremity function in persons with partial paralysis following stroke when used as part of a comprehensive rehabilitation program The following are unproven and not medically necessary due to insufficient evidence of efficacy: • Interferential therapy (IFT) for treating musculoskeletal disorders/injuries, or to facilitate healing of nonsurgical soft tissue injuries or bone fractures • Microcurrent electrical nerve stimulation (MENS) • NMES for treating any other indication not listed above • Percutaneous electrical nerve stimulation (PENS), percutaneous electrical nerve field stimulation (PENFS) or percutaneous neuromodulation therapy (PNT) • Percutaneous peripheral nerve stimulation (PNS)* • Peripheral subcutaneous field stimulation (PSFS) or peripheral nerve field stimulation (PNFS)

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Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation (for Tennessee Only) (continued)	Jul. 1, 2022	information regarding dorsal root ganglion (DRG) stimulation **Applicable Codes** • Removed CPT code 64566 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	• Pulsed electrical stimulation (PES) • Scrambler Therapy (ST) • Translingual Stimulation for gait rehabilitation (TS) *For information regarding percutaneous peripheral nerve stimulation for occipital neuralgia and headache, refer to Medical Policy titled Occipital Neuralgia and Headache Treatment (for Tennessee Only). **For information regarding dorsal root ganglion (DRG) stimulation, refer to the Medical Policy titled Implanted Electrical Stimulator for Spinal Cord (for Tennessee Only).

Epiduroscopy, Epidural Lysis of Adhesions and Discography (for Tennessee Only)	Jul. 1, 2022	**Application**
		• Added language to indicate this Medical Policy applies to CoverKids
		Coverage Rationale
		• Added language to indicate chemonucleolysis is unproven and not medically necessary for the diagnosis or treatment of any type of neck, back, or spinal disorder
		Applicable Codes
		• Added CPT code 62292
		Supporting Information
		• Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information
		• Removed *CMS* section
			The following are unproven and not medically necessary for the diagnosis or treatment of any type of neck, back, or spinal disorder due to insufficient evidence of efficacy:
			• Discography
			  ○ Chemonucleolysis
			  ○ Functional anesthetic discography
			  ○ Provocative discography
			• Epiduroscopy (including spinal myeloscopy)
			• Percutaneous and endoscopic epidural lysis of adhesions

Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for Tennessee Only)	Jul. 1, 2022	**Coverage Rationale** • Updated list of examples of liquid biopsy tumor tests for genetic analysis or tumor screening: ○ Added “Foundation One Liquid	**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

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Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for Tennessee Only) (continued)	Jul. 1, 2022	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, 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	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 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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for Tennessee Only) (continued)	Jul. 1, 2022	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 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	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 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/PPARγ) 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:

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Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for Tennessee Only) (continued)	Jul. 1, 2022	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 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	• 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 • 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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for Tennessee Only) (continued)	Jul. 1, 2022	"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/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,	**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 **Unproven** 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 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,

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Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for Tennessee Only) (continued)	Jul. 1, 2022	HRAS, NRAS, RET/PTC1, RET/PTC3, PAX8/PPARγ) 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., 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., Decision Dx-UM) Definitions	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 Tennessee Only) (continued)	Jul. 1, 2022	• Added definition of:
		  ○ Predictive Molecular Markers
		  ○ Prognostic Molecular Markers
		• Updated definition of:
		  ○ Comparative Genome Hybridization (CGH)
		  ○ Chromosome Microarray Analysis
		Applicable Codes
		• Added CPT codes 0120U and 86152
		Supporting Information
		• Updated *Clinical Evidence* and *References* sections to reflect the most current information	

Plagiocephaly and Craniosynostosis Treatment (for Tennessee Only)	Jul. 1, 2022	**Application**
		• Added language to indicate this Medical Policy applies to CoverKids
		Coverage Rationale
		Documentation Requirements
		• Updated list of clinical information/items to be documented in the medical notes for cranial orthosis (HCPCS code S1040), when applicable:
		Initial Request
		○ Added:
		▪ Presence or absence of torticollis
		▪ At least one of the following (for more details about the definition of these measurements, refer to the
			Cranial orthotic devices are proven and medically necessary for treating infants following craniosynostosis surgery or for non-synostotic (non-fusion) deformational or positional plagiocephaly. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Orthoses, Cranial Remodeling.
			
			Click here to view the InterQual® criteria.
			
			Documentation Requirements
			Surgical Treatment (CPT 21175)
			Medical notes documenting the following, when applicable:
			• History of medical conditions requiring treatment or surgical invention which includes all of the following:
			  ○ To prove medical necessity, a well-defined physical/physiologic abnormality resulting in a medical condition that requires treatment
			  ○ Recurrent or persistent functional impairment caused by the abnormality
			• Clinical studies/tests addressing the physical/physiologic abnormality confirming its presence and degree to which it causes impairment

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Plagiocephaly and Craniosynostosis Treatment (for Tennessee Only) (continued)	Jul. 1, 2022	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: ▪ Cephalic index in orthotist notes **Replacement Request** ○ Added: ▪ Adjustments/modifications to current cranial helmet if applicable ▪ Compliance with wear **Supporting Information** • Removed *CMS* section	• Physician plan of care with proposed procedures and whether this request is part of a staged procedure; indicate how the procedure will improve and/or restore function ***Cranial Orthosis (HCPCS S1040)*** **Initial Request** Medical notes documenting the following, when applicable: • Current prescription from physician • Reason for the orthotic • Diagnosis • Physical exam related to support the need of the orthotic; include the neurological, circulatory, skin, and musculoskeletal examination that supports the request, as well as presence or absence of torticollis • At least one of the following: ○ Cranial vault asymmetry index (CVAI) ○ Cephalic index (CI) ○ Transcranial diameter difference (TDD) ○ Cranial vault asymmetry (CVA) Children's Healthcare of Atlanta (CHOA) level For more details about the definition of these measurements, see InterQual criteria informational notes • Documentation of treatments tried, failed, contraindicated. Include the dates and reason for discontinuation, including: ○ Repositioning ○ Physical or occupational therapy • Orthotist notes to include the following: ○ Equipment quote with billing codes and cost ○ Reason for the orthotic ○ Anthropometric Measurements • Date and type of injury/surgery, if applicable ○ Plan to treat torticollis with cranial orthosis **Replacement Request**

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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Pneumatic Compression Devices (for Tennessee Only) (continued)	Jul. 1, 2022	▪ Pulmonary edema ▪ Severe arteriosclerosis ▪ Severe congestive heart failure ▪ Skin or tissue condition that may be negatively impacted by the use of garments ▪ Suspected or known DVT ● Added notation to indicate the InterQual® criteria [listed in the policy] does not apply to HCPCS code E0675; use available criteria from the DME MAC in LCD L33829 **Supporting Information** ● Added *Description of Services*, *Clinical Evidence*, and *References* sections	
Surgery of the Elbow (for Tennessee Only)	Jul. 1, 2022	**Application** ● Added language to indicate this Medical Policy applies to CoverKids **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	Surgery of the elbow is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 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

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Surgery of the Elbow (for Tennessee Only) (continued)	Jul. 1, 2022	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 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) ○ Prior therapies/treatments tried,	○ 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) ● 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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgery of the Elbow (for Tennessee Only) (continued)	Jul. 1, 2022	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 Tennessee Only)	Jul. 1, 2022	Application ● Added language to indicate this Medical Policy applies to CoverKids Coverage Rationale ● Revised language pertaining to medical necessity clinical coverage criteria: ○ Added reference to the InterQual® CP: Procedures, Arthroscopy, Surgical, Hip (Pediatric) ○ Replaced reference to the "InterQual® CP: Procedures, Arthroscopy, Surgical, Hip *(includes FAI)*" with "InterQual® CP: Procedures, Arthroscopy, Surgical, Hip" ● Added language to indicate surgical treatment for femoroacetabular impingement (FAI) syndrome is unproven and not medically	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® CP: Procedures: ● Arthroscopy, Diagnostic, +/- Synovial Biopsy, Hip ● 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:

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Surgery of the Hip (for Tennessee Only) (continued)	Jul. 1, 2022	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 documentation requirements for surgical treatment for femoroacetabular impingement (FAI) syndrome • Updated documentation requirements for surgery of the hip 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 • Removed *CMS* section	• 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) • 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

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Surgery of the Hip (for Tennessee Only) (continued)	Jul. 1, 2022		(29914 29915 29916), also include radiographic reports of presence and severity of cartilage damage using Tönnis or Outerbridge grading
Surgery of the Knee (for Tennessee Only)	Jul. 1, 2022	**Application** • Added language to indicate this Medical Policy applies to CoverKids **Coverage Rationale** • Revised language pertaining to medical necessity clinical coverage criteria; added reference to the InterQual® CP: Procedures, Arthroscopy or Arthroscopically Assisted Surgery, Knee (Pediatric) ***Documentation Requirements*** • Updated list of clinical information/items to be documented in the medical notes, when applicable: ○ Added: ▪ 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) ▪ Consideration of arthroscopic approach	Surgery of the knee is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP Procedures: • Arthroscopy, Diagnostic, +/- Synovial Biopsy, Knee • Removal and Replacement, Total Joint Replacement (TJR), Knee • Total Joint Replacement (TJR), Knee • Arthroscopy or Arthroscopically Assisted Surgery, Knee • Arthroscopy or Arthroscopically Assisted Surgery, Knee (Pediatric) • Arthrotomy, 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)

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Surgery of the Knee (for Tennessee Only) (continued)	Jul. 1, 2022	▪ Prior therapies/treatments tried, failed, or contraindicated; include the dates and reason for discontinuation ○ Removed: ▪ Diagnostic image(s) report(s) ▪ Therapies tried and failed of the following, including dates: – Orthotics – Medications/injections – Physical therapy – Surgical – Other pain management procedures ○ Replaced: ▪ "Specific diagnostic image(s) that show the abnormality for which surgery is being requested" with "*upon request, we may require the* specific diagnostic image(s) that shows the abnormality for which surgery is being requested" ▪ "Diagnostic images must be labeled" with "*when requested*, diagnostic images must be labeled" ▪ "Submission of diagnostic *image(s) is required* via the	○ 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 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

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Surgery of the Knee (for Tennessee Only) (continued)	Jul. 1, 2022	external portal" with "*upon request*, diagnostic *imaging must be submitted* via the external portal" ▪ "For revision surgery, include *documentation* of the complication" with "for revision surgery, *also* include *details* of the complication" ▪ "*For CPT codes 27446 and 27447,* if the location is being requested as an inpatient stay, provide medical notes to support *at least one of the* [listed situations]" with "if the location is being requested as an inpatient stay, provide medical notes to support the [listed situations], *when applicable*" **Definitions** • Added definition of: ○ Knee Injury and Osteoarthritis Outcome Score (KOOS) ○ Western Ontario and McMaster Universities Arthritis Index (WOMAC) **Applicable Codes** • Removed CPT codes 29850, 29851, 29855, and 29856 **Supporting Information** • Updated *References* section to	

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Surgery of the Knee (for Tennessee Only) (continued)	Jul. 1, 2022	reflect the most current information	
Surgery of the Shoulder (for Tennessee Only)	Jul. 1, 2022	**Application** • Added language to indicate this Medical Policy applies to CoverKids **Coverage Rationale** • Revised language pertaining to medical necessity clinical coverage criteria; added reference to the InterQual® CP: Procedures, Removal and Replacement, Total Joint Replacement (TJR), Shoulder ***Documentation Requirements*** • Revised documentation requirements for surgery of the shoulder **Applicable Codes** • Removed CPT code 23412	Surgery of the shoulder is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the: • InterQual® CP: Procedures: ○ Joint Replacement, Shoulder ○ Arthroscopy, Diagnostic, +/- Synovial Biopsy, Shoulder ○ Arthroscopy or Arthroscopically Assisted Surgery, Shoulder ○ Arthroscopy or Arthroscopically Assisted Surgery, Shoulder (Adolescent) ○ Arthrotomy, Shoulder ○ Removal and Replacement, Total Joint Replacement (TJR), Shoulder • InterQual® Client Defined CP Procedures: ○ Arthroplasty, Removal or Revision, Shoulder (Custom) - UHG Click here to view the InterQual® criteria. **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)

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Surgery of the Shoulder (for Tennessee Only) (continued)	Jul. 1, 2022		○ 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 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

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Surgical Treatment for Spine Pain (for Tennessee Only)	Jul. 1, 2022	**Related Policies**
		• Added reference link to the Medical Policy titled:
		  ○ *Discogenic Pain Treatment (for Tennessee only)*
		  ○ *Vertebral Body Tethering for Scoliosis (for Tennessee only)*
		Coverage Rationale
		• Added language to indicate:
		  ○ 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 [policy] criteria:
		  ▪ Congenital or idiopathic deformity or bone disease
		  ▪ Muscular dystrophy
		  ▪ Laminectomy procedure to provide surgical exposure to treat lesions within the spinal canal
		  ○ For information on vertebral body tethering, refer to the Medical Policy titled *Vertebral Body Tethering for Scoliosis (for Tennessee Only)*
		• Replaced language indicating "interlaminar lumbar instrumented fusion (ILIF) is unproven and not medically necessary" with "interlaminar lumbar instrumented
			Spinal procedures for the treatment of spine pain are proven and medically necessary in certain circumstances.
			For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures:
			• Decompression +/- Fusion, Cervical
			• Decompression +/- Fusion, Lumbar
			• Decompression +/- Fusion, Thoracic
			• Fusion, Cervical Spine
			• Fusion, Lumbar Spine
			• Fusion, Thoracic Spine
			
			Click here to view the InterQual® criteria.
			
			The following techniques for lumbar interbody fusion (LIF) are proven and medically necessary:
			• Anterior LIF (ALIF) including lateral approaches, e.g., extreme lateral interbody fusion (XLIF®), Direct lateral interbody fusion (DLIF)]
			• Posterior LIF (PLIF), including transforaminal lumbar interbody fusion (TLIF)
			
			The following indications for a surgical spine procedure that is performed to alleviate symptoms or prevent clinical deterioration are considered proven and medically necessary if not addressed in the above criteria:
			• Congenital or idiopathic deformity or bone disease
			• Muscular dystrophy
			• Laminectomy procedure to provide surgical exposure to treat lesions within the spinal canal
			
			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)

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Surgical Treatment for Spine Pain (for Tennessee Only) (continued)	Jul. 1, 2022	fusion (ILIF) *utilizing an interspinous process fusion device* is unproven and not medically necessary"
		Definitions
		• Added definition of "Corpectomy"
		• Removed definition of "Spinal Instability of the Lumber Spine"
		Applicable Codes
		• Added CPT codes 20930, 20931, and 20939
		Supporting Information
		• Updated *Clinical Evidence* and *References* sections to reflect the most current information
			• Axial lumbar interbody fusion (AxiaLIF®)
			• Interlaminar lumbar instrumented fusion (ILIF) utilizing an interspinous process fusion device
			• 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®)]
			• 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 procedure:
			  ○ 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 Tennessee Only).
			
			Documentation Requirements
			Provide medical notes documenting the following:
			• Condition requiring procedure
			• History and co-morbid medical condition(s)
			• 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

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Surgical Treatment for Spine Pain (for Tennessee Only) (continued)	Jul. 1, 2022		measurements over time, if applicable ● Disabling Symptoms, if applicable ● Specific diagnostic image(s) that shows the abnormality for which surgery is being requested which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting surgeon may be needed to select the optimal image(s) ○ Note: 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) ○ Submission of diagnostic imaging is required via the external portal at www.uhcprovider.com/paan; faxes will not be accepted ● Diagnostic image(s) report(s) ● Physical exam, including neurologic exam, including degree and progression of curvature (for scoliosis), if applicable ● Whether the surgery will be performed with direct visualization or only with endoscopic visualization ● Complete report(s) of diagnostic tests ● 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 Tennessee Only)	Jul. 1, 2022	Application ● Added language to indicate this Medical Policy applies to CoverKids Coverage Rationale ● Revised language pertaining to medical necessity clinical coverage criteria: ○ Added reference to the InterQual® Client Defined CP: Procedures, Arthroplasty, Temporomandibular Joint (TMJ) (Custom) - UHG	The following services are proven and medically necessary for treating disorders of the temporomandibular joint (TMJ): ● Arthrocentesis ● Arthroscopy ● Intra-articular Injections of corticosteroids ● 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:

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Temporomandibular Joint Disorders (for Tennessee Only) (continued)	Jul. 1, 2022	○ Removed reference to the InterQual® 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 **Applicable Codes** • Removed CPT code 21299 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	• InterQual® CP: Procedures: ○ Arthroscopy, Temporomandibular Joint (TMJ) ○ Discectomy, Temporomandibular Joint (TMJ) ○ Reconstruction, Temporomandibular Joint (TMJ) • InterQual® Client Defined 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.
Vagus and External Trigeminal Nerve Stimulation (for Pennsylvania Only)	Jul. 1, 2022	**Application** • Added language to indicate this Medical Policy applies to CoverKids • Replaced language indicating: ○ "Implantable vagus nerve stimulators are proven and medically necessary for treating epilepsy" with "*conventional*	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;

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Vagus and External Trigeminal Nerve Stimulation (for Pennsylvania Only) (continued)	Jul. 1, 2022	implantable vagus nerve stimulators, *also known as non-responsive or open loop stimulators*, are proven and medically necessary for treating epilepsy" ○ "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" with "*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) are unproven and not medically necessary for treating epilepsy" • 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 Applicable Codes • Added CPT code 61886	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 • 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

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Vagus and External Trigeminal Nerve Stimulation (for Pennsylvania Only) (continued)	Jul. 1, 2022	**Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Removed *CMS* section	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 Tennessee Only).
Video Electroencephalographic (vEEG) Monitoring and Recording (for Tennessee Only)	Jul. 1, 2022	**Title Change** • Previously titled *Electroencephalographic (EEG) Monitoring and Video Recording (for Tennessee Only)* **Application** • Added language to indicate this Medical Policy applies to CoverKids **Coverage Rationale** • Replaced language indicating "*electroencephalographic (EEG) monitoring and video recording* is proven and medically necessary in certain circumstances" with "*video electroencephalographic (vEEG) monitoring and recording* is proven and medically necessary in certain circumstances" • Added language to indicate inpatient	Video Electroencephalographic (vEEG) monitoring and recording is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures: • Video Electroencephalographic (EEG) Monitoring • Video Electroencephalographic (EEG) Monitoring (Pediatric) Click here to view the InterQual® criteria. If the InterQual criteria for video EEG monitoring referred to above are met, then inpatient admission is proven and medically necessary for any of the following circumstances: • Individual is not expected to have a seizure or seizure-like diagnostic event within a timeframe that is reasonable for an ambulatory vEEG recording* • Individual is undergoing preoperative evaluation for epilepsy surgery • Seizure provocation maneuvers are required that warrant direct observation in an inpatient setting • Seizure medication is being adjusted in such a way as to risk provoking an event that would require inpatient management • Seizure medication discontinuation is required to provoke seizure for diagnostic purposes

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Video Electroencephalographic (vEEG) Monitoring and Recording (for Tennessee Only) (continued)	Jul. 1, 2022	admission is proven and medically necessary for any of the following circumstances when the [listed] InterQual® criteria for video EEG are met: ○ Individual is not expected to have a seizure or seizure-like diagnostic event within a timeframe that is reasonable for an ambulatory vEEG recording (Note: Most individuals will have an event within 48 hours) ○ Individual is undergoing preoperative evaluation for epilepsy surgery ○ Seizure provocation maneuvers are required that warrant direct observation in an inpatient setting ○ Seizure medication is being adjusted in such a way as to risk provoking an event that would require inpatient management ○ Seizure medication discontinuation is required to provoke seizure for diagnostic purposes **Supporting Information** • Added *Description of Services*, *Clinical Evidence*, and *References* sections	*Note: Most individuals will have an event within 48 hours

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Whole Exome and Whole Genome Sequencing (for Tennessee Only)	Jul. 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, 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	**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 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 ○ 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; or • 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

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Whole Exome and Whole Genome Sequencing (for Tennessee Only) (continued)	Jul. 1, 2022	"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 • Removed *CMS* section	**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.

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

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

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

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

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

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

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

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

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Botulinum Toxins A and B (continued)	Aug. 1, 2022	G51.39, G51.4, G51.8, G51.9, G80.0, G80.1, G80.2, G80.3, G80.4, G80.8, G80.9, G81.10, G81.11, G81.12, G81.13, G81.14, G83.4, H50.89, H51.0, J38.5, K11.7, K22.0, K59.4, K60.1, K60.2, L74.510, L74.511, L74.512, L74.513, L74.519, L74.52, N31.0, N31.1, N31.9, N32.81, N36.44, N39.41, N39.46, R25.0, R25.1, R25.2, R25.3, R25.8, R25.9, R29.891, R49.0, R49.9, S04.50XA, S04.51XA, and S04.52XA **Supporting Information** • Added *Background*, *Clinical Evidence*, *FDA*, and *References* sections	• Gustatory epiphora (Crocodile tears) • Head tremor • Lateral epicondylitis (tennis elbow) • Lichen simplex • Lower urinary tract (voiding) dysfunction • Motor tics • Myofascial pain syndrome • Nasal hypersecretion • Pain and/or wound healing after hemorrhoidectomy • Pancreas divisum • Pelvic floor spasticity (and associated pain conditions)[18] • Piriformis syndrome • Post-parotidectomy sialoceles • Post-thoracotomy pseudoangina • Proctalgia fugax • Severe bruxism • Severe paradoxical vocal cord movement • Sphincter of Oddi dysfunction • Stiff-person syndrome • Temporomandibular disorders • Tension headache • Thyroid associated ophthalmopathy[47] • Tourette's syndrome • Traumatic sixth nerve palsy • Trigeminal neuralgia • Trismus and stridor in amyotrophic lateral sclerosis
Complement Inhibitors (Soliris® & Ultomiris®)	Jul. 1, 2022	**Coverage Rationale** • Removed language indicating Soliris is proven and medically necessary for initial therapy for treatment of generalized Myasthenia Gravis when the patient is currently on a stable dose	This policy refers to the following complement inhibitor drug products: • Soliris® (eculizumab) • Ultomiris® (ravulizumab-cwvz) Refer to the policy for complete details.

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

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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Entyvio® (Vedolizumab) (continued)	Aug. 1, 2022		and ○ Patient is receiving a checkpoint inhibitor [e.g., Keytruda (Pembrolizumab), Opdivo (Nivolumab)]; and ○ One of the following: ▪ History of failure, contraindication, or intolerance to infliximab ▪ Patient has immune-related hepatitis and ○ Authorization will be for no more than 3 doses of Entyvio.
Erythropoiesis-Stimulating Agents	Aug. 1, 2022	**Coverage Rationale** • Replaced instruction to refer to the current release of the [listed] InterQual® guideline with Diagnosis-Specific Criteria • Added language to indicate: ○ "ESAs" will be used to refer to all erythropoiesis stimulating agents, unless otherwise specified ○ For the purposes of [this policy], all hematocrit (Hct) values are either pretreatment (for the first 4-6 weeks of therapy) or obtained during treatment to assess ongoing titration and safety ○ For the purposes of this policy, a conversion factor of 3 should be used to estimate hematocrit when only the hemoglobin is measured, e.g., hemoglobin of 10 g/dL is approximately equal to a hematocrit of 30%, a hemoglobin of 11 g/dL is	Epidural Steroid Injections (ESI) are proven and medically necessary when the following criteria are met: • The injection is intended for the short term management of acute or subacute radicular pain; and • The radicular pain is unresponsive to Conservative Treatment: ○ Pharmacotherapy such as NSAIDS or acetaminophen ≥ 3 weeks; or ○ Activity modification ≥ 4 weeks (including but not limited to heavy lifting, bending, spinal torsion activities); or ○ PT or home exercise ≥ 4 weeks The following are unproven and not medically necessary due to insufficient evidence of efficacy: • The use of ultrasound guidance for ESIs • ESI for all other indications of the spine not included above **Epidural Steroid Injection Limitations** • A maximum of three (3) ESI sessions (per region, regardless of level, location, or side) per year ○ A session is defined as one date of service in which ESI(s) is performed ○ A region is defined by either the region of the cervical, thoracic or lumbosacral ○ A year is defined as the 12-month period starting from the date of service of the first approved injection • Repeat ESIs may be provided only if: ○ The initial injection resulted in ≥ 50% pain relief achieved for 3 or more

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Erythropoiesis-Stimulating Agents (continued)	Aug. 1, 2022	approximately equal to a hematocrit of 33%, and a hemoglobin of 12 g/dL is approximately equal to a hematocrit of 36% ○ ESAs are proven and medically necessary for the following indications when the criteria listed in the policy are met: ▪ Anemia due to chronic kidney disease (CKD) ▪ Anemia due to cancer chemotherapy ▪ Anemia Associated with Myelodysplastic Syndromes (MDS) ▪ Anemia Associated with Zidovudine Treatment in HIV-Infected Patients ▪ Anemia Associated with Hepatitis C with Ribavirin and Interferon Therapy ▪ Preoperative Use for Reduction of Allogeneic Blood Transfusions In Surgery Patients ○ ESAs are unproven to treat: ▪ Anemia of CKD in patients on dialysis for a hematocrit greater than or equal to 33% ▪ Anemia of CKD in patients not on dialysis for a	months ○ The initial injection resulted in a functional improvement as measured by validated measurement tools, such as The Oswestry Disability Index ○ Repeat injections do not exceed 3 per year, per region

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Erythropoiesis-Stimulating Agents (continued)	Aug. 1, 2022	hematocrit greater than 30% ▪ Anemia in patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure ▪ Anemia in patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion ○ Mircera is unproven for the treatment of anemia due to cancer chemotherapy ○ ESAs are unproven for: ▪ Patients undergoing curative chemotherapy; for information regarding use of ESAs in patients receiving cancer chemotherapy, refer to information in the National Comprehensive Cancer Network (NCCN) Practice Guideline, Cancer- and Chemotherapy-Induced Anemia, as referenced in the *Professional Societies* section of this policy ▪ Patients with cancer	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Erythropoiesis-Stimulating Agents (continued)	Aug. 1, 2022	receiving hormonal agents, biologic products or radiotherapy (unless also receiving concomitant myelosuppressive chemotherapy) ▪ Patients who require an immediate correction of anemia as a substitute for RBC transfusions ▪ Patients undergoing cardiac or vascular surgery ▪ Patients scheduled for surgery who will donate autologous blood ▪ Patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure ▪ Patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion Supporting Information ● Added *Background*, *Clinical Evidence*, *FDA*, and *References* sections	

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Immune Globulin (IVIG and SCIG)	Aug. 1, 2022	Coverage Rationale
		• Replaced instruction to refer to the current release of the [listed] InterQual® guideline with Diagnosis-Specific Criteria
		• Added language to indicate immune globulin is:
		  ○ Proven and medically necessary for the treatment of the following indications when the criteria listed in the policy are met:
		  ▪ Asthma (severe, persistent, high-dose steroid-dependent)
		  ▪ Autoimmune bullous diseases
		  ▪ Autoimmune uveitis
		  ▪ Bone marrow transplantation (BMT)
		  ▪ Chronic inflammatory demyelinating polyneuropathy
		  ▪ Chronic lymphocytic leukemia (CLL), prevention of infection in B-cell CLL
		  ▪ Cytomegalovirus (CMV) induced pneumonitis in solid organ transplants
		  ▪ Dermatomyositis or polymyositis
		  ▪ Diabetes mellitus
		  ▪ Enteroviral
			This policy refers to FDA approved intravenous (IV) and subcutaneous (SC) immune globulin (IG) products including but not limited to the following (list not all inclusive):
			• Asceniv™ (IV)
			• Bivigam® (IV)
			• Cutaquig® (SC)
			• Cuvitru® (SC)
			• Flebogamma® DIF (IV)
			• Gammagard® Liquid (IV, SC)
			• Gammagard® S/D (IV)
			• Gammaked™ (IV, SC)
			• Gammaplex® (IV)
			• Gamunex®-C (IV, SC)
			• Hizentra® (SC)
			• HyQvia® (SC)
			• Octagam® (IV)
			• Panzyga® (IV)
			• Privigen® (IV)
			• Xembify® (SC)
			
			Refer to the policy for complete details.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) (continued)	Aug. 1, 2022	meningoencephalitis ▪ Feto-neonatal alloimmune thrombocytopenia ▪ Graves' ophthalmopathy ▪ Guillain-Barré syndrome (GBS) ▪ HIV-infection, prevention of bacterial infection in pediatric HIV ▪ Immune thrombocytopenia ▪ IgM antimyelin-associated glycoprotein paraprotein-associated peripheral neuropathy ▪ Kawasaki disease ▪ Lambert-Eaton myasthenic syndrome (LEMS) ▪ Lennox Gastaut syndrome ▪ Lymphoproliferative disease, treatment of bacterial infections ▪ Monoclonal gammopathy ▪ Multifocal motor neuropathy (MMN) ▪ Multiple sclerosis, relapsing forms ▪ Multiple myeloma, prevention of infection ▪ Myasthenia gravis ▪ Neuromyeltis optica ▪ Paraproteinemic neuropathy ▪ Posttransfusion purpura	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) (continued)	Aug. 1, 2022	▪ Post B-cell targeted therapies ▪ Primary immunodeficiency syndromes ▪ Rasmussen syndrome ▪ Renal transplantation, prevention of acute humoral rejection ▪ Rheumatoid arthritis, severe ▪ Rotaviral enterocolitis ▪ Staphylococcal toxic shock ▪ Stiff-person syndrome ▪ Thrombocytopenia, secondary to HCV, HIV, or pregnancy ▪ Toxic epidermal necrolysis or Stevens-Johnson syndrome ▪ Urticaria, delayed pressure ○ Unproven and not medically necessary for: ▪ Acquired hemophilia ▪ Acute disseminated encephalomyelitis (ADEM) ▪ Adrenoleukodystrophy ▪ Alzheimer's disease ▪ Amyotrophic lateral sclerosis (ALS) ▪ Antiphospholipid antibody syndrome (APS) in pregnancy	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) (continued)	Aug. 1, 2022	▪ Asthma, non-steroid dependent ▪ Atopic dermatitis ▪ Autism spectrum disorders ▪ Autoimmune liver disease ▪ Autoimmune neutropenia ▪ Bone marrow transplantation (BMT), prevention of acute graft vs. host disease (GVHD) after autologous BMT ▪ Bone marrow transplantation (BMT), prevention of chronic graft vs. host disease (GVHD) after autologous BMT ▪ Bone marrow transplantation (BMT), prevention of infection after autologous BMT ▪ Campylobacter species-induced enteritis ▪ Cerebral infarctions with antiphospholipid antibodies ▪ Chronic fatigue syndrome ▪ Demyelinative brain stem encephalitis ▪ Demyelinating neuropathy associated with monoclonal IgM ▪ Dilated cardiomyopathy ▪ HIV infection, to reduce	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) (continued)	Aug. 1, 2022	viral load ▪ HTLV-1-associated myelopathy ▪ Idiopathic dysautonomia, acute ▪ Inclusion body myositis ▪ Isolated IgA deficiency ▪ Isolated IgE deficiency ▪ Isolated IgG4 deficiency ▪ Isolated IgM deficiency ▪ Lumbosacral or brachial plexitis ▪ Myocarditis, acute ▪ Neonatal isoimmune hemolytic jaundice ▪ Neonatal sepsis, prevention ▪ Ocular myasthenia ▪ Opsoclonus myoclonus ▪ Paraneoplastic cerebellar degeneration, sensory neuropathy, or encephalopathy ▪ Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) ▪ POEMS syndrome ▪ Postinfectious cerebellar ataxia ▪ Postoperative sepsis ▪ Pseudomembranous	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) (continued)	Aug. 1, 2022	colitis ▪ Rheumatic fever, acute ▪ Sjogren's syndrome ▪ Spontaneous recurrent abortions, prevention ▪ Urticaria, chronic ▪ Vasculitides and antineutrophil antibody syndromes **Applicable Codes** ● Added list of applicable ICD-10 diagnosis codes **Supporting Information** ● Added *Background*, *Clinical Evidence*, *FDA*, and *References* sections	
Infliximab (Avsola™, Inflectra®, Remicade®, & Renflexis®)	Aug. 1, 2022	**Coverage Rationale** ● Replaced instruction to refer to the current release of the [listed] InterQual® guideline with Diagnosis-Specific Criteria ● Added language to indicate: ○ "Infliximab" will be used [in this policy] to refer to all infliximab products ○ Infliximab is proven and medically necessary for the treatment of the following indications when the criteria listed in the policy are met: ▪ Ankylosing spondylitis ▪ Crohn's disease ▪ Noninfectious uveitis	This policy refers to the following infliximab products: ● Avsola™ (infliximab-axxq) ● Inflectra® (infliximab-dyyb) ● Remicade® (infliximab) ● Renflexis® (infliximab-abda) ● Any FDA-approved infliximab biosimilar product not listed here* *Any U.S. Food and Drug Administration approved and launched infliximab biosimilar product not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare. Refer to the policy for complete details.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Infliximab (Avsola™, Inflectra®, Remicade®, & Renflexis®) (continued)	Aug. 1, 2022	▪ Plaque psoriasis ▪ Psoriatic arthritis ▪ Rheumatoid arthritis ▪ Sarcoidosis ▪ Ulcerative colitis ▪ Acute graft-versus-host disease (GVHD) ▪ Immune checkpoint inhibitor-related toxicities ○ Infliximab is unproven and not medically necessary for the treatment of: ▪ Hidradenitis suppurativa ▪ Juvenile idiopathic arthritis (juvenile rheumatoid arthritis) ▪ Myelodysplastic syndromes ▪ Reiter's syndrome ▪ Sjögren's syndrome ▪ Still's disease ▪ Undifferentiated spondyloarthropathy ▪ Wegener's granulomatosis ○ Infliximab is unproven for the treatment of the above conditions because statistically robust randomized controlled trials are needed to address the issue of whether infliximab has sufficient superiority in clinical efficacy compared to other available treatments to	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Infliximab (Avsola™, Inflectra®, Remicade®, & Renflexis®) (continued)	Aug. 1, 2022	justify the inherent clinical risk in the use of a monoclonal antibody anti-tumor necrosis factor agent **Applicable Codes** • Added list of applicable ICD-10 diagnosis codes **Supporting Information** • Added *Documentation Requirements*, *Background*, *Clinical Evidence*, *FDA*, and *References* sections	
Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®)	Aug. 1, 2022	**Coverage Rationale** • Removed instruction to refer to the current release of the [listed] InterQual® guideline for medical necessity clinical coverage criteria • Added language to indicate Feraheme® (ferumoxytol), Injectafer® (ferric carboxymaltose), and Monoferric® (ferric derisomaltose) are proven and medically necessary for the treatment of the following indications when the criteria listed in the policy are met: ○ Iron Deficiency Anemia (IDA) without chronic kidney disease (CKD) ○ Iron Deficiency Anemia (IDA) associated with chronic kidney disease (CKD), without end stage renal disease (ESRD)	This policy refers to the following intravenous iron replacements: • Feraheme® (ferumoxytol) • Injectafer® (ferric carboxymaltose) • Monoferric® (ferric derisomaltose) The following intravenous iron replacements are not subject to the coverage criteria in this section: • Ferrlecit (sodium ferric gluconate complex) • Infed® (iron dextran) • Venofer® (iron sucrose) Feraheme (ferumoxytol), Injectafer (ferric carboxymaltose), and Monoferric (ferric derisomaltose) are proven for the following indications: • Iron Deficiency Anemia (IDA) without Chronic Kidney Disease (CKD) Feraheme, Injectafer, and Monoferric are medically necessary when the following criteria are met: ○ For initial therapy, all of the following: ▪ Submission of medical records (e.g., lab values, chart notes, etc.) supporting the diagnosis of IDA; and ▪ Patient does not have CKD; and ▪ One of the following:

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) (continued)	Aug. 1, 2022	○ Iron Deficiency Anemia (IDA) associated with chronic kidney disease (CKD), with end stage renal disease (ESRD) **Supporting Information** • Updated *References* section to reflect the most current information	– History of failure, contraindication, or intolerance, to oral iron therapy; or – One of the following: Patient has severe iron deficiency in late stage pregnancy Patient has impaired absorption due to prior gastric surgery or inflammatory bowel disease Blood loss exceeds the ability to replete iron orally and ▪ One of the following: – Both of the following: Submission of laboratory values demonstrating treatment failure after at least 3 weeks of therapy, to at least two of the following intravenous iron therapies each (Note: Laboratory values should be obtained within 1 to 3 weeks following the last dose of intravenous iron in a treatment course): ○ Infed® (iron dextran) ○ Ferrlecit (sodium ferric gluconate complex) ○ Venofer® (iron sucrose) and • Physician attests that in their clinical opinion, the clinical response would be expected to be superior with Feraheme, Injectafer, or Monoferric than experienced with the other products or – Both of the following: History of intolerance, contraindication, or severe adverse event, to all of the following intravenous iron therapies not previously tried and experienced treatment failure: ○ Infed® (iron dextran) ○ Ferrlecit (sodium ferric gluconate complex) ○ Venofer® (iron sucrose) and

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

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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) (continued)	Aug. 1, 2022		• Physician attests that in their clinical opinion, the clinical response would be expected to be superior with Feraheme, Injectafer, or Monoferric than experienced with the other products or – Both of the following: • History of intolerance, contraindication, or severe adverse event, to all of the following intravenous iron therapies not previously tried and experienced treatment failure: ○ Infed® (iron dextran) ○ Ferrlecit (sodium ferric gluconate complex) ○ Venofer® (iron sucrose) and • Physician attests that in their clinical opinion, the same intolerance, contraindication, or severe adverse event would not be expected to occur with Feraheme, Injectafer, or Monoferric than experienced with the other products and ▪ One of the following: – Feraheme dose does not exceed 510 mg elemental iron per dose and 2.04g elemental iron per course – Injectafer dose does not exceed 750 mg elemental iron per dose and 1500mg elemental iron per course – Monoferric dose does not exceed 1000 mg elemental iron per dose/course and ▪ Initial authorization will be for no longer than 3 months ○ For continuation of therapy, all of the following: ▪ Coverage has previously been provided by UnitedHealthcare for Feraheme, Injectafer, or Monoferric for the treatment of IDA with CKD based on documented history of one of the following: – Intolerance, contraindication, or severe adverse event to all three preferred intravenous iron products; or

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) (continued)	Aug. 1, 2022		– Treatment failure of at least two of the three preferred intravenous iron products and ▪ Patient does not have ESRD; and ▪ Submission of recent laboratory results (within the past 4 weeks) since the last Feraheme, Injectafer, or Monoferric administration to demonstrate need for additional therapy; and ▪ One of the following: – Feraheme dose does not exceed 510 mg elemental iron per dose and 2.04g elemental iron per course – Injectafer dose does not exceed 750 mg elemental iron per dose and 1500mg elemental iron per course – Monoferric dose does not exceed 1000 mg elemental iron per dose/course and ▪ Continuation authorization will be for no longer than 3 months
Ocrevus® (Ocrelizumab)	Aug. 1, 2022	Coverage Rationale ● Removed instruction to refer to the current release of the [listed] InterQual® guideline for medical necessity clinical coverage criteria ● Added language to indicate: ○ Ocrevus is proven and medically necessary for the treatment of the following indications when the criteria listed in the policy are met: ▪ Primary progressive multiple sclerosis (PPMS) ▪ Relapsing forms of multiple sclerosis (MS)	**Primary Progressive Multiple Sclerosis** Ocrevus is proven and medically necessary for the treatment of primary progressive multiple sclerosis (PPMS) when all of the following criteria are met: ● Diagnosis of primary progressive multiple sclerosis (PPMS); and ● One of the following: ○ Initial therapy for ocrelizumab when meeting all of the following: ▪ Patient is not receiving ocrelizumab in combination with any of the following: – Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide) – B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab) – Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) and

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ocrevus® (Ocrelizumab) (continued)	Aug. 1, 2022	○ Ocrevus is unproven and not medically necessary for the treatment of: ▪ Lupus nephritis ▪ Rheumatoid arthritis ▪ Systemic lupus erythematosus **Applicable Codes** ● Added ICD-10 diagnosis code G35 **Supporting Information** ● Added *Background*, *Clinical Evidence*, *FDA*, and *References* sections	▪ Initial dosing: One time 300 mg intravenous course of doses on days 1 and 15; and ▪ Initial authorization is for no more than 6 months; or ○ Continuation of therapy for ocrelizumab when meeting all of the following: ▪ Patient has previously received treatment with ocrelizumab; and ▪ Documentation of positive clinical response to ocrelizumab therapy; and ▪ Patient is not receiving ocrelizumab in combination with any of the following: – Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide) – B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab) – Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) and ▪ Continued dosing: One 600 mg intravenous dose every 6 months; and ▪ Authorization is for no more than 12 months **Relapsing Forms of Multiple Sclerosis** Ocrevus is proven and medically necessary for the treatment of relapsing forms of multiple sclerosis (MS) when both of the following criteria are met: ● Diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses); and ● One of the following: ○ Initial therapy for ocrelizumab meeting all of the following: ○ Both of the following:* – Submission of medical records (e.g., chart notes, laboratory

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

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

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Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Jul. 1, 2022	▪ Macular Edema Following Retinal Vein Occlusion (RVO) ▪ Myopic Choroidal Neovascularization (mCNV) ○ Vabysmo (faricimab-svoa) is proven and medically necessary for the treatment of: ▪ Neovascular age-related macular degeneration (AMD) ▪ Diabetic macular edema (DME) **Applicable Codes** ● Added HCPCS codes C9097, J3490, J3590, and Q5124 ● Updated list of applicable ICD-10 diagnosis codes: ○ For HCPCS codes C9097, J0178, J0179, J2503, J3490, and J3590: ▪ Added H35.351, H35.352, and H35.353 ○ For HCPCS codes J2778 and J9035: ▪ Added H35.351, H35.352, and H35.353 ▪ Removed B39.4 ○ For HCPCS code Q5124: ▪ Added H35.351, H35.352, H35.353, H44.2A1,	○ Intravitreal VEGF or dual VEGF/Ang-2 inhibitor administration is no more than 12 doses per year per eye, regardless of diagnosis ● For continuation of therapy, both of the following: ○ Documentation of positive clinical response to anti - VEGF therapy; and ○ Intravitreal VEGF or dual VEGF/Ang-2 inhibitor administration is no more than 12 doses per year per eye, regardless of diagnosis **Diagnosis-Specific Requirements** The information below indicates the list of proven and medically necessary indications. Beovu (brolucizumab) is proven and medically necessary for the treatment of: ● Neovascular age-related macular degeneration (AMD) Avastin (bevacizumab) is proven and medically necessary for the treatment of: ● Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome (OHS) ● Diabetic macular edema (DME) ● Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) ● Neovascular age-related macular degeneration (AMD) ● Neovascular glaucoma ● Neovascularization of the iris (NVI) (rubeosis iridis) ● Proliferative diabetic retinopathy ● Type I retinopathy of prematurity Byooviz (ranibizumab-nuna) is proven and medically necessary for the treatment of: ● Neovascular age - related macular degeneration (AMD) ● Macular Edema Following Retinal Vein Occlusion (RVO)

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Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Jul. 1, 2022	H44.2A2, H44.2A3, and H44.2A9 ▪ Removed H34.8110, H34.8111, H34.8112, H34.8121, H34.8122, H34.8131, H34.8132, H34.8190, H34.8191, H34.8192, H34.8311, H34.8312, H34.8321, H34.8322, H34.8331, H34.8332, H34.8391, H34.8392, H35.051, H35.052, H35.053, and H35.059 • Added Maximum Allowed Frequencies for: *Byooviz (Ranibizumab-Nuna)* ○ Neovascular age-related macular degeneration: The recommended dose is 0.5 mg (0.05 ML) administered by intravitreal injection once a month (approximately 28 days) ▪ Patients may be treated with 3 monthly doses followed by less frequent dosing ▪ Patients may also be treated with one dose every 3 months after 4 monthly doses ▪ Maximum of 12 doses per year per eye	• Myopic Choroidal Neovascularization (mCNV) Eylea (aflibercept) is proven and medically necessary for the treatment of: • Diabetic macular edema (DME) • Diabetic retinopathy • Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) • Neovascular age - related macular degeneration (AMD) Lucentis (ranibizumab) is proven and medically necessary for the treatment of: • Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome (OHS) • Diabetic macular edema (DME) • Diabetic retinopathy • Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) • Neovascular age - related macular degeneration (AMD) Macugen (pegaptanib) is proven and medically necessary for the treatment of: • Diabetic macular edema • Neovascular age - related macular degeneration (AMD) Vabysmo (faricimab-svoa) is proven and medically necessary for the treatment of: • Neovascular age-related macular degeneration (AMD) • Diabetic macular edema (DME) **Additional Information** Avastin (bevacizumab) is supplied in sterile vials containing a solution of 25 mg/mL. Doses utilized in ophthalmic conditions generally range from 6.2 mcg to

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Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Jul. 1, 2022	○ Macular edema following retinal vein occlusion (RVO): The recommended dose is 0.5 mg (0.05 ML) administered by intravitreal injection once a month (approximately 28 days); maximum of 12 doses per year per eye ○ Myopic choroidal neovascularization (mCNV): The recommended dose is 0.5 mg (0.05 ML) administered by intravitreal injection once a month (approximately 28 days) for up to 3 months *Vabysmo (Faricimab)* ○ Diabetic macular edema: ▪ The recommended dose is 6 mg by intravitreal injection every 4 weeks for the first 4 doses, followed by one of the following three regimens: – Weeks 28 and 44 – Weeks 24, 36, and 48 – Weeks 20, 28, 36 and 44 ▪ Although most patients require dosing every 8 weeks, some patients may need dosing every 4 weeks ▪ Maximum of 12 doses per	2.5 mg. Therefore, bevacizumab in vials is often divided into single-dose, prefilled syringes for intravitreal use by compounding pharmacies. Compounding pharmacies must comply with United States Pharmacopeia (USP) Chapter 797, which sets standards for the compounding, transportation, and storage of compounded sterile products (CSP). The Pharmacy Compounding Accreditation Board can verify that the pharmacy is adhering to these standards. The American Society of Retinal Specialists (ASRS) is committed to ensuring that retina specialists have access to compounded drugs (such as Avastin) that are prepared with high - quality material following good quality controls and sound engineering design by appropriately trained personnel. Refer to their information page at https://www.asrs.org/advocacy-practice/access-to-safe-compounded-agents for resources pertaining to access of safe compounded agents. Refer to the *U.S. Food and Drug Administration (FDA)* section of the policy for information related to contamination of compounded bevacizumab. In an effort to guard against contamination during the compounding process, the United States Veterans Health Administration (USVHA) requires that only USVHA pharmacies may dispense bevacizumab for intravitreal administration to Veterans Administration beneficiaries. The medication must be dispensed directly to the VA ophthalmologist, who will then be responsible for preparing and administering the bevacizumab dose for each patient. In addition to strict labeling and storage requirements, the ophthalmologist is required to prepare only one dose of medication from each vial; if both eyes are to be treated, a separate vial and syringe must be utilized.

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Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Jul. 1, 2022	year per eye ○ Neovascular age-related macular degeneration: ▪ The recommended dose is one of the following regimens: – 6 mg administered by intravitreal injection every 4 weeks for at least 4 doses, followed by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on response – 6 mg administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injections at intervals of every 8 weeks over the next 28 weeks ▪ Although most patients require dosing every 8 weeks, some patients may need dosing every 4 weeks ▪ Maximum of 12 doses per year per eye	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Jul. 1, 2022	Supporting Information • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Orencia® (Abatacept) Injection for Intravenous Infusion	Aug. 1, 2022	Coverage Rationale • Removed instruction to refer to the current release of the [listed] InterQual® guideline for medical necessity clinical coverage criteria • Removed language indicating the prescriber attestation that the patient or caregiver is not able to be trained or is physically unable to administer Orencia FDA labeled for self-administration; the prescriber must submit an explanation • Added language to indicate Orencia is: ○ Proven and medically necessary for the treatment of the following indications when the criteria listed in the policy are met: ▪ Polyarticular juvenile idiopathic arthritis ▪ Rheumatoid arthritis ▪ Psoriatic arthritis ▪ Chronic graft-versus-host disease (GVHD) ▪ Acute graft-versus-host disease (aGVHD)	This policy refers to Orencia (abatacept) injection for intravenous infusion. Orencia (abatacept) for self-administered subcutaneous injection is obtained under the pharmacy benefit. Orencia is proven and medically necessary for the treatment of: • Polyarticular juvenile idiopathic arthritis when all of the following criteria are met: ○ For initial therapy, all of the following: ▪ Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA); and Orencia is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for polyarticular juvenile idiopathic arthritis; and ▪ Patient is not receiving Orencia in combination with either of the following: – Biologic disease-modifying antirheumatic drug (DMARD) *[e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]* – Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)][18] and ▪ Prescribed by or in consultation with a rheumatologist; and ▪ Initial authorization is for no more than 12 months ○ For continuation of therapy, all of the following: ▪ Patient has previously received Orencia injection for intravenous infusion; and

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

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

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Orencia® (Abatacept) Injection for Intravenous Infusion (continued)	Aug. 1, 2022		Simponi (golimumab), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz (tofacitinib), Otezla (apremilast)]; or – Patient is currently on Orencia and ▪ Orencia is initiated and titrated according to FDA labeled dosing for psoriatic arthritis; and ▪ Patient is not receiving Orencia in combination with any of the following: – Biologic DMARD *[e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]* – Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)][18] – Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] and ▪ Prescribed by or in consultation with one of the following: – Rheumatologist – Dermatologist and ▪ Initial authorization is for no more than 12 months ○ For continuation of therapy, all of the following: ▪ Patient has previously received Orencia injection for intravenous infusion; and ▪ Documentation of a positive clinical response; and ▪ Orencia is dosed according to FDA labeled dosing for psoriatic arthritis; and ▪ Patient is not receiving Orencia in combination with any of the following: – Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] – Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] – Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] and

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

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

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

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

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

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

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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Sodium Hyaluronate (continued)	Aug. 1, 2022		Visco-3 — 3 injections Intra-articular injections of sodium hyaluronate are unproven and not medically necessary for treating any other indication due to insufficient evidence of efficacy including but not limited to the following: • Hip osteoarthritis • Temporomandibular joint osteoarthritis • Temporomandibular joint disc displacement Hyaluronic acid gel preparations to improve the skin's appearance, contour and/or reduce depressions due to acne, scars, injury or wrinkles are considered cosmetic and are not covered.
White Blood Cell Colony Stimulating Factors	Jul. 1, 2022	Coverage Rationale • Revised list of applicable short-acting filgrastim agents; added Releuko® (filgrastim-ayow) • Added langauge to indicate: ○ Coverage for Releuko will be provided contingent on the criteria in the *Preferred Product Criteria* section and the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ Treatment with Releuko is medically necessary for the indications specified in the policy when one of the following is met: ▪ Both of the following: – History of a trial of adequate dose and duration of Zarxio,	This policy refers to the following white blood cell colony stimulating factors (CSFs): • Long-acting pegfilgrastim agents: ○ Fulphila® (pegfilgrastim-jmdb) ○ Neulasta® (pegfilgrastim) ○ Nyvepria™ (pegfilgrastim-apgf) ○ Udenyca® (pegfilgrastim-cbqv) ○ Ziextenzo® (pegfilgrastim-bmez) • Short-acting filgrastim agents: ○ Granix® (tbo-filgrastim) ○ Neupogen® (filgrastim) ○ Nivestym® (filgrastim-aafi) ○ Releuko® (filgrastim-ayow) ○ Zarxio® (filgrastim-sndz) • Leukine® (sargramostim) (refer to the Diagnosis-Specific Criteria) • Any FDA-approved white blood cell colony stimulating factor product not listed here* *Any U.S. Food and Drug Administration (FDA) approved white blood cell colony stimulating factor product not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare.

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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	chemotherapy-induced febrile neutropenia (FN) ▪ Secondary prophylaxis of febrile neutropenia (FN) ▪ Treatment of febrile neutropenia ▪ Severe chronic neutropenia (SCN) ▪ Hematopoietic syndrome of acute radiation syndrome ● Revised coverage criteria for: *Bone Marrow/Stem Cell Transplant* ○ Removed criterion requiring medication is: ▪ Dosed in accordance with the U.S. Food and Drug Administration (FDA) approved labeling ▪ Prescribed by or in consultation with a hematologist or oncologist *Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia* ○ Added criterion to allow coverage for the applicable products when the patient is receiving myelosuppressive anticancer drugs given with a curative intent (curative chemotherapy, chemotherapy	**Short-Acting Filgrastim Agents (Granix®, Neupogen®, Nivestym®, Releuko®, & Zarxio®): Preferred Product** The short-acting preferred product criteria in this section applies to the following states: CA, HI, KY, MD, MI, MN, NE, NJ, NY, OH, RI, TN, VA. For all other states, coverage will be provided contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Zarxio® is the preferred filgrastim product. Coverage will be provided for Zarxio® contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Coverage for Granix®, Neupogen®, Nivestym®, or Releuko® will be provided contingent on the criteria in this section and the coverage criteria in the Diagnosis-Specific Criteria section. ***Preferred Product Criteria*** Treatment with Granix, Neupogen, Nivestym, Releuko, or other filgrastim biosimilar is medically necessary for the indications specified in the policy when one of the following is met: ● Both of the following: ○ History of a trial of adequate dose and duration of Zarxio, resulting in minimal clinical response; and ○ Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Granix, Neupogen, Nivestym, Releuko or other filgrastim biosimilar product, than experienced with Zarxio; or ● Both of the following: ○ History of intolerance, contraindication, or adverse event to Zarxio; and ○ Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with Granix, Neupogen, Nivestym, Releuko or other filgrastim biosimilar product

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	in curative adjuvant/neoadjuvant setting) or the patient is receiving myelosuppressive anticancer drugs for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease) ○ Updated list of risk factors for chemotherapy-induced febrile neutropenia; replaced persistent neutropenia due to prior chemotherapy, radiation therapy, or bone marrow involvement by tumor measure of "ANC < 1500 neutrophils/mcL" with "< 500 neutrophils/mcL or < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours" ○ Replaced language indicating "chemotherapy regimen associated incidence of febrile neutropenia (FN) will be based on the clinical trial(s) with the highest level of evidence *according to the GRADE criteria*" with "chemotherapy regimen associated incidence of FN will be based on the	**Diagnosis-Specific Criteria** For the coverage criteria below, in absence of specified drug products, the term "colony stimulating factors" or "CSFs" will be used in this policy where the coverage criteria apply to all products listed above. ● Bone Marrow/Stem Cell Transplant (Leukine, Neupogen, Nivestym, Releuko, Zarxio) Leukine, Neupogen, Nivestym, Releuko, and Zarxio are proven and medically necessary when all of the following criteria are met: ○ One of the following: ▪ Patient has nonmyeloid malignancies and is undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT); or ▪ Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; or ▪ Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy; ● Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy (Leukine, Neupogen, Nivestym, Releuko, Zarxio) Leukine, Neupogen, Nivestym, Releuko and Zarxio are proven and medically necessary when the following criteria are met: ○ Both of the following: ▪ Diagnosis of AML; and ▪ Patient has completed either induction or consolidation chemotherapy ● Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (FN) (Fulphila, Granix, Leukine, Neulasta, Neupogen, Nivestym, Nyvepria, Releuko, Udenyca, Zarxio, Ziextenzo) White blood cell colony stimulating factors are proven and medically necessary when the following criteria are met: ○ One of the following:

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	clinical trial(s) with the highest level of evidence" ○ Added language to indicate: ▪ Chemotherapy regimens and associated incidence of FN based on the clinical trial(s) according to the grade based on Common Terminology Criteria for Adverse Events (CTCAE) by the National Cancer Institute (NCI) criteria are available for reference at uhcprovider.com ▪ The reference document is not a substitute for the experience and judgment of a physician or other health care professional; any clinician must use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment *Secondary Prophylaxis of Febrile Neutropenia* ○ Added criterion to allow coverage for the applicable products: ▪ When the patient is receiving	▪ Patient is receiving myelosuppressive anticancer drugs given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting); or ▪ Patient is receiving myelosuppressive anticancer drugs for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease); and ○ One of the following: ▪ Patient is receiving dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin) for bladder cancer; or ▪ Patient is receiving dose dense AC (doxorubicin, cyclophosphamide) followed by dose-dense paclitaxel for breast cancer; or ▪ Patient is receiving chemotherapy regimen(s) associated with > 20% incidence of FN; or ○ Both of the following: ▪ Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN; and ▪ Patient has one or more risk factors for chemotherapy-induced febrile neutropenia such as: – Persistent neutropenia due to prior chemotherapy, radiation therapy or bone marrow involvement by tumor (< 500 neutrophils/mcL or < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours) – Liver dysfunction (bilirubin > 2.0) – Renal dysfunction (creatinine clearance < 50) – Age > 65 years receiving full chemotherapy dose intensity *Note: Chemotherapy regimen associated incidence of FN will be based on the clinical trial(s) with the highest level of evidence. Chemotherapy regimens and associated incidence of FN based on the clinical trial(s)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	myelosuppressive anticancer drugs given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting) or the patient is receiving myelosuppressive anticancer drugs for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease) ▪ Patient has a documented history of a neutropenic event (febrile neutropenia or low neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen at full dose for which primary prophylaxis was not received ○ Removed criterion allowing coverage for the applicable products when the patient is receiving myelosuppressive anticancer drugs associated with neutropenia (ANC ≤ 1500 neutrophils/mcL)	according to the grade based on Common Terminology Criteria for Adverse Events (CTCAE) by the National Cancer Institute (NCI) criteria are available for reference at uhcprovider.com. The reference document is not a substitute for the experience and judgment of a physician or other health care professional. Any clinician must use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment. ● Secondary Prophylaxis of Febrile Neutropenia (FN) (Fulphila, Granix, Leukine, Neulasta, Neupogen, Nivestym, Nyvepria, Releuko, Udenyca, Zarxio, Ziextenzo) White blood cell colony stimulating factors are proven and medically necessary when the following criteria are met: ○ One of the following: ▪ Patient is receiving myelosuppressive anticancer drugs given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting); or ▪ Patient is receiving myelosuppressive anticancer drugs for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease); and ○ One of the following: ▪ Patient has a documented history of a neutropenic event (febrile neutropenia or low neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen at full dose for which primary prophylaxis was not received; or ▪ Patient has a documented history of neutropenic event from a previous course of chemotherapy ● Treatment of Febrile Neutropenia (FN) (Fulphila, Leukine, Neulasta, Neupogen, Nivestym, Nyvepria, Releuko, Udenyca, Zarxio, Ziextenzo) (Off-Label) Fulphila, Leukine, Neulasta, Neupogen, Nivestym, Nyvepria, Releuko,

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	*Treatment of Febrile Neutropenia* ○ Added criterion requiring the patient has not received long-acting prophylactic pegfilgrastim in the last 14 days ○ Removed criterion requiring the score of < 21 on the *Multinational Association of Supportive Care in Cancer (MASCC)* scoring system in patients with cancer and febrile neutropenia ○ Revised list of examples of risk factors for an infection-associated complication: ▪ Added: – Sepsis syndrome – Age > 65 years – Absolute Neutrophil Count (ANC) < 100/mcL – Neutropenia expected to be > 10 days in duration – Pneumonia – Clinically documented infections including invasive fungal infection – Hospitalization at the time of fever	Udenyca, Zarxio, and Ziextenzo are proven and medically necessary when the following criteria are met: ○ All of the following: ▪ Diagnosis of febrile neutropenia; and ▪ Patient has not received long-acting prophylactic pegfilgrastim in the last 14 days; and ▪ Patient has one or more risk factors for an infection-associated complication such as: – Sepsis syndrome – Age > 65 years – Absolute Neutrophil Count (ANC) < 100/mcL – Neutropenia expected to be > 10 days in duration – Pneumonia – Clinically documented infections including invasive fungal infection – Hospitalization at the time of fever – Prior episode(s) of FN • Severe Chronic Neutropenia (SCN) (Neupogen, Nivestym, Releuko, Zarxio) Neupogen®, Nivestym®, Releuko®, and Zarxio® are proven and medically necessary when the following criteria are met: ○ All of the following: ▪ Diagnosis of SCN (i.e., congenital, cyclic, and idiopathic neutropenias with chronic ANC ≤ 500 neutrophils/mcL); and ▪ Medication is dosed in accordance with the U.S. Food and Drug Administration (FDA) approved labeling; and ▪ Prescribed by or in consultation with a hematologist or oncologist • Hematopoietic Syndrome of Acute Radiation Syndrome (Fulphila®, Leukine®, Neulasta®, Neupogen®, Nivestym®, Nyvepria™, Udenyca®, Releuko®, Zarxio®, Ziextenzo®) Fulphila®, Leukine®, Neulasta®, Neupogen®, Nivestym®, Nyvepria™, Releuko®, Udenyca®, Zarxio®, and Ziextenzo® are proven and medically

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	– Prior episode(s) of FN ▪ Removed: – Hypotension – Acute renal failure – Acute respiratory failure – Acute heart failure **Definitions** ● Updated definition of "Febrile Neutropenia" **Applicable Codes** ● Added HCPCS codes C9096 and J3590 **Supporting Information** ● Updated *FDA* and *References* sections to reflect the most current information	necessary when all of the following criteria are met: ○ All of the following: ▪ Patient has been acutely exposed to myelosuppressive doses of radiation; and ▪ Medication is dosed in accordance with the U.S. Food and Drug Administration (FDA) approved labeling; and ▪ Prescribed by or in consultation with a hematologist or oncologist
Xolair® (Omalizumab)	Aug. 1, 2022	**Coverage Rationale** ● Removed instruction to refer to the current release of the [listed] InterQual® guideline for medical necessity clinical coverage criteria ● Added language to indicate Xolair for provider administration is: ○ Proven and medically necessary for treatment of the following indications when the criteria listed in the policy are met: ▪ Moderate to severe persistent asthma ▪ Chronic urticaria ▪ Nasal polyps	This policy refers to Xolair® (omalizumab) subcutaneous injection for administration by a healthcare professional. Xolair® (omalizumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit. Refer to the policy for complete details.

Medical Benefit Drug Policy Updates

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

Coverage Determination Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Speech Generating Devices (for Tennessee Only)	Jul. 1, 2022	**Application**
		• Added language to indicate this Coverage Determination Guideline applies to:
		  ○ CoverKids
		  ○ Members aged 20 and under; for members age 21 and over, refer to the *Rules of Tennessee Department of Finance and Administration, Bureau of TennCare, Chapter 1200-13-13.10 Exclusions*
		Coverage Rationale
		• Updated list of examples of a Dedicated Speech Generating Device:
		  ○ Added Prentke Romich (or PRC)
		  ○ Replaced "Dynavox" with "*Tobii* Dynavox"
		• Added notation to indicate most benefit plans require a 3-month rental period before a purchase can be made
		Definitions
		• Replaced instruction to "check the definitions within the member benefit plan document that supersede the definitions [listed in the policy]" with "check the federal, state or contractual definitions that supersede the definitions [listed in the policy]"
			Indications for Coverage
			Speech Generating Devices
			Speech Generating Devices are covered as DME when:
			• The device(s) are not explicitly excluded from coverage; and
			• The treating physician determines that the member has either a severe speech impairment (impediment) or lack of speech resulting from a sickness or injury; and
			• The medical condition warrants the use of a device.
			
			The physician attestation must be consistent with and based upon the recommendation of a qualified speech and language pathologist. The speech and language pathology evaluation must reach all of the following conclusions:
			• Other forms of treatment have been attempted or considered and ruled out. Examples of a Speech Generating Device are:
			  ○ Freedom
			  ○ Prentke Romich (or PRC)
			  ○ Say-it!™
			  ○ Tobii Dynavox
			• The member's medical condition is one resulting in a severe expressive speech impairment (impediment) or lack of speech directly related to Sickness or Injury;
			• The member's speaking needs cannot be met using natural communication methods;
			
			Note: Most benefit plans require a 3-month rental period before a purchase can be made.
			
			For medical necessity clinical coverage criteria, refer to the InterQual® Medicare: Durable Medical Equipment, Speech Generating Devices (SGD).
			
			Click here to view the InterQual® criteria.

Coverage Determination Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Speech Generating Devices (for Tennessee Only) (continued)	Jul. 1, 2022		**Coverage Limitations and Exclusions** • When more than one piece of DME can meet the member's functional needs, benefits are available only for the item that meets the minimum specifications for member needs • Additional accessories to DME items or devices which are primarily for the comfort or convenience of the member • Replacement of items due to malicious damage, neglect or abuse • Replacement of lost or stolen items • Routine periodic maintenance (e.g., testing, cleaning, regulating and checking of equipment) for which the owner or vendor is generally responsible • Upgrade or replacement of DME when the existing equipment is still functional

Utilization Review Guideline Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Chemotherapy Observation or Inpatient Hospitalization (for Tennessee Only)	Jun. 1, 2022	**Application** ● Added language to indicate this Medical Policy applies to CoverKids **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" ● Removed reference to specific InterQual® release date; refer to the most current InterQual® criteria **Supporting Information** ● Updated *References* section to reflect the most current information

General Information

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

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

UnitedHealthcare respects the expertise of the physicians, health care professionals, and their staff who participate in our network. Our goal is to support you and your patients in making the most informed decisions regarding the choice of quality and cost-effective care, and to support practice staff with a simple and predictable administrative experience. The Medical Policy Update Bulletin was developed to share important information regarding UnitedHealthcare Community Plan of Tennessee 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 Tennessee Medical Policies, Medical Benefit Drug Policies, Coverage Determination Guidelines, and Utilization Review Guidelines is available at UHCprovider.com/Tennessee > Medicaid (Community Plan) > Current Policies and Clinical Guidelines > UnitedHealthcare Community Plan of Tennessee Medical & Drug Policies and Coverage Determination Guidelines.