United Healthcare Community Plan

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

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.

In This Issue

Medical Policy Updates — Page

Updated

Revised

Medical Benefit Drug Policy Updates

Revised

United Healthcare Community Plan

In This Issue

Medical Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Genetic Testing for Hereditary Cancer (for Kentucky Only)	Jul. 1, 2022	Coverage Rationale *Other Hereditary Cancer Syndrome Multi-Gene Panel Testing* • Updated coverage criteria; added language to clarify *at least one of the [listed]* criteria pertaining to personal history or close blood relative(s) is required
Proton Beam Radiation Therapy (for Kentucky Only)	Jul. 1, 2022	Coverage Rationale • Added language to indicate proton beam radiation therapy is proven and medically necessary in certain circumstances • Replaced language indicating "proton beam radiation therapy (PBT) and intensity-modulated radiation therapy (IMRT) are proven and considered clinically equivalent for treating prostate cancer; *medical necessity will be determined based on the benefit plan*" with "PBT and IMRT are proven and considered clinically equivalent for treating prostate cancer; *as a result, the principles of medical necessity will be applied*" Applicable Codes • Added ICD-10 diagnosis codes C69.0, C69.00, C69.01, C69.02, C69.1, C69.10, C69.11, C69.12, C69.20, C69.21, C69.22, C69.50, C69.51, C69.52, C69.6, C69.60, C69.61, C69.62, C69.8, C69.80, C69.81, C69.82, C69.9, C69.90, C69.91, and C69.92 • Replaced ICD-10 diagnosis code C61.0 with C61 Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Genitourinary Pathogen Nucleic Acid Detection Panel Testing (for Kentucky Only)	Jul. 1, 2022	Coverage Rationale • Added language to indicate screening of asymptomatic individuals for vaginitis is unproven and not medically necessary • Replaced language indicating "[the listed indications are] proven and medically necessary to evaluate symptomatic *women* for Vaginitis" with "[the listed indications are] proven and medically necessary to evaluate symptomatic *individuals* for Vaginitis"	The following are proven and medically necessary to evaluate symptomatic individualsfor Vaginitis: • Direct and amplified DNA probe testing for Trichomoniasis vaginalis • Direct probe testing for Candida sp Due to insufficient evidence of efficacy, the following are unproven and not medically necessary: • Amplified DNA probe testing for vulvovaginitis due to Candida sp • Direct and amplified DNA probe testing for bacterial Vaginosis (i.e., Gardnerella vaginalis) • Multiplex polymerase chain reaction (PCR) panel testing of genitourinary pathogens, including but not limited to pathogens commonly associated with Vaginitis

Medical Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genitourinary Pathogen Nucleic Acid Detection Panel Testing (for Kentucky Only) (continued)	Jul. 1, 2022	**Applicable Codes** ● Revised description for CPT code 81514 **Supporting Information** ● Updated *Clinical Evidence* and *References* sections to reflect the most current information	● Screening of asymptomatic individuals for vaginitis Note: This policy does not apply to tests for gonorrhea and chlamydia.
Implanted Electrical Stimulator for Spinal Cord (for Kentucky Only)	Jul. 1, 2022	**Coverage Rationale** ● Replaced language indicating: ○ "Implanted electrical spinal cord stimulators, *including high-frequency spinal cord stimulators and burst spinal cord stimulators*, are proven and medically necessary for treating the [listed] indications" with "implanted electrical spinal cord stimulators are proven and medically necessary for treating the [listed] indications *in certain circumstances when performed according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions*" ○ "Implanted electrical spinal cord stimulators are unproven and not medically necessary for treating refractory angina pectoris" with "implanted electrical spinal cord	Implanted electrical spinal cord stimulators, are proven and medically necessary for treating the following indications in certain circumstances, when performed according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions: ● Complex regional pain syndrome (CRPS) ● Painful lower limb diabetic neuropathy ● Failed back surgery syndrome Implanted electrical spinal cord stimulators are unproven and not medically necessary for treating refractory angina pectoris due to insufficient evidence of efficacy. Dorsal root ganglion (DRG) stimulation is proven and medically necessary for treating refractory complex regional pain syndrome (CRPS I, CPRS II) in certain circumstances when performed according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions. Dorsal root ganglion (DRG) stimulation is unproven and not medically necessary for treating all other indications due to insufficient evidence of efficacy. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Spinal Cord Stimulator (SCS) Insertion. Click here to view the InterQual® criteria.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Implanted Electrical Stimulator for Spinal Cord (for Kentucky Only) (continued)	Jul. 1, 2022	stimulators are unproven and not medically necessary for treating refractory angina pectoris *due to insufficient evidence of efficacy*" ○ "Dorsal root ganglion (DRG) stimulation is proven and medically necessary for treating refractory complex regional pain syndrome (CRPS I, CPRS II) when *used* according to U.S. Food and Drug Administration (FDA) *guidelines*" with "dorsal root ganglion (DRG) stimulation is proven and medically necessary for treating refractory complex regional pain syndrome (CRPS I, CPRS II) *in certain circumstances* when *performed* according to U.S. Food and Drug Administration (FDA) *labeled indications, contraindications, warnings and precautions*" ● Revised list of indications for which implanted electrical spinal cord stimulators are proven and medically necessary; replaced "diabetic neuropathy" with "*painful lower limb* diabetic neuropathy" Supporting Information ● Updated *Clinical Evidence* and	Note: ● Coverage of a replacement battery/generator for a previously implanted electrical stimulator is appropriate when the individual's existing battery/generator is malfunctioning, cannot be repaired, and is no longer under warranty.

Medical Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Implanted Electrical Stimulator for Spinal Cord (for Kentucky Only) (continued)	Jul. 1, 2022	*References* sections to reflect the most current information	
Manipulation Under Anesthesia (for Kentucky Only)	Jul. 1, 2022	Coverage Rationale • Replaced language indicating "manipulation under anesthesia (MUA) is proven and medically necessary for shoulder joint for adhesive capsulitis (frozen shoulder)" with "MUA is proven and medically necessary for shoulder joint for adhesive capsulitis (frozen shoulder) *when certain criteria are met*" • Added instruction to refer to the InterQual® CP: Manipulation Under Anesthesia, Shoulder for medical necessity clinical coverage criteria • Removed language indicating MUA is unproven and not medically necessary for any shoulder condition other than adhesive capsulitis (frozen shoulder) Applicable Codes • Removed pelvis ICD-10 diagnosis codes M99.14, S32.10XA, S32.111A, S32.112A, S32.119A, S32.121A, S32.122A, S32.129A, S32.131A, S32.132A, S32.139A, S32.14XA, S32.15XA, S32.16XA, S32.17XA, S32.19XA, S32.2XXA,	Manipulation under anesthesia (MUA) is proven and medically necessary for: • Knee joint for arthrofibrosis following total knee arthroplasty, knee surgery, or fracture • Shoulder joint for adhesive capsulitis (frozen shoulder) when certain criteria are met. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Manipulation Under Anesthesia, Shoulder. Click here to view the InterQual® criteria. MUA is unproven and not medically necessary for all other conditions (whether for single or serial manipulations) including but not limited to the following, due to insufficient evidence of efficacy: • Ankle • Finger • Hip joint or adhesive capsulitis of the hip • Knee joint - any condition other than for arthrofibrosis following total knee arthroplasty, knee surgery, or fracture • Pelvis • Spine • Temporomandibular joint (TMJ) • Toe • Wrist This policy does not apply to the following: • Manipulation of the finger on the day following the injection of collagenase clostridium histolyticum (Xiaflex®) to treat Dupuytren's contracture • Closed reduction of a fracture or joint dislocation unless specified • Elbow joint for arthrofibrosis following elbow surgery or fracture

Medical Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Manipulation Under Anesthesia (for Kentucky Only) (continued)	Jul. 1, 2022	S32.301A, S32.302A, S32.309A, S32.311A, S32.312A, S32.313A, S32.391A, S32.392A, S32.399A, S32.401A, S32.402A, S32.409A, S32.411A, S32.412A, S32.413A, S32.421A, S32.422A, S32.423A, S32.431A, S32.432A, S32.433A, S32.441A, S32.442A, S32.443A, S32.451A, S32.452A, S32.453A, S32.461A, S32.462A, S32.463A, S32.471A, S32.472A, S32.473A, S32.481A, S32.482A, S32.483A, S32.491A, S32.492A, S32.499A, S32.501A, S32.502A, S32.509A, S32.511A, S32.512A, S32.519A, S32.591A, S32.592A, S32.599A, S32.601A, S32.602A, S32.609A, S32.611A, S32.612A, S32.613A, S32.614A, S32.615A, S32.616A, S32.691A, S32.692A, S32.699A, S32.810A, S32.811A, S32.82XA, S32.89XA, S32.9XXA, and S33.2XXA **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	
Prescribed Pediatric Extended Care (for Kentucky Only)	Jul. 1, 2022	**Title Change** • Previously titled *Pediatric Prescribed Extended Care (for Kentucky Only)* **Template Update** • Changed policy type classification	Prescribed Pediatric Extended Care (PPEC) is considered medically necessary when all the following criteria are met: • Criteria for Admission, Preadmission Conference, Admission Procedure and Provision of Services requirements are met; and • Appropriate level of care is assigned to the member utilizing the PPEC Leveling Evaluation Tool prior to admission.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Prescribed Pediatric Extended Care (for Kentucky Only) (continued)	Jul. 1, 2022	from "Coverage Determination Guideline" to "Medical Policy" **Coverage Rationale** • Removed language indicating Prescribed Pediatric Extended Care (PPEC) is considered medically necessary when the caregiver has provided proof of a work or school schedule • Added notation to indicate the Criteria for Admission, Preadmission Conference, Admission Procedure and Provision of Services requirements contained in this policy are set forth in accordance with state requirements; for most recent medical necessity clinical coverage criteria, refer to the *Kentucky Administrative Regulations 907 20:280, Prescribed Pediatric Extended Care Centers* • Removed language pertaining to renewal of services (refer to the *Benefit Considerations* section of the policy) ***Prescribed Pediatric Extended Care Leveling Evaluation Tool: Levels of Care*** • Removed language indicating every member can receive up to four (4) Leveling Tool baseline points	Note: The Criteria for Admission, Preadmission Conference, Admission Procedure and Provision of Services requirements contained in this policy are set forth below in accordance with State requirements. For most recent medical necessity clinical coverage criteria, refer to the Kentucky Administrative Regulations 907 20:280, Prescribed pediatric extended care centers. **Criteria for Admission** • Children considered for admission to the PPEC center must have a medically complex condition requiring continual care, including but not limited to supplemental oxygen, ventilator dependence, cystic fibrosis, apnea, spinal cord injury, or malignancy. • Children should be medically stable, require skilled nursing care or other interventions, and be appropriate for outpatient care. • The primary care provider, in consultation with the parent or legal guardian, shall be responsible for recommending placement in a PPEC center upon consideration of medical, emotional, psychosocial, and environmental factors. • Children must not present significant risk of infection to other children or personnel. The medical and nursing director may review, on a case-by-case basis, any child with suspected infectious disease to determine appropriateness of admission. **Preadmission Conference** If a child meets the admission criteria, the primary care provider or designee shall contact the medical or nursing director of the PPEC center to schedule a preadmission conference. • If a child is hospitalized at the time of referral, preadmission planning shall include: ○ The parent or legal guardian; and ○ Relevant hospital medical, nursing, social services, and developmental staff to assure that the discharge plans shall be implemented upon admission to the PPEC center.

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Prescribed Pediatric Extended Care (for Kentucky Only) (continued)	Jul. 1, 2022	*Coverage Limitations and Exclusions*
		• Removed language indicating PPEC services may not be used as respite care or for the convenience of the caregiver
		Definitions
		• Added definition of:
		  ○ Medically Dependent or Technologically Dependent Child
		  ○ Prescribed Pediatric Extended Care Center (PPECC)
		Applicable Codes
		Modifiers
		• Removed language indicating there is no modifier for Level 1 [of Care]
		Benefit Considerations
		• Replaced language indicating "authorization must be updated every *60 days*" with "authorization must be updated every *6 months*"
		• Removed language indicating requests for renewal of services will require submission of an updated parent or guardian's work and/or school schedule to support reauthorization
		Supporting Information
		• Updated *FDA* and *References* sections to reflect the most current information
			• If a child is not hospitalized at the time of referral, preadmission planning shall be conducted with the:
			  ○ Primary care provider;
			  ○ Parent or legal guardian;
			  ○ PPEC center representatives; and
			  ○ Representatives of other relevant agencies as determined by the primary care provider and nursing director.
			• A preadmission planning conference shall:
			  ○ Be scheduled at least seventy-two (72) hours prior to placement; and
			  ○ Allow sufficient time to assure that the therapeutic plan can be implemented upon placement in the PPEC center.
			• The protocol of care shall:
			  ○ Be developed under the direction of the PPEC center's nursing director during the pre-admission planning conference;
			  ○ Specify the treatment plan needed to accommodate the medical, nursing, psychosocial, and educational needs of the child and family;
			  ○ Identify specific goals for care, including plans for achieving those goals;
			  ○ Include a schedule for evaluation of progress;
			  ○ Include procedures to follow in an emergency situation;
			  ○ Include criteria for discharge from the PPEC center; and
			  ○ Be signed by the:
			  ▪ Physician;
			  ▪ Authorized representative of the PPEC center; and
			  ▪ Parent or legal guardian.
			• A consent form outlining the purpose of the PPEC center, family responsibilities, authorized treatment, appropriate liability release, and emergency disposition plans shall be signed by the parent or legal guardian and witnessed prior to admission to the PPEC center.
			• A copy of the consent form shall be provided to the parent or legal guardian and maintained in the child's medical record.
			Admission Procedures

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

Prescribed Pediatric Extended Care (for Kentucky Only) (continued)	Jul. 1, 2022		• In consultation with the parent or legal guardian, a child may be referred to the PPEC center medical or nursing director for determination of placement.
			• Each child admitted to a PPEC center shall be admitted in accordance with a physician's written order placed in the child's medical record.
			• A copy of the order shall be provided to the child's parent or legal guardian.
			
			Provision of Services
			
			Medical Staff Services
			
			• Each child admitted to a PPEC center shall be admitted upon prescription by the
			  ○ Child's prescribing physician; or
			  ○ Medical director.
			• The child's primary care provider shall maintain responsibility for the overall medical therapeutic plan.
			• The medical director shall participate in review of the protocol of care. Prescribed therapies shall be adjusted in consultation with the primary care provider to accommodate the child's condition.
			• The PPEC center shall coordinate the prescribed therapies for the child.
			
			Nursing Staff Services
			
			• A PPEC center nursing staff member shall participate in preadmission planning.
			• Nursing personnel, under the direction of the nursing director, shall be responsible for implementing the nursing care.
			• Nursing personnel shall be responsible for monitoring and documenting the effects of prescribed therapies.
			• Nursing personnel shall inform the primary care provider and medical director of the results of therapeutic interventions.
			• Nursing personnel shall participate in interdisciplinary staff meetings regarding the child's progress.
			• Nursing personnel shall assure that the PPEC center provides an environment conducive to the:
			  ○ Stabilization of the child's medical condition; and

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Prescribed Pediatric Extended Care (for Kentucky Only) (continued)	Jul. 1, 2022		○ Promotion of the child's development. ● Nursing personnel shall be responsible for maintaining the child's record in accordance with facility policies and procedures. ● Nursing personnel shall instruct the parent or legal guardian in how to provide the necessary therapies in the home. ***Developmental Services*** ● Each child shall have a functional assessment and an individualized program plan to accommodate the child's developmental needs. ● The following functional areas shall be included as appropriate: ○ Self-care; ○ Communication skills; ○ Social skills; ○ Motor skills; ○ Cognitive areas; ○ Play; and ○ Growth and development appropriate for age. ● The child's program plan shall: ○ Include specific programs and action steps to facilitate developmental progress; ○ Be reviewed at least quarterly; ○ Include measurable goals in need areas, or goals to enhance and normalize independent functioning in daily activities; ○ Describe the child's strengths and present performance level with respect to each goal; ○ Document skill areas in priority order; and ○ Include anticipatory planning for specific areas identified as at-risk for future problems. ● The child life specialist shall participate in interdisciplinary staff meetings. ● Each PPEC center shall: ○ Include the parent or legal guardian in care-related conferences; and ○ Train the parent or legal guardian on how to: ▪ Perform necessary therapies; and

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Prescribed Pediatric Extended Care (for Kentucky Only) (continued)	Jul. 1, 2022		▪ Meet the developmental and psychosocial needs of their child at home. • PPEC center staff shall: ○ Make referrals to appropriate resources; ○ Refer to community, social, educational, and financial services; and ○ Refer or provide counseling to enhance coping skills, interpersonal relationships, and family functioning. ***Nutritional Services*** • Therapeutic diets shall be maintained in the child's file. • A registered dietician shall be available to provide assistance with: ○ Nutritional needs; ○ Special diets of individual children; and ○ The development of policies and procedures for the handling, serving, and storage of food. • All food and formula, except for specialized formula, shall be provided by PPEC center staff under the supervision of the nursing director. • Prepared foods shall be: ○ Kept under refrigeration with identifying dates; and ○ Labeled with the child's name. **Prescribed Pediatric Extended Care Leveling Evaluation Tool Levels of Care** Leveling Tool is available to providers upon request. Levels of Care / Measuring Levels Level 1: Mild Acuity / Level 1: 12 to 16 points Level 2: Moderate Acuity / Level 2: 17-32 points Level 3: Moderate to Maximal Acuity / Level 3: 33-48 points Level 4: Maximal Acuity / Level 4: 49+ points

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Spinal Fusion Enhancement Products (for Kentucky Only)	Jul. 1, 2022	**Coverage Rationale**
		• Revised list of products proven and medically necessary for the enhancement of spinal fusion; replaced "Autografts" with "Autografts *(including bone marrow aspirate used for bone grafting)*"
		Applicable Codes
		• Added CPT code 20939
		Supporting Information
		• Updated *Description of Services*, *Clinical Evidence*, and *References* section to reflect the most current information
			The following are proven and medically necessary for the enhancement of spinal fusion:
			• Autografts (including bone marrow aspirate used for bone grafting)
			• Demineralized bone matrix (DBM) without added products listed below as unproven and not medically necessary
			• Allograft-based products not listed below as unproven and not medically necessary
			• Infuse® Bone Graft Recombinant human bone morphogenetic protein-2 (rhBMP-2) of the lumbar spine when the following criteria are met:
			  ○ The approach is anterior or oblique and used in conjunction with an FDA-approved interbody fusion device
			  ○ Skeletally mature individual (18 years of age or older or radiographic evidence of epiphyseal closure) with degenerative disc disease (DDD)
			  ○ The fusion involves vertebral bodies L2-S1, without or with spondylolisthesis of no more than grade 1 (25% displacement) at the involved level
			  ○ The fusion is single level
			• The InFUSE/MASTERGRAFT™ Posterolateral Revision Device System (or InFUSE BMP used with MASTERGRAFT) when used according to U.S. Food and Drug Administration (FDA) indications in individuals who meet all of the following criteria:
			  ○ Implanted via a posterolateral approach
			  ○ Presence of symptomatic posterolateral lumbar spine pseudoarthrosis
			  ○ Skeletally mature patient (older than 21 years of age or radiographic evidence of epiphyseal closure)
			  ○ Autologous bone and/or bone marrow harvest is not feasible or is not expected to promote fusion
			
			The following are unproven and not medically necessary for the enhancement of spinal fusion due to insufficient evidence of efficacy:
			• Allograft based products
			  ○ Cell-based (e.g., mesenchymal stem cells (MSC))
			  ○ Ceramic-based products (e.g., beta tricalcium phosphate (b-TCP),

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Spinal Fusion Enhancement Products (for Kentucky Only) (continued)	Jul. 1, 2022		calcium phosphate, calcium sulfate and bioactive glass) used alone or in combination with other grafts including bone marrow aspirate ○ Human amniotic tissue materials, including amniotic fluid stem cell substitutes for the treatment of spine disease or in spine surgery ● Recombinant human bone morphogenetic protein-2 (e.g., rhBMP-2, InFUSE) and InFUSE/MASTERGRAFT™ (or InFUSE BMP used with Mastergraft or Mastergraft alone) Posterolateral Revision Device for all other indications not included above ● The OptiMesh® Expandable Interbody Fusion System
Surgical Treatment for Spine Pain (for Kentucky Only)	Jul. 1, 2022	Coverage Rationale *Documentation Requirements* ● Updated list of clinical information/items to be documented in the medical notes, when applicable; added "surgical history, including date(s) and outcome(s)" Applicable Codes ● Removed CPT code 20939; refer to the Medical Policy titled *Spinal Fusion Enhancement Products (for Kentucky Only)*	Spinal procedures for the treatment of spine pain are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual®: ● CP: Procedures: ○ Decompression +/- Fusion, Cervical ○ Decompression +/- Fusion, Thoracic ○ Decompression +/- Fusion, Lumbar ○ Fusion, Cervical Spine ○ Fusion, Lumbar Spine ○ Fusion, Thoracic Spine ● CP: Procedures, Interspinous Process Decompression Click here to view the InterQual® criteria. The following indications for a surgical spine procedure that is performed to alleviate symptoms or prevent clinical deterioration are considered proven and medically necessary if not addressed in the above criteria: ● Congenital or idiopathic deformity or bone disease other than scoliosis ● Muscular dystrophy ● Laminectomy procedure to provide surgical exposure to treat lesions within the spinal canal Interspinous process fusion devices are proven and medically necessary when used in conjunction with any of the following procedures: ● Open laminar and/or facet decortication and fusion

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

Surgical Treatment for Spine Pain (for Kentucky Only) (continued)	Jul. 1, 2022		• Autograft inter-and extra-spinous process decortication and fusion
			• Interbody fusion of the same motion segment
			
			The following spinal procedures are unproven and not medically necessary due to insufficient evidence of efficacy (this includes procedures that utilize interbody cages, screws, and pedicle screw fixation devices):
			• Laparoscopic anterior lumbar interbody fusion (LALIF)Axial lumbar interbody fusion (AxiaLIF®)
			• Spinal decompression and interspinous process decompression systems for the treatment of lumbar spinal stenosis (e.g., Interspinous process decompression (IPD), Minimally invasive lumbar decompression (mild®)
			• Dividing treatment of symptomatic, multi-site spinal pathology via anterior or posterior approach into serial, multiple, or staged sessions when one session can address all sites
			• Spinal stabilization systems
			  ○ Stabilization systems for the treatment of degenerative spondylolisthesis
			  ○ Total facet joint arthroplasty, including facetectomy, laminectomy, foraminotomy, vertebral column fixation
			  ○ Percutaneous sacral augmentation (sacroplasty) with or without a balloon or bone cement for the treatment of back pain
			• Stand-alone facet fusion without an accompanying decompressive 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 Kentucky Only).
			
			Documentation Requirements
			Medical notes documenting the following, when applicable:
			• Condition requiring procedure
			• History and co-morbid medical condition(s)
			  ○ Smoking history/ status, including date of last smoking cessation
			• Member's symptoms, pain, location, and severity including functional

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical Treatment for Spine Pain (for Kentucky Only) (continued)	Jul. 1, 2022		impairment that is interfering with activities of daily living (meals, walking, getting dressed, driving) • Failure of Conservative Therapy through lack of clinically significant improvement between at least two measurements, on a validated pain or function scale or quantifiable symptoms despite concurrent Conservative Therapies (see definition), if applicable • Progressive deficits with clinically significant worsening based on at least two measurements over time, if applicable • Surgical history, including date(s) and outcome(s) • Disabling Symptoms, if applicable • Upon request, we may request the specific diagnostic image(s) that shows the abnormality for which surgery is being requested which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting surgeon may be needed to select the optimal image(s) ○ Note: When requested, diagnostic images must be labeled with the: ▪ Date taken ▪ Applicable case number obtained at time of notification, or the member's name and ID number on the image(s) ○ Upon request, diagnostic imaging must be submitted via the external portal at www.uhcprovider.com/paan; faxes will not be accepted • Diagnostic image(s) report(s), including presence or absence of: ○ Segment (s) instability ○ Spinal cord compression ○ Disc herniation ○ Nerve root compression ○ Quantification of subluxation, translation by flexion, angulation when appropriate ○ Discitis ○ Epidural abscess • Physical exam, including neurologic exam, including degree and progression of curvature (for scoliosis), if applicable ○ Degree and progression of curvature (for scoliosis) ○ Quantification of relevant muscle strength

Medical Policy Updates

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

Surgical Treatment for Spine Pain (for Kentucky Only) (continued)	Jul. 1, 2022		• Whether the surgery will be performed with direct visualization or only with endoscopic visualization
			• Complete report(s) of diagnostic tests
			  ○ Results of biopsy(ies)
			  ○ Results of bone aspirate
			• Describe the surgical technique(s) planned [e.g., AxiaLIF®, XLIF, ILIF, OLIF, LALIF, image-guided minimally invasive lumbar decompression (mild®), percutaneous endoscopic discectomy with or without laser, etc.]

Transcranial Magnetic Stimulation (for Kentucky Only)	Jul. 1, 2022	**Coverage Rationale**
		• Added instruction to refer to the InterQual® CP: Procedures: Transcranial Magnetic Stimulation (TMS) for medical necessity clinical coverage criteria
		Supporting Information
		• Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
			For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures: Transcranial Magnetic Stimulation (TMS).
			
			Click here to view the InterQual® criteria.
			
			The following are unproven and not medically necessary due to insufficient evidence of efficacy:
			• Transcranial magnetic stimulation for treating all medical (i.e., non-behavioral) conditions including but not limited to:
			  ○ Alzheimer's disease
			  ○ Chronic neuropathic pain
			  ○ Dystonia
			  ○ Epilepsy
			  ○ Headaches
			  ○ Parkinson's disease
			  ○ Stroke
			  ○ Tinnitus
			• Navigated transcranial magnetic stimulation (nTMS) for treatment planning or for diagnosing motor neuron diseases or neurological disorders
			
			For Behavioral Disorders, refer to the Optum Behavioral Clinical Policy titled Transcranial Magnetic Stimulation at Optum Provider Express > Clinical Resources > Guidelines/Policies & Manuals > Behavioral Clinical Policies.

Utilization Review Guideline Updates

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

Apokyn® (Apomorphine) (for Kentucky Only)	Jul. 1, 2022	Coverage Rationale
		• Revised coverage criteria:
		  ○ Added criterion requiring Apokyn is prescribed by or in consultation with a neurologist or specialist in the treatment of Parkinson's disease
		  ○ Removed criterion requiring the patient is not receiving Apokyn in combination with serotonin 5-hydroxytryptamine-3 (5-HT(3)) receptor antagonists including antiemetics or other apomorphine formulations (e.g., Kynmobi film)
		  ○ Replaced criterion requiring "diagnosis of *advanced* Parkinson's disease" with "diagnosis of Parkinson's disease"
			Apokyn® is proven and medically necessary for the treatment of Parkinson's disease when all of the following criteria are met:
			• Diagnosis of Parkinson's disease; and
			• Patient is experiencing acute intermittent hypomobility (defined as "off" episodes characterized by muscle stiffness, slow movements, or difficulty starting movements); and
			• Patient is currently on a stable dose of a carbidopa/levodopa-containing medication and will continue receiving treatment with a carbidopa/levodopa-containing medication while on therapy; and
			• Prescribed by or in consultation with a neurologist or specialist in the treatment of Parkinson's disease; and
			• Confirmation that healthcare practitioner administration is only for the initiation of treatment; and
			• Apokyn dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling; and
			• Patient continues to experience ≥ 2 hours of OFF time per day despite optimal management of carbidopa-levodopa therapy including both of the following
			  ○ Taking carbidopa/levodopa on an empty stomach or at least one half-hour or more before or one hour after a meal or avoidance of high protein diet; and
			  ○ Dose and dosing interval optimization; and
			• History of failure, contraindication, or intolerance to two anti-Parkinson's disease therapy from the following adjunctive pharmacotherapy classes (trial must be from two different classes):
			  ○ Dopamine agonists (e.g., pramipexole, ropinirole); or
			  ○ Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone); or
			  ○ Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline); and and
			• Authorization is for no more than 1 month

Botulinum Toxins A and B	Aug. 1, 2022	Coverage Rationale • Replaced instruction to refer to the current release of the [listed]	This policy refers to the following Botulinum toxin type A and B drug products: • Dysport® (abobotulinumtoxinA) • Xeomin® (incobotulinumtoxinA)

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Botulinum Toxins A and B (continued)	Aug. 1, 2022	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 diagnosis ▪ For continuation of therapy, both of the	• 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 having specific medical necessity criteria in the list of proven indications. Dysport (abobotulinumtoxinA) is medically necessary in the treatment of the following conditions:

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Botulinum Toxins A and B (continued)	Aug. 1, 2022	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 known as detrusor hyperreflexia) or detrusor-sphincter dyssynergia due	● 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 ○ 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

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Botulinum Toxins A and B (continued)	Aug. 1, 2022	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 necessary for the treatment of the following indications when the criteria listed in the policy	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 ● Voice tremor Xeomin (incobotulinumtoxinA) is medically necessary in the treatment of the following conditions:

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Botulinum Toxins A and B (continued)	Aug. 1, 2022	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 hyperreflexia) or detrusor-sphincter dyssynergia due to spinal cord injury or	● 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 ▪ Long-acting nitrate and ○ Other causes of dysphagia (e.g., peptic stricture, carcinoma, extrinsic compression) ruled out by upper gastrointestinal endoscopy

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Botulinum Toxins A and B (continued)	Aug. 1, 2022	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 ○ Myobloc (rimabotulinumtoxinB) is proven and medically	● 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 ▪ Diagnosis of detrusor-sphincter dyssynergia due to spinal cord injury or disease and ○ History of failure, contraindication, or intolerance to two anticholinergic

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Botulinum Toxins A and B (continued)	Aug. 1, 2022	necessary for the treatment of the following indications when the criteria listed in the policy are met: ▪ 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: ▪ Acquired nystagmus ▪ Anismus (pelvic floor dyssynergia)	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: ○ Diagnosis of overactive bladder; and ○ One of the following symptoms: ▪ Urge urinary incontinence ▪ Urgency

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Botulinum Toxins A and B (continued)	Aug. 1, 2022	▪ 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) ▪ Piriformis syndrome ▪ Post-parotidectomy sialoceles	▪ 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 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

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Botulinum Toxins A and B (continued)	Aug. 1, 2022	▪ 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, 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,	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) ● Gustatory epiphora (Crocodile tears) ● Head tremor ● Lateral epicondylitis (tennis elbow) ● Lichen simplex

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Botulinum Toxins A and B (continued)	Aug. 1, 2022	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	• 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 • 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 (at least two months) of immunosuppressive therapy	Refer to the policy for complete details.

Utilization Review Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
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, K51.213, K51.214, K51.218, K51.219, K51.30, K51.311, K51.312, K51.313, K51.314,	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 ▪ 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:

Utilization Review Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Entyvio® (Vedolizumab) (continued)	Aug. 1, 2022	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	▪ 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; and ○ Patient is receiving a checkpoint inhibitor [e.g., Keytruda (Pembrolizumab), Opdivo (Nivolumab)]; and

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Entyvio® (Vedolizumab) (continued)	Aug. 1, 2022		○ 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	Application *Kentucky* ● Removed language indicating the Preferred Product Criteria specific to Epogen and Procrit does not apply to the state of Kentucky Coverage Rationale ● Replaced instruction to refer to the current release of the [listed] InterQual® guideline with Diagnosis-Specific Criteria ● Added language to indicate: ○ The epoetin alfa (i.e., Retacrit, Epogen, Procrit) preferred product criteria in this [policy] applies to the state of Kentucky ○ "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	This policy addresses the following erythropoiesis-stimulating agents (ESAs): ● Aranesp® (darbepoetin alfa) ● Epogen® (epoetin alfa) ● Mircera® (methoxy polyethylene glycol-epoetin beta [MPG-epoetin beta]) ● Procrit® (epoetin alfa) ● Retacrit® (epoetin alfa) The epoetin alfa (i.e., Retacrit, Epogen, Procrit) preferred product criteria in this section applies to the following states: CA, HI, KY, MD, MI, MN, MS, NE, NJ, NY, OH, RI, and TN. For all other states, coverage will be provided contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Coverage for Retacrit is contingent on criteria in the Diagnosis-Specific Criteria section. Prior authorization is not required. Coverage for Epogen or Procrit is contingent on Preferred Product Criteria and Diagnosis-Specific Criteria. In order to continue coverage, members already on these products will be required to change therapy to Retacrit unless they meet the criteria below. **Preferred Product Criteria** Treatment with Epogen® or Procrit® 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 Retacrit®, 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 Retacrit®; or

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Erythropoiesis-Stimulating Agents (continued)	Aug. 1, 2022	○ 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 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	● Both of the following: ○ History of failure, contraindication, or intolerance to Retacrit®; and ○ Physician attests that, in their clinical opinion, the same failure, contraindication, or intolerance would not be expected to occur with Epogen® or Procrit® **Diagnosis-Specific Criteria** "ESAs" will be used to refer to all erythropoiesis stimulating agents, unless otherwise specified. For the purposes of the *Coverage Rationale*, 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. ***Anemia Due to Chronic Kidney Disease*** **Patients Receiving Dialysis** ESAs are proven and medically necessary for the treatment of anemia of chronic kidney disease (CKD) when all of the following criteria are met: ● For initial therapy, all of the following: ○ Patient is on dialysis; and ○ Hematocrit is less than 30% at initiation of therapy ; and ○ Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency); and ○ Initial authorization will be for no more than 12 months ● For continuation of therapy, all of the following: ○ Patient is on dialysis; and ○ Documentation of positive clinical response to ESA therapy; and ○ Hematocrit remains less than 33%; and ○ Reauthorization will be for no more than 12 months ESAs are unproven to treat anemia of CKD in patients on dialysis for a hematocrit greater than or equal to 33%.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Erythropoiesis-Stimulating Agents (continued)	Aug. 1, 2022	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 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	**Patients Not Receiving Dialysis** ESAs are proven and medically necessary for the treatment of anemia of chronic kidney disease (CKD) when all of the following criteria are met: ● For initial therapy, all of the following: ○ Patient is not on dialysis; and ○ Hematocrit is less than 30% at initiation of therapy; and ○ The rate of hematocrit decline indicates the likelihood of requiring a red blood cell (RBC) transfusion; and ○ Therapeutic goal is reducing the risk of alloimmunization and/or other RBC transfusion-related risks ; and ○ Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency); and ○ Initial authorization will be for no more than 12 months ● For continuation of therapy, all of the following: ○ Patient is not on dialysis; and ○ Documentation of positive clinical response to ESA therapy; and ○ Therapeutic goal is reducing the risk of alloimmunization and/or other RBC transfusion-related risks ; and ○ Hematocrit remains less than 30% for continuation of therapy; and ○ Reauthorization will be for no more than 12 months ESAs are unproven to treat anemia of CKD in patients not on dialysis for a hematocrit greater than 30%. ***Anemia Due to Cancer Chemotherapy*** Aranesp, Epogen, Procrit, and Retacrit are proven and medically necessary when used to treat anemia in cancer chemotherapy when both of the following criteria are met: ● For initial therapy, all of the following: ○ Hematocrit less than or equal to 30% at initiation of therapy; and ○ There is a minimum of two additional months of planned chemotherapy; and

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Erythropoiesis-Stimulating Agents (continued)	Aug. 1, 2022	Comprehensive Cancer Network (NCCN) Practice Guideline, Cancer- and Chemotherapy-Induced Anemia, as referenced in the *Professional Societies* section of this policy ▪ Patients with cancer 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	○ Chemotherapy not being administered with curative intent (i.e., adjuvant therapy or definitive therapy); and ○ Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency) and there is documentation of normal iron stores; and ○ Initial authorization will be for no more than 12 months ● For continuation of therapy, all of the following: ○ Documentation of positive clinical response to ESA therapy; and ○ There is a minimum of two additional months of planned chemotherapy; and ○ Chemotherapy not being administered with curative intent (i.e., adjuvant therapy or definitive therapy); and ○ Hematocrit remains less than or equal to 30% for continuation of therapy; and ○ Reauthorization will be for no more than 12 months Mircera is unproven for the treatment of anemia due to cancer chemotherapy. ESAs are unproven to treat anemia in patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.[1, 4, 5] ESAs are unproven to treat anemia in patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion. ***Anemia Associated with Myelodysplastic Syndromes (MDS)*** Aranesp, Epogen, Procrit, and Retacrit are proven and medically necessary to treat anemia associated with myelodysplastic syndromes when the following criteria are met: ● For initial therapy, all of the following: ○ Serum erythropoietin level less than or equal to 500 mUnits/mL; and ○ Hematocrit is less than or equal to 30% at the initiation of therapy; and

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Erythropoiesis-Stimulating Agents (continued)	Aug. 1, 2022	the anemia can be managed by transfusion Supporting Information • Added *Background*, *Clinical Evidence*, *FDA*, and *References* sections	○ Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency); and ○ Initial authorization will be for no more than 12 months • For continuation of therapy, all of the following: ○ Documentation of positive clinical response to ESA therapy; and ○ Serum erythropoietin level less than or equal to 500 mUnits/mL; and ○ Hematocrit remains less than or equal to 36% for continuation of therapy; and ○ Reauthorization will be for no more than 12 months ***Anemia Associated with Zidovudine Treatment in HIV-Infected Patients*** Epogen, Procrit, and Retacrit are proven and medically necessary to treat anemia in HIV-infected patients when the following criteria are met: • For initial therapy, all of the following: ○ Patient is receiving zidovudine administered at less than or equal to 4200 mg/week; and ○ Endogenous serum erythropoietin level less than or equal to 500 mUnits/mL; and ○ Hematocrit is less than 30% at initiation of therapy; and ○ Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency); and ○ Initial authorization will be for no more than 12 months • For continuation of therapy, all of the following: ○ Documentation of positive clinical response to ESA therapy; and ○ Patient is receiving zidovudine administered at less than or equal to 4200 mg/week; and ○ Endogenous serum erythropoietin level less than or equal to 500 mUnits/mL; and ○ Hematocrit remains less than or equal to 36% for continuation of therapy; and ○ Reauthorization will be for no more than 12 months

Utilization Review Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Erythropoiesis-Stimulating Agents (continued)	Aug. 1, 2022		***Anemia Associated with Hepatitis C with Ribavirin and Interferon Therapy***
			Epogen, Procrit, and Retacrit are proven and medically necessary to treat anemia associated with hepatitis C virus infection when the following criteria are met:
			• For initial therapy, all of the following:
			  ○ Patient is receiving ribavirin and interferon therapy; and
			  ○ Hematocrit is less than or equal to 30% at initiation of therapy; and
			  ○ Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency); and
			  ○ Initial authorization will be for no more than 12 months
			• For continuation of therapy, all of the following:
			  ○ Documentation of positive clinical response to ESA therapy; and
			  ○ Patient is receiving ribavirin and interferon therapy; and
			  ○ Hematocrit remains less than or equal to 36% for continuation of therapy; and
			  ○ Reauthorization will be for no more than 12 months
			
			Preoperative Use for Reduction of Allogeneic Blood Transfusions In Surgery Patients
			Epogen, Procrit, and Retacrit are proven and medically necessary perioperatively to reduce the need for allogeneic blood transfusions when the following criteria are met:
			• For initial therapy, all of the following:
			  ○ Perioperative hematocrit is greater than 30% and less than or equal to 39%; and
			  ○ Patient is expected to require at least 2 units of blood during the surgical procedure; and
			  ○ Patient is at high risk for blood loss during surgery; and
			  ○ Patient is unable or unwilling to donate autologous blood; and
			  ○ Surgery procedure is elective, noncardiac, and nonvascular; and
			  ○ Authorization will be for no more than 3 months

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Erythropoiesis-Stimulating Agents (continued)	Aug. 1, 2022		ESAs are unproven for patients who are willing to donate autologous blood pre-operatively or in patient undergoing cardiac or vascular surgery. ***Additional Information*** 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 approximately equal to a hematocrit of 33%, and a hemoglobin of 12 g/dL is approximately equal to a hematocrit of 36%. **Unproven** 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 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.
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	Refer to the policy for complete details.

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) (continued)	Aug. 1, 2022	• 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 meningoencephalitis ▪ Feto-neonatal alloimmune thrombocytopenia ▪ Graves' ophthalmopathy ▪ Guillain-Barré syndrome	

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) (continued)	Aug. 1, 2022	(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 ▪ Post B-cell targeted therapies ▪ Primary immunodeficiency syndromes ▪ Rasmussen syndrome	

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) (continued)	Aug. 1, 2022	▪ 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 ▪ Asthma, non-steroid dependent ▪ Atopic dermatitis ▪ Autism spectrum disorders ▪ Autoimmune liver disease	

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) (continued)	Aug. 1, 2022	▪ 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 viral load ▪ HTLV-1-associated myelopathy ▪ Idiopathic dysautonomia, acute	

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) (continued)	Aug. 1, 2022	▪ 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 colitis ▪ Rheumatic fever, acute ▪ Sjogren's syndrome ▪ Spontaneous recurrent abortions, prevention	

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) (continued)	Aug. 1, 2022	▪ 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 ▪ Plaque psoriasis ▪ Psoriatic arthritis ▪ Rheumatoid arthritis ▪ Sarcoidosis ▪ Ulcerative colitis	Refer to the policy for complete details.

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Infliximab (Avsola™, Inflectra®, Remicade®, & Renflexis®) (continued)	Aug. 1, 2022	▪ 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 justify the inherent clinical risk in the use of a monoclonal antibody anti-tumor necrosis factor agent Applicable Codes	

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Infliximab (Avsola™, Inflectra®, Remicade®, & Renflexis®) (continued)	Aug. 1, 2022	• Added list of applicable ICD-10 diagnosis codes Supporting Information • Added *Documentation Requirements*, *Background*, *Clinical Evidence*, *FDA*, and *References* sections	
Intravenous Iron Replacement Therapy (for Kentucky Only)	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), Monoferric® (ferric derisomaltose), Infed® (iron dextran), and Venofer® (iron sucrose) proven and medically necessary for the treatment of the following indications when the criteria listed in the policy are met: ○ Iron Deficiency Anemia (IDA) without chronic kidney disease (CKD) ○ Iron Deficiency Anemia (IDA) associated with chronic kidney disease (CKD), without end stage renal disease (ESRD) ○ Iron Deficiency Anemia (IDA) associated with chronic kidney disease (CKD), with end stage renal disease (ESRD)	Refer to the policy for complete details.

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Intravenous Iron Replacement Therapy (for Kentucky Only) (continued)	Aug. 1, 2022	**Supporting Information** ● Updated *References* section to reflect the most current information	
Ocrevus® (Ocrelizumab)	Aug. 1, 2022	**Coverage Rationale** ● Removed instruction to refer to the current release of the [listed] InterQual® guideline for medical necessity clinical coverage criteria ● Added language to indicate: ○ Ocrevus is proven and medically necessary for the treatment of the following indications when the criteria listed in the policy are met: ▪ Primary progressive multiple sclerosis (PPMS) ▪ Relapsing forms of multiple sclerosis (MS) ○ Ocrevus is unproven and not medically necessary for the treatment of: ▪ Lupus nephritis ▪ Rheumatoid arthritis ▪ Systemic lupus erythematosus **Applicable Codes** ● Added ICD-10 diagnosis code G35 **Supporting Information** ● Added *Background*, *Clinical Evidence*, *FDA*, and *References* sections	**Primary Progressive Multiple Sclerosis** Ocrevus is proven and medically necessary for the treatment of primary progressive multiple sclerosis (PPMS) when all of the following criteria are met: ● Diagnosis of primary progressive multiple sclerosis (PPMS); and ● One of the following: ○ Initial therapy for ocrelizumab when meeting all of the following: ▪ Patient is not receiving ocrelizumab in combination with any of the following: – Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide) – B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab) – Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) and ▪ Initial dosing: One time 300 mg intravenous course of doses on days 1 and 15; and ▪ Initial authorization is for no more than 6 months; 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,

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ocrevus® (Ocrelizumab) (continued)	Aug. 1, 2022		dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide) – B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab) – Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) and ▪ Continued dosing: One 600 mg intravenous dose every 6 months; and ▪ Authorization is for no more than 12 months **Relapsing Forms of Multiple Sclerosis** Ocrevus is proven and medically necessary for the treatment of relapsing forms of multiple sclerosis (MS) when both of the following criteria are met: ● Diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses); and ● One of the following: ○ Initial therapy for ocrelizumab meeting all of the following: ○ Both of the following:* – Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting either a history of intolerance or severe adverse event to rituximab or a contraindication to rituximab that would not be applicable to 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:

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ocrevus® (Ocrelizumab) (continued)	Aug. 1, 2022		– Disease modifying therapy (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide) – B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab) – Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) and ▪ Initial dosing: One time 300 mg intravenous course of doses on days 1 and 15; and ▪ Initial authorization is for no more than 6 months; or ○ Continuation of therapy for ocrelizumab when meeting all of the following: ▪ Patient has previously received treatment with ocrelizumab; and ▪ Documentation of positive clinical response to ocrelizumab therapy; and ▪ Patient is not receiving ocrelizumab in combination with any of the following: – Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide) – B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab) – 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

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ocrevus® (Ocrelizumab) (continued)	Aug. 1, 2022		• Rheumatoid arthritis • Systemic lupus erythematosus
Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors	Jul. 1, 2022	**Coverage Rationale** • Revised list of applicable vascular endothelial growth factor (VEGF) inhibitors and dual VEGF/angiopoietin-2 (Ang-2) inhibitors; added Byooviz™ (ranibizumab-nuna) and Vabysmo™ (faricimab-svoa) • Added language to indicate: ○ Dual VEGF/Ang-2 inhibitor administration is no more than 12 doses per year per eye, regardless of diagnosis ○ Byooviz (ranibizumab-nuna) is proven and medically necessary for the treatment of: ▪ Neovascular age - related macular degeneration (AMD) ▪ Macular Edema Following Retinal Vein Occlusion (RVO) ▪ Myopic Choroidal Neovascularization (mCNV) ○ Vabysmo (faricimab-svoa) is proven and medically necessary for the treatment of: ▪ Neovascular age-related macular degeneration	This policy provides information about the use of certain specialty pharmacy medications administered by the intravitreal route for ophthalmologic conditions. This policy refers to the following vascular endothelial growth factor (VEGF) inhibitors and dual VEGF/angiopoietin-2 (Ang-2) inhibitors: • Avastin® (bevacizumab) • Beovu® (brolucizumab-dbll) • Byooviz™ (ranibizumab-nuna) • Eylea™ (aflibercept) • Lucentis® (ranibizumab) • Macugen® (pegaptanib) • Vabysmo™ (faricimab-svoa) The following information pertains to medical necessity review: **General Requirements (applicable to all medical necessity requests)** • For initial therapy, both of the following: ○ Diagnosis; and ○ Intravitreal VEGF or dual VEGF/Ang-2 inhibitor administration is no more than 12 doses per year per eye, regardless of diagnosis • For continuation of therapy, both of the following: ○ 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.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Jul. 1, 2022	(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, 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,	Beovu (brolucizumab) is proven and medically necessary for the treatment of: • Neovascular age-related macular degeneration (AMD) Avastin (bevacizumab) is proven and medically necessary for the treatment of: • Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome (OHS) • Diabetic macular edema (DME) • Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) • Neovascular age-related macular degeneration (AMD) • Neovascular glaucoma • Neovascularization of the iris (NVI) (rubeosis iridis) • Proliferative diabetic retinopathy • Type I retinopathy of prematurity Byooviz (ranibizumab-nuna) is proven and medically necessary for the treatment of: • Neovascular age - related macular degeneration (AMD) • Macular Edema Following Retinal Vein Occlusion (RVO) • Myopic Choroidal Neovascularization (mCNV) Eylea (aflibercept) is proven and medically necessary for the treatment of: • 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

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Jul. 1, 2022	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 ○ 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	of: • Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome (OHS) • Diabetic macular edema (DME) • Diabetic retinopathy • Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) • Neovascular age-related macular degeneration (AMD) Macugen (pegaptanib) is proven and medically necessary for the treatment of: • Diabetic macular edema • Neovascular age-related macular degeneration (AMD) Vabysmo (faricimab-svoa) is proven and medically necessary for the treatment of: • Neovascular age-related macular degeneration (AMD) • Diabetic macular edema (DME) **Additional Information** Avastin (bevacizumab) is supplied in sterile vials containing a solution of 25 mg/mL. Doses utilized in ophthalmic conditions generally range from 6.2 mcg to 2.5 mg. Therefore, bevacizumab in vials is often divided into single-dose, prefilled syringes for intravitreal use by compounding pharmacies. Compounding pharmacies must comply with United States Pharmacopeia (USP) 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

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Jul. 1, 2022	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 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	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.

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Jul. 1, 2022	increments or reductions of up to 8 week interval increments based on response – 6 mg administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injections at intervals of every 8 weeks over the next 28 weeks ▪ Although most patients require dosing every 8 weeks, some patients may need dosing every 4 weeks ▪ Maximum of 12 doses per year per eye **Supporting Information** ● 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	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

Utilization Review Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Orencia® (Abatacept) Injection for Intravenous Infusion (continued)	Aug. 1, 2022	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) ▪ 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*	idiopathic arthritis (PJIA); and Orencia is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for polyarticular juvenile idiopathic arthritis; and ▪ Patient is not receiving Orencia in combination with either of the following: – Biologic disease-modifying antirheumatic drug (DMARD) *[e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]* – Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] and ▪ Prescribed by or in consultation with a rheumatologist; and ▪ Initial authorization is for no more than 12 months ○ For continuation of therapy, all of the following: ▪ Patient has previously received Orencia injection for intravenous infusion; and ▪ 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);

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Orencia® (Abatacept) Injection for Intravenous Infusion (continued)	Aug. 1, 2022	sections	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 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:

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Orencia® (Abatacept) Injection for Intravenous Infusion (continued)	Aug. 1, 2022		– 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), Simponi (golimumab), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz (tofacitinib), Otezla (apremilast)]; or – Patient is currently on Orencia and ▪ Orencia is initiated and titrated according to FDA labeled dosing for psoriatic arthritis; and ▪ Patient is not receiving Orencia in combination with any of the following: – Biologic DMARD *[e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]* – Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] – Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] and ▪ Prescribed by or in consultation with one of the following: – Rheumatologist

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Orencia® (Abatacept) Injection for Intravenous Infusion (continued)	Aug. 1, 2022		– 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 ▪ 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:

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Orencia® (Abatacept) Injection for Intravenous Infusion (continued)	Aug. 1, 2022		– 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 ○ 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

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Orencia® (Abatacept) Injection for Intravenous Infusion (continued)	Aug. 1, 2022		○ 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: ▪ 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	Refer to the policy for complete details.

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Aug. 1, 2022	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, 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	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

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Sodium Hyaluronate (continued)	Aug. 1, 2022	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 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,	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 ○ 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

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Sodium Hyaluronate (continued)	Aug. 1, 2022	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	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 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

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Sodium Hyaluronate (continued)	Aug. 1, 2022		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 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:	This policy refers to the following white blood cell colony stimulating factors (CSFs): • Long-acting pegfilgrastim agents: ○ Fulphila® (pegfilgrastim-jmdb) ○ Neulasta® (pegfilgrastim)

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	○ Coverage for Releuko will be provided contingent on the criteria in the *Preferred Product Criteria* section and the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ Treatment with Releuko is medically necessary for the indications specified in the policy when one of the following is met: ▪ Both of the following: – History of a trial of adequate dose and duration of Zarxio, resulting in minimal clinical response; and – Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Releuko than experienced with Zarxio ▪ Both of the following: – History of intolerance, contraindication, or adverse event to Zarxio; and – Physician attests that, in their clinical	○ 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. **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.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with Releuko ○ Releuko is medically necessary for the following indications when the criteria listed in policy are met: ▪ Bone marrow/stem cell transplant ▪ Acute myeloid leukemia (AML) induction or consolidation therapy ▪ Primary prophylaxis of chemotherapy-induced febrile neutropenia (FN) ▪ Secondary prophylaxis of febrile neutropenia (FN) ▪ Treatment of febrile neutropenia ▪ Severe chronic neutropenia (SCN) ▪ Hematopoietic syndrome of acute radiation syndrome ● Revised coverage criteria for: *Bone Marrow/Stem Cell Transplant* ○ Removed criterion requiring medication is: ▪ Dosed in accordance with	*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 **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.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	the U.S. Food and Drug Administration (FDA) approved labeling ▪ Prescribed by or in consultation with a hematologist or oncologist *Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia* ○ Added criterion to allow coverage for the applicable products when the patient is receiving myelosuppressive anticancer drugs given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting) or the patient is receiving myelosuppressive anticancer drugs for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease) ○ Updated list of risk factors for chemotherapy-induced febrile neutropenia; replaced persistent neutropenia due to prior chemotherapy, radiation therapy, or bone marrow involvement by tumor measure of "ANC < 1500	***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 **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

Utilization Review Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	neutrophils/mcL" with "< 500 neutrophils/mcL or < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours" ○ Replaced language indicating "chemotherapy regimen associated incidence of febrile neutropenia (FN) will be based on the clinical trial(s) with the highest level of evidence *according to the GRADE criteria*" with "chemotherapy regimen associated incidence of FN will be based on the clinical trial(s) with the highest level of evidence" ○ Added language to indicate: ▪ Chemotherapy regimens and associated incidence of FN based on the clinical trial(s) according to the grade based on Common Terminology Criteria for Adverse Events (CTCAE) by the National Cancer Institute (NCI) criteria are available for reference at uhcprovider.com ▪ The reference document is not a substitute for the experience and judgment	▪ 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: ▪ 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;

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	of a physician or other health care professional; any clinician must use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment *Secondary Prophylaxis of Febrile Neutropenia* ○ Added criterion to allow coverage for the applicable products: ▪ When the patient is receiving myelosuppressive anticancer drugs given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting) or the patient is receiving myelosuppressive anticancer drugs for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease) ▪ Patient has a documented history of a neutropenic	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) 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

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	event (febrile neutropenia or low neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen at full dose for which primary prophylaxis was not received ○ Removed criterion allowing coverage for the applicable products when the patient is receiving myelosuppressive anticancer drugs associated with neutropenia (ANC ≤ 1500 neutrophils/mcL) *Treatment of Febrile Neutropenia* ○ Added criterion requiring the patient has not received long-acting prophylactic pegfilgrastim in the last 14 days ○ Removed criterion requiring the score of < 21 on the *Multinational Association of Supportive Care in Cancer (MASCC)* scoring system in patients with cancer and febrile neutropenia ○ Revised list of examples of risk factors for an infection-associated complication:	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, 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

Utilization Review Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	▪ Added: – Sepsis syndrome – Age > 65 years – Absolute Neutrophil Count (ANC) < 100/mcL – Neutropenia expected to be > 10 days in duration – Pneumonia – Clinically documented infections including invasive fungal infection – Hospitalization at the time of fever – Prior episode(s) of FN ▪ Removed: – Hypotension – Acute renal failure – Acute respiratory failure – Acute heart failure **Definitions** ● Updated definition of "Febrile Neutropenia" **Applicable Codes** ● Added HCPCS codes C9096 and J3590 **Supporting Information** ● Updated *FDA* and *References* sections to reflect the most current information	– 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 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

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
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 ○ 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**	Refer to the policy for complete details.

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Xolair® (Omalizumab) (continued)	Aug. 1, 2022	• Added *Background*, *Clinical Evidence*, *FDA*, and *References* sections	

General Information

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

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

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

Policy Update Classifications

New

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

Updated

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

Revised

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

Replaced

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

Retired

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

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