United Healthcare Community Plan

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

In This Issue

Take Note

Medical Policy Updates

Updated

Revised

Medical Benefit Drug Policy Updates

New

Updated

United Healthcare Community Plan

In This Issue

Revised

Coverage Determination Guideline Updates

Revised

Utilization Review Guideline Updates

Updated

Retired

InterQual® 2022 Clinical Criteria: Apr. 2022 Release

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

Policy Title	Policy Type
Ablative Treatment for Spinal Pain (for Kentucky Only)	Medical Policy
Abnormal Uterine Bleeding and Uterine Fibroids (for Kentucky Only)	Medical Policy
Airway Clearance Devices (for Kentucky Only)	Medical Policy
Articular Cartilage Defect Repairs (for Kentucky Only)	Medical Policy
Attended Polysomnography for Evaluation of Sleep Disorders (for Kentucky Only)	Medical Policy
Balloon Sinus Ostial Dilation (for Kentucky Only)	Medical Policy
Bariatric Surgery (for Kentucky Only)	Medical Policy
Beds and Mattresses (for Kentucky Only)	Coverage Determination Guideline
Blepharoplasty, Blepharoptosis, and Brow Ptosis Repair (for Kentucky Only)	Coverage Determination Guideline
Breast Reconstruction Post Mastectomy and Poland Syndrome (for Kentucky Only)	Coverage Determination Guideline
Breast Reduction Surgery (for Kentucky Only)	Coverage Determination Guideline
Breast Repair/Reconstruction Not Following Mastectomy (for Kentucky Only)	Coverage Determination Guideline
Cardiac Event Monitoring (for Kentucky Only)	Medical Policy
Catheter Ablation for Atrial Fibrillation (for Kentucky Only)	Medical Policy
Chemotherapy Observation or Inpatient Hospitalization (for Kentucky Only)	Utilization Review Guideline
Cochlear Implants (for Kentucky Only)	Medical Policy
Computed Tomographic Colonography (for Kentucky Only)	Utilization Review Guideline
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for Kentucky Only)	Medical Policy
Cosmetic and Reconstructive Procedures (for Kentucky Only)	Coverage Determination Guideline
Deep Brain and Cortical Stimulation (for Kentucky Only)	Medical Policy
Electric Tumor Treatment Field Therapy (for Kentucky Only)	Medical Policy
Electrical and Ultrasound Bone Growth Stimulators (for Kentucky Only)	Medical Policy
Epiduroscopy, Epidural Lysis of Adhesions and Discography (for Kentucky Only)	Medical Policy

United Healthcare Community Plan

Take Note

Policy Title	Policy Type
Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds (for Kentucky Only)	Medical Policy
Functional Endoscopic Sinus Surgery (FESS) (for Kentucky Only)	Medical Policy
Gastrointestinal Motility Disorders, Diagnosis and Treatment (for Kentucky Only)	Medical Policy
Gynecomastia Treatment (for Kentucky Only)	Coverage Determination Guideline
Home Health Care Services (for Kentucky Only)	Coverage Determination Guideline
Home Traction Therapy (for Kentucky Only)	Medical Policy
Hysterectomy (for Kentucky Only)	Medical Policy
Implantable Beta-Emitting Microspheres for Treatment of Malignant Tumors (for Kentucky Only)	Medical Policy
Implanted Electrical Stimulator for Spinal Cord (for Kentucky Only)	Medical Policy
Lower Extremity Invasive Diagnostic and Endovascular Procedures (for Kentucky Only)	Medical Policy
Lung Volume Reduction Surgery (for Kentucky Only)	Medical Policy
Manual Wheelchairs (for Kentucky Only)	Coverage Determination Guideline
Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) and Achalasia (for Kentucky Only)	Medical Policy
Negative Pressure Wound Therapy (for Kentucky Only)	Medical Policy
Neurophysiologic Testing and Monitoring (for Kentucky Only)	Medical Policy
Neuropsychological Testing Under the Medical Benefit (for Kentucky Only)	Medical Policy
Obstructive and Central Sleep Apnea Treatment (for Kentucky Only)	Medical Policy
Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache) (for Kentucky Only)	Medical Policy
Oral and Enteral Nutrition (for Kentucky Only)	Coverage Determination Guideline
Orthognathic (Jaw) Surgery (for Kentucky Only)	Coverage Determination Guideline
Panniculectomy and Body Contouring Procedures (for Kentucky Only)	Coverage Determination Guideline
Patient Lifts (for Kentucky Only)	Coverage Determination Guideline
Pectus Deformity Repair (for Kentucky Only)	Coverage Determination Guideline
Pediatric Gait Trainers, Standing Systems and Walkers (for Kentucky Only)	Coverage Determination Guideline
Percutaneous Vertebroplasty and Kyphoplasty (for Kentucky Only)	Medical Policy
Plagiocephaly and Craniosynostosis Treatment (for Kentucky Only)	Medical Policy

United Healthcare Community Plan

Take Note

Policy Title	Policy Type
Pneumatic Compression Devices (for Kentucky Only)	Medical Policy
Power Mobility Devices (for Kentucky Only)	Coverage Determination Guideline
Prostate Surgeries and Interventions (for Kentucky Only)	Medical Policy
Prosthetic Devices, Wigs, Specialized, Microprocessor or Myoelectric Limbs (for Kentucky Only)	Coverage Determination Guideline
Proton Beam Radiation Therapy (for Kentucky Only)	Medical Policy
Rhinoplasty and Other Nasal Surgeries (for Kentucky Only)	Coverage Determination Guideline
Sacroiliac Joint Interventions (for Kentucky Only)	Coverage Determination Guideline
Speech Generating Devices (for Kentucky Only)	Coverage Determination Guideline
Surgery of the Ankle (for Kentucky Only)	Medical Policy
Surgery of the Elbow (for Kentucky Only)	Medical Policy
Surgery of the Foot (for Kentucky Only)	Medical Policy
Surgery of the Hand or Wrist (for Kentucky Only)	Medical Policy
Surgery of the Hip (for Kentucky Only)	Medical Policy
Surgery of the Knee (for Kentucky Only)	Medical Policy
Surgery of the Shoulder (for Kentucky Only)	Medical Policy
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Kentucky Only)	Medical Policy
Surgical Treatment for Spine Pain (for Kentucky Only)	Medical Policy
Temporomandibular Joint Disorders (for Kentucky Only)	Medical Policy
Total Artificial Disc Replacement for the Spine (for Kentucky Only)	Medical Policy
Total Artificial Heart and Ventricular Assist Devices (for Kentucky Only)	Medical Policy
Transcatheter Heart Valve Procedures (for Kentucky Only)	Medical Policy
Transcutaneous Electrical Nerve/Joint Stimulators (for Kentucky Only)	Coverage Determination Guideline
Vagus and External Trigeminal Nerve Stimulation (for Kentucky Only)	Medical Policy
Video Electroencephalographic (vEEG) Monitoring and Recording (for Kentucky Only)	Medical Policy
Wheelchair Options and Accessories (for Kentucky Only)	Coverage Determination Guideline
Wheelchair Seating (for Kentucky Only)	Coverage Determination Guideline

Medical Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Cardiovascular Disease Risk Tests (for Kentucky Only)	Jun. 1, 2022	**Applicable Codes** • Added CPT code 84999 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Ablative Treatment for Spinal Pain (for Kentucky Only)	Jun. 1, 2022	**Coverage Rationale**
		Proven and Medically Necessary
		• Replaced language indicating "*Thermal Radiofrequency Ablation* of lumbar and cervical facet joint *nerves* is proven and medically necessary in certain circumstances" with "*ablative treatment* of cervical, *thoracic*, and lumbar facet joint *pain* is proven and medically necessary in certain circumstances"
		Unproven and Not Medically Necessary
		• Revised list of facet joint nerve ablation techniques that are unproven and not medically necessary:
		  ○ Added "ablative treatment of sacroiliac pain"
		  ○ Removed:
		  ▪ Chemical ablation (including, but not limited to, alcohol, phenol or sodium morrhuate)
		  ▪ Cryoablation
			Ablative treatment of cervical, thoracic, and lumbar facet joint pain is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to InterQual® 2022, Apr. 2022 Release, CP: Procedures, Neuroablation, Percutaneous.
			
			Click here to view the InterQual® criteria.
			
			The following facet joint nerve ablation techniques are unproven and not medically necessary due to insufficient evidence of efficacy:
			• Ablative treatment of sacroiliac pain
			• Pulsed Radiofrequency Ablation of the facet nerves of the cervical, thoracic or lumbar region, sacral nerve root or dorsal root ganglion
			• Cooled radiofrequency ablation
			• Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept®)

Medical Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ablative Treatment for Spinal Pain (for Kentucky Only) (continued)	Jun. 1, 2022	(cryodenervation, cryoneurolysis, cryosurgery or cryoanesthesia) ▪ Endoscopic radiofrequency ablation/endoscopic rhizotomy ▪ Laser ablation (including pulsed, continuous or low level) • Removed language pertaining to unproven and mot medically necessary indications for: ○ Thermal Radiofrequency Ablation of facet joint nerves ○ Radiofrequency Ablation, including Thermal and Cooled Radiofrequency Ablation **Definitions** • Updated definition of: ○ Conventional (Thermal) Radiofrequency Ablation ○ Cooled Radiofrequency Ablation **Applicable Codes** • Added CPT codes 64628 and 64629 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Discogenic Pain Treatment (for Kentucky Only)	Jun. 1, 2022	**Coverage Rationale**
		• Added instruction to refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Decompression +/- Fusion, Lumbar for medical necessity clinical coverage criteria of decompression procedures
		• Revised list of unproven and not medically necessary procedures:
		  ○ Added:
		  ▪ Annular closure devices (ACDs)
		  ▪ Percutaneous injection of allogeneic cellular/tissue-based products
		  ○ Removed:
		  ▪ Annulus fibrosus repair following spinal surgery
		  ▪ Percutaneous discectomy and decompression procedures for treating discogenic pain
		Applicable Codes
		• Added CPT codes 0627T, 0628T, 0629T, 0630T, and 22526
		Supporting Information
		• Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
			For medical necessity clinical coverage criteria of decompression procedures, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Decompression +/- Fusion, Lumbar.
			
			Click here to view the InterQual® criteria.
			
			The following procedures are unproven and not medically necessary due to insufficient evidence of efficacy:
			• Annular Closure Devices (ACDs)
			• Percutaneous injection of allogeneic cellular/tissue based products
			• Thermal intradiscal procedures (TIPs) for treating discogenic pain

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Hearing Aids and Devices Including Wearable, Bone-Anchored and Semi-Implantable (for Kentucky Only)	Jun. 1, 2022	**Coverage Rationale** • Replaced instruction to "refer to the Kentucky Administrative Regulations 907 KAR 1:038 for *Medically Necessary* criteria for Hearing Program coverage" with "refer to the Kentucky Administrative Regulations 907 KAR 1:038, Hearing Program Coverage *Provisions and Requirements* for *medical necessity clinical coverage* criteria" **Definitions** • Removed definition of: ○ Conductive Hearing Loss ○ Degree of Hearing Loss ○ Frequency Modulated Systems (Auditory Trainers) ○ Hearing Aid(s) ○ Hearing Impairment ○ Mixed Hearing Loss ○ Sensorineural Hearing Loss (SNHL) **Applicable Codes** • Removed CPT/HCPCS codes 92537, 92538, 92541, 92542, 92544, 92545, 92546, 92547, 92550, 92552, 92553, 92555, 92556, 92557, 92567, 92568, 92579, 92582, 92583, 92587, 92588, 92590, 92601, 92602, 92603, 92604, 92626, V5170, V5180, V5210, V5220, and V5266	For medical necessity clinical coverage criteria, refer to the Kentucky Administrative Regulations 907 KAR 1:038, Hearing Program Coverage Provisions and Requirements.

Medical Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Hearing Aids and Devices Including Wearable, Bone-Anchored and Semi-Implantable (for Kentucky Only) (continued)	Jun. 1, 2022	• Revised description for CPT codes 69714 and 69717 **Supporting Information** • Updated *References* section to reflect the most current information • Removed *Description of Services* and *Clinical Evidence* sections	
Negative Pressure Wound Therapy (for Kentucky Only)	Jun. 1, 2022	**Related Policies** • Added reference link to the Medical Policy titled *Skin and Soft Tissue Substitutes (for Kentucky Only)* **Coverage Rationale** • Revised list of indications and devices that are unproven and not medically necessary; added "negative pressure wound therapy (NPWT) systems with instillation" **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	Notes: • The proven and medically necessary coverage statements in this policy apply to the use of negative pressure wound therapy (NPWT) in the outpatient setting. • The unproven and not medically necessary coverage statements in this policy apply to all settings. NPWT in an outpatient setting or upon discharge from an inpatient setting is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Durable Medical Equipment, Negative Pressure Wound Therapy (NPWT) Pump. Click here to view the InterQual® criteria. The following indications and devices are unproven and not medically necessary due to insufficient evidence of efficacy: • NPWT for treating all other indications, including, but not limited to, pilonidal disease • Disposable/single-use NPWT systems • NPWT systems with instillation
Obstructive and Central Sleep Apnea Treatment (for Kentucky Only)	Jun. 1, 2022	**Coverage Rationale** *Nonsurgical Treatment* • Revised list of services/devices that are unproven and not medically necessary for treating	**Nonsurgical Treatment** Removable Oral Appliances are proven and medically necessary for treating Obstructive Sleep Apnea (OSA) as documented by a sleep study (e.g., polysomnography or Home Sleep Apnea Testing). Refer to the Medical Policy titled Attended Polysomnography for Evaluation of Sleep Disorders (for

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Obstructive and Central Sleep Apnea Treatment (for Kentucky Only) (continued)	Jun. 1, 2022	Obstructive Sleep Apnea (OSA); added: ○ Non-surgical electrical muscular training ○ Morning repositioning devices *Surgical Treatment* ● Revised coverage criteria for implantable hypoglossal nerve stimulation: ○ Added criterion requiring total AHI < 25% for central + mixed apneas ○ Replaced reference to "polysomnography" with "Polysomnography *(Attended)*" ● Revised list of surgical procedures that are unproven and not medically necessary for treating Obstructive Sleep Apnea (OSA); added "distraction osteogenesis for maxillary expansion (DOME)" Definitions ● Added definition of "Polysomnogram (Attended)" Applicable Codes ● Added CPT/HCPCS codes 21142, E1399, K1028, and K1029 ● Added notation to indicate: ○ HCPCS code E0486 applies to the custom fabricated oral device/appliance used to reduce upper airway collapsibility, adjustable or	Kentucky Only) for further information. For many individuals, Oral Appliance Therapy (OAT) may be an effective alternative to failed continuous positive airway pressure (CPAP) therapy. Documentation of the following is required: ● A patient presenting with symptoms of OSA be seen in a face-to-face evaluation with a qualified physician (MD or DO) trained in sleep medicine or with an Advanced Practice Provider working under the direct supervision of a sleep medicine physician prior to beginning treatment for OAT (AASM and AADSM, December 2012, AAO-HNS, November 2019) ● A treating physician (MD or DO) or an Advanced Practice Provider must diagnose OSA and recommend course of treatment (AAO-HNS, November 2019) ● If the patient refuses CPAP therapy, documentation of the refusal from the patient's treating physician (MD or DO) or an Advanced Practice Provider must be supplied For information on snoring and Oral Appliances, refer to the Coverage Determination Guideline titled Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (for Kentucky Only). For medical necessity clinical coverage criteria for removable Oral Appliances, refer to the InterQual® 2022, Apr. 2022 Release, CP: Durable Medical Equipment, Noninvasive Airway Assistive Devices. Click here to view the InterQual® criteria. The following are unproven and not medically necessary due to insufficient evidence of efficacy: ● Devices for treating Positional OSA ● Nasal dilator devices for treating OSA ● Removable Oral Appliances for treating Central Sleep Apnea ● Prefabricated Oral Appliance/Device ● Non-surgical electrical muscular training

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Obstructive and Central Sleep Apnea Treatment (for Kentucky Only) (continued)	Jun. 1, 2022	nonadjustable and includes fitting and adjustment ○ Dental services (e.g., HCPCS codes D9947, D9948, and D9949) are excluded from coverage under the medical plan; the member specific benefit plan document must be referenced prior to determining any coverage decision **Supporting Information** ● Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	● Morning repositioning devices **Surgical Treatment** The following surgical procedures are proven and medically necessary for treating OSA as documented by polysomnography. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures: ● Maxillomandibular Advancement ● Osteotomy, Anterior Segment, Mandible ● Uvulopalatopharyngoplasty (UPPP) Click here to view the InterQual® criteria. Implantable hypoglossal nerve stimulation is proven and medically necessary in an adult patient with moderate to severe OSA when all the following criteria are met: ● Body Mass Index of (BMI) less than or equal to 32kg/m^2; and ● Apnea Hypopnea Index (AHI) of ≥ 20 and ≤ 65 as determined with Polysomnography (Attended); and ● Total AHI < 25% for central + mixed apneas; and ● Absence of complete concentric collapse at the soft palate level; and ● Failure or intolerance of Positive Airway Pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines) ○ PAP failure is defined as an inability to eliminate OSA (AHI of greater than 20 despite PAP usage) and PAP intolerance is defined as: ▪ Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night); or ▪ Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it) Implantable neurostimulation devices for the treatment of Central Sleep Apnea (CSA) are unproven and not medically necessary due to insufficient

Medical Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Obstructive and Central Sleep Apnea Treatment (for Kentucky Only) (continued)	Jun. 1, 2022		evidence of safety and/or efficacy. The following surgical procedures are unproven and not medically necessary for treating OSA due to insufficient evidence of efficacy: • Laser-assisted uvulopalatoplasty (LAUP) • Lingual suspension – Also referred to as tongue stabilization, tongue stitch or tongue fixation • Palatal implants • Radiofrequency ablation of the soft palate and/or tongue base • Transoral robotic surgery (TORS) • Distraction osteogenesis for maxillary expansion (DOME)
Pneumatic Compression Devices (for Kentucky Only)	Jun. 1, 2022	Coverage Rationale • Replaced language indicating "pneumatic compression devices are proven and medically necessary in certain circumstances" with "pneumatic compression devices are proven and medically necessary in certain circumstances *for the treatment of lymphedema or chronic venous insufficiency with edema and non-healing lower extremity ulcers*" • Added instruction to refer to the InterQual® 2022, Apr. 2022 Release, Medicare: Durable Medical Equipment, Pneumatic Compression Devices for medical necessity clinical coverage criteria for pneumatic compression devices for the treatment of arterial insufficiency (HCPCS code E0675) • Added language to indicate	Pneumatic compression devices are proven and medically necessary in certain circumstances for the treatment of lymphedema or chronic venous insufficiency with edema and non-healing lower extremity ulcers. For medical necessity clinical coverage criteria, refer the InterQual® 2022, Apr. 2022 Release, CP: Durable Medical Equipment, Pneumatic Compression Devices. For medical necessity clinical coverage criteria of pneumatic compression devices for the treatment of arterial insufficiency (E0675), refer to the InterQual® 2022, Apr. 2022 Release, Medicare: Durable Medical Equipment, Pneumatic Compression Devices. Click here to view the InterQual® criteria. Intermittent limb compression devices are proven and medically necessary in an outpatient setting or upon discharge from an inpatient setting for the prevention of deep venous thrombosis (DVT) when all the following criteria are met: • Immobility (i.e. not able to get up from a chair / out of bed and walk to the toilet without the help of another person) • Contraindication to pharmaceutical anti-coagulation • None of the following contraindications are present: ○ Active infection

Medical Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Pneumatic Compression Devices (for Kentucky Only) (continued)	Jun. 1, 2022	intermittent limb compression devices are proven and medically necessary in an outpatient setting or upon discharge from an inpatient setting for the prevention of deep venous thrombosis (DVT) when all the following criteria are met: ○ Immobility (i.e., not able to get up from a chair/out of bed and walk to the toilet without the help of another person) ○ Contraindication to pharmaceutical anti-coagulation ○ None of the following contraindications are present: ▪ Active infection ▪ Pulmonary edema ▪ Severe arteriosclerosis ▪ Severe congestive heart failure ▪ Skin or tissue condition that may be negatively impacted by the use of garments ▪ Suspected or known DVT • Removed notation pertaining to HCPCS code E0652 **Supporting Information** • Added *Description of Services*, *Clinical Evidence*, and *References* sections	○ Pulmonary edema ○ Severe arteriosclerosis ○ Severe congestive heart failure ○ Skin or tissue condition that may be negatively impacted by the use of garments ○ Suspected or known DVT

Medical Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Skin and Soft Tissue Substitutes (for Kentucky Only)	Jun. 1, 2022	Coverage Rationale • Revised list of skin and soft tissue substitutes that are unproven and not medically necessary for any indication; added: ○ Apis ○ Cygnus matrix ○ InnovaMatrix AC ○ Microlyte Matrix ○ Mirragen Advanced Wound Matrix ○ NovoSorb SynPath ○ Restrata ○ Symphony ○ TheraGenesis ○ XCelliStem Applicable Codes • Added HCPCS codes A2001, A2002, A2004, A2005, A2006, A2007, A2008, A2009, A2010, and Q4199 Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information	Refer to the policy for complete details.
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Kentucky Only)	Jun. 1, 2022	Coverage Rationale *Varicose Vein Ablative and Stripping Procedures* • Replaced language indicating "*the initial and subsequent radiofrequency ablation, endovenous laser ablation,*	**Varicose Vein Ablative and Stripping Procedures** Varicose vein ablative and stripping procedures are considered reconstructive, proven, and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures: • Ablation, Endovenous, Varicose Vein • Ligation/Excision, Varicose Vein, +/- Stripping

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Kentucky Only) (continued)	Jun. 1, 2022	stripping, *ligation and excision of the great saphenous vein (GSV) and small saphenous veins (SSV)* are considered reconstructive, proven, and medically necessary in certain circumstances" with "*Varicose Vein ablative and* stripping *procedures* are considered reconstructive, proven, and medically necessary in certain circumstances" • Removed language indicating ablation of perforator veins is considered reconstructive, proven, and medically necessary when [criteria are met] • Replaced medical necessity clinical coverage criteria with reference to the InterQual® 2022, Apr. 2022 Release, CP: Procedures: ○ Ablation, Endovenous, Varicose Vein ○ Ligation/Excision, Varicose Vein, +/- Stripping *Other Procedures* • Added language to indicate Sclerotherapy is proven and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Sclerotherapy, Varicose Vein	Click here to view the InterQual® criteria. Refer to the *Coding Clarification* section of the policy. Adherence to American Medical Association (AMA) coding guidance is required when requesting coverage of endovenous ablation procedures. Note that only one primary code may be requested for the initial vein treated, and only one add-on code per extremity may be requested for any subsequent vein(s) treated. Endovenous mechanochemical ablation (MOCA) of Varicose Veins is unproven and not medically necessary due to insufficient evidence of efficacy **Ligation Procedures** The following procedure is proven and medically necessary: • Ligation at the saphenofemoral junction, as a stand-alone procedure, when used to prevent the propagation of an active clot to the deep venous system in individuals with ascending Superficial Thrombophlebitis who fail or are intolerant of anticoagulation therapy. The following procedure is proven and medically necessary in certain circumstances: • Ligation, subfascial, endoscopic surgery for treatment of perforating veins associated with chronic Venous Insufficiency. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Ligation, Subfascial, Endoscopic, Perforating Vein. Click here to view the InterQual® criteria. The following procedures are unproven and not medically necessary for treating Venous Reflux due to insufficient evidence of efficacy: • Ligation of the GSV at the saphenofemoral junction, as a stand-alone procedure • Ligation of the SSV at the saphenopopliteal junction, as a stand-alone

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Kentucky Only) (continued)	Jun. 1, 2022	• Removed language indicating endovenous low-nitrogen foam sclerotherapy of incompetent GSV, lesser saphenous veins, and accessory saphenous veins is unproven and not medically necessary for treating Venous Reflux *Documentation Requirements* • Added language to indicate medical notes documenting the following are required, when applicable: ○ Diagnosis ○ History of the medical condition(s) requiring treatment or surgical intervention ○ Documentation of signs and symptoms; including onset, duration, frequency, and which extremity (right, left, or both) ○ Relevant medical history, including: ▪ DVT (deep vein thrombosis) ▪ Aneurysm ▪ Tortuosity ○ Physical exam, including: ▪ Which extremity (right, left, or both) ▪ Vein(s) that will be treated [e.g., great saphenous vein	procedure • Ligation at the saphenofemoral junction, as an adjunct to radiofrequency ablation or endovenous laser ablation of the main saphenous veins. **Ambulatory Phlebectomy** Ambulatory phlebectomy for treating varicose veins is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Ambulatory Phlebectomy, Varicose Vein for: • Hook Phlebectomy • Microphlebectomy • Mini Phlebectomy • Stab Avulsion • Stab Phlebectomy Click here to view the InterQual® criteria. **Other Procedures** Sclerotherapy is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Sclerotherapy, Varicose Vein. Click here to view the InterQual® criteria. The following procedures are unproven and not medically necessary for treating Venous Reflux due to insufficient evidence of efficacy: • Endovascular embolization of Varicose Veins using cyanoacrylate-based adhesive **Documentation Requirements** Medical notes documenting the following, when applicable: • Diagnosis

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Kentucky Only) (continued)	Jun. 1, 2022	(GSV) and small saphenous vein (SSV), etc.] ▪ Vein diameter including the specific anatomic location where the measurement was taken (e.g., proximal thigh, proximal calf, etc.) ▪ Duration of reflux including the position of member at the time of measurement and the anatomic location where the measurement was taken [e.g., standing, saphenofemoral junction (SFJ)] ○ Severity of pain or other symptoms that interfere with activities of daily living related to vein disease ○ Functional disability(ies), as documented on a validated functional disability scale, (interfering with the ability to stand or sit for long periods of time, such as, preparing meals, performing work functions, driving, walking, etc.) ○ Diagnostic study/imaging reports ○ Pulses ○ Prior conservative treatments	• History of the medical condition(s) requiring treatment or surgical intervention • Documentation of signs and symptoms; including onset, duration, frequency, and which extremity (right, left, or both) • Relevant medical history, including: ○ DVT (deep vein thrombosis) ○ Aneurysm ○ Tortuosity • Physical exam, including: ○ Which extremity (right, left, or both) ○ Vein(s) that will be treated [e.g., great saphenous vein (GSV) and small saphenous vein (SSV), etc.] ○ Vein diameter including the specific anatomic location where the measurement was taken (e.g., proximal thigh, proximal calf, etc.) ○ Duration of reflux including the position of member at the time of measurement and the anatomic location where the measurement was taken [e.g., standing, saphenofemoral junction (SFJ)] • Severity of pain or other symptoms that interfere with activities of daily living related to vein disease • Functional disability(ies), as documented on a validated functional disability scale, (interfering with the ability to stand or sit for long periods of time, such as, preparing meals, performing work functions, driving, walking, etc.) • Diagnostic study/imaging reports • Pulses • Prior conservative treatments tried, failed, or contraindicated. Include the dates and reason for discontinuation • Proposed treatment plan with procedure code, including specific vein(s) that will be treated (e.g., great saphenous vein (GSV) and small saphenous vein (SSV), etc.), which extremity (left, right, or both) and date of procedure for each vein to be treated

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Kentucky Only) (continued)	Jun. 1, 2022	tried, failed, or contraindicated. Include the dates and reason for discontinuation ○ Proposed treatment plan with procedure code, including specific vein(s) that will be treated (e.g., great saphenous vein (GSV) and small saphenous vein (SSV), etc.), which extremity (left, right, or both) and date of procedure for each vein to be treated **Supporting Information** ● Updated *Clinical Evidence* and *References* sections to reflect the most current information	
Surgical Treatment for Spine Pain (for Kentucky Only)	Jun. 1, 2022	**Coverage Rationale** ● Revised language pertaining to medical necessity clinical coverage criteria for spinal procedures for the treatment of spine pain; added reference to InterQual® 2022, Apr. 2022 Release, CP: Procedures, Interspinous Process Decompression ● Added language to indicate: ○ Interspinous process fusion devices is proven and medically necessary when used in conjunction with any of the following procedures: ▪ Open laminar and/or facet decortication and fusion	Spinal procedures for the treatment of spine pain are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual®2022, Apr. 2022 Release, CP: Procedures: ● Decompression +/- Fusion, Cervical ● Decompression +/- Fusion, Lumbar ● Decompression +/- Fusion, Thoracic ● Fusion, Cervical Spine ● Fusion, Lumbar Spine ● Fusion, Thoracic Spine ● 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:

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical Treatment for Spine Pain (for Kentucky Only) (continued)	Jun. 1, 2022	▪ Autograft inter-and extra-spinous process decortication and fusion ▪ Interbody fusion of the same motion segment ○ Dividing treatment of symptomatic, multi-site spinal pathology via anterior or posterior approach into serial, multiple, or staged sessions when one session can address all sites is unproven and not medically necessary ● Removed language indicating: ○ The following techniques for lumbar interbody fusion (LIF) are proven and medically necessary: ▪ Anterior LIF (ALIF) including lateral approaches, e.g., extreme lateral interbody fusion (XLIF®), Direct lateral interbody fusion (DLIF) ▪ Posterior LIF (PLIF), including transforaminal lumbar interbody fusion (TLIF) ○ Transforaminal lumbar interbody fusion (TLIF) which utilizes only endoscopy visualization (such as a percutaneous incision with	● Congenital or idiopathic deformity or bone disease other than scoliosis ● Muscular dystrophy ● Laminectomy procedure to provide surgical exposure to treat lesions within the spinal canal Interspinous process fusion devices is proven and medically necessary when used in conjunction with any of the following procedures: ● Open laminar and/or facet decortication and fusion ● Autograft inter-and extra-spinous process decortication and fusion ● Interbody fusion of the same motion segment The following spinal procedures are unproven and not medically necessary due to insufficient evidence of efficacy (this includes procedures that utilize interbody cages, screws, and pedicle screw fixation devices): ● Laparoscopic anterior lumbar interbody fusion (LALIF) ● 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

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgical Treatment for Spine Pain (for Kentucky Only) (continued)	Jun. 1, 2022	video visualization) is unproven and not medically necessary ○ Interlaminar lumbar instrumented fusion (ILIF) utilizing an interspinous process fusion device is unproven and not medically necessary • Revised coverage criteria for surgical spine procedures that are performed to alleviate symptoms or prevent clinical deterioration; replaced criterion requiring "congenital or idiopathic deformity or bone disease" with "congenital or idiopathic deformity or bone disease *other than scoliosis*" • Added list of documentation requirements **Definitions** • Added definition of "Staged Multi-Session" **Applicable Codes** • Removed CPT/HCPCS codes 27096, 27279, 27280, 62287, 63273, 63276, 63278, 63281, 63283, 63295, 63661, 63662, G0259, G0260, S2350, and S2351 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	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 impairment that is interfering with activities of daily living (meals, walking, getting dressed, driving) • Failure of Conservative Therapy through lack of clinically significant improvement between at least two measurements, on a validated pain or function scale or quantifiable symptoms despite concurrent Conservative Therapies (see definition), if applicable • Progressive deficits with clinically significant worsening based on at least two measurements over time, if applicable • Disabling Symptoms, if applicable • Upon request, we may request the specific diagnostic image(s) that shows the abnormality for which surgery is being requested which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting 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

Medical Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical Treatment for Spine Pain (for Kentucky Only) (continued)	Jun. 1, 2022		○ Quantification of subluxation, translation by flexion, angulation when appropriate ○ Discitis ○ Epidural abscess • Physical exam, including neurologic exam, including degree and progression of curvature (for scoliosis), if applicable ○ Degree and progression of curvature (for scoliosis) ○ Quantification of relevant muscle strength • Whether the surgery will be performed with direct visualization or only with endoscopic visualization • Complete report(s) of diagnostic tests ○ Results of biopsy(ies) ○ Results of bone aspirate • Describe the surgical technique(s) planned [e.g., AxiaLIF®, XLIF, ILIF, OLIF, LALIF, image-guided minimally invasive lumbar decompression (mild®), percutaneous endoscopic discectomy with or without laser, etc.]
Vagus and External Trigeminal Nerve Stimulation (for Kentucky Only)	Jun. 1, 2022	Coverage Rationale • Replaced language indicating "implantable vagus nerve stimulators are proven and medically necessary for treating *focal or partial seizure disorder or generalized seizure disorder*" with "implantable vagus nerve stimulators are proven and medically necessary for treating *epilepsy in certain circumstances*" • Revised list of conditions for which implantable vagus nerve stimulators are unproven and not medically necessary; added: ○ Autoimmune disorders ○ Musculoskeletal disorders	Implantable vagus nerve stimulators are proven and medically necessary for treating epilepsy in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures: • Vagus Nerve Stimulation (VNS) • Vagus Nerve Stimulation (VNS) (Pediatric) Click here to view the InterQual® criteria. Implantable vagus nerve stimulators are unproven and not medically necessary for treating all other conditions due to insufficient evidence of efficacy. These conditions include but are not limited to: • Alzheimer's disease • Anxiety disorder • Autism spectrum disorder • Autoimmune disorders • Back and neck pain

Medical Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Vagus and External Trigeminal Nerve Stimulation (for Kentucky Only) (continued)	Jun. 1, 2022	○ Upper limb impairment related to stroke • Removed language indicating vagus nerve stimulation implants that allow detection and stimulation of increased heart rate (e.g., AspireSR™ Model 106, SenTiva™ Model 1000) are unproven and not medically necessary for treating epilepsy **Definitions** • Removed definition of "Shared Decision Making" **Applicable Codes** • Added CPT/HCPCS codes 61886, K1016, K1017, and K1020 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	• Bipolar disorder • Bulimia • Cerebral palsy • Chronic pain syndrome • Cluster headaches • Depression • Fibromyalgia • Heart failure • Migraines • Morbid obesity • Musculoskeletal disorders • Narcolepsy • Obsessive-compulsive disorder • Paralysis agitans • Sleep disorders • Tourette's syndrome • Upper limb impairment related to stroke The following devices are unproven and not medically necessary due to insufficient evidence of efficacy: • Transcutaneous (non-implantable) vagus nerve stimulation (e.g., gammaCore® for headaches) for preventing or treating all indications • External or transcutaneous (non-implantable) trigeminal nerve stimulation devices (e.g., Monarch® eTNS System, Cefaly®) for preventing or treating all conditions including but not limited to: ○ Attention deficit hyperactivity disorder (ADHD) ○ Depression ○ Epilepsy ○ Headache Note: For vagus nerve blocking for the treatment of obesity, refer to the Medical Policy titled Bariatric Surgery (for Kentucky Only).

Medical Benefit Drug Policy Updates

New

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

Medical Benefit Drug Policy Updates

Updated

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

Revised

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

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Actemra® (Tocilizumab) Injection for Intravenous Infusion (continued)	Jun. 1, 2022	(adalimumab), Cimzia (certolizumab), Simponi (golimumab)] – Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] ▪ Prescribed by or in consultation with a rheumatologist ▪ Initial authorization is for no more than 12 months *Continuation of Therapy* ▪ Patient has previously received Actemra injection for intravenous infusion ▪ Documentation of positive clinical response to Actemra ▪ Actemra is dosed according to FDA labeled dosing for giant cell arteritis ▪ Patient is not receiving Actemra in combination with either of the following: – Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]	(baricitinib)] and ○ Prescribed by or in consultation with a rheumatologist; and ○ Initial authorization is for no more than 12 months ● For continuation of therapy, all of the following: ○ Patient has previously received Actemra injection for intravenous infusion; and ○ Documentation of positive clinical response to Actemra; and ○ Actemra is dosed according to FDA labeled dosing for polyarticular juvenile idiopathic arthritis; and ○ Patient is not receiving Actemra in combination with either of the following: ▪ Biologic disease-modifying antirheumatic drug (DMARD) *[e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]* ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] and ○ Authorization is for no more than 12 months **Rheumatoid Arthritis** Actemra is proven and medically necessary for the treatment of rheumatoid arthritis when all of the following criteria are met: ● For initial therapy, all of the following: ○ Diagnosis of moderately to severely active rheumatoid arthritis (RA); and ○ One of the following: ▪ History of failure intolerance to a 3-month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses , unless contraindicated or clinically significant adverse effects are experienced; or ▪ Patient has been previously treated with a biologic or targeted

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Actemra® (Tocilizumab) Injection for Intravenous Infusion (continued)	Jun. 1, 2022	– Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] ▪ Authorization is for no more than 12 months **Applicable Codes** • Added ICD-10 diagnosis codes M31.5 and M31.6 **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	synthetic DMARD FDA-approved for the treatment of rheumatoid arthritis [e.g., Humira (adalimumab), Simponi (golimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)]; or ▪ Patient is currently on Actemra and ○ Actemra is dosed according to FDA labeled dosing for rheumatoid arthritis; and ○ Patient is not receiving Actemra in combination with either of the following: ▪ Biologic DMARD *[e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]* ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] and ○ Prescribed by or in consultation with a rheumatologist; and ○ Initial authorization is for no more than 12 months • For continuation of therapy, all of the following: ○ Patient has previously received Actemra injection for intravenous infusion; and ○ Documentation of positive clinical response; and ○ Actemra is dosed according to FDA labeled dosing for rheumatoid arthritis; and ○ Patient is not receiving Actemra in combination with either of the following: ▪ Biologic DMARD *[e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]* ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] and ○ Authorization is for no more than 12 months **Systemic Juvenile Idiopathic Arthritis** Actemra is proven and medically necessary for the treatment of systemic

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Actemra® (Tocilizumab) Injection for Intravenous Infusion (continued)	Jun. 1, 2022		juvenile idiopathic arthritis when all of the following criteria are met: ● For initial therapy, all of the following: ○ Diagnosis of systemic juvenile idiopathic arthritis (SJIA); and ○ Actemra is dosed according to FDA labeled dosing for systemic juvenile idiopathic arthritis; and ○ Patient is not receiving Actemra in combination with either of the following: ▪ Biologic DMARD *[e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]* ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] and ○ Prescribed by or in consultation with a rheumatologist; and ○ Initial authorization is for no more than 12 months ● For continuation of therapy, all of the following: ○ Patient has previously received Actemra injection for intravenous infusion; and ○ Documentation of positive clinical response; and ○ Actemra is dosed according to FDA labeled dosing for systemic juvenile idiopathic arthritis; and ○ Patient is not receiving Actemra in combination with either of the following:1 ▪ Biologic DMARD *[e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]* ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] and ○ Authorization is for no more than 12 months **Giant Cell Arteritis** Actemra is proven and medically necessary for the treatment of giant cell arteritis when all of the following criteria are met: ● For initial therapy, all of the following:

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Actemra® (Tocilizumab) Injection for Intravenous Infusion (continued)	Jun. 1, 2022		○ Diagnosis of giant cell arteritis (GCA) and ○ Actemra is dosed according to U.S. Food and Drug Administration (FDA) labeled dosing for giant cell arteritis; and ○ Patient is not receiving Actemra in combination with either of the following: ▪ Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] and ○ Prescribed by or in consultation with a rheumatologist; and ○ Initial authorization is for no more than 12 months ● For continuation of therapy, all of the following: ○ Patient has previously received Actemra injection for intravenous infusion; and ○ Documentation of positive clinical response to Actemra; and ○ Actemra is dosed according to FDA labeled dosing for giant cell arteritis; and ○ Patient is not receiving Actemra in combination with either of the following: ▪ Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] and ○ Authorization is for no more than 12 months **Cytokine Release Syndrome** Actemra is proven and medically necessary for the treatment of cytokine release syndrome when all of the following criteria are met: ● For initial therapy, all of the following:

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

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

Revised

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

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

Revised

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

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

Revised

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

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

Revised

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

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

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	▪ One of the following: – BMD T-score ≤ -2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); or – History of one of the following resulting from minimal trauma: • Vertebral compression fracture • Fracture of the hip • Fracture of the distal radius • Fracture of the pelvis • Fracture of the proximal humerus or – One of the following: • FRAX 10-year fracture probabilities: major osteoporotic fracture at 20% or more • FRAX 10-year fracture probabilities: hip	insufficiency), or intolerance to treatment with intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid); and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ○ Authorization is for no more than 12 months • Reauthorization/Continuation of Care Criteria For patients currently on Xgeva for the prevention of skeletal-related events in men with castration-resistant prostate cancer who have bone metastases, continued use will be approved based on the following criteria: ○ Provider attests to a positive clinical response; and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ○ Authorization is for no more than 12 months Xgeva is proven and medically necessary for the treatment of osteopenia/osteoporosis in patients with systemic mastocytosis with bone pain not responding to bisphosphonates when all of the following criteria are met: • Initial Therapy ○ Diagnosis of systemic mastocytosis; and ○ Patient has bone pain; and ○ Diagnosis of osteoporosis or osteopenia based on one of the following: ▪ BMD T-score ≤-1 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); or ▪ History of one of the following resulting from minimal trauma: – Vertebral compression fracture – Fracture of the hip – Fracture of the distal radius – Fracture of the pelvis – Fracture of the proximal humerus;

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	fracture at 3% or more and ▪ One of the following: – Both of the following: • History of intolerance to oral bisphosphonate therapy; and • History of failure, contraindication, or intolerance to intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid) or – History of failure or contraindication to oral bisphosphonate therapy; or – History of failure, contraindication, or intolerance to IV bisphosphonate therapy and ▪ Prolia dosing is in accordance with the FDA approved labeling: maximum dosing of 60 mg every 6 months; and	and ○ Refractory (within the past 30 days), contraindication (including renal insufficiency), or intolerance to treatment with intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid); and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ○ Authorization for no more than 12 months • Reauthorization/Continuation of Care Criteria For patients currently on Xgeva for the treatment of osteopenia/osteoporosis in patients with systemic mastocytosis with bone pain not responding to bisphosphonates, continued use will be approved based on the following criteria: ○ Provider attests to a positive clinical response; and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ○ Authorization is for no more than 12 months **Unproven and Not Medically Necessary** Denosumab is unproven and not medically necessary for the following indications: • Combination therapy of denosumab and intravenous bisphosphonates • Bone loss associated with hormone-ablation therapy (other than aromatase inhibitors) in breast cancer • Cancer pain • Central giant cell granuloma • Hyper-parathyroidism • Immobilization hypercalcemia • Osteogenesis imperfecta • Osteopenia

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

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	○ How supplied: 60 mg/1 ml vial ○ Maximum allowed: 60 HCPCS units (1 mg per unit); 1 vial/1 ml **Supporting Information** • Updated *Clinical Evidence* and *FDA* sections to reflect the most current information	
Vyvgart™ (Efgartigimod Alfa-Fcab)	Jun. 1, 2022	**Coverage Rationale** • Revised coverage criteria for continuation of therapy; replaced criterion requiring "improvement and/or maintenance of at least a *3* point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline" with "improvement and/or maintenance of at least a *2* point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline"	**Myasthenia Gravis** Vyvgart™ is proven and medically necessary when the following criteria are met: • Initial Therapy: ○ Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of generalized myasthenia gravis (gMG) by a neurologist or in consultation with a neurologist confirming all of the following: ▪ Patient has not failed a previous course of Vyvgart™ therapy; and ▪ Positive serologic test for anti-AChR antibodies; and ▪ One of the following: – History of abnormal neuromuscular transmission test demonstrated by single-fiber electromyography (SFEMG) or repetitive nerve stimulation – History of positive anticholinesterase test, e.g., edrophonium chloride test – Patient has demonstrated improvement in MG signs on oral cholinesterase inhibitors as assessed by the treating neurologist and ▪ Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy; and ▪ Patient has a Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score ≥ 5 at initiation of therapy and ○ Both of the following:

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Vyvgart™ (Efgartigimod Alfa-Fcab) (continued)	Jun. 1, 2022		▪ History of failure of at least two immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, methotrexate, cyclosporine, mycophenylate, etc.); and ▪ Patient has required 2 or more courses of plasmapheresis/plasma exchanges and/or intravenous immune globulin for at least 12 months without symptom control and ○ Patient is currently on a stable dose (at least 2 months) of immunosuppressive therapy; and ○ Patient is not receiving Vyvgart™ in combination with Soliris (eculizumab); and ○ Vyvgart™ is initiated and titrated according to the U.S. FDA labeled dosing for gMG, up to a maximum of 1200 mg per dose; and ○ Prescribed by or in consultation with a neurologist; and ○ Initial authorization will be for no more than 6 months. • Continuation of Therapy: ○ Patient has previously been treated with Vyvgart™; and ○ Submission of medical records (e.g., chart notes, laboratory tests) to demonstrate a positive clinical response from baseline as demonstrated by all of the following: ▪ Improvement and/or maintenance of at least a 2-point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline. ▪ Reduction in signs and symptoms of myasthenia gravis ▪ Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Vyvgart™. Note: add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on Vyvgart™ therapy will be considered as treatment failure. and ○ Patient is not receiving Vyvgart™ in combination with Soliris (eculizumab); and ○ Vyvgart™ is dosed according to the U.S. FDA labeled dosing for gMG:

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Vyvgart™ (Efgartigimod Alfa-Fcab) (continued)	Jun. 1, 2022		up to a maximum of 1200 mg per dose; and ○ Prescribed by or in consultation with a neurologist; and ○ Reauthorization will be for no more than 12 months.
White Blood Cell Colony Stimulating Factors	Jun. 1, 2022	Coverage Rationale • Added language to indicate the preferred product criteria in [the policy] apply to the state of Kentucky	This policy refers to the following white blood cell colony stimulating factors (CSFs): • Long-acting pegfilgrastim agents: ○ Fulphila® (pegfilgrastim-jmdb) ○ Neulasta® (pegfilgrastim) ○ Nyvepria™ (pegfilgrastim-apgf) ○ Udenyca® (pegfilgrastim-cbqv) ○ Ziextenzo® (pegfilgrastim-bmez) • Short-acting filgrastim agents: ○ Granix® (tbo-filgrastim) ○ Neupogen® (filgrastim) ○ Nivestym® (filgrastim-aafi) ○ Zarxio® (filgrastim-sndz) • Leukine® (sargramostim) (see 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

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jun. 1, 2022		will be provided for Neulasta® and Ziextenzo® contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Coverage for Fulphila®, Nyvepria™, or Udenyca® will be provided contingent on the criteria in this section and the coverage criteria in the Diagnosis-Specific Criteria section. ***Preferred Product Criteria*** Treatment with Fulphila®, Nyvepria™, Udenyca®, or other pegfilgrastim biosimilar is medically necessary for the indications specified in the policy when one of the following is met: • Both of the following: ○ History of a trial of adequate dose and duration of Neulasta® or Ziextenzo®, resulting in minimal clinical response; and ○ Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Fulphila®, Nyvepria™, Udenyca®, or other pegfilgrastim biosimilar product than experienced with Neulasta® or Ziextenzo®; or • Both of the following: ○ History of intolerance, contraindication, or adverse event to Neulasta® or Ziextenzo®; and ○ Physician attests that, in their clinical opinion, the same intolerance, contraindication or adverse event would not be expected to occur with Fulphila, Nyvepria, Udenyca, or other pegfilgrastim biosimilar product **Short-Acting Filgrastim Agents (Granix®, Neupogen®, Nivestym®, & 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.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (continued)	Jun. 1, 2022		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®, or Nivestym® will be provided contingent on the criteria in this section and the coverage criteria in the Diagnosis-Specific Criteria section. ***Preferred Product Criteria*** Treatment with Granix®, Neupogen® or Nivestym®, 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®, 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®, 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®, Zarxio®) Leukine®, Neupogen®, Nivestym®, and Zarxio® are proven and medically necessary when all of the following criteria are met:

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (continued)	Jun. 1, 2022		○ One of the following: ▪ Patient has non-myeloid malignancies and is undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT); or ▪ Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; or ▪ Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy; 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 ● Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy (Leukine®, Neupogen®, Nivestym®, Zarxio®) Leukine®, Neupogen®, Nivestym®, and Zarxio® are proven and medically necessary when all of the following criteria are met: ○ 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™, Udenyca®, Zarxio®, Ziextenzo®) White blood cell colony stimulating factors are proven and medically necessary when all of the following criteria are met: ○ One of the following: ▪ Patient is receiving dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin) for bladder cancer; or ▪ Patient is receiving dose dense AC (doxorubicin, cyclophosphamide) followed by dose-dense paclitaxel for breast cancer; or ▪ Patient is receiving chemotherapy regimen(s) associated with > 20% incidence of FN; or ○ Both of the following:

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (continued)	Jun. 1, 2022		▪ 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: – Persistent neutropenia due to prior chemotherapy, radiation therapy or bone marrow involvement by tumor (ANC < 1,500 neutrophils/mcL[50]) – Liver dysfunction (bilirubin > 2.0) – Renal dysfunction (creatinine clearance < 50) – Age > 65 years receiving full chemotherapy dose intensity Note: Chemotherapy regimen associated incidence of febrile neutropenia will be based on the clinical trial(s) with the highest level of evidence according to the GRADE criteria. • Secondary Prophylaxis of Febrile Neutropenia (FN) (Fulphila®, Granix®, Leukine®, Neulasta®, Neupogen®, Nivestym®, Nyvepria™, Udenyca®, Zarxio®, Ziextenzo®) White blood cell colony stimulating factors are proven and medically necessary when all of the following criteria are met: ○ Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (ANC ≤ 1,500 neutrophils/mcL[50]); and ○ A documented history of febrile neutropenia during a previous course of chemotherapy • Treatment of Febrile Neutropenia (FN) (Fulphila®, Leukine®, Neulasta®, Neupogen®, Nivestym®, Nyvepria™, Udenyca®, Zarxio®, Ziextenzo®) [Off-Label] Fulphila®, Leukine®, Neulasta®, Neupogen®, Nivestym®, Nyvepria™, Udenyca®, Zarxio®, and Ziextenzo® are proven and medically necessary when all of the following criteria are met: ○ Diagnosis of febrile neutropenia; and ○ Patient is considered high risk for infection-associated complications (e.g., hypotension, acute renal, respiratory, heart failure) with the score of < 21 on Multinational Association of Supportive Care in Cancer (MASCC) Scoring system in patients with cancer and febrile

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (continued)	Jun. 1, 2022		neutropenia • Severe Chronic Neutropenia (SCN) (Neupogen®, Nivestym®, Zarxio®) Neupogen®, Nivestym®, and Zarxio® are proven and medically necessary when all of the following criteria are met: ○ Diagnosis of SCN (i.e., congenital, cyclic, and idiopathic neutropenias with chronic ANC ≤ 500 neutrophils/mcL[50]); and ○ Medication is dosed in accordance with the U.S. Food and Drug Administration (FDA) approved labeling; and ○ Prescribed by or in consultation with a hematologist or oncologist • Hematopoietic Syndrome of Acute Radiation Syndrome (Fulphila®, Leukine®, Neulasta®, Neupogen®, Nivestym®, Nyvepria™, Udenyca®, Zarxio®, Ziextenzo®) Fulphila®, Leukine®, Neulasta®, Neupogen®, Nivestym®, Nyvepria™, Udenyca®, Zarxio®, and Ziextenzo® are proven and medically necessary when all of the following criteria are met: ○ 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

Coverage Determination Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ambulance Services (for Kentucky Only)	Jun. 1, 2022	Coverage Rationale *Emergency Air Ambulance* • Revised coverage criteria: ○ Added criterion requiring the member's destination is an appropriate medical facility or provider other than a hospital emergency room in the absence of a hospital emergency room in the medical service area ○ Removed criterion requiring the services are requested by police or medical authorities at the site of an emergency ○ Replaced criterion requiring "the member's destination is an *acute care* hospital" with "the member's destination is a hospital *emergency room*" *Emergency Ambulance (Ground, Water, or Air)* • Added language to clarify coverage includes Emergency Ambulance Transportation (including wait time and treatment at the scene) by a licensed ambulance service from the location of the sudden illness or injury to the nearest hospital *emergency room* where Emergency Health Care Services can be performed • Added language to indicate	**Indications for Coverage** ***Emergency Air Ambulance*** Emergency Air Ambulance services may be deployed when the member's condition requires immediate transportation that cannot be provided by ground ambulance. Examples may include situations when a member's medical condition is unstable and transportation by ground ambulance poses a threat to the member's survival or seriously endangers the member's health and the member's care cannot be provided/stabilized at the current location. Emergency Air Ambulance Transportation may also be considered when ground transport times exceed 30-60 minutes and the lengthy transport times may endanger the member's life or seriously endanger the member's health. In addition, emergency Air Ambulance may be considered when the pickup point is inaccessible by ground ambulance or is in a remote or sparsely populated area. Emergency Air Ambulance Transportation should meet the following criteria: • The member's destination is a hospital emergency room; or • The member's destination is an appropriate medical facility or provider other than a hospital emergency room in the absence of a hospital emergency room in the medical service area; and • Emergency Air Ambulance Transportation requiring advanced life support; or • Weather or traffic conditions make ground Ambulance Transportation impractical, impossible, or overly time consuming ***Emergency Ambulance (Ground, Water, or Air)*** Coverage includes Emergency Ambulance Transportation (including wait time and treatment at the scene) by a licensed ambulance service from the location of the sudden illness or injury to the nearest hospital emergency room where Emergency Health Care Services can be performed. In the absence of a hospital

Coverage Determination Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ambulance Services (for Kentucky Only) (continued)	Jun. 1, 2022	Emergency Ambulance Transportation to an appropriate medical facility or provider other than a hospital emergency room where Emergency Health Care Services can be performed may be covered in the absence of a hospital emergency room in the medical service area *Coverage Limitations and Exclusions* • Replaced language indicating "Air Ambulance Transportation that does not meet the covered indications in the *Emergency Air Ambulance Transportation* criteria listed [in the policy] is not eligible for coverage" with "Ambulance Transportation that does not meet the covered indications in the *Indications for Coverage* criteria listed [in the policy] *or the Kentucky Administrative Regulations 907 KAR 1:060 Ambulance Transportation* is not eligible for coverage" • Removed language indicating: ○ Ambulance Transportation to a home, residential, domiciliary or custodial facility that does not meet the Non-Emergency Ambulance criteria [listed in the policy] is not covered	emergency room in the medical service area, Emergency Ambulance Transportation to an appropriate medical facility or provider other than a hospital emergency room where Emergency Health Care Services can be performed may be covered. The following Emergency ambulance services are covered: • Transportation to the nearest hospital that can provide services appropriate to the covered person's illness or injury • Transportation to the nearest neonatal special care unit for newborn infants' treatment of illness, injuries, congenital birth defects, or complications of premature birth that require that level of care • Ground ambulance or Air Ambulance Transportation requiring basic life support or advanced life support • Supplies that are needed for advanced life support or basic life support to stabilize a member's medical condition • Treatment at the scene (paramedic services) without Ambulance Transportation • Wait time associated with covered Ambulance Transportation • Transportation to a hospital that provides a required higher level of care that was not available at the original hospital ***Non-Emergency Ambulance (Ground or Air) Between Facilities*** Coverage includes non-Emergency Ambulance Transportation by a licensed ambulance service (either ground or Air Ambulance, as UnitedHealthcare determines appropriate) between facilities only when the transport meets one of the following: • A non-Emergency ambulance service to a provider within the Medical Service Area shall be covered if: ○ The member's medical condition warrants transport by stretcher; ○ The member is traveling to or from a Medicaid-covered service, exclusive of a pharmacy service; and ○ The service is the least expensive available transportation for the member's need.

Coverage Determination Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ambulance Services (for Kentucky Only) (continued)	Jun. 1, 2022	○ If the member is at a Skilled Nursing Facility/Inpatient Rehabilitation Facility and has met the annual day/visit limit on Skilled Nursing Facility/Inpatient Rehabilitation Facility Services, nonemergent ambulance transports (during the non-covered days) are not eligible for coverage ○ Ambulance Transportation deemed not appropriate that does not meet above *Indications of Coverage* criteria [listed in the policy] is not eligible for coverage; examples include but are not limited to: ▪ Hospital to home ▪ Home to physician's office ▪ Home (e.g., residence, nursing home, domiciliary or custodial facility) to a hospital for a scheduled service **Definitions** ● Added definition of "Air Ambulance" **Supporting Information** ● Updated *References* section to reflect the most current information	● A non-Emergency ambulance service to a provider outside the Medical Service Area shall be covered if ○ The criteria specified above are satisfied; ○ The medical service required by the member is not available in the Medical Service Area; and ○ The member is referred by a physician. **Coverage Limitations and Exclusions** The following services are not eligible for coverage: ● Ambulance services from providers that are not properly licensed to be performing the ambulance services rendered. ● Ambulance Transportation that does not meet the covered indications in the Indications for Coverage criteria listed above or the Kentucky Administrative Regulations 907 KAR 1:060 Ambulance transportation. ● Air Ambulance services: ○ Outside of the 50 United States and the District of Columbia; or ○ From a country or territory outside the United States to a location within the 50 United States or the District of Columbia; or ○ From a location within the 50 United States or the District of Columbia to a country or territory outside the United States. ● Ambulance Transportation for member convenience or other miscellaneous reasons for member and/or family. Examples include but are not limited to: ○ Member wants to be at a certain hospital or facility for personal/preference reasons ○ Member is in foreign country, or out of state, and wants to come home for a surgical procedure or treatment (this includes those recently discharged from inpatient care) ○ Member is going for a routine service and is medically able to use another mode of transportation ○ Member is deceased and family wants transportation to the coroner's office or mortuary

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

Ambulance Services (for Kentucky Only) (continued)	Jun. 1, 2022		For nonemergency medical transportation, please refer to Kentucky Administrative Rules 3:066.
			
			Documentation Requirements for Determination of Coverage
			For Emergency Ambulance Services:
			• Documentation must be maintained for post payment review to indicate immediate emergency medical attention was provided in the emergency room.
			• An Emergency ambulance service to an Appropriate Medical Facility or Provider other than a hospital emergency room shall require documentation from the attending physician of:
			  ○ Medical Necessity;
			  ○ Absence of a hospital emergency room in the Medical Service Area; and
			  ○ Delivery of emergency care to the patient.
			
			The necessity for an Ambulance Transportation service shall be:
			• Determined by The Plan; and
			• Based upon a statement of medical necessity by an attending physician which shall:
			  ○ Be maintained on file by the transportation provider for a period of five (5) years; and
			  ○ Include the following information:
			  ▪ Verification by the provider of the:
			  – Date of ambulance service;
			  – Patient's name;
			  – Patient's Medicaid identification number;
			  – Patient's address;
			  – Origin of ambulance service; and
			  – Destination of ambulance service; and
			  ▪ A signed and dated statement by the attending physician, or other medical professional carrying out the orders of the attending physician, which verifies the patient's diagnosis and whether or not

Coverage Determination Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ambulance Services (for Kentucky Only) (continued)	Jun. 1, 2022		the patient: – Received treatment in an outpatient setting following transport; – Required admission to the hospital following transport; – Transferred from one (1) medical facility to another; – Was confined to bed before and after transport; – Required movement by stretcher; or – Had a medical condition which contraindicated transportation by means other than an ambulance (907 KAR 1:060)
Patient Lifts (for Kentucky Only)	Jun. 1, 2022	Coverage Rationale *Indications for Coverage* • Revised language pertaining to medical necessity clinical coverage criteria; replaced reference to the "InterQual® 2022, Apr. 2022 Release, *Medicare*: Durable Medical Equipment, Patient *Lifts*" with "InterQual® 2022, Apr. 2022 Release, *CP*: Durable Medical Equipment, Patient *Lift System*" *Coverage Limitations and Exclusions* • Replaced list of excluded items with instruction to refer to the *Kentucky Administrative Regulations 907 KAR 1:479 Durable Medical Equipment Covered Benefits and Reimbursement* for coverage limitations and exclusions Applicable Codes • Removed HCPCS code E0625	**Indications for Coverage** Patient lifts are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Durable Medical Equipment, Patient Lift System. Click here to view the InterQual® criteria. **Coverage Limitations and Exclusions** Refer to the Kentucky Administrative Regulations 907 KAR 1:479 Durable Medical Equipment Covered Benefits and Reimbursement for coverage limitations and exclusions.

Coverage Determination Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Speech Generating Devices (for Kentucky Only)	Jun. 1, 2022	**Coverage Rationale** • Revised language pertaining to medical necessity clinical coverage criteria; replaced reference to the "InterQual® 2022, Apr. 2022 Release, *Medicare*: Durable Medical Equipment, Speech Generating Devices (SGD)" with "InterQual® 2022, Apr. 2022 Release, *CP*: Durable Medical Equipment, Speech Generating Devices (SGD)" • Replaced list of excluded items with instruction to refer to the Kentucky Administrative Regulations *907 KAR 1:479 Durable Medical Equipment Covered Benefits and Reimbursement* for coverage limitations and exclusions **Definitions** • Added definition of: ○ Injury ○ Sickness **Supporting Information** • Updated *References* section to reflect the most current information	**Indications for Coverage** ***Speech Generating Devices*** Speech Generating Devices are covered as durable medical equipment (DME) when: • The device(s) are not explicitly excluded from coverage; and • The treating physician determines that the member has either a severe speech impairment (impediment) or lack of speech directly due to sickness or injury; and • The medical condition warrants the use of a device The physician attestation must be consistent with and based upon the recommendation of a qualified speech and language pathologist. The speech and language pathology evaluation must reach all of the following conclusions: • Other forms of treatment have been attempted or considered and ruled out. Examples of a Speech Generating Device are: ○ Freedom ○ Prentke Romich (or PRC) ○ Say-it!™ ○ Tobii Dynavox • The member's medical condition is one resulting in a severe expressive speech impairment (impediment), or lack of speech directly related to Sickness or Injury • The member's speaking needs cannot be met using natural communication methods For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Durable Medical Equipment, Speech Generating Devices (SGD). Click here to view the InterQual® criteria. **Coverage Limitations and Exclusions** Refer to the Kentucky Administrative Regulations 907 KAR 1:479 Durable

Coverage Determination Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Speech Generating Devices (for Kentucky Only) (continued)	Jun. 1, 2022		Medical Equipment Covered Benefits and Reimbursement for coverage limitations and exclusions.

Utilization Review Guideline Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Elective Inpatient Services (for Kentucky Only)	Jul. 1, 2022	Coverage Rationale • Updated list of procedure-related factors that may increase risk of anesthetic complications; removed "class III obesity (body mass index greater than 40) with hemodynamic or respiratory problems" (duplicative of "American Society of Anesthesiologists class III or greater") Definitions • Added definition of "Hemodynamic Instability" • Updated definition of "Acute Kidney Injury" Supporting Information • Updated *References* section to reflect the most current information

Retired		
Policy Title	**Effective Date**	**Summary of Changes**
Propranolol Treatment for Infantile Hemangiomas: Inpatient Protocol (for Kentucky Only)	May 1, 2022	• Policy retired; propranolol treatment for infantile hemangiomas in the inpatient setting no longer requires clinical review

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 Kentucky 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.