United Healthcare Community Plan

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

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Quarterly CPT® and HCPCS Code Updates

The following Medical Policies and Medical Benefit Drug Policies have been updated to reflect the quarterly Current Procedural Terminology (CPT®) and Healthcare Common Procedure Coding System (HCPCS) code additions, revisions, and deletions. Refer to the following sources for information on the code updates:

- American Medical Association. Current Procedural Terminology: CPT®
- Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System: HCPCS Level II

Policy Title	Policy Type	Summary of Changes
Autologous Cellular Therapy (for Tennessee Only)	Medical Policy	• Added CPT codes 0717T and 0718T
Cell-Free Fetal DNA Testing (for Tennessee Only)	Medical Policy	• Added CPT code 0327U
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for Tennessee Only)	Medical Policy	• Added HCPCS codes G0308 and G0309
Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation (for Tennessee Only)	Medical Policy	• Added CPT code 0720T
Enjaymo™ (Sutimlimab-Jome)	Medical Benefit Drug Policy	• Replaced HCPCS code C9399 with C9094
Genitourinary Pathogen Nucleic Acid Detection Panel Testing (for Tennessee Only)	Medical Policy	• Added CPT code 0330U
Immune Globulin (IVIG and SCIG)	Medical Benefit Drug Policy	• Added HCPCS code J1551
Leqvio® (Inclisiran)	Medical Benefit Drug Policy	• Replaced HCPCS codes C9399, J3490, and J3590 with J1306
Long-Acting Injectable Antiretroviral Agents for HIV	Medical Benefit Drug Policy	• Replaced HCPCS codes C9399 and J3490 with J0739
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for Tennessee Only)	Medical Policy	• Added CPT codes 0326U, 0329U, and 0331U • Revised description for CPT code 0016M
Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF)	Medical Benefit Drug Policy	• Replaced HCPCS code C9399 with C9097
Ryplazim® (Plasminogen, Human-Tvmh)	Medical Benefit Drug Policy	• Replaced J3490 and J3590 with J2998 • Removed C9090
Surgical Treatment for Spine Pain (for Tennessee Only)	Medical Policy	• Added CPT code 0719T

Take Note

Policy Title	Policy Type	Summary of Changes
Tezspire™ (Tezepelumab)	Medical Benefit Drug Policy	• Replaced HCPCS codes C9399, J3490, and J3590 with J2356
Vyvgart™ (Efgartigimod Alfa-Fcab)	Medical Benefit Drug Policy	• Replaced HCPCS codes C9399, J3490, and J3590 with J9332

Medical Policy Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Deep Brain and Cortical Stimulation (for Tennessee Only)	Jul. 1, 2022	Coverage Rationale • Updated language to clarify responsive cortical stimulation is proven and medically necessary for treating *refractory* partial or focal seizure disorder Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information
Intensity-Modulated Radiation Therapy (for Tennessee Only)	Jul. 1, 2022	Application • Added language to indicate this Medical Policy applies to CoverKids Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information
Total Artificial Disc Replacement for the Spine (for Tennessee Only)	Jul. 1, 2022	Application • Added language to indicate this Medical Policy applies to CoverKids Coverage Rationale *Cervical Artificial Disc Replacement* • Replaced language indicating "cervical artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary *in certain circumstances*" with "cervical artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary *for treating one-level or two contiguous levels of cervical Degenerative Disc Disease (C3 to C7) a Skeletally Mature individual with symptomatic radiculopathy and/or myelopathy*" • Added language to clarify cervical artificial disc replacement at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent), *as part of the same surgical plan*, is unproven and not medically necessary due to insufficient evidence of efficacy *Lumbar Artificial Total Disc Replacement* • Replaced language indicating "lumbar artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary *in certain circumstances*" with "lumbar artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary *for treating single level lumbar Degenerative Disc Disease with symptomatic intractable discogenic low back pain in a Skeletally Mature individual when there are no contraindications*" • Added language to indicate: ○ Contraindications to lumbar artificial total disc replacement include but are not limited to the following: ▪ Moderate or severe facet arthropathy or pars defect at the operative level on a preoperative MRI scan, CT scan or plain radiograph ▪ Lumbosacral spinal fracture

Medical Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Total Artificial Disc Replacement for the Spine (for Tennessee Only) (continued)	Jul. 1, 2022	▪ Scoliosis of the lumbosacral spine ▪ Active systemic infection or infection localized to the site of implantation ▪ Tumor in the peritoneum, retroperitoneum, or site of implantation ▪ Osteoporosis or osteopenia as defined by recent (within one year) DEXA scan ▪ Isolated radicular compression syndromes especially due to disc herniation ▪ Spinal stenosis or radiculopathy ▪ Previous lumbar spine surgery where the previous surgery destabilized the spine or where the spine at the level of the previous surgery is an alternate source of pain ▪ Vascular, urological, or other peritoneal or retroperitoneal pathology that may preclude safe and adequate anterior spine exposure as required for the surgery ○ Lumbar artificial total disc replacement is unproven and not medically necessary in the following situations due to insufficient evidence of efficacy: ▪ More than one spinal level ▪ Prior history of lumbar fusion or when combined with a lumbar fusion at any level ▪ Treating any other indications not listed above **Definitions** ● Updated definition of: ○ Degenerative Disc Disease (DDD) ○ Grade 1 Spondylolisthesis ○ Modic Changes **Supporting Information** ● Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information ● Removed *CMS* section
Transcatheter Heart Valve Procedures (for Tennessee Only)	Jul. 1, 2022	**Coverage Rationale** ● Added instruction to refer to the following sources for additional information pertaining to Volume Requirements consistent with the Centers for Medicare and Medicaid Services (CMS): ○ CMS National Coverage Determination 20.32: *Transcatheter Aortic Valve Replacement (TAVR)* ○ Society of Thoracic Surgeons/American College of Cardiology (STS/ACC) *Transcatheter Valve Therapy (TVT) Registry* **Definitions** ● Updated definition of "CMS Volume Requirements for Transcatheter Aortic Heart Valve Replacement (TAVR)"

Medical Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Transcatheter Heart Valve Procedures (for Tennessee Only) (continued)	Jul. 1, 2022	**Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
Vertebral Body Tethering for Scoliosis (for Tennessee Only)	Jul. 1, 2022	**Application** • Added language to indicate this Medical Policy applies to CoverKids **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation (for Tennessee Only)	Sep. 1, 2022	Notice of Implementation Delay: The changes noted below will not be effective on Jul. 1, 2022, as previously announced. Implementation of the revised policy has been postponed until Sep. 1, 2022.
		
		Coverage Rationale
		• Added language to indicate neuromuscular electrical stimulation (NMES) is proven and medically necessary when used as part of a comprehensive lower limb rehabilitation program following total knee arthroplasty
		• Replaced language indicating "NMES is proven and medically necessary to improve *wrist and finger* function *and prevent or correct shoulder subluxation* in persons with partial paralysis following stroke" with "NMES is
			For specific guidelines for functional electrical stimulation (FES), refer to the coverage statements and criteria in the *Rules of Tennessee Department of Finance and Administration Bureau of Tenncare, Chapter 1200-1313 Tenncare Medicaid*.
			
			Neuromuscular electrical stimulation (NMES) is proven and medically necessary for treating the following indications:
			• Disuse muscle atrophy if:
			  ○ The nerve supply to the muscle is intact; and
			  ○ The disuse muscle atrophy is not of neurological origin but results from other conditions including but not limited to casting, splinting or contractures
			• When used as part of a comprehensive lower limb rehabilitation program following total knee arthroplasty
			• To improve upper extremity function in persons with partial paralysis following stroke when used as part of a comprehensive rehabilitation program
			
			The following are unproven and not medically necessary due to insufficient evidence of efficacy:
			• Interferential therapy (IFT) for treating musculoskeletal disorders/injuries, or to facilitate healing of nonsurgical soft tissue injuries or bone fractures

Medical Policy Updates

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

Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation (for Tennessee Only) (continued)	Sep. 1, 2022	proven and medically necessary to improve *upper extremity* function in persons with partial paralysis following stroke *when used as part of a comprehensive rehabilitation program*"
		• Revised list of unproven and not medically necessary indications:
		  ○ Added "translingual stimulation (TS) for gait rehabilitation"
		  ○ Removed "dorsal root ganglion (DRG) stimulation"
		• Added reference link to the Medical Policy titled *Implanted Electrical Stimulator for Spinal Cord* for information regarding dorsal root ganglion (DRG) stimulation
		Applicable Codes
		• Removed CPT code 64566
		Supporting Information
		• Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
			• Microcurrent electrical nerve stimulation (MENS)
			• NMES for treating any other indication not listed above
			• Percutaneous electrical nerve stimulation (PENS), percutaneous electrical nerve field stimulation (PENFS) or percutaneous neuromodulation therapy (PNT)
			• Percutaneous peripheral nerve stimulation (PNS)*
			• Peripheral subcutaneous field stimulation (PSFS) or peripheral nerve field stimulation (PNFS)
			• Pulsed electrical stimulation (PES)
			• Scrambler Therapy (ST)
			• Translingual Stimulation for gait rehabilitation (TS)
			
			*For information regarding percutaneous peripheral nerve stimulation for occipital neuralgia and headache, refer to Medical Policy titled Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache) (for Tennessee Only).
			
			Note: For information regarding dorsal root ganglion (DRG) stimulation, refer to the Medical Policy titled Implanted Electrical Stimulator for Spinal Cord (for Tennessee Only).

Negative Pressure Wound Therapy (for Tennessee Only)	Aug. 1, 2022	**Application** • Added language to indicate this Medical Policy applies to CoverKids **Coverage Rationale** • Revised list of indications and devices that are unproven and not medically necessary:	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

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Negative Pressure Wound Therapy (for Tennessee Only) (continued)	Aug. 1, 2022	○ Added "negative pressure wound therapy (NPWT) systems with instillation" ○ Replaced "NPWT for treating closed surgical *wounds*" with "NPWT for treating closed surgical *incisions*" **Definitions** ● Updated definition of "National Pressure Injury Advisory Panel (NPIAP) Staging System" **Applicable Codes** ● Removed instruction to refer to the Coverage Determination Guideline titled *Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (for Tennessee Only)* for use of HCPCS codes K0743 and K0746 **Supporting Information** ● Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	NPWT, in an outpatient setting or upon discharge from an inpatient setting, is proven and medically necessary for treating individuals who have undergone a complete wound therapy program and meet indication-specific criteria as noted below. A complete wound therapy program, meeting the following criteria, must have been tried or considered and ruled out prior to initiation of NPWT: ● Documentation of evaluation, care and wound measurements; and ● Application of dressings to maintain a moist wound environment; and ● Debridement of necrotic tissue, if present; and ● Evaluation of and provision for adequate nutritional status; and ● Documentation, by provider, of indication for NPWT; and ● Documentation that open wound has not responded to conventional treatment after 30 days **Indications** ● Pressure ulcer (Stage III or IV) with documentation of the following: ○ Complete wound therapy program, as outlined above; and ○ Appropriate turning and positioning; and ○ Use of a pressure-reducing support surface; and ○ Moisture and incontinence management ● Neuropathic ulcer (e.g., Diabetic ulcer) with documentation of the following: ○ Complete wound therapy program, as outlined above; and ○ Comprehensive diabetic management program; and ○ Reduction in pressure on ulcer ● Venous insufficiency ulcer with documentation of the following: ○ Complete wound therapy program, as outlined above; and ○ Compression bandages and/or garments have been used consistently, for at least 30 days; and ○ Leg elevation and ambulation ● Open surgical wound with documentation of the following: ○ Post-operative dehiscence (separation of a previously closed surgical incision) with documentation of a complete wound therapy program, as

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Negative Pressure Wound Therapy (for Tennessee Only) (continued)	Aug. 1, 2022		outlined above; or ○ Open, non-healing amputation site in diabetics; or ○ Post-sternotomy infection (mediastinitis); or ○ Delayed healing or non-healing of skin graft is likely due to irregularly contoured or inadequate blood flow of the graft bed • High-risk open fracture (Gustilo Grade III) 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: ○ Closed surgical incisions ○ Pilonidal disease • Disposable/single-use NPWT systems • NPWT systems with instillation **Contraindications to NPWT** • Active bleeding or exposed vasculature in wound • Eschar or necrotic tissue present in wound • Exposed bone, nerves or organs in vicinity of wound • Malignancy present in wound • Uncontrolled soft tissue infection or osteomyelitis within vicinity of wound • Presence of an open fistula to body organs or cavities within vicinity of wound NPWT should be discontinued when any of the following criteria are present: • Documentation of weekly assessment of the wound's dimensions and characteristics by the provider indicate failure of progressive wound healing (i.e., wound is not diminishing in size [either surface area or depth] within 30 days); or • The depth of the wound is 1 mm or less; or • Uniform granulation tissue has been obtained

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Obstructive and Central Sleep Apnea Treatment (for Tennessee Only)	Aug. 1, 2022	**Application** • Added language to indicate this Medical Policy applies to CoverKids **Coverage Rationale** *Nonsurgical Treatment* • Revised list of services/devices that are unproven and not medically necessary for treating 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)"	**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). 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, Ostomy Supplies, Medical Supplies and Repairs/Replacements (for Tennessee Only). For medical necessity clinical coverage criteria for removable oral appliances, refer to the InterQual® 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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Obstructive and Central Sleep Apnea Treatment (for Tennessee Only) (continued)	Aug. 1, 2022	**Applicable Codes** • Added CPT/HCPCS codes 21142, E1399, K1027, 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 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	• Nasal dilator devices for treating OSA • Removable Oral Appliances for treating Central Sleep Apnea • Prefabricated Oral Appliance/Device • Non-surgical electrical muscular training • 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® Client Defined: Procedures: • Mandibular Osteotomy (Custom) - UHG • Maxillomandibular Osteotomy and Advancement (Custom) - UHG • Uvulopalatopharyngoplasty (UPPP) (Custom) - UHG 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 of 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)

Medical Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Obstructive and Central Sleep Apnea Treatment (for Tennessee Only) (continued)	Aug. 1, 2022		Implantable neurostimulation devices for the treatment of Central Sleep Apnea (CSA) are unproven and not medically necessary due to insufficient 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)

Medical Benefit Drug Policy Updates

New

Policy Title	Effective Date	Coverage Rationale
Korsuva™ (Difelikefalin)	Aug. 1, 2022	**Initial Therapy** Korsuva (Difelikefalin) is proven and medically necessary for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis when the following criteria are met: • Diagnosis of moderate-to-severe pruritus associated with chronic kidney disease; and • Patient is on hemodialysis; and • Pruritus is not attributed to a cause other than end stage renal disease or its complications (e.g., pruritic dermatological disease, cholestatic liver disease); and • Pruritus is not limited to occurring only during the dialysis session; and • Pruritis is not localized to just the palms of the hands, and • History of failure, contraindication, or intolerance to other pruritis treatments (e.g., antihistamines, corticosteroids, gabapentin, pregabalin, capsaicin); and • Prescribed by or in consultation with a nephrologist; and • Dosing is in accordance with the United States Food and Drug Administration approved labeling; and • Initial authorization will be for no longer than 3 months. **Continuation Therapy** Korsuva (Difelikefalin) will be reauthorized based on all of the following criteria: • Documentation of a positive clinical response (i.e., reduction in itch from baseline); and • Prescribed by or in consultation with a nephrologist; and • Dosing is in accordance with the United States Food and Drug Administration approved labeling; and • Reauthorization will be for no longer than 12 months.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gonadotropin Releasing Hormone Analogs	Aug. 1, 2022	**Coverage Rationale** • Revised list of applicable gonadotropin releasing hormone analog (GnRH analog) drug products; added Camcevi™ (leuprolide mesylate) **Applicable Codes** • Added HCPCS code J1952 **Supporting Information**	Refer to the policy for complete details.

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Gonadotropin Releasing Hormone Analogs (continued)	Aug. 1, 2022	• Updated *Background*, *FDA*, and *References* sections to reflect the most current information	
Long-Acting Injectable Antiretroviral Agents for HIV	Aug. 1, 2022	Coverage Rationale *Cabenuva* • Revised coverage criteria for initial therapy; removed criterion requiring the provider confirms that tolerability will be assessed using a 28-day oral lead-in of Vocabria (cabotegravir) and Edurant® (rilpivirine) tablets prior to the first injection of Cabenuva Supporting Information • Updated *References* section to reflect the most current information	This policy refers to the following long-acting injectable antiretroviral products: • Apretude (cabotegravir) • Cabenuva (cabotegravir/rilpivirine) Apretude (cabotegravir) is proven to reduce the risk of sexually acquired HIV-1 infection in at-risk adults and adolescents weighing at least 35kg. Apretude is medically necessary when the following additional criteria are met: • For initial therapy, all of the following: ○ Used for HIV-1 pre-exposure prophylaxis (PrEP); and ○ Patient has a negative HIV-1 test; and ○ Provider confirms that the patient will be tested for HIV-1 infection with each subsequent injection; and ○ Patient is not an appropriate candidate for oral PrEP (e.g. difficulty with adherence to prior oral PrEP, significant renal disease); and ○ Provider attests that patient demonstrates treatment readiness by both of the following: ▪ Patient understands the risks of missed doses of Apretude ▪ Patient has the ability to adhere to the required every 2 months injection and testing appointments; and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Initial authorization is for no more than 12 months. • For continuation therapy, all of the following: ○ Patient has previously received treatment with Apretude; and ○ Patient has a negative HIV-1 test; and ○ Provider confirms that the patient will be tested for HIV-1 infection with each subsequent injection; and ○ Dosing is in accordance with the United States Food and Drug

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Long-Acting Injectable Antiretroviral Agents for HIV (continued)	Aug. 1, 2022		Administration approved labeling; and ○ Authorization is for no more than 12 months. Apretude is unproven and not medically necessary for the treatment of human immunodeficiency virus type-1 (HIV-1). Cabenuva (cabotegravir/rilpivirine) is proven for the treatment of a human immunodeficiency virus type-1 (HIV-1) in patients who are virologically suppressed (HIV-1 RNA less than 50 copies per mL). Cabenuva is medically necessary when the following additional criteria are met: • For initial therapy, all of the following: ○ Diagnosis of HIV-1 infection; and ○ Patient has no prior virologic failures or baseline resistance to either cabotegravir or rilpivirine; and ○ Patient is currently on a stable antiretroviral regimen; and ○ Submission of medical records (e.g., chart notes, laboratory results) showing viral suppression (HIV-1 RNA less than 50 copies per mL) for at least 6 months prior to initiation of Cabenuva; and ○ Provider attests that patient demonstrates treatment readiness by both of the following: ▪ Patient understands the risks of missed doses of Cabenuva ▪ Patient has the ability to adhere to the required monthly or every 2 months injection appointments and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Initial authorization is for no more than 12 months • For continuation therapy, all of the following: ○ Patient has previously received treatment with Cabenuva; and ○ Provider confirms that the patient has achieved and maintained viral suppression (HIV-1 RNA less than 50 copies per mL) while on Cabenuva therapy; and ○ Dosing is in accordance with the United States Food and Drug

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Long-Acting Injectable Antiretroviral Agents for HIV (continued)	Aug. 1, 2022		Administration approved labeling; and ○ Authorization is for no more than 12 months Cabenuva is unproven and not medically necessary for the treatment of Human immunodeficiency virus type-1 (HIV-1) in patients who are not currently virally suppressed (HIV-1 RNA less than 50 copies per mL)
Off-Label/Unproven Specialty Drug Treatment	Aug. 1, 2022	**Coverage Rationale** • Replaced reference(s) to: ○ "*Injectable* specialty drug" with "specialty drug" ○ "*Injectable* oncology medications" with "oncology medications" • Added language to indicate this policy provides parameters for coverage of off-label and unproven indications of FDA-approved medications covered under the medical benefit for patient self-administered specialty drugs covered under the medical benefit **Supporting Information** • Updated *References* section to reflect the most current information	**Description** This policy provides parameters for coverage of off-label and unproven indications of FDA-approved medications covered under the medical benefit for one of the following: • Provider administered or supervised specialty drug or patient self-administered specialty drug covered under the medical benefit with a corresponding UnitedHealthcare policy that does not address the requested indication • Provider administered or supervised specialty drug or patient self-administered specialty drug covered under the medical benefit with a corresponding UnitedHealthcare policy that lists the drug as unproven for the requested indication • Provider administered or supervised specialty drug or patient self-administered specialty drug covered under the medical benefit without a UnitedHealthcare drug policy This policy does not address coverage for self-administered medications covered under the pharmacy benefit. Please refer to pharmacy benefit coverage. This policy does not address coverage of oncology medications (including, but not limited to octreotide acetate, leuprolide acetate, leucovorin and levoleucovorin), including therapeutic radiopharmaceuticals, covered under the medical benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®). Refer to the Medical Benefit Drug Policy titled Oncology Medication Clinical Coverage for more information. This policy does not address coverage of vaccines.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Off-Label/Unproven Specialty Drug Treatment (continued)	Aug. 1, 2022		**Indications of Coverage** A specialty drug may be determined medically necessary for the requested off-label or unproven indication when all of the criteria are met: • The drug is approved by the U.S. Food and Drug Administration (FDA); and • The requested drug is a covered benefit by the member's state Medicaid agency; and • One of the following: ○ The requested drug is considered 'unproven' per UnitedHealthcare drug policy, where applicable ○ The indication for the requested drug is not addressed by a UnitedHealthcare drug policy, where applicable ○ A UnitedHealthcare drug policy does not exist for the requested drug; and • The requested drug is intended to treat a chronic and seriously debilitating, or Serious Rare Disease; and • The patient has not failed a previous course or trial of the requested drug; and • The patient is not currently in an eligible clinical trial; and • Documented history of failure, contraindication, or intolerance to standard, conventional therapies to treat or manage the disease or condition, where available; and • Diagnosis is clinically supported as a use by at least one of the following: ○ One of the following compendia: ▪ The American Hospital Formulary Service Drug Information (AHFS - DI) under the Therapeutic Uses section ▪ The Elsevier Gold Standard's Clinical Pharmacology under the Indications section ▪ DRUGDEX System by Micromedex® has a Strength of Recommendation rating of Class I, Class IIa, or Class IIb under the Therapeutic Uses section; or ○ Clinical indications supported by InterQual® Specialty Rx; or ○ Two (2) articles from major peer reviewed medical journals that present

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Off-Label/Unproven Specialty Drug Treatment (continued)	Aug. 1, 2022		data supporting the proposed off-label use or uses as generally safe and effective unless there is validated, and uncontested contradictory evidence presented in a major peer-reviewed medical journal. (Examples of accepted journals include, but are not limited to, Journal of American Medical Association, New England Journal of Medicine, and Lancet. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. Evidence limited to case studies or case series is not sufficient to meet the standard of this criterion.)
Oncology Medication Clinical Coverage	Aug. 1, 2022	**Related Policies** • Added reference link to the Medical Benefit Drug Policy titled *Antiemetics for Oncology* **Coverage Rationale** • Revised list of UnitedHealthcare non-preferred oncology products; added Alymsys (bevacizumab-maly)	**Description** This policy provides parameters for coverage of injectable oncology medications (including, but not limited to, octreotide acetate, leuprolide acetate, leucovorin, and levoleucovorin), including therapeutic radiopharmaceuticals, covered under the medical benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®). The Compendium lists the appropriate drugs and biologics for specific cancers using US Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category. Coverage of White Blood Cell Colony Stimulating Factors and Erythropoiesis-Stimulating Agents are addressed in separate policies. This policy does not provide coverage criteria for Chimeric Antigen Receptor (CAR)-T Cell products. Coverage determinations are based on the member's benefits and the OptumHealth Transplant Solutions criteria for covered transplants in the Clinical Guideline titled Chimeric Antigen Receptor T-cell Therapy. **Coverage Rationale** The Oncology Products table below lists the UnitedHealthcare preferred oncology products and respective non-preferred products. Coverage will be provided for the UnitedHealthcare preferred oncology product contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Coverage for any respective non-preferred oncology product will be provided

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Oncology Medication Clinical Coverage (continued)	Aug. 1, 2022		contingent on the criteria in the Preferred Product Criteria and the Diagnosis-Specific Criteria sections.

Preferred Product Criteria

Treatment with the respective non-preferred product specified in the Oncology Products table below is medically necessary for oncology indications when both of the following are met:

- History of intolerance or contraindication to one of UnitedHealthcare's preferred oncology products; and
- Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with the respective non-preferred product

Oncology Products

Below are UnitedHealthcare preferred oncology products with therapeutically equivalent and/or biosimilar* non-preferred products as determined by the UnitedHealthcare P&T Committee:

Preferred Oncology Product	Non-Preferred Oncology Product
Mvasi (bevacizumab-awwb)	Avastin (bevacizumab) Zirabev (bevacizumab-bvzr) Alymsys (bevacizumab-maly)
Kanjinti (trastuzumab-anns)	Herceptin (trastuzumab) Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) Herzuma (trastuzumab-pkrb) Ogivri (trastuzumab-dkst) Ontruzant (trastuzumab-dttb) Trazimera (trastuzumab-qyyp)
Gemcitabine	Infugem (gemcitabine in sodium chloride injection)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Oncology Medication Clinical Coverage (continued)	Aug. 1, 2022		

Leucovorin	Levoleucovorin
Ruxience (rituximab-pvvr) Truxima (rituximab-abbs)	Riabni (rituximab-arrx) Rituxan (rituximab) Rituxan Hycela (rituximab/hyaluronidase human, recombinant)
Eligard, Lupron Depot 7.5mg (J9217)	Lupron Depot 3.75mg (J1950)

*Biosimilar means that the biological product is FDA-approved based on data demonstrating that it is highly similar to an already FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product.

Diagnosis-Specific Criteria

Injectable Oncology Medications

UnitedHealthcare recognizes indications and uses of injectable oncology medications, including therapeutic radiopharmaceuticals, in the NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and Categories of Evidence and Consensus of 3 as unproven and not medically necessary.

UnitedHealthcare will cover all chemotherapy agents for individuals under the age of 19 years for oncology indications. The majority of pediatric patients receive treatments on national pediatric protocols that are quite similar in concept to the NCCN patient care guidelines.

Refer to Preferred Product Criteria for the UnitedHealthcare preferred oncology products that have therapeutically equivalent and/or biosimilar products available.

Medical Benefit Drug Policy Updates

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Tezspire™ (Tezepelumab-Ekko)	Aug. 1, 2022	**Title Change** • Previously titled *Tezspire™ (Tezepelumab)* **Coverage Rationale** • Revised coverage criteria; added criterion requiring one of the following: ○ History of failure, contraindication, or intolerance to a 4-month trial of an anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Fasenra (benralizumab)] ○ Patient's asthma is not of the eosinophilic phenotype ○ Patient is currently on Tezspire	Tezspire is proven and medically necessary when all of the following criteria is met: • For initial therapy, all of the following: ○ Diagnosis of severe asthma; and ○ Classification of asthma as uncontrolled or inadequately controlled as defined by at least one of the following: ▪ Poor symptom control (e.g., ACQ score consistently greater than 1.5 or ACT score consistently less than 20); or ▪ Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months; or ▪ Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment); or ▪ Airflow limitation (e.g., after appropriate bronchodilator withhold FEV1 less than 80% predicted (in the face of reduced FEV1/FVC defined as less than the lower limit of normal); or ▪ Patient is currently dependent on maintenance therapy with oral corticosteroids for the treatment of asthma and ○ Used in combination with one of the following: ▪ One maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta$_2$ agonist (LABA) product [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]; or ▪ Combination therapy including both of the following: – One high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco®), mometasone furoate (Asmanex®), beclomethasone dipropionate (QVAR®)]; and – One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi®) or indacaterol (Arcapta®), leukotriene receptor antagonist – montelukast (Singulair®), theophylline] and

Medical Benefit Drug Policy Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Tezspire™ (Tezepelumab-Ekko) (continued)	Aug. 1, 2022		○ One of the following: ▪ History of failure, contraindication, or intolerance to a 4 month trial of an anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Fasenra (benralizumab)]; or ▪ Patient's asthma is not of the eosinophilic phenotype; or ▪ Patient is currently on Tezspire and ○ Patient is not receiving Tezspire in combination with any of the following: ▪ Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab)] ▪ Anti-IgE therapy [e.g., Xolair (omalizumab)] ▪ Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] ○ Tezspire dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Tezspire is prescribed by a pulmonologist or allergist/immunologist; and ○ Initial authorization will be for no more than 6 months. ● For continuation of therapy, all of the following: ○ Documentation of a positive clinical response as demonstrated by at least one of the following: ▪ Reduction in the frequency of exacerbations ▪ Decreased utilization of rescue medications ▪ Increase in percent predicted FEV1 from pretreatment baseline ▪ Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.) and ○ Used in combination with an ICS-containing controller medication; and ○ Patient is not receiving Tezspire in combination with any of the following: ▪ Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab)] ▪ Anti-IgE therapy [e.g., Xolair (omalizumab)]

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Tezspire™ (Tezepelumab-Ekko) (continued)	Aug. 1, 2022		▪ Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] and ○ Tezspire dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Reauthorization will be for no more than 12 months.
White Blood Cell Colony Stimulating Factors	Jul. 1, 2022	Coverage Rationale • Revised list of applicable short-acting filgrastim agents; added Releuko® (filgrastim-ayow) • Added language to indicate: ○ Coverage for Releuko will be provided contingent on the criteria in the *Preferred Product Criteria* section and the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ Treatment with Releuko is medically necessary for the indications specified in the policy when one of the following is met: ▪ Both of the following: – History of a trial of adequate dose and duration of Zarxio, resulting in minimal clinical response; and – Physician attests that, in their clinical opinion, the clinical response would be expected to be	This policy refers to the following white blood cell colony stimulating factors (CSFs): • Long-acting pegfilgrastim agents: ○ Fulphila® (pegfilgrastim-jmdb) ○ Neulasta® (pegfilgrastim) ▪ Nyvepria™ (pegfilgrastim-apgf) ○ Udenyca® (pegfilgrastim-cbqv) ○ Ziextenzo® (pegfilgrastim-bmez) • Short-acting filgrastim agents: ○ Granix® (tbo-filgrastim) ○ Neupogen® (filgrastim) ○ Nivestym® (filgrastim-aafi) ○ Releuko® (filgrastim-ayow) ○ Zarxio® (filgrastim-sndz) • Leukine® (sargramostim) (refer to the Diagnosis-Specific Criteria) • Any FDA-approved white blood cell colony stimulating factor product not listed here* *Any U.S. Food and Drug Administration (FDA) approved white blood cell colony stimulating factor product not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare. **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.

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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	▪ Severe chronic neutropenia (SCN) ▪ Hematopoietic syndrome of acute radiation syndrome • Revised coverage criteria for: *Bone Marrow/Stem Cell Transplant* ○ Removed criterion requiring medication is: ▪ Dosed in accordance with the U.S. Food and Drug Administration (FDA) approved labeling ▪ Prescribed by or in consultation with a hematologist or oncologist *Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia* ○ Added criterion to allow coverage for the applicable products when the patient is receiving myelosuppressive anticancer drugs given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting) or the patient is receiving myelosuppressive anticancer drugs for definitive therapy (bridge to stem cell transplant,	Zarxio® is the preferred filgrastim product. Coverage will be provided for Zarxio® contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Coverage for Granix®, Neupogen®, Nivestym®, or Releuko will be provided contingent on the criteria in this section and the coverage criteria in the Diagnosis-Specific Criteria section. ***Preferred Product Criteria*** Treatment with Granix, Neupogen, Nivestym, Releuko, or other filgrastim biosimilar is medically necessary for the indications specified in the policy when one of the following is met: • Both of the following: ○ History of a trial of adequate dose and duration of Zarxio, resulting in minimal clinical response; and ○ Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Granix, Neupogen, Nivestym, Releuko or other filgrastim biosimilar product, than experienced with Zarxio; or • Both of the following: ○ History of intolerance, contraindication, or adverse event to Zarxio; and ○ Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with Granix, Neupogen, Nivestym, Releuko or other filgrastim biosimilar product **Diagnosis-Specific Criteria** For the coverage criteria below, in absence of specified drug products, the term “colony stimulating factors” or “CSFs” will be used in this policy where the coverage criteria apply to all products listed above. • Bone Marrow/Stem Cell Transplant (Leukine, Neupogen, Nivestym, Releuko, Zarxio) Leukine, Neupogen, Nivestym, Releuko, and Zarxio are proven and

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	organ transplant, definitive surgery for oligometastatic disease) ○ Updated list of risk factors for chemotherapy-induced febrile neutropenia; replaced persistent neutropenia due to prior chemotherapy, radiation therapy, or bone marrow involvement by tumor measure of "ANC < 1500 neutrophils/mcL" with "< 500 neutrophils/mcL or < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours" ○ Replaced language indicating "chemotherapy regimen associated incidence of febrile neutropenia (FN) will be based on the clinical trial(s) with the highest level of evidence *according to the GRADE criteria*" with "chemotherapy regimen associated incidence of FN will be based on the clinical trial(s) with the highest level of evidence" ○ Added language to indicate: ▪ Chemotherapy regimens and associated incidence of FN based on the clinical	medically necessary when all of the following criteria are met: ○ 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; • Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy (Leukine, Neupogen, Nivestym, Releuko, Zarxio) Leukine, Neupogen, Nivestym, Releuko and Zarxio are proven and medically necessary when the following criteria are met: ○ Both of the following: ▪ Diagnosis of AML; and ▪ Patient has completed either induction or consolidation chemotherapy • Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (FN) (Fulphila, Granix, Leukine, Neulasta, Neupogen, Nivestym, Nyvepria, Releuko, Udenyca, Zarxio, Ziextenzo) White blood cell colony stimulating factors are proven and medically necessary when the following criteria are met: ○ One of the following: ▪ Patient is receiving myelosuppressive anticancer drugs given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting); or ▪ Patient is receiving myelosuppressive anticancer drugs for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease); and ○ One of the following: ▪ Patient is receiving dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin) for bladder cancer; or

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White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	trial(s) according to the grade based on Common Terminology Criteria for Adverse Events (CTCAE) by the National Cancer Institute (NCI) criteria are available for reference at uhcprovider.com ▪ The reference document is not a substitute for the experience and judgment of a physician or other health care professional; any clinician must use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment *Secondary Prophylaxis of Febrile Neutropenia* ○ Added criterion to allow coverage for the applicable products: ▪ When the patient is receiving myelosuppressive anticancer drugs given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant	▪ Patient is receiving dose dense AC (doxorubicin, cyclophosphamide) followed by dose-dense paclitaxel for breast cancer; or ▪ Patient is receiving chemotherapy regimen(s) associated with > 20% incidence of FN; or ○ Both of the following: ▪ Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN; and ▪ Patient has one or more risk factors for chemotherapy-induced febrile neutropenia such as: – Persistent neutropenia due to prior chemotherapy, radiation therapy or bone marrow involvement by tumor (< 500 neutrophils/mcL or < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours) – Liver dysfunction (bilirubin > 2.0) – Renal dysfunction (creatinine clearance < 50) – Age > 65 years receiving full chemotherapy dose intensity *Note: Chemotherapy regimen associated incidence of FN will be based on the clinical trial(s) with the highest level of evidence. Chemotherapy regimens and associated incidence of FN based on the clinical trial(s) according to the grade based on Common Terminology Criteria for Adverse Events (CTCAE) by the National Cancer Institute (NCI) criteria are available for reference at uhcprovider.com. The reference document is not a substitute for the experience and judgment of a physician or other health care professional. Any clinician must use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment. ● Secondary Prophylaxis of Febrile Neutropenia (FN) (Fulphila, Granix, Leukine, Neulasta, Neupogen, Nivestym, Nyvepria, Releuko, Udenyca, Zarxio, Ziextenzo) White blood cell colony stimulating factors are proven and medically

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White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	setting) or the patient is receiving myelosuppressive anticancer drugs for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease) ▪ Patient has a documented history of a neutropenic event (febrile neutropenia or low neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen at full dose for which primary prophylaxis was not received ○ Removed criterion allowing coverage for the applicable products when the patient is receiving myelosuppressive anticancer drugs associated with neutropenia (ANC ≤ 1500 neutrophils/mcL) *Treatment of Febrile Neutropenia* ○ Added criterion requiring the patient has not received long-acting prophylactic pegfilgrastim in the last 14	necessary when the following criteria are met: ○ One of the following: ▪ Patient is receiving myelosuppressive anticancer drugs given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting); or ▪ Patient is receiving myelosuppressive anticancer drugs for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease); and ○ One of the following: ▪ Patient has a documented history of a neutropenic event (febrile neutropenia or low neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen at full dose for which primary prophylaxis was not received; or ▪ Patient has a documented history of neutropenic event from a previous course of chemotherapy • Treatment of Febrile Neutropenia (FN) (Fulphila, Leukine, Neulasta, Neupogen, Nivestym, Nyvepria, Releuko, Udenyca, Zarxio, Ziextenzo) (Off-Label) Fulphila, Leukine, Neulasta, Neupogen, Nivestym, Nyvepria, Releuko, Udenyca, Zarxio, and Ziextenzo are proven and medically necessary when the following criteria are met: ○ All of the following: ▪ Diagnosis of febrile neutropenia; and ▪ Patient has not received long-acting prophylactic pegfilgrastim in the last 14 days; and ▪ Patient has one or more risk factors for an infection-associated complication such as: – Sepsis syndrome – Age > 65 years – Absolute Neutrophil Count (ANC) < 100/mcL – Neutropenia expected to be > 10 days in duration – Pneumonia

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	days ○ Removed criterion requiring the score of < 21 on the *Multinational Association of Supportive Care in Cancer (MASCC)* scoring system in patients with cancer and febrile neutropenia ○ Revised list of examples of risk factors for an infection-associated complication: ▪ Added: – Sepsis syndrome – Age > 65 years – Absolute Neutrophil Count (ANC) < 100/mcL – Neutropenia expected to be > 10 days in duration – Pneumonia – Clinically documented infections including invasive fungal infection – Hospitalization at the time of fever – Prior episode(s) of FN ▪ Removed: – Hypotension – Acute renal failure – Acute respiratory failure	– Clinically documented infections including invasive fungal infection – Hospitalization at the time of fever – Prior episode(s) of FN • Severe Chronic Neutropenia (SCN) (Neupogen, Nivestym, Releuko, Zarxio) Neupogen®, Nivestym®, Releuko, and Zarxio® are proven and medically necessary when the following criteria are met: ○ All of the following: ▪ Diagnosis of SCN (i.e., congenital, cyclic, and idiopathic neutropenias with chronic ANC ≤ 500 neutrophils/mcL); and ▪ Medication is dosed in accordance with the U.S. Food and Drug Administration (FDA) approved labeling; and ▪ Prescribed by or in consultation with a hematologist or oncologist • Hematopoietic Syndrome of Acute Radiation Syndrome (Fulphila®, Leukine®, Neulasta®, Neupogen®, Nivestym®, Nyvepria™, Udenyca®, Releuko, Zarxio®, Ziextenzo®) Fulphila®, Leukine®, Neulasta®, Neupogen®, Nivestym®, Nyvepria™, Releuko, Udenyca®, Zarxio®, and Ziextenzo® are proven and medically necessary when all of the following criteria are met: ○ All of the following: ▪ Patient has been acutely exposed to myelosuppressive doses of radiation; and ▪ Medication is dosed in accordance with the U.S. Food and Drug Administration (FDA) approved labeling; and ▪ Prescribed by or in consultation with a hematologist or oncologist

Medical Benefit Drug Policy Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	– Acute heart failure **Definitions** • Updated definition of "Febrile Neutropenia" **Applicable Codes** • Added HCPCS codes C9096, C9399 J3490, and J3590 **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information	

Utilization Review Guideline Updates

Updated

Policy Title	Effective Date	Summary of Changes
Observation Services (for Tennessee Only)	Aug. 1, 2022	**Application** • Added language to indicate this Utilization Review Guideline applies to CoverKids **Coverage Rationale** • Replaced notation indicating "this policy does not apply to *obstetric conditions*" with "this policy does not apply to an obstetric *member during pregnancy, childbirth, or the post-partum period*" **Supporting Information** • Updated *References* section to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs – Site of Care (for Tennessee Only)	Aug. 1, 2022	**Related Policies** • Added reference link to the Medical Benefit Drug Policy titled: ○ *Actemra® (Tocilizumab) Injection for Intravenous Infusion* ○ *Amondys 45™ (Casimersen)* ○ *Entyvio® (Vedolizumab)* ○ *Exondys 51® (Eteplirsen)* ○ *Immune Globulin (IVIG and SCIG)* ○ *Infliximab (Avsola™, Inflectra®, Remicade®, & Renflexis®)* ○ *Orencia® (Abatacept) Injection for Intravenous Infusion* ○ *Simponi Aria® (Golimumab) Injection for Intravenous Infusion* ○ *Vyondys 53™ (Golodirsen)* **Application and Coverage Rationale** • Revised list of applicable medications that require healthcare	This guideline addresses the criteria for consideration of allowing hospital outpatient facility medication infusion services. This includes claim submission for hospital based services with the following CMS/AMA Place of Service codes: • 22 On Campus-Outpatient Hospital; and • 19 Off Campus-Outpatient Hospital Alternative sites of care, such as non-hospital outpatient infusion, physician office, ambulatory infusion or home infusion services are well accepted places of service for medication infusion therapy. If a patient does not meet criteria for outpatient hospital facility infusion, alternative sites of care may be used. Outpatient hospital facility-based intravenous medication infusion is medically necessary for individuals who meet at least one of the following criteria (submission of medical records is required): • Documentation that the individual is medically unstable for administration of the prescribed medication at the alternative sites of care as determined by any of the following: ○ The individual's complex medical status or therapy requires enhanced monitoring and potential intervention above and beyond the capabilities of the office or home infusion setting; or ○ The individual's documented history of a significant comorbidity (e.g., cardiopulmonary disorder) or fluid overload status that precludes treatment at an alternative Site of Care; or

Utilization Review Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs – Site of Care (for Tennessee Only) (continued)	Aug. 1, 2022	provider administration to reflect/include: ○ Actemra® (Tocilizumab) ○ Amondys 45™ (casimersen) ○ Asceniv™ (IV) ○ Avsola™ (Infliximab-axxq) ○ Bivigam® (IV) ○ Carimune® NF (IV) ○ Cutaquig® (SC) ○ Cuvitru® (SC) ○ Entyvio® (Vedolizumab) ○ Exondys 51® (eteplirsen) ○ Flebogamma® DIF (IV) ○ Gammagard® Liquid (IV, SC) ○ Gammagard® S/D (IV) ○ Gammaked™ (IV, SC) ○ Gammaplex® (IV) ○ Gamunex®-C (IV, SC) ○ Hizentra® (SC) ○ HyQvia® (SC) ○ Inflectra® (Infliximab-dyyb) ○ Octagam® (IV) ○ Orencia® (Abatacept) ○ Panzyga® (IV) ○ Privigen® (IV) ○ Remicade® (Infliximab) ○ Renflexis® (Infliximab-abda) ○ Simponi Aria® (Golimumab) ○ Viltepso™ (viltolarsen) ○ Vyondys 53™ (golodirsen) ○ Xembify® (SC) **Applicable Codes** • Added CPT codes 90283 and	○ Outpatient treatment in the home or office setting presents a health risk due to a clinically significant physical or cognitive impairment; or ○ Difficulty establishing and maintaining patent vascular access; or ○ To initiate or re-initiate products for a short duration (e.g., 4 weeks); or • Documentation (e.g., infusion records, medical records) of episodes of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) that have not been responsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual when administration is in the home or office setting; or • Initial infusion or re-initiation of therapy after more than 6 months; or • Homecare or infusion provider has deemed that the individual, home caregiver, or home environment is not suitable for home infusion therapy (if the prescriber cannot infuse in the office setting) Ongoing outpatient hospital facility-based infusion duration of therapy will be no more than 6 months to allow for reassessment of the individual's ability to receive therapy at an alternative Site of Care. This policy applies to these medications that require healthcare provider administration: • Actemra® (Tocilizumab) • Amondys 45™ (casimersen) • Asceniv™ (IV) • Avsola™ (Infliximab-axxq) • Bivigam® (IV) • Carimune® NF (IV) • Cutaquig® (SC) • Cuvitru® (SC) • Entyvio® (Vedolizumab)

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Provider Administered Drugs – Site of Care (for Tennessee Only) (continued)	Aug. 1, 2022	90284 • Added HCPCS codes J0129, J1426, J1427, J1428, J1429, J1459, J1554, J1555, J1556, J1557, J1558, J1559, J1561, J1566, J1568, J1569, J1572, J1575, J1599, J1602, J1745, J3262, J3380, J3590, Q5103, Q5104, and Q5121	• Exondys 51® (eteplirsen) • Flebogamma® DIF (IV) • Gammagard® Liquid (IV, SC) • Gammagard® S/D (IV) • Gammaked™ (IV, SC) • Gammaplex® (IV) • Gamunex®-C (IV, SC) • Hizentra® (SC) • HyQvia® (SC) • Ilumya™ (Tildrakizumab-asmn) • Inflectra® (Infliximab-dyyb) • Octagam® (IV) • Orencia® (Abatacept) • Panzyga® (IV) • Privigen® (IV) • Remicade® (Infliximab) • Renflexis® (Infliximab-abda) • Simponi Aria® (Golimumab) • Viltepso™ (viltolarsen) • Vyondys 53™ (golodirsen) • Xembify® (SC)

General Information

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

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

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

Policy Update Classifications

New

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

Updated

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

Revised

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

Replaced

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

Retired

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

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