United Healthcare

UnitedHealthcare Commercial

Medical Policy Update Bulletin: February 2023

In This Issue

Take Note

Medical Policy Updates

Updated

Revised

United Healthcare®

In This Issue

Medical Benefit Drug Policy Updates

New

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Coverage Determination Guideline Updates

Replaced

Medical Policy Consolidation for UnitedHealthcare Commercial and Individual Exchange Plans

Effective April 1, 2023, the UnitedHealthcare Commercial and Individual Exchange Plans will share the same Medical Policies (MPs) and Coverage Determination Guidelines (CDGs); we will no longer maintain separate policy documents for these plans except the versions listed below:

Policy Title	Policy Type
Enteral Nutrition (for Commercial Only)	CDG
Enteral Nutrition (for Individual Exchange Only)	CDG
Gender Dysphoria Treatment (for Commercial Only)	MP
Gender Dysphoria Treatment (for Individual Exchange Only)	MP
Hearing Aids and Devices Including Wearable, Bone Anchored and Semi-Implantable (for Commercial Only)	MP
Hearing Aids and Devices Including Wearable, Bone Anchored and Semi-Implantable (for Individual Exchange Only)	MP
Home Health, Skilled, and Custodial Care Services (for Commercial Only)	MP
Home Health, Skilled, and Custodial Care Services (for Individual Exchange Only)	MP
Hospice Care (for Individual Exchange Only)	CDG
Outpatient Surgical Procedures – Site of Service	MP
Outpatient Surgical Procedures – Site of Service (for Individual Exchange Only)	MP
Referral to Out-of-Network Specialists (for Individual Exchange Only)	MP

The Medical Policies and Coverage Determination Guidelines will be updated to specify the plan(s) to which they apply on Apr. 1, 2023. Unless otherwise announced, there will be no change to policy guidelines as a result of this template update.

The policy libraries and corresponding bulletins will continue to be available for your reference at their current locations on UHCprovider.com.

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Beds and Mattresses	Feb. 1, 2023	Documentation Requirements • Updated list of HCPCS codes with associated documentation requirements; added E0296

Elective Inpatient Services	Apr. 1, 2023	Template Update
		• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans (no change to coverage guidelines)
		• Changed policy type classification from "Utilization Review Guideline" to "Medical Policy"
		• Added *Application* section to indicate this Medical Policy applies to:
		  ○ All UnitedHealthcare Commercial benefit plans
		  ○ Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Nevada, and New York
		Supporting Information
		• Added *Clinical Evidence* section
		• Updated *References* section to reflect the most current information

Liposuction for Lipedema	Apr. 1, 2023	Template Update
		• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans (no change to coverage guidelines)
		• Added *Application* section to indicate this Medical Policy applies to:
		  ○ All UnitedHealthcare Commercial benefit plans
		  ○ Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Nevada, and New York
		Coverage Rationale
		• Added notation to indicate quality evidence does not support the superiority of one liposuction technique/approach (such as water-assisted or high-volume liposuction) over another technique/approach for Lipedema
		Definitions
		• Updated definition of:
		  ○ Class II or III Obesity
		  ○ Lipedema
		Supporting Information
		• Updated *Clinical Evidence* and *References* sections to reflect the most current information

Office Based Procedures – Site of Service	Apr. 1, 2023	Template Update • Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans (no change to coverage guidelines) • Changed policy type classification from "Utilization Review Guideline" to "Medical Policy" • Added *Application* section to indicate this Medical Policy applies to:

Updated

Policy Title	Effective Date	Summary of Changes
Office Based Procedures – Site of Service (continued)	Apr. 1, 2023	○ All UnitedHealthcare Commercial benefit plans ○ Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Nevada, New York, and Texas
Outpatient Surgical Procedures – Site of Service	Apr. 1, 2023	Template Update • Changed policy type classification from "Utilization Review Guideline" to "Medical Policy"

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ablative Treatment for Spinal Pain	Apr. 1, 2023	Template Update • Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans (no change to coverage guidelines) • Added *Application* section to indicate this Medical Policy applies to: ○ All UnitedHealthcare Commercial benefit plans ○ Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Nevada, and New York Coverage Rationale • Added language to indicate Conventional (Thermal) Radiofrequency Ablation requires site of service review; refer to the Medical Policy titled *Office Based Procedures – Site of Service* • Removed coverage guidelines for	Note: Conventional (Thermal) Radiofrequency Ablation requires site of service review. Refer to the Medical Policy titled Office Based Procedures – Site of Service. The following facet joint nerve ablation techniques are unproven and not medically necessary due to insufficient evidence of efficacy: • Pulsed Radiofrequency Ablation of the facet nerves of the cervical, thoracic or lumbar region, sacral nerve root or dorsal root ganglion • Endoscopic radiofrequency ablation/endoscopic rhizotomy • Cryoablation (cryodenervation, cryoneurolysis, cryosurgery or cryoanesthesia) • Cooled Radiofrequency Ablation • Chemical ablation (including, but not limited to, alcohol, phenol or sodium morrhuate) • Laser ablation (including pulsed, continuous or low level) Ablation for treating sacroiliac pain is unproven and not medically necessary due to insufficient evidence of efficacy. Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept®) for the treatment of spinal pain is unproven and not medically necessary due to insufficient evidence of efficacy.

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

Ablative Treatment for Spinal Pain (continued)	Apr. 1, 2023	Conventional (Thermal) Radiofrequency Ablation
		• Replaced language indicating:
		  ○ "*All forms of radiofrequency* ablation are unproven and not medically necessary for treating sacroiliac pain" with "ablation for treating sacroiliac pain is unproven and not medically necessary *due to insufficient evidence of efficacy*"
		  ○ "Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept®) is unproven and not medically necessary" with "intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept®) *for the treatment of spinal pain* is unproven and not medically necessary"
		Definitions
		• Removed definition of:
		  ○ Chronic Pain (Nonmalignant)
		  ○ Complex Regional Pain Syndrome (CRPS)
		  ○ Facet Joint Injection
		  ○ Facet Nerve Block
		  ○ Functional Impairment
		  ○ Medial Branch Block
		Applicable Codes
		• Removed CPT codes 64633,	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ablative Treatment for Spinal Pain (continued)	Apr. 1, 2023	64634, 64635, and 64636 • Removed notation pertaining to CPT codes 64633, 64634, 64635, and 64636 Supporting Information • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information • Removed *Documentation Requirements* section	
Apheresis	Mar. 1, 2023	Notice of Revision: The following summary of changes has been modified. Revisions to the previous policy update announcement are outlined in red below. Please take note of the additional updates to be applied on Mar. 1, 2023. Coverage Rationale • Revised list of conditions/diagnoses for which therapeutic apheresis is unproven and not medically necessary; replaced "*PANDAS*; Sydenham's chorea, severe" with "Sydenham's chorea, severe" Definitions • Added definition of: ○ Photopheresis ○ Plasma Exchange ○ Therapeutic Apheresis	Therapeutic Apheresis is proven and medically necessary for treating or managing the following conditions/diagnoses: • Acute inflammatory demyelinating polyneuropathy (Guillain-Barré syndrome), primary treatment • Acute liver failure (requiring High Volume Therapeutic Plasma Exchange (TPE-HV)) • Anti-glomerular basement membrane disease (Goodpasture's syndrome) ○ Dialysis independent ○ Diffuse alveolar hemorrhage (DAH) • Chronic inflammatory demyelinating polyneuropathy (CIDP) • Cryoglobulinemia, second line therapy • Cutaneous T-cell lymphoma (CTCL); mycosis fungoides; Sézary syndrome, erythrodermic • Dilated cardiomyopathy, idiopathic, New York Heart Association Class II-IV, via Immunoadsorption • Familial hypercholesterolemia ○ Homozygous ○ Heterozygous, second line therapy • Focal segmental glomerulosclerosis, recurrent in transplanted kidney, second line therapy • Graft-versus-host disease ○ Acute

Revised			
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Apheresis (continued)	Mar. 1, 2023	Supporting Information • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	○ Chronic, second line therapy • Hereditary hemochromatosis • Hypertriglyceridemic pancreatitis, severe • Hyperviscosity in hypergammaglobulinemia • Inflammatory bowel disease, ulcerative colitis/Crohn's Disease via Adsorptive Cytapheresis • Lipoprotein(a) hyperlipoproteinemia • Multiple sclerosis, second line therapy • Acute central nervous system (CNS) inflammatory, demyelinating • Relapsing form with steroid resistant exacerbations • Myasthenia gravis, acute • Myeloma cast nephropathy, second line therapy • Neuromyelitis optica spectrum disorders (NMOSD/Devic's syndrome), acute or relapse, second line therapy • N-methyl D-aspartate receptor antibody encephalitis • Paraproteinemic demyelinating neuropathies via Therapeutic Plasma Exchange (TPE) ○ Anti- myelin-associated glycoprotein (MAG) ○ Multifocal motor neuropathy ○ IgG/IgA ○ IgM • Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) exacerbation • Peripheral vascular diseases • Polycythemia vera; erythrocytosis • Progressive multifocal leukoencephalopathy (PML) associated with natalizumab • Pruritus due to hepatobiliary diseases • Rheumatoid arthritis, refractory, second line therapy • Sickle cell disease ○ Acute stroke or multiorgan failure ○ Acute chest syndrome (ACS), severe, second line therapy ○ Stroke prevention

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Apheresis (continued)	Mar. 1, 2023		○ Individuals requiring chronic transfusion (receiving transfusions once every 5 weeks or more frequently) ● Thrombotic microangiopathy, thrombotic thrombocytopenic purpura (TTP) ● Transplantation, cardiac, second line therapy ○ Cellular/recurrent rejection, ○ Desensitization ○ In children less than 40 months of age, ABO incompatible ● Transplantation, hematopoietic stem cell, ABO incompatible (ABOi), second line therapy ○ Haemopoietic progenitor cells collected from marrow HPC(M) ○ Haemopoietic progenitor cells collected by apheresis HPC(A) ● Transplantation, Liver, desensitization, ABOi living donor ● Transplantation, Lung, bronchiolitis obliterans syndrome ● Transplantation, Renal, ABO compatible ○ Antibody mediated rejection ○ Desensitization, living donor ● Transplantation, Renal, ABO incompatible, second line therapy ○ Antibody mediated rejection ● Vasculitis, Antineutrophil cytoplasmic antibodies (ANCA) -associated ○ Dialysis dependent ○ DAH ● Vasculitis ○ Behcet's disease (Adsorptive Cytapheresis), ○ Idiopathic polyarteritis nodosa (PAN) (TPE) ● Voltage gated potassium channel (VGKC) antibody-related diseases ● Wilson's disease, fulminant Due to insufficient evidence of efficacy, Therapeutic Apheresis including Plasma Exchange, Plasmaexchange, or Photopheresis is unproven and not medically necessary for treating or managing the following conditions/ diagnoses, including but not limited to: ● Acute disseminated encephalomyelitis (ADEM) ● Acute liver failure (requiring TPE)

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Apheresis (continued)	Mar. 1, 2023		• Age related macular degeneration, dry • Amyloidosis, systemic • Amyotrophic lateral sclerosis • ANCA-associated rapidly progressive glomerulonephritis, dialysis independent (Granulomatosis with polyangiitis; and Microscopic Polyangiitis) • Anti-glomerular basement membrane disease, dialysis dependent, without DAH (Goodpasture's syndrome) • Aplastic anemia; pure red cell aplasia • Atopic (neuro-) dermatitis (atopic eczema), recalcitrant • Autoimmune hemolytic anemia; severe warm autoimmune hemolytic anemia (WAIHA); severe cold agglutinin disease • Babesiosis, severe • Burn shock resuscitation • Cardiac neonatal lupus • Catastrophic antiphospholipid syndrome/Hemolytic uremic syndrome • Chronic focal encephalitis (Rasmussen's encephalitis) • Coagulation factor inhibitors • Complex regional pain syndrome • Cutaneous T-cell lymphoma; mycosis fungoides; Sézary syndrome, non-erythrodermic • Dilated cardiomyopathy, idiopathic, New York Heart Association Class II-IV, via TPE • Erythropoietic porphyria, liver disease • Focal segmental glomerulosclerosis, recurrent kidney transplant or steroid resistant in native kidney via LA or TPE • Hemolysis, Elevated Liver enzymes and Low Platelets (HELLP) syndrome • Hemophagocytic lymphohistiocytosis (HLH)/Hemophagocytic syndrome/Macrophage activating syndrome • Heparin induced thrombocytopenia and thrombosis (HIT/HITT) • Hyperleukocytosis • Hypertriglyceridemic pancreatitis, prevention of relapse • Immune thrombocytopenia

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

Apheresis (continued)	Mar. 1, 2023		• IgA nephropathy (Berger's Disease)
			• Inflammatory bowel disease, Crohn's Disease, via Extracorporeal Photopheresis
			• Lambert-Eaton myasthenic syndrome
			• Malaria
			• Multiple sclerosis, chronic
			• Myasthenia Gravis, long term treatment
			• Myeloma cast nephropathy
			• Nephrogenic systemic fibrosis
			• Neuromyelitis optica spectrum disorders (NMOSD), maintenance
			• Overdose, envenomation, and poisoning
			• Paraneoplastic neurologic syndromes
			• Paraproteinemic demyelinating polyneuropathies, multiple myeloma (2C)
			• Pemphigus vulgaris
			• Phytanic acid storage disease (Refsum's disease)
			• Post transfusion purpura (PTP))
			• Psoriasis
			• Red cell alloimmunization, prevention and treatment
			• Scleroderma (systemic sclerosis)
			• Sepsis with multiorgan failure
			• Sickle cell disease (unless noted above as proven)
			• Steroid-responsive encephalopathy associated with autoimmune thyroiditis (Hashimoto's encephalopathy)
			• Stiff-person syndrome
			• Sudden sensorineural hearing loss
			• Sydenham's chorea, severe
			• Systemic lupus erythematosus, severe complications
			• Thrombocytosis
			• Thrombotic microangiopathy
			  ○ Coagulation mediated (THBD, DGKE and PLG mutations)
			  ○ Complement mediated (Factor H autoantibody and complement factor gene mutations)
			  ○ Drug associated

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Apheresis (continued)	Mar. 1, 2023		○ Infection associated (STEC-HUS, severe; pHUS) ○ Transplantation associated • Thyroid storm • Toxic epidermal necrolysis (TEN) • Transplantation, cardiac ○ Rejection prophylaxis ○ Antibody mediated rejection • Transplantation, hematopoietic stem cell ABOi: ○ HLA desensitized ○ Minor ABOi HPC(A) ○ Major/minor ABOi w/ pure RBC aplasia • Transplantation, hematopoietic stem cell, HLA desensitization • Transplantation, Liver ○ ABO incompatible ○ Antibody mediated rejection • Transplantation, Lung ○ Antibody mediated rejection ○ Desensitization • Transplantation, Renal, ABO compatible, desensitization, deceased donor • Vasculitis, ANCA-associated (AAV) ○ MPA/GPA/RLV: RPGN, Cr <5.7 ○ EGPA • Vasculitis, IgA (Henoch-Schönlein purpura) • Vasculitis (unless noted above as proven) Note: Refer to the *Description of Services* section [of the policy] for information regarding all apheresis-based procedures.
Articular Cartilage Defect Repairs	Apr. 1, 2023	Template Update • Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans (no change to coverage guidelines)	Autologous Chondrocyte Transplantation (ACT) is proven and medically necessary for treating individuals with symptomatic full-thickness articular cartilage defects when all the following criteria are met: • Each individual lesion is: ○ Greater than or equal to 2 squared centimeters ○ A result of acute or repetitive trauma

Revised

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Articular Cartilage Defect Repairs (continued)	Apr. 1, 2023	• Added *Application* section to indicate this Medical Policy applies to: ○ All UnitedHealthcare Commercial benefit plans ○ Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Nevada, and New York Coverage Rationale *Autologous Chondrocyte Transplantation (ACT)* • Revised coverage criteria: ○ Replaced criterion requiring "the lesion [meets the listed criteria]" with "*each individual* lesion [meets the listed criteria]" ○ Removed criterion requiring "inadequate response to a prior arthroscopic or other surgical repair procedure (e.g., debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft)" • Removed language indicating ACT is unproven and not medically necessary as the initial or first line of surgical therapy *Articular Cartilage Repair* • Replaced reference to "*focal* articular cartilage repair" with	○ Single or multiple full thickness (Outerbridge Classification of grade III or IV) articular cartilage defect of the femoral condyle (medial, lateral or trochlea) and/or patella • Knee is stable with intact menisci and ligaments • Normal joint space and alignment confirmed by X-ray • No active inflammatory or other arthritis, clinically and by X-ray • Failed non-surgical conservative management (e.g., physical therapy, braces, and/or nonsteroidal anti-inflammatory drugs) • Individual is less than 55 years of age. ACT is unproven and not medically necessary for treating individuals with the following indications due to insufficient evidence of efficacy: • Treatment of joints other than the knee • Growth plates have not closed • History of partial-thickness defects • Osteochondritis dissecans (OCD) • Malignancy in the bone, cartilage, fat, or muscle of the treated limb • Active infection in the affected knee • Instability of the knee • History of total meniscectomy • Repeat ACT • Active inflammatory degenerative, rheumatoid or osteoarthritis Microfracture repair to treat full and partial thickness chondral defects of the knee is proven and medically necessary when all the following criteria are met: • Symptomatic focal cartilage defects of the weight-bearing Femoral Condyles, tibial plateau, trochlea, and patella • Defect has been identified by Magnetic resonance imaging (*MRI), arthrogram or arthroscopy • Outerbridge Grade 3-4 cartilage lesions • Measure less than or equal to 4 square centimeters

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Articular Cartilage Defect Repairs (continued)	Apr. 1, 2023	"articular cartilage repair" • Added language to indicate the use of Xenograft implantation into the articular surface of any joint is unproven and not medically necessary for articular cartilage repair **Definitions** • Added definition of "Xenograft" **Applicable Codes** • Added CPT code 0737T **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	Microfracture repair of the knee is unproven and not medically necessary with any of the following indications: • Misalignment of the knee • Osteoarthritis • Systemic immune-mediated disease, disease-induced arthritis, or cartilage disease • Unwilling or unable to participate in post-operative physical rehabilitation program Osteochondral Autograft and Allograft transplantation is proven and medically necessary for treating individuals with cartilage defects of the knee. For medical necessity clinical coverage criteria for Osteochondral Autograft and Allograft Transplantation, refer to the InterQual® CP: Procedures: • Arthroscopy or Arthroscopically Assisted Surgery, Knee • Arthroscopy or Arthroscopically Assisted Surgery, Knee (Pediatric) • Arthrotomy, Knee Click here to view the InterQual® criteria. Osteochondral Autograft and Allograft transplantation is unproven and not medically necessary for all other indications than those listed above. Articular cartilage repair is unproven and not medically necessary for treating individuals with any of the following due to insufficient evidence of efficacy: • Use of minced articular cartilage repair (whether synthetic, Allograft or Autograft) for treating osteochondral defects of the knee • Use of Xenograft implantation into the articular surface of any joint • Use of cryopreserved viable Osteochondral Allograft products (e.g., Cartiform)
Discogenic Pain Treatment	Apr. 1, 2023	**Template Update** • Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and	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

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

Discogenic Pain Treatment (continued)	Apr. 1, 2023	Individual Exchange benefit plans (no change to coverage guidelines)
		• Added *Application* section to indicate this Medical Policy applies to:
		  ○ All UnitedHealthcare Commercial benefit plans
		  ○ Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Nevada, and New York
		Coverage Rationale
		• Removed language indicating percutaneous discectomy and decompression procedures are unproven and not medically necessary for treating discogenic pain
		• Added instruction to refer to the Medical Policy titled *Minimally Invasive Spine Surgery Procedures* for percutaneous discectomy for the treatment of axial or radicular pain
		Applicable Codes
		• Removed CPT codes 62287 and 62380
		Supporting Information
		• Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
			• Thermal intradiscal procedures (TIPs) for treating discogenic pain
			
			Note: For percutaneous discectomy for the treatment of axial or radicular pain, refer to the Medical Policy titled Minimally Invasive Spine Surgery Procedures.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation	Apr. 1, 2023	**Template Update**
		• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans (no change to coverage guidelines)
		• Added *Application* section to indicate this Medical Policy applies to:
		  ○ All UnitedHealthcare Commercial benefit plans
		  ○ Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Nevada, and New York
		Coverage Rationale
		• Added language to indicate:
		  ○ Restorative neurostimulation is unproven and not medically necessary due to insufficient evidence of efficacy
		  ○ For information regarding cranial electrical stimulation/cranial electrotherapy, refer to the Behavioral Clinical Policy titled *Cranial Electrotherapy* (providerexpress.com)
		Applicable Codes
		• Removed HCPCS codes A4558, A4630, E0762, and K1023
		Supporting Information
		• Updated *Description of Services*,
			Transcutaneous electrical nerve stimulator (TENS) is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Transcutaneous Electrical Nerve Stimulation (TENS).
			
			Click here to view the InterQual® criteria.
			
			Functional electrical stimulation (FES) is proven and medically necessary as a component of a comprehensive ambulation rehabilitation program in members with lower limb paralysis due to spinal cord injury (SCI) when all the following criteria are met:
			• Demonstration of intact lower motor units (L1 and below) (both muscle and peripheral nerves);
			• Muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently;
			• Demonstration of brisk muscle contraction;
			• Demonstration of sensory perception sufficient for muscle contraction;
			• Demonstration of a high level of motivation, commitment and cognitive ability for device use;
			• Ability to transfer independently;
			• Demonstration of independent standing tolerance for at least 3 minutes;
			• Demonstration of hand and finger function to manipulate controls;
			• Post-recovery from SCI and restorative surgery of at least 6 months;
			• Absence of hip and knee degenerative disease;
			• Absence of history of long bone fracture secondary to osteoporosis
			
			Neuromuscular electrical stimulation (NMES) is proven and medically necessary for treating any of 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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation (continued)	Apr. 1, 2023	*Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	contractures or • When used as part of a comprehensive lower limb rehabilitation program following total knee arthroplasty; or • 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: • FES for treating any other indication not listed above • Interferential therapy (IFT) for treating musculoskeletal disorders/injuries, or to facilitate healing of nonsurgical soft tissue injuries or bone fractures • Microcurrent electrical nerve stimulation (MENS) • NMES for treating any other indication not listed above • Percutaneous electrical nerve stimulation (PENS), percutaneous electrical nerve field stimulation (PENFS) or percutaneous neuromodulation therapy (PNT) • Percutaneous peripheral nerve stimulation (PNS)* • Peripheral subcutaneous field stimulation (PSFS) or peripheral nerve field stimulation (PNFS) • Pulsed electrical stimulation (PES) • Restorative neurostimulation • Scrambler Therapy (ST) • Translingual Stimulation for gait rehabilitation (TS) *For information regarding percutaneous peripheral nerve stimulation for occipital neuralgia and headache, refer to the Medical Policy titled Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache). Notes: • For information regarding dorsal root ganglion (DRG) stimulation, refer to the Medical Policy titled Implanted Electrical Stimulator for Spinal Cord.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation (continued)	Apr. 1, 2023		• For information regarding cranial electrical stimulation/cranial electrotherapy, refer to the Behavioral Clinical Policy titled Cranial Electrotherapy - Behavioral Clinical Policy (providerexpress.com)
Habilitation and Rehabilitation Therapy (Occupational, Physical and Speech)	Apr. 1, 2023	**Title Change** • Previously titled *Habilitative Services and Outpatient Rehabilitation Therapy* **Template Update** • Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans (no change to coverage guidelines) • Changed policy type classification from "Coverage Determination Guideline" to "Medical Policy" • Added *Application* section to indicate this Medical Policy applies to: ○ All UnitedHealthcare Commercial benefit plans ○ Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Nevada, and New York **Coverage Rationale** • Revised coverage guidelines to indicate: ○ This Medical Policy does not apply to cognitive therapy; for outpatient cognitive therapy,	Note: This medical policy does not apply to cognitive therapy; for outpatient cognitive therapy, refer to the Medical Policy titled Cognitive Rehabilitation. Outpatient habilitation, rehabilitation and maintenance therapy may be covered when Medically Necessary when all the following criteria is met: • The member has a disabling condition • Treatment is prescribed by a physician • Treatment is administered by a licensed speech-language pathologist (and clinical fellows, licensed occupational therapist, licensed physical therapist, physician, or other provider who acts within the scope of his or her license) • Treatment must be proven and meet generally accepted standards of practice, and is targeted and effective in the treatment of the member's diagnosed impairment or condition • Treatment is expected to produce clinically significant and measurable improvement in the member's level of functioning within a reasonable and medically predictable period of time; or the treatment is part of a Medically Necessary program to prevent significant functional regression and meets one of the following criteria: ○ When a member achieves a functional plateau, the provider adjusts the plan of care (POC) accordingly and provides monthly (or as appropriate) reassessments to update and modify the home program ○ When members who have received physical and occupational therapy services experience a loss or regression of present level of function it may be Medically Necessary to resume or increase frequency of therapy • The services are not duplicate services of another service provided concurrently by any other type of therapy (such as speech, physical and occupational therapy), and must provide different treatment goals, plans, and therapeutic modalities

Revised			
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Habilitation and Rehabilitation Therapy (Occupational, Physical and Speech) (continued)	Apr. 1, 2023	refer to the Medical Policy titled *Cognitive Rehabilitation* ○ Outpatient habilitation, rehabilitation, and maintenance therapy may be covered when Medically Necessary when all the following criteria is met: ▪ The member has a disabling condition ▪ Treatment is prescribed by a physician ▪ Treatment is administered by a licensed speech-language pathologist (and clinical fellows), licensed occupational therapist, licensed physical therapist, physician, or other provider who acts within the scope of his or her license ▪ Treatment must be proven and meet generally accepted standards of practice, and is targeted and effective in the treatment of the member's diagnosed impairment or condition ▪ Treatment is expected to produce clinically significant and measurable	**Habilitation Services** Health care services that help a person keep, learn or improve skills and functioning for daily living. **Rehabilitation Services** Health care services that help a person keep, get back, or improve skills and functioning for daily living that have been lost or impaired because a person was sick, hurt, or disabled. **Maintenance Services** A maintenance program consists of activities and/or mechanisms a clinician establishes to help a beneficiary maximize or maintain the progress made during therapy, or to prevent or slow further deterioration due to a disease or illness. (ASHA) **For Medical Necessity Clinical Coverage Criteria** Refer to the InterQual® LOC: Outpatient Rehabilitation & Chiropractic: • Habilitation • Rehabilitation • Maintenance Click here to view the InterQual® criteria. Note: Many plans specifically exclude maintenance therapy. Before reviewing services for medical necessity, check the federal, state or contractual requirements that may apply. **Required Documentation** ***Initial Therapy Evaluation/Initial Therapy Visit Requests*** A provider (PCP) (MD, DO, PA or NP) or appropriate specialist referral for the speech, physical and occupational therapy evaluation must be on file prior to the

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Habilitation and Rehabilitation Therapy (Occupational, Physical and Speech) (continued)	Apr. 1, 2023	improvement in the member's level of functioning within a reasonable and medically predictable period of time; or the treatment is part of a Medically Necessary program to prevent significant functional regression and meets one of the following criteria: – When a member achieves a functional plateau, the provider adjusts the plan of care (POC) accordingly and provides monthly (or as appropriate) reassessments to update and modify the home program – When members who have received physical and occupational therapy services experience a loss or regression of present level of function it may be Medically Necessary to resume or increase frequency of therapy	completion of the evaluation. The therapy evaluation report must include all of the following: • A statement of the member's medical history; and • A comparison prior level of function to current level of function, as applicable; and • A description of the member's functional impairment including its impact on their health, safety, and/or independence; and • A clear diagnosis including the appropriate ICD-10 code; and • Reasonable prognosis, including the member's potential for meaningful and significant progress; and • Baseline objective measurements (current versions of standardized assessments), including a description of the member's current deficits and their severity level which include: ○ Current standardized assessment scores, age equivalents, percentage of functional delay, criterion-referenced scores and/or other objective information as appropriate for the member's condition or impairment ○ Standardized assessments administered must correspond to the delays identified and relate to the long- and short-term goals ○ Standardized assessments results will not be used as the sole determinant as to the medical necessity of the requested initial therapy visit ○ If the member has a medical condition that prevents them from completing standardized assessment(s), alternative could include: ▪ The therapist provides in-depth objective clinical information using task analysis to describe the member's deficit area(s) in lieu of standardized assessments ▪ The therapist should include checklists, caregiver reports or interviews, and clinical observation ***Plan of Care*** The initial authorization for therapy must also include a plan of care (POC). The POC must be signed and dated by the referring provider (PCP) (MD, DO, PA or NP) or appropriate specialist. Providers must develop a member's POC based

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Habilitation and Rehabilitation Therapy (Occupational, Physical and Speech) (continued)	Apr. 1, 2023	▪ The services are not duplicate services of another service provided concurrently by any other type of therapy (such as speech, physical and occupational therapy), and must provide different treatment goals, plans, and therapeutic modalities ○ For medical necessity clinical coverage criteria, refer to the InterQual® LOC: Outpatient Rehabilitation & Chiropractic: ▪ Habilitation ▪ Rehabilitation ▪ Maintenance ○ Many plans specifically exclude maintenance therapy; before reviewing services for medical necessity, check the federal, state, or contractual requirements that may apply ○ Discharge criteria includes but is not limited to all of the following (as applicable): ▪ Treatment goals and objectives have been met ▪ Functional abilities have become comparable to those of others of the same chronological age and gender	on the results of the evaluation. The POC must include all the following: ● Functional or physical impairment; and ● Short and long-term therapeutic goals and objectives: ○ Treatment goals should be specific to the member's diagnosed condition or functional or physical impairment ○ Treatment goals must be functional, measurable, attainable and time based ○ Treatment goals must relate to member-specific functional skills and ● Treatment frequency, duration, and anticipated length of treatment session(s) ***Requests for Continuation of Therapy Visits*** Progress Reports (Summary of Progress) Intermittent progress reports must demonstrate that the member is making functional progress related to the treatment goals to reflect that continued services are Medically Necessary. Progress reports must include all of the following: ● Start of care date; and ● Time period covered by the report; and ● Member's current status as compared to evaluation baseline data and the prior progress reports, including objective measures of member performance in functional terms that relate to the treatment goals; and ● If the member is not making the progress expected, describe any changes in prognosis, POC and goals and why; and ● Consultations with other professionals or coordination of services, if applicable; and ● Signature and date of licensed professional responsible for the therapy services; and ● Signature and date of prescribing physician ***Re-Evaluations*** Re-evaluations must be completed at least once every twelve months or more

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Habilitation and Rehabilitation Therapy (Occupational, Physical and Speech) (continued)	Apr. 1, 2023	▪ The desired level of function that has been agreed to by the member and provider has been achieved ▪ The skill of a therapist or other licensed healthcare professional (within the scope of his/her licensure) is not required ▪ The member exhibits behavior that interferes with improvement or participation in treatment and efforts to address these factors have not been successful ▪ In some situations, the member, family, or designated guardian may choose not to participate in treatment, may relocate, or may seek another provider if the therapeutic relationship is not satisfactory; therefore, discharge is also appropriate in the following situations, provided that the member/client, family, and/or guardian have been advised of the likely	frequently based on state regulatory requirements to support the need for on-going services. Re-evaluations performed more often than once should only be completed when the member experiences a significant change in functional Level in their condition or functional status. The documentation must be reflective of this change. Re-evaluations must include current Standardized Assessment scores, percentage of functional delay, criterion referenced scores or other objective information as appropriate for the member's condition or impairment. The therapy re-evaluation report must include all of the following: ● Date of last therapy evaluation; and ● Number of therapy visits authorized, and number of therapy visits attended; and ● Compliance to home program; and ● Description of the member's current deficits and their severity level documented using objective data; and ● Objective demonstration of the member's progress towards each treatment goal: ○ Using consistent and comparable methods to report progress on long- and short-term treatment goals established ○ For all unmet goals, baseline and current function so that the member's progress towards goals can be measured and ● An updated statement of the prescribed treatment modalities and their recommended frequency/duration; and ● A brief prognosis with clearly established discharge criteria; and ● An updated individualized POC must include updated measurable, functional and time-based goals: ○ The updated POC/progress summary must not be older than 90 days; and ○ If the majority of the long and short-term goals were not achieved, the plan of care must include a description of the barriers or an explanation why the goal(s) needed to be modified or discontinued and ● A revised POC that the treating therapist has not made a meaningful update

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Habilitation and Rehabilitation Therapy (Occupational, Physical and Speech) (continued)	Apr. 1, 2023	outcomes of discontinuation: – There is a request to be discharged or request continuation of services with another provider – The individual is transferred or discharged to another location where ongoing service from the current provider is not reasonably available; efforts should be made to ensure continuation of services in the new locale ▪ The member is unable to tolerate treatment because of a serious medical, psychological, or other condition ○ Bilingual and multilingual speakers are frequently misclassified as developmentally delayed ▪ Equivalent proficiency in both languages should not be expected ▪ Members with limited English proficiency must	to support the need for continued services will not be accepted. In addition, the notation of the percentage accuracy towards the member's goals alone is not sufficient to establish a need for continued, Medically Necessary therapy. ***Treatment Session Notes*** All treatment session notes must include: • Date of treatment • Specific treatment(s) provided that match the CPT code(s) billed • Start and stop time in treatment • The individual's response to treatment • Skilled ongoing reassessment of the individual's progress toward the goals • All progress toward the goals in objective, measurable terms using consistent and comparable methods • Any problems or changes to the POC • Member or caregiver involvement in and feedback about home program activities • Signature and date of the treating provider ***Group Therapy*** The documentation must include all of the following: • Prescribing provider's order for group therapy; and • Individualized treatment plan that includes frequency and duration of the prescribed group therapy and individualized treatment goals; and • Name and signature of licensed therapist providing supervision over the group therapy session; and • Specific treatment techniques utilized during the group therapy session and how the techniques will restore function, and • Start and stop times for each session; and • Group therapy setting or location; and • Number of clients in the group

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Habilitation and Rehabilitation Therapy (Occupational, Physical and Speech) (continued)	Apr. 1, 2023	receive culturally and linguistically adapted norm referenced standardized testing in all languages the child is exposed to in order to compare potential deficits ▪ For speech and language therapy services to be Medically Necessary for a member with limited English proficiency, all of the following criteria must be met: – All speech deficits must be present in the language in which the member has the highest proficiency – All language deficits must be present in the language in which the member has the highest proficiency – Delivery of services must be in the language in which the member has the highest receptive language proficiency ○ For members with dyslexia, test results substantiating a diagnosis of receptive or	***Feeding and Swallowing Disorders*** For feeding and swallowing evaluations, all of the following must be submitted: ● Interview/case history; and ● Medical/clinical records including the potential impact of medications, if any; and ● Physical examination; and ● Previous screening and assessments; and ● Collaboration with providers and other caregivers ○ During assessment, therapist's determine whether the member is an appropriate candidate for treatment and/or management; this determination is based on findings that include medical stability, cognitive status, nutritional status, and psychosocial, environmental, and behavioral factors and ● Assessment must result in one or more of the following outcomes: ○ Description of the characteristics of swallowing function, including any breakdowns in swallow physiology ○ Diagnosis of a Swallowing Disorder ○ Determination of the safest and most efficient route (oral vs. non-oral) of nutrition and hydration intake ○ Identification of the effectiveness of intervention and support ○ Recommendations for intervention and support for oral, pharyngeal, and/or laryngeal disorders ○ Prognosis for improvement and identification of other relevant factors, if appropriate **Discharge Criteria** Discharge criteria includes but is not limited to all of the following (as applicable): ● Treatment goals and objectives have been met ● Functional abilities have become comparable to those of others of the same chronological age and gender ● The desired level of function that has been agreed to by the member and

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Habilitation and Rehabilitation Therapy (Occupational, Physical and Speech) (continued)	Apr. 1, 2023	expressive language delay must be included with goals addressing the corresponding language deficits • Added description of: ○ Habilitation services ○ Rehabilitation services ○ Maintenance services *Required Documentation* • Added documentation requirements for: ○ Initial Therapy Evaluation/Initial Therapy Visit Requests ○ Plan of Care ○ Requests for Continuation of Therapy Visits ○ Re-Evaluations ○ Treatment Session Notes ○ Group Therapy ○ Feeding and Swallowing Disorders Definitions • Removed definition of: ○ Alternate Facility ○ Autism Spectrum Disorder ○ Cardiac Rehabilitation ○ Cognitive Rehabilitation ○ Congenital Anomaly ○ Developmental Delay ○ Illness ○ Injury ○ Maintenance Program ○ Physician	provider has been achieved • The skill of a therapist or other licensed healthcare professional (within the scope of his/her licensure) is not required • The member exhibits behavior that interferes with improvement or participation in treatment and efforts to address these factors have not been successful • In some situations, the member, family, or designated guardian may choose not to participate in treatment, may relocate, or may seek another provider if the therapeutic relationship is not satisfactory. Therefore, discharge is also appropriate in the following situations, provided that the member/client, family, and/or guardian have been advised of the likely outcomes of discontinuation: ○ There is a request to be discharged or request continuation of services with another provider ○ The individual is transferred or discharged to another location where ongoing service from the current provider is not reasonably available; efforts should be made to ensure continuation of services in the new locale • The member is unable to tolerate treatment because of a serious medical, psychological, or other condition **Additional Considerations** • Bilingual and multilingual speakers are frequently misclassified as developmentally delayed. Equivalent proficiency in both languages should not be expected. Members with limited English proficiency must receive culturally and linguistically adapted norm referenced standardized testing in all languages the child is exposed to in order to compare potential deficits. For speech and language therapy services to be Medically Necessary for a member with limited English proficiency, all of the following criteria must be met: ○ All speech deficits must be present in the language in which the member has the highest proficiency; and ○ All language deficits must be present in the language in which the

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Habilitation and Rehabilitation Therapy (Occupational, Physical and Speech) (continued)	Apr. 1, 2023	○ Pulmonary Rehabilitation ○ Restorative Therapy/Rehabilitation ○ Sickness ○ Speech Delay – Bilingualism ○ Speech-Language Pathologists ○ Stuttering • Updated definition of "Experimental or Investigational Service(s)" **Applicable Codes** • Added CPT/HCPCS codes for: *Occupational Therapy* ○ 0552T, 97012, 97014, 97016, 97022, 97024, 97026, 97028, 97032, 97033, 97034, 97035, 97036, 97039, 97112, 97113, 97139, 97140, 97150, 97750, 97760, 97761, 97763, 97799, G0129, G0281, G0282, G0283, G0283, S8948, S8990, and S9129 *Physical Therapy* ○ 97014, 97039, 97139, 97799, G0282, and S9131 *Speech Therapy* ○ 92609 and 92610 ○ Removed CPT/HCPCS codes 92626, 92627, 92630, 92633, 93668, 93797, 93798, 94625, 94626, 97129, 97130, 98925, 98926, 98927, 98928, 98929, 98940, 98941, 98942, 98943,	○ member has the highest proficiency; and ○ Delivery of services must be in the language in which the member has the highest receptive language proficiency • For members with dyslexia, test results substantiating a diagnosis of receptive or expressive language delay must be included with goals addressing the corresponding language deficits.

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Habilitation and Rehabilitation Therapy (Occupational, Physical and Speech) (continued)	Apr. 1, 2023	G0237, G0238, G0239, G0302, G0303, G0304, G0305, G0422, G0423, S9472, S9473, V5362, V5363, and V5364 • Removed notations pertaining to the rehabilitation therapy benefit and habilitative services • Removed list of applicable revenue codes: 0420, 0421, 0422, 0423, 0424, 0429, 0430, 0431, 0432, 0433, 0434, 0439, 0440, 0441, 0442, 0443, 0444, 0449, 0943, 0948, and 0979 Supporting Information • Added *Description of Services* section • Updated *Benefits Considerations* and *References* sections to reflect the most current information	
Hearing Aids and Devices Including Wearable, Bone-Anchored and Semi-implantable	Apr. 1, 2023	Title/Template Update • Updated template to specify this policy applies to UnitedHealthcare Commercial plans only: ○ Modified title ○ Added *Application* section Coverage Rationale • Revised list of proven and medically necessary devices for hearing loss in an individual who is not a candidate for an air-conduction Hearing Aid; replaced "bilateral or unilateral *bone-anchored* Hearing Aids utilizing a	Wearable air-conduction Hearing Aids required for the correction of a Hearing Impairment are proven and medically necessary. When used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions, the following are proven and medically necessary for hearing loss in an individual who is not a candidate for an air-conduction Hearing Aid: • Bilateral fully or partially implantable bone-anchored Hearing Aids for Conductive or Mixed Hearing Loss in both ears • Bilateral or unilateral bone conduction Hearing Aids utilizing a headband or adhesive (without osseointegration) • Semi-implantable electromagnetic Hearing Aid for Sensorineural Hearing Loss • Unilateral fully or partially implantable bone-anchored Hearing Aids for

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Hearing Aids and Devices Including Wearable, Bone-Anchored and Semi-implantable (continued)	Apr. 1, 2023	headband (without osseointegration)" with "bilateral or unilateral *bone-conduction* Hearing Aids utilizing a headband *or adhesive* (without osseointegration)" • Added notation for equipment upgrades to indicate: ○ A change in the member's medical condition and equipment needs requires the same criteria as a new request ○ Equipment upgrades are equivalent to a new service **Documentation Requirements** • Updated list of CPT codes with associated documentation requirements; removed 69717 and 69799 **Applicable Codes** • Removed CPT codes 69711, 69726, and 69727 **Supporting Information** • Updated *Description of Services*, *Benefits Considerations*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	Conductive or Mixed Hearing Loss in one or both ears • Unilateral fully or partially implantable bone-anchored Hearing Aids for Sensorineural Hearing Loss in one ear The following are unproven and not medically necessary for treating hearing loss due to insufficient evidence of efficacy: • Intraoral bone conduction Hearing Aids • Laser or light-based Hearing Aids • Totally implanted middle ear hearing systems Note: Equipment Upgrades • A change in the member's medical condition and equipment needs requires the same criteria as a new request • Equipment upgrades are equivalent to a new service
Hysterectomy	Apr. 1, 2023	**Template Update** • Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans	Hysterectomy is proven and medically necessary in certain circumstances, including management of individuals with BRCA1 or BRCA2 gene mutation, or chronic pelvic pain. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy.

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Hysterectomy (continued)	Apr. 1, 2023	• Added *Application* section to indicate this Medical Policy applies to:
		  ○ All UnitedHealthcare Commercial benefit plans
		  ○ Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Nevada, and New York
		Coverage Rationale
		• Added language to clarify hysterectomy is proven and medically necessary in certain circumstances, *including management of individuals with BRCA1 or BRCA2 gene mutation, or chronic pelvic pain*
		• Revised language pertaining to medical necessity clinical coverage criteria:
		  ○ Added reference to the InterQual® CP: Procedures, Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
		  ○ Removed reference to the InterQual® Client Defined, CP: Procedures, Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy (Custom) - UHG
			Click here to view the InterQual® criteria.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Hysterectomy (continued)	Apr. 1, 2023	**Documentation Requirements** • Updated list of CPT codes with associated documentation requirements; removed 58263, 58275, and 58280 • Removed notation pertaining to CPT code 58263 **Applicable Codes** • Removed CPT codes 58275 and 58280 **Supporting Information** • Added *Clinical Evidence* and *References* sections • Updated *FDA* section to reflect the most current information	

Interspinous Fusion and Decompression Devices	Apr. 1, 2023	**Title Change/Template Update**
		• Relocated and reformatted content previously included in the Medical Policy titled *Surgical Treatment for Spine Pain*
		• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans
		• Added *Application* section to indicate this Medical Policy applies to:
		  ○ All UnitedHealthcare Commercial benefit plans
		  ○ Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Nevada, and New York
			Interspinous bony fusion devices are proven and medically necessary when performed according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions and all of the following criteria are met:
			• Used with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1-S1)
			• Back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies
			• No more than Grade 1 spondylolisthesis
			
			Interspinous bony fusion devices used for stand-alone procedures are considered off-label and not medically necessary.
			
			Interspinous decompression systems (without fusion) for the treatment of spine pain or spinal stenosis are unproven and not medically necessary due to insufficient evidence of efficacy.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Interspinous Fusion and Decompression Devices (continued)	Apr. 1, 2023	Coverage Rationale • Revised language to indicate: ○ Interspinous bony fusion devices are proven and medically necessary when performed according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions, and all of the following criteria are met: ▪ Used with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1-S1) ▪ Back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies ▪ No more than Grade 1 spondylolisthesis ○ Interspinous bony fusion devices used for stand-alone procedures are considered off-label and not medically necessary ○ Interspinous decompression systems (without fusion) for the treatment of spine pain or spinal stenosis are unproven and not medically necessary due to insufficient evidence of	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Interspinous Fusion and Decompression Devices (continued)	Apr. 1, 2023	efficacy Documentation Requirements • Updated list of CPT codes with associated documentation requirements to reflect/include 22853, 22854, 22859, and 22899 • Updated list of *Required Clinical Information* to reflect/include: ○ Condition requiring procedure including origin of the back pain ○ Surgical history, including date(s) and outcome(s) ○ Upon request, we may require the specific diagnostic image(s) that show the abnormality for which surgery is being requested, which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting surgeon may be of benefit to select the optimal images ▪ Note: When requested, diagnostic image(s) must be labeled with: – The date taken – Applicable case number obtained at time of notification, or member's name and ID number on the image(s)	

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Interspinous Fusion and Decompression Devices (continued)	Apr. 1, 2023	▪ Upon request, diagnostic imaging must be submitted via the external portal at uhcprovider.com/paan; faxes will not be accepted ○ Diagnostic image(s) report(s) by a radiologist, including presence or absence of: ▪ Degeneration of the disc ▪ Spondylolisthesis including Grade ○ Describe the surgical technique(s) planned, including name of interspinous bony fusion device requested and use of an interbody cage **Definitions** • Added definition of: ○ Interspinous Fixation Devices • Removed definition of: ○ Anterior Lumbar Spine Surgery ○ Axial Lumbar Interbody Fusion (AxiaLIF) ○ Conservative Therapy ○ Corpectomy ○ Direct Lateral Interbody Fusion (DLIF) ○ Disabling Symptoms ○ Dynamic Stabilization ○ Facet Arthroplasty ○ Facet Fusion ○ Facet Syndrome	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Interspinous Fusion and Decompression Devices (continued)	Apr. 1, 2023	○ Image-Guided Minimally Invasive Lumbar Decompression (mild®) ○ Laparoscopic Anterior Lumbar Interbody Fusion (LALIF) ○ Percutaneous or Endoscopic Lumbar Fusion ○ Posterior Lumbar Spine Surgery ○ Progressive ○ Radicular Pain ○ Sacroplasty ○ Spinal Fusion ○ Spondylolisthesis ○ Spondylolysis ○ Staged Multi Session ○ Total Facet Joint Arthroplasty ○ Transforaminal Lumbar Interbody Fusion (TLIF) ○ Unremitting ○ X-STOP Interspinous Process Decompression (IPD) System Applicable Codes • Added HCPCS code C1821 • Removed CPT codes 0200T, 0201T, 0202T, 0219T, 0220T, 0221T, 0222T, 0274T, 0275T, 0719T, 20930, 20931, 22100, 22101, 22102, 22103, 22110, 22112, 22114, 22116, 22206, 22207, 22208, 22210, 22212, 22214, 22216, 22220, 22222, 22224, 22226, 22532, 22533,	

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Interspinous Fusion and Decompression Devices (continued)	Apr. 1, 2023	22534, 22548, 22551, 22552, 22554, 22556, 22558, 22585, 22586, 22590, 22595, 22600, 22610, 22612, 22614, 22630, 22632, 22633, 22634, 22800, 22802, 22804, 22808, 22810, 22812, 22818, 22819, 22830, 22840, 22841, 22842, 22843, 22844, 22845, 22846, 22847, 22848, 22849, 22850, 22852, 22855, 62380, 63001, 63003, 63005, 63011, 63012, 63015, 63016, 63017, 63020, 63030, 63035, 63040, 63042, 63043, 63044, 63045, 63046, 63047, 63048, 63050, 63051, 63052, 63053, 63055, 63056, 63057, 63064, 63066, 63075, 63076, 63077, 63078, 63081, 63082, 63085, 63086, 63087, 63088, 63090, 63091, 63101, 63102, 63103, 63170, 63172, 63173, 63185, 63190, 63191, 63197, 63200, 63250, 63251, 63252, 63265, 63266, 63267, 63268, 63270, 63271, 63272, 63275, 63277, 63280, 63282, 63285, 63286, 63287, 63290, 63300, 63301, 63302, 63303, 63304, 63305, 63306, 63307, and 63308 • Removed coding notations Supporting Information • Updated *Description of Services*,	

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Interspinous Fusion and Decompression Devices (continued)	Apr. 1, 2023	*Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	

Lower Extremity Prosthetics	Apr. 1, 2023	**Title Change/Template Update**
		• Relocated and reformatted content previously included in the Coverage Determination Guideline titled *Prosthetic Devices, Wigs, Specialized, Microprocessor or Myoelectric Limbs*
		• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans
		• Changed policy type classification from "Coverage Determination Guideline" to "Medical Policy"
		• Added *Application* section to indicate this Medical Policy applies to:
		  ○ All UnitedHealthcare Commercial benefit plans
		  ○ Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Nevada, and New York
		Related Policies
		• Added reference link to the Medical Policy titled *Upper Extremity Myoelectric Prosthetic Devices*
			A lower extremity prosthetic for amputations is proven and Medically Necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment Prosthetics, Lower Extremity.
			
			Click here to view the InterQual® criteria.
			
			An endoskeletal knee-shin system with microprocessor control feature (swing/stance phase) is unproven and not Medically Necessary due to insufficient evidence of efficacy for the following:
			• Amputee with functional classification status of K1 or K2; and
			• Transfemoral (above knee) amputation (includes knee disarticulation); or
			• Hip disarticulation or hemipelvectomy
			
			A combined microprocessor-controlled ankle foot system with power assist is unproven and not Medically Necessary due to insufficient evidence of efficacy for the following:
			• Transfemoral (above knee) amputation (includes knee disarticulation)
			• Transtibial (below knee) amputation
			• Hip disarticulation or hemipelvectomy

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Lower Extremity Prosthetics (continued)	Apr. 1, 2023	Coverage Rationale • Revised language to indicate: ○ A lower extremity prosthetic for amputations is proven and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment Prosthetics, Lower Extremity ○ An endoskeletal knee-shin system with microprocessor control feature (swing/stance phase) is unproven and not medically necessary due to insufficient evidence of efficacy for the following: ▪ Amputee with functional classification status of K1 or K2, and ▪ Transfemoral (above knee) amputation (includes knee disarticulation), or ▪ Hip disarticulation or hemipelvectomy ○ A combined microprocessor-controlled ankle foot system with power assist is unproven and not medically necessary due to insufficient evidence of efficacy for the following: ▪ Transfemoral (above knee)	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Lower Extremity Prosthetics (continued)	Apr. 1, 2023	amputation (includes knee disarticulation) ▪ Transtibial (below knee) amputation ▪ Hip disarticulation or hemipelvectomy **Documentation Requirements** ● Updated list of HCPCS codes with associated documentation requirements; removed L5420 and L5530 ● Updated list of *Required Clinical Information* to reflect/include: ○ *Vendor Coversheet* with the narrative describing the request ○ Vendor invoice listing the HCPCS codes, make model description, indicate if the item is right or left ○ Other healthcare professional notes (i.e. physical therapist) ○ Current prescription ○ Physician office notes including documentation of: ▪ History related to the prosthetic request ▪ Examination findings to include strength, range of motion (ROM), condition of the contralateral limb, residual limb length and shape, and skin integrity of	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Lower Extremity Prosthetics (continued)	Apr.1, 2023	residual limb ▪ Co-morbidities ▪ Specify absent limb, including the date, level and etiology of amputation ▪ Current functional classification level include specific examples and expected rehab potential ▪ Describe limitations to Activities of Daily Living (ADLs) include assistive devices to facilitate ambulation within and outside the home ▪ Surfaces normally traversed include distance and environment ▪ Prosthetist notes to include medical justification for each of the requested prosthetic components ○ Specify if the request is for initial prosthetic, preparatory prosthetic, definitive prosthetic, replacement of the entire prosthetic leg, replacement of the prosthetic components/accessories, or request for additional components and accessories ○ For replacement prosthesis, also include:	

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Lower Extremity Prosthetics (continued)	Apr.1, 2023	▪ The age of the current prosthesis and reason for replacement ▪ The components on the current prosthesis including socket, knee, foot, ankle, sock ply, and liner thickness ▪ Describe changes in limb including, but not limited to, comparative residual limb measurements ○ For socket replacement, also describe what adjustments have been tried and failed **Definitions** ● Added definition of: ○ Activities of Daily Living (ADLs) ○ Instrumental Activities of Daily Living (IADLs) ○ CMS Modifiers/Medicare Functional Classification Level (MFCL) ○ Modifier ○ Prosthesis ● Removed definition of: ○ Lower Limb Rehabilitation Classification Levels ● Updated definition of: ○ Medically Necessary ○ Myoelectric Prosthetic ○ Prosthetist	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Lower Extremity Prosthetics (continued)	Apr. 1, 2023	**Applicable Codes** • Added HCPCS codes L5781, L5782, L5990, L7367, and L7368 • Removed HCPCS codes K1022, L7510, L7520, L8499, and L9900 **Supporting Information** • Added *Description of Services*, *Benefit Considerations*, *Clinical Evidence*, and *FDA* sections • Updated *References* section to reflect the most current information	

Minimally Invasive Spine Surgery Procedures	Apr. 1, 2023	**Title Change/Template Update**
		• Relocated and reformatted content previously included in the Medical Policy titled *Surgical Treatment for Spine Pain*
		• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans
		• Added *Application* section to indicate this Medical Policy applies to:
		  ○ All UnitedHealthcare Commercial benefit plans
		  ○ Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Nevada, and New York
		Coverage Rationale
		• Revised language to indicate the following spinal procedures are unproven and not medically
			The following spinal procedures are unproven and not medically necessary due to insufficient evidence of efficacy:
			• Axial lumbar interbody fusion (AxiaLIF®), a percutaneous pre-sacral access route to the L5 - S1 vertebral bodies
			• Percutaneous image-guided lumbar decompression (PILD)
			• Percutaneous sacral augmentation (sacroplasty) with or without a balloon or bone cement
			• Automated percutaneous and percutaneous endoscopic discectomy (APLD) for intervertebral disc decompression
			• Minimally invasive lumbar decompression (mild®)
			• Laparoscopic Anterior Lumbar Interbody Fusion (LALIF)
			• Transforaminal lumbar interbody fusion (TLIF) which utilizes only endoscopy visualization (such as a percutaneous incision with video visualization)

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Minimally Invasive Spine Surgery Procedures (continued)	Apr. 1, 2023	necessary due to insufficient evidence of efficacy: ○ Axial lumbar interbody fusion (AxiaLIF®), a percutaneous pre-sacral access route to the L5-S1 vertebral bodies ○ Percutaneous image-guided lumbar decompression (PILD) ○ Percutaneous sacral augmentation (sacroplasty) with or without a balloon or bone cement ○ Automated percutaneous and percutaneous endoscopic discectomy (APLD) for intervertebral disc decompression ○ Minimally invasive lumbar decompression (mild®) ○ Laparoscopic anterior lumbar interbody fusion (LALIF) ○ Transforaminal lumbar interbody fusion (TLIF) which utilizes only endoscopy visualization (such as a percutaneous incision with video visualization) Definitions • Added definition of: ○ Automated Percutaneous Lumbar Discectomy (APLD) ○ Endoscope ○ Endoscopic Discectomy	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Minimally Invasive Spine Surgery Procedures (continued)	Apr. 1, 2023	○ Fluoroscopy ○ Interbody Fusion ○ Nucleoplasty ○ Open Spine Surgery ○ Percutaneous Endoscopic Lumbar Diskectomy (PELD) ○ Percutaneous Image-Guided Lumbar Decompression (PILD) ○ Presacral ○ Spinal Decompression ○ Transforaminal (TESSYS®) and Interlaminar Endoscopic Surgical Systems ○ Tubular Retractor • Removed definition of: ○ Arthrodesis ○ Conservative Therapy ○ Corpectomy ○ Direct Lateral Interbody Fusion (DLIF) ○ Disabling Symptoms ○ Dynamic Stabilization ○ Facet Arthroplasty ○ Facet Fusion ○ Facet Syndrome ○ Interlaminar Stabilization Device ○ Interspinous Process Decompression (IPD) ○ Lumbar Spinal Stenosis (LSS) ○ Neurogenic Claudication (also known as pseudoclaudication) ○ Progressive	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Minimally Invasive Spine Surgery Procedures (continued)	Apr. 1, 2023	○ Radicular Pain ○ Spinal Fusion ○ Spinal Stabilization ○ Spondylolisthesis ○ Spondylolysis ○ Staged Multi Session ○ Total Facet Joint Arthroplasty ○ Transforaminal Lumbar Interbody Fusion (TLIF) ○ Unremitting ○ X-STOP Interspinous Process Decompression (IPD) System **Applicable Codes** • Added CPT/HCPCS codes 62287 and G0276 • Removed CPT codes 0202T, 0219T, 0220T, 0221T, 0222T, 0274T, 0719T, 20930, 20931, 22100, 22101, 22102, 22103, 22110, 22112, 22114, 22116, 22206, 22207, 22208, 22210, 22212, 22214, 22216, 22220, 22222, 22224, 22226, 22532, 22533, 22534, 22548, 22551, 22552, 22554, 22556, 22558, 22585, 22590, 22595, 22600, 22610, 22612, 22614, 22632, 22633, 22634, 22800, 22802, 22804, 22808, 22810, 22812, 22818, 22819, 22830, 22840, 22841, 22842, 22843, 22844, 22845, 22846, 22847, 22848, 22849, 22850, 22852, 22853,	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Minimally Invasive Spine Surgery Procedures (continued)	Apr. 1, 2023	22854, 22855, 22859, 22867, 22868, 22869, 22870, 63001, 63003, 63005, 63011, 63012, 63015, 63016, 63017, 63020, 63030, 63035, 63040, 63042, 63043, 63044, 63045, 63046, 63047, 63048, 63050, 63051, 63052, 63053, 63055, 63056 63057, 63064, 63066, 63075, 63076, 63077, 63078, 63081, 63082, 63085, 63086, 63087, 63088, 63090, 63091, 63101, 63102, 63103, 63170, 63172, 63173, 63185, 63190, 63191, 63197, 63200, 63250, 63251, 63252, 63265, 63266, 63267, 63268, 63270, 63271, 63272, 63275, 63277, 63280, 63282, 63285, 63286, 63287, 63290, 63300, 63301, 63302, 63303, 63304, 63305, 63306, 63307, and 63308 • Removed coding notations Supporting Information • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Removed *Documentation Requirements* section	

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions	Apr. 1, 2023	**Template Update**
		• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans
		• Added *Application* section to indicate this Medical Policy applies to:
		  ○ All UnitedHealthcare Commercial benefit plans
		  ○ Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Nevada, and New York
		Coverage Rationale
		• Added coverage guidelines for the following indications (refer to the policy for complete details):
		  ○ Prostate Cancer Gene Expression Profiling (GEP)
		  ○ Companion Diagnostics via Tissue Sample for Solid Tumor Cancers
		  ○ Companion Diagnostics via Plasma Sample/Liquid Biopsy (cell-free DNA [cfDNA] or circulating tumor DNA [ctDNA]) for Solid Tumor Cancers
		• Replaced language indicating "molecular testing, such as gene expression profiling, *Chromosome Microarray Analysis*, and multi-gene
			Solid Tumor Testing
			Breast Cancer Gene Expression Profiling (GEP)
			The use of one of the following GEP tests: MammaPrint®, Oncotype Dx® Breast, Prosigna® Breast Cancer Prognostic Gene Signature Assay (formerly PAM-50), Breast Cancer Index™ (BCI) and EndoPredict®, is proven and medically necessary when used to inform treatment decisions in individuals with invasive breast cancer in the following situations:
			• Newly diagnosed (within the last 6 months) when all the following criteria are met:
			  ○ Lymph node negative (including lymph nodes with micrometastases no greater than 2 mm) or 1-3 positive ipsilateral axillary lymph nodes diagnosed via surgical resection of tumor (not biopsy); and
			  ○ No distant metastases; and
			  ○ Hormone receptor-positive (estrogen receptor positive, progesterone receptor positive or both); and
			  ○ HER2 receptor negative; and
			  ○ Adjuvant chemotherapy is not precluded due to any other factor (e.g., advanced age and/or significant co-morbidities); or
			• Currently receiving adjuvant hormonal therapy (e.g., Tamoxifen or an aromatase inhibitor) for a breast cancer when all of the following criteria are met:
			  ○ Hormone receptor-positive (estrogen receptor positive, progesterone receptor positive or both); and
			  ○ HER2 receptor negative; and
			  ○ Individual and treating physician have had a discussion prior to testing regarding the potential results of the test and determined to use the results to guide a decision regarding extended adjuvant hormonal therapy
			
			The use of more than one predictive GEP for the same tumor in an individual with breast cancer is unproven and not medically necessary due to insufficient evidence of efficacy.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Apr. 1, 2023	*cancer* panels are unproven and not medically necessary for all other indications *[not listed as proven in the policy]*" with "molecular testing, such as GEP, multigene *Next Generation Sequencing (NGS)* panels, and *Comprehensive Genomic Profiling (CGP)*, is unproven and not medically necessary for all indications *other than those described [in the policy] as proven*" • Revised list of unproven and not medically necessary molecular testing (profiling/panels) to reflect/include: ○ NGS panels of > 50 genes unless otherwise specified ○ Decipher® Bladder ○ ResponseDx Tissue of Origin™, CancerTYPE ID®, Rosetta Cancer Origin™, ProOnc ○ PancraGEN®, PancreaSeq® ○ Oncotype DX® colon cancer assay, Colorectal Cancer DSA™, Genefx℠ Colon (also known as ColDx), OncoDefender™-CRC, ColoPrint® ○ DecisionDx® Melanoma, DermTech PLATM, myPath®-Melanoma) ○ MyPRS®/MyPRS Plus™	Note: This does not apply to BCI testing, which can be used once in the evaluation of the role of extended endocrine therapy in a breast cancer that may have already had GEP to determine the role of adjuvant chemotherapy. Due to insufficient evidence of efficacy, GEP for breast cancer for indications (including ductal carcinoma in situ [DCIS]) or treatment decisions other than those previously described as proven are unproven and not medically necessary. Such tests may include, but are not limited to: • BluePrint • DCISionRT® • Oncotype DX Breast DCIS Score® test ***Lung Cancer*** Molecular profiling of solid tumor tissue in metastatic non-small cell lung cancer is proven and medically necessary when all of the following criteria are met: • No prior molecular profiling has been performed on the same tumor; and • One of the following: ○ The multigene Next Generation Sequencing (NGS) panel selected has no more than 50 genes; or ○ Individual meets criteria for companion diagnostic testing below Liquid Biopsy (cell-free DNA [cfDNA] or circulating tumor DNA [ctDNA]) molecular profiling tests of non-small cell lung cancer are proven and medically necessary when the following criteria are met: • No prior molecular profiling has been performed on the same tumor; and • The individual is not medically fit for invasive biopsy or tumor tissue testing is not feasible; and • One of the following: ○ The multigene NGS panel selected has no more than 50 genes; or ○ Individual meets criteria for companion diagnostic testing below

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Apr. 1, 2023	○ Multi-cancer early detection/screening tests (e.g., Galleri®) ○ TMPRSS2 fusion gene, Prolaris® Prostate Cancer Test, ExoDX Prostate Test, MiPS (Mi Prostate Score Urine test), MyProstateScore (MPS, formerly MiPS), Confirm MDx, Select MDx ○ Tumor-informed assays (e.g., Invitae Personalized Cancer Monitoring, Signatera™, RaDaR®) ○ MRD monitoring for solid tumors (e.g., Guardant Reveal™) ○ Percepta® GSC for suspicious lung nodules ○ Solid tumor profiling that includes Whole Exome, Whole Genome or whole transcriptome Sequencing (e.g., Caris MI Tumor Seek™, Caris MI Profile™, Tempus xE) *Breast Cancer Gene Expression Profiling (GEP)* ● Replaced language indicating "the use of one of the [listed] GEP tests is proven and medically necessary when used to *make a* treatment decision *regarding adjuvant chemotherapy* in *females or males*	***Prostate Cancer Gene Expression Profiling (GEP)*** The use of the 17 gene mRNA score (e.g., Oncotype DX® Genomic Prostate Score [GPS]) is proven and medically necessary for individuals with biopsy-proven, untreated, localized adenocarcinoma of the prostate (no clinical evidence of metastasis or lymph node involvement) when: ● Test is ordered by a urologist or medical oncologist; and ● Results will be used to assist with treatment decision-making when the individual has not yet received treatment for prostate cancer and is a candidate for either active surveillance or definitive therapy and all of the following: ○ Life expectancy greater than 10 years; and ○ Risk group (as per NCCN) is one of the following: ▪ Very-Low-Risk Prostate Cancer; or ▪ Low-Risk Prostate Cancer: or ▪ Favorable Intermediate-Risk Prostate Cancer The use of the 22 gene mRNA score (e.g., Decipher® Prostate RP genomic classifier) is proven and medically necessary to inform adjuvant treatment if adverse features (e.g., high-grade disease, Gleason score 8 or higher, extracapsular extension, positive surgical margins, seminal vesicle invasion) are found after radical prostatectomy or with PSA persistence or recurrence. Molecular screening panel tests for prostate cancer are unproven and not medically necessary due to insufficient evidence of efficacy (e.g., ExoDx™ Prostate Test, My Prostate Score™, Confirm MDx™, Select MDx™). ***Thyroid Cancer or Indeterminate Thyroid Nodule Testing*** The use of GEP testing for thyroid nodules with indeterminate cytology (e.g., Afirma® Genomic Sequencing Classifier [GSC], ThyroSeq® V3, ThyGeNEXT®/ThyraMIR®) is proven and medically necessary when all of the following criteria are met: ● Follicular pathology on fine needle aspiration is indeterminate (Bethesda III/IV)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Apr. 1, 2023	with invasive breast cancer in the [listed] situations" with "the use of one of the [listed] GEP tests is proven and medically necessary when used to *inform* treatment decisions in *individuals* with invasive breast cancer in the [listed] situations" • Revised coverage criteria for GEP test for newly diagnosed invasive breast cancer; replaced criterion requiring "lymph node negative or 1-3 positive ipsilateral axillary lymph nodes" with "lymph node negative *(including lymph nodes with micrometastases no greater than 2 mm)* or 1-3 positive ipsilateral axillary lymph nodes *diagnosed via surgical resection of tumor (not biopsy)*" • Added language to clarify BCI testing *can be used once in the evaluation of the role of extended endocrine therapy in a breast cancer that may have already had GEP to determine the role of adjuvant chemotherapy* • Revised list of GEP tests that are unproven and not medically necessary for breast cancer indications to reflect/include: ○ BluePrint ○ DCISionRT®	• The results of the test will be used for making decisions about further surgery Due to insufficient evidence of efficacy, molecular tests for indeterminate thyroid nodules other than those previously described as proven are unproven and not medically necessary, including but not limited to: • Afirma® Xpression Atlas (XA) • Comprehensive Genomic Profiling (CGP) (e.g., NeoTYPE® Thyroid Profile) The use of more than one molecular profile test in an individual with an indeterminate thyroid nodule is unproven and not medically necessary due to insufficient evidence of efficacy. CGP of confirmed anaplastic thyroid cancer is proven and medically necessary. For all other primary thyroid cancers see criteria for FoundationOne® CDx below. ***Uveal Melanoma Gene Expression Profiling (GEP)*** GEP (e.g., DecisionDx®-UM) is considered proven and medically necessary when used to assist with predicting disease severity and making treatment decisions in the following situations: • Individual has primary, localized uveal melanoma; and • There is no evidence of metastatic disease; and • Individual has not previously had DecisionDx-UM testing for current diagnosis ***Companion Diagnostics via Tissue Sample for Solid Tumor Cancers*** Specific biomarker identification for solid tumors is considered medically necessary when biomarker confirmation is required per the "Indications and Usage" of the U.S. FDA-approved prescribing label prior to initiation of therapy.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Apr. 1, 2023	○ Oncotype DX Breast DCIS Score® test *Lung Cancer* • Replaced language indicating "*multigene* molecular profiling of metastatic non-small cell lung cancer is proven and medically necessary when all of the [listed] criteria are met" with "molecular profiling of *solid tumor tissue in* metastatic non-small cell lung cancer is proven and medically necessary when all of the [listed] criteria are met" • Replaced reference to "Liquid Biopsy (circulating tumor DNA)" with "Liquid Biopsy [*cell-free DNA (cfDNA) or* circulating tumor DNA*(ctDNA)*]" • Revised coverage criteria for: Molecular Profiling of Solid Tumor Tissue in Metastatic Non-Small Cell Lung Cancer ○ Replaced criterion requiring "the panel selected has no more than 50 genes" with "the multigene *NGS* panel selected has no more than 50 genes o*r the individual meets criteria for companion diagnostic testing [listed in the policy]*"	FoundationOne® CDx (0037U ONLY) testing using tumor tissue is considered proven and medically necessary when all the following criteria are met: • Individual has an unresectable or metastatic primary solid tumor (excluding primary CNS tumors in individuals less than 18 years of age); and • Immune checkpoint inhibitor therapy (e.g., pembrolizumab, nivolumab, cemiplimab, atezolizumab, avelumab, durvalumab, ipilimumab, relatimab) is being considered for treatment; and • There has been progression of disease and there are no satisfactory alternative treatment options; and • No Comprehensive Genomic Profiling (CGP) has been performed previously for this primary tumor type Repeat testing with FoundationOne CDx on tumor tissue after initial use of FoundationOne CDx is considered unproven and not medically necessary due to insufficient evidence of efficacy. Any other CGP test for solid tumors not addressed above (e.g., oncomap™ ExTra, NeoTYPE® Discovery Profile for Solid Tumors, MSK-IMPACT®, TheraMap™ Solid Tumor, CANCERPLEX®, Solid Tumor Profile Plus, Tempus xT) is considered unproven and not medically necessary for use as a companion diagnostic due to insufficient evidence of efficacy. ***Companion Diagnostics via Plasma Sample/Liquid Biopsy (cell-free DNA [cfDNA] or circulating tumor DNA [ctDNA]) for Solid Tumor Cancers*** Specific biomarker identification for solid tumors via Liquid Biopsy is considered medically necessary when biomarker confirmation is required per the "Indications and Usage" of the U.S. FDA-approved prescribing label prior to initiation of therapy. FoundationOne® Liquid CDx (0239U ONLY) is proven and medically necessary for advanced or metastatic breast cancer, metastatic non-small cell lung cancer, metastatic castration-resistant prostate cancer (mCRPC) or

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Apr. 1, 2023	**Liquid Biopsy Molecular Profiling Tests of Non-Small Cell Lung Cancer** ○ Removed criterion requiring: ▪ Non-small cell lung cancer has been pathologically confirmed, but there is insufficient material available for molecular testing ▪ Individual and treating physician have had a discussion prior to testing regarding the potential results of the test and determined to use the results to guide therapy ○ Replaced criterion requiring: ▪ "The individual is not medically fit for invasive biopsy" with "the individual is not medically fit for invasive biopsy *or tumor tissue testing is not feasible*" ▪ "The *test* selected has no more than 50 genes" with "the *multigene NGS panel* selected has no more than 50 genes o*r the individual meets criteria for companion diagnostic*	recurrent ovarian, fallopian tube, or primary peritoneal cancer when all of the following criteria are met: ● No CGP has been performed previously for this primary tumor type; and ● The individual is not medically fit for invasive biopsy or tumor tissue testing is not feasible; and ● Treatment with an FDA-approved drug for use in the individual's cancer is being considered Guardant360® CDx (0242U ONLY) comprehensive Liquid Biopsy is proven and medically necessary when the individual has a recurrent, relapsed, refractory, metastatic, or advanced NCSLC that did not originate from the central nervous system and all of the following criteria are met: ● NSCLC has been pathologically confirmed; and ● No CGP has been performed previously for this primary tumor type; and ● The individual is not medically fit for invasive biopsy or tumor tissue testing is not feasible; and ● Treatment with an FDA-approved drug for use in the individual's cancer is being considered Circulating tumor cell (CTC) testing (e.g., CellSearch®) is unproven and not medically necessary for all indications due to insufficient evidence of efficacy. Liquid Biopsy (using cfDNA/ctDNA) for any other tumor genetic analysis or tumor screening (e.g., ColonSentry®, Epi proColon®, FoundationOne® Heme, Tempus xF) is considered unproven and not medically necessary for use as a companion diagnostic due to insufficient evidence of efficacy. **Hematological Cancer Testing** ***Testing at initial diagnosis*** Clonality assessment at initial diagnosis (e.g., ClonoSeq® Clonality ID) on one specimen only is proven and medically necessary when ordered by a hematologist or oncologist for individuals with:

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Apr. 1, 2023	*testing [listed in the policy]*" • Removed language indicating Liquid Biopsy (circulating tumor cell free DNA or circulating tumor cells) for any other tumor genetic analysis or tumor screening (e.g., Guardant360, ColoSentry, epi ProColon, OncoCEE CTC, Foundation One Liquid CDx) or multi-cancer early detection tests (e.g., Galleri) are unproven and not medically necessary due to insufficient evidence of efficacy *Thyroid Cancer or Indeterminate Thyroid Nodule Testing* • Revised language to indicate: ○ The use of GEP testing for thyroid nodules with indeterminate cytology [e.g., Afirma® Genomic Sequencing Classifier (GSC), ThyroSeq® V3, ThyGeNEXT®/ThyraMIR®] is proven and medically necessary when all of the following criteria are met: ▪ Follicular pathology on fine needle aspiration is indeterminate (Bethesda III/IV) ▪ The results of the test will be used for making decisions about further	• Acute lymphoblastic leukemia • Multiple myeloma The use of multigene panels (50 genes or fewer) at initial diagnosis is medically necessary when ordered by a hematologist or oncologist for individuals with: • Acute lymphoblastic leukemia • Acute myeloid leukemia • Multiple myeloma • Myelodysplastic syndrome suspected • Myeloproliferative neoplasm ***Measurable Residual Disease (MRD) testing after treatment*** MRD testing (e.g., ClonoSeq® MRD) is proven and medically necessary when ordered by a hematologist or oncologist for individuals with all of the following: • Acute lymphoblastic leukemia or multiple myeloma; and • Testing occurs after completing a course of therapy ***Companion Diagnostics for Hematological Cancers*** Specific biomarker identification for hematologic cancers is considered medically necessary when biomarker confirmation is required per the "Indications and Usage" of the US FDA-approved prescribing label prior to initiation of therapy. CGP (e.g., FoundationOne Heme) for hematological malignancies is unproven and not medically necessary due to insufficient evidence of efficacy. Due to insufficient evidence of efficacy, molecular testing such as GEP, multigene NGS panels and CGP is unproven and not medically necessary for all indications other than those previously described as proven, including but not limited to:

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Apr. 1, 2023	surgery ○ Due to insufficient evidence of efficacy, molecular tests for indeterminate thyroid nodules other than those previously described as proven are unproven and not medically necessary, including but not limited to: ▪ Afirma® Xpression Atlas (XA) ▪ Comprehensive Genomic Profiling (CGP) (e.g., NeoTYPE® Thyroid Profile) ○ The use of more than one molecular profile test in an individual with an indeterminate thyroid nodule is unproven and not medically necessary due to insufficient evidence of efficacy ○ CGP of confirmed anaplastic thyroid cancer is proven and medically necessary; for all other primary thyroid cancers, refer to the criteria for FoundationOne® CDx [in the policy] *Hematological Cancer Testing* ● Revised language to indicate: ○ Clonality assessment at initial diagnosis (e.g., ClonoSeq® Clonality ID) on one specimen	● NGS panels of > 50 genes unless otherwise specified ● Decipher® Bladder ● ResponseDx Tissue of Origin™, CancerTYPE ID®, Rosetta Cancer Origin™, ProOnc ● PancraGEN®, PancreaSeq® ● Oncotype DX® colon cancer assay, Colorectal Cancer DSA™, Genefx℠ Colon (also known as ColDx), OncoDefender™-CRC, ColoPrint® ● DecisionDx® Melanoma, DermTech PLA™, myPath®-Melanoma) ● MyPRS®/MyPRS Plus™ ● Multi-cancer early detection/screening tests (e.g., Galleri®) ● TMPRSS2 fusion gene, Prolaris® Prostate Cancer Test, ExoDX Prostate Test, MiPS (Mi Prostate Score Urine test), MyProstateScore (MPS, formerly MiPS), Confirm MDx, Select MDx ● Tumor-informed assays (e.g., Invitae Personalized Cancer Monitoring, Signatera™, RaDaR®) ● MRD monitoring for solid tumors (e.g., Guardant Reveal™) ● Percepta® GSC for suspicious lung nodules ● Solid tumor profiling that includes Whole Exome, Whole Genome or whole transcriptome Sequencing (e.g., Caris MI Tumor Seek™, Caris MI Profile™, Tempus xE)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Apr. 1, 2023	only is proven and medically necessary when ordered by a hematologist or oncologist for individuals with: ▪ Acute lymphoblastic leukemia ▪ Multiple myeloma ○ The use of multigene panels (50 genes or fewer) at initial diagnosis is medically necessary when ordered by a hematologist or oncologist for individuals with: ▪ Acute lymphoblastic leukemia ▪ Acute myeloid leukemia ▪ Multiple myeloma ▪ Myelodysplastic syndrome suspected ▪ Myeloproliferative neoplasm ○ Measurable residual disease (MRD) testing (e.g., ClonoSeq® MRD) is proven and medically necessary when ordered by a hematologist or oncologist for individuals with all of the following: ▪ Acute lymphoblastic leukemia or multiple myeloma; and ▪ Testing occurs after completing a course of	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Apr. 1, 2023	therapy ○ Specific biomarker identification for hematologic cancers is considered medically necessary when biomarker confirmation is required per the *Indications and Usage* of the US FDA-approved prescribing label prior to initiation of therapy ○ CGP (e.g., FoundationOne Heme) for hematological malignancies is unproven and not medically necessary due to insufficient evidence of efficacy **Definitions** ● Added definition of: ○ Comprehensive Genomic Profiling (CGP) ○ Favorable Intermediate-Risk Prostate Cancer ○ Liquid Biopsy ○ Low-Risk Prostate Cancer ○ Very-Low-Risk Prostate Cancer ● Updated definition of: ○ Comparative Genome Hybridization (CGH) ○ Gene Expression Profiling (GEP) **Applicable Codes** ● Revised description for CPT code 0298U	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Apr. 1, 2023	Supporting Information • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	
Pneumatic Compression Devices	Apr. 1, 2023	Template Update • Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans (no change to coverage guidelines) • Added *Application* section to indicate this Medical Policy applies to: ○ All UnitedHealthcare Commercial benefit plans ○ Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Nevada, and New York Coverage Rationale • Added language to indicate advanced intermittent pneumatic compression devices (e.g., Flexitouch) for treating lymphedema of the head, face, or neck are considered unproven and not medically necessary • Revised medical necessity clinical coverage criteria for:	Advanced intermittent pneumatic compression devices (e.g., Flexitouch) for treating lymphedema of the head, face or neck are considered unproven and not medically necessary. Pneumatic compression devices are proven and medically necessary in certain circumstances for the treatment of lymphedema or chronic venous insufficiency with edema and non-healing lower extremity ulcers. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Pneumatic and other Powered 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). For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Pneumatic and other Powered Compression Devices Click here to view the InterQual® criteria. Note: The InterQual® criteria does not apply to HCPCS code E0652 and E0675. For E0652 (not related to lymphedema of the head, face or neck) and E0675, use available criteria from the CMS.gov website in LCD L33829.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Pneumatic Compression Devices (continued)	Apr. 1, 2023	*Pneumatic Compression Devices* ○ Added reference to the InterQual® CP: Durable Medical Equipment, Pneumatic and other Powered Compression Devices ○ Removed reference to the InterQual® CP: Durable Medical Equipment, Pneumatic Compression Devices *Intermittent Limb Compression Devices* ○ Replaced coverage criteria with reference to the InterQual® CP: Durable Medical Equipment, Pneumatic and other Powered Compression Devices • Updated notation to clarify the available criteria from the CMS.gov website in LCD L33829 should be used for HCPCS code E0652 *(not related to lymphedema of the head, face, or neck)* and E0675 Supporting Information • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	

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

Spinal Fusion and Decompression	Apr. 1, 2023	**Title Change/Template Update**
		• Relocated and reformatted content previously included in the Medical Policy titled *Surgical Treatment for Spine Pain*
		• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans
		• Added *Application* section to indicate this Medical Policy applies to:
		  ○ All UnitedHealthcare Commercial benefit plans
		  ○ Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Nevada, and New York
		Coverage Rationale
		• Revised language to indicate:
		  ○ Spinal procedures for the treatment of spine pain are proven and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures:
		  ▪ Decompression +/- Fusion, Cervical
		  ▪ Decompression +/- Fusion, Lumbar
			Spinal procedures for the treatment of spine pain are proven and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures:
			• Decompression +/- Fusion, Cervical
			• Decompression +/- Fusion, Lumbar
			• Decompression +/- Fusion, Thoracic
			• Fusion, Cervical Spine
			• Fusion, Lumbar Spine
			• Fusion, Thoracic Spine
			
			Click here to view the InterQual® criteria.
			
			Laminectomy procedures to provide surgical exposure to treat lesions within the spinal canal are proven and medically necessary.
			
			Isolated Facet Fusion, with or without instrumentation, is unproven and not medically necessary due to insufficient evidence of efficacy.
			
			Dynamic Stabilization systems for the treatment of degenerative spondylolisthesis are unproven and not medically necessary due to insufficient evidence of efficacy.
			
			Total facet joint arthroplasty is unproven and not medically necessary due to insufficient evidence of efficacy.
			
			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 due to insufficient evidence of safety and efficacy.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Spinal Fusion and Decompression (continued)	Apr. 1, 2023	▪ Decompression +/- Fusion, Thoracic ▪ Fusion, Cervical Spine ▪ Fusion, Lumbar Spine ▪ Fusion, Thoracic Spine ○ Laminectomy procedures to provide surgical exposure to treat lesions within the spinal canal are proven and medically necessary ○ The following are unproven and not medically necessary due to insufficient evidence of efficacy: ▪ Isolated facet fusion, with or without instrumentation ▪ Dynamic Stabilization systems for the treatment of degenerative spondylolisthesis ▪ Total facet joint arthroplasty ▪ 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	

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

Spinal Fusion and Decompression (continued)	Apr. 1, 2023	**Documentation Requirements**
		• Updated list of CPT codes with associated documentation requirements; removed 22100, 22101, 22102, 22103, 22110, 22112, 22114, 22116, 22206, 22207, 22208, 22210, 22212, 22214, 22216, 22220, 22222, 22224, 22226, 22586, 22818, 22819, 22859, 63011, and 63268
		• Updated list of *Required Clinical Information*:
		  ○ Replaced "diagnostic image(s) report(s)" with "diagnostic image(s) report(s) *by a radiologist*"
		  ○ Removed:
		  ▪ Progressive deficits with clinically significant worsening based on at least two measurements over time, if applicable
		  ▪ Degree and progression of curvature (for scoliosis)
		  ▪ Examples of:
		  – Activities of daily living
		  – Surgical techniques
		Definitions
		• Removed definition of:
		  ○ Anterior Lumbar Spine Surgery
		  ○ Arthrodesis
		  ○ Axial Lumbar Interbody Fusion (AxiaLIF)	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Spinal Fusion and Decompression (continued)	Apr. 1, 2023	○ Conservative Therapy ○ Corpectomy ○ Direct Lateral Interbody Fusion (DLIF) ○ Disabling Symptoms ○ Facet Syndrome ○ Image-Guided Minimally Invasive Lumbar Decompression (mild®) ○ Interlaminar Lumbar Instrumented Fusion (ILIF) ○ Interlaminar Stabilization Device ○ Interspinous Process Decompression (IPD) ○ Laparoscopic Anterior Lumbar Interbody Fusion (LALIF) ○ Neurogenic Claudication (also known as pseudoclaudication) ○ Percutaneous or Endoscopic Lumbar Fusion ○ Posterior Lumbar Spine Surgery ○ Progressive ○ Radicular Pain ○ Sacroplasty ○ Spinal Stabilization ○ Spondylolisthesis ○ Spondylolysis ○ Total Facet Joint Arthroplasty ○ Transforaminal Lumbar Interbody Fusion (TLIF) ○ Unremitting	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Spinal Fusion and Decompression (continued)	Apr. 1, 2023	○ X-STOP Interspinous Process Decompression (IPD) System ● Updated definition of: ○ Dynamic Stabilization ○ Isolated Facet Fusion **Applicable Codes** ● Removed CPT codes 0200T, 0201T, 0274T, 0275T, 20930, 20931, 22100, 22101, 22102, 22103, 22110, 22112, 22114, 22116, 22206, 22207, 22208, 22210, 22212, 22214, 22216, 22220, 22222, 22224, 22226, 22586, 22818, 22819, 22859, 22867, 22868, 22869, 22870, and 63011 ● Removed coding notations **Supporting Information** ● Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	
Transcatheter Heart Valve Procedures	Apr. 1, 2023	**Template Update** ● Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans (no change to coverage guidelines) ● Added *Application* section to indicate this Medical Policy applies to: ○ All UnitedHealthcare Commercial benefit plans	**Aortic** Transcatheter aortic heart valve replacement is proven and medically necessary when performed according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions and all of the following criteria are met: ● Diagnosis of severe calcific native aortic valve stenosis as indicated by one of the following: ○ Mean aortic valve gradient ≥ 40 mmHg; or ○ Peak aortic jet velocity ≥ 4.0 m/s; or ○ Aortic valve area of ≤ 0.8 cm^2

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Transcatheter Heart Valve Procedures (continued)	Apr. 1, 2023	○ Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Nevada, and New York **Coverage Rationale** ● Revised coverage criteria for transcatheter aortic heart valve replacement; removed criterion requiring "the individual does not have a congenitally bicuspid aortic valve" **Supporting Information** ● Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	● Individual is symptomatic (New York Heart Association [NYHA] class II or greater) and symptoms are due to aortic valve stenosis ● An interventional cardiologist and an experienced cardiothoracic surgeon have determined that the procedure is appropriate ● Individual has engaged in a Shared Decision Making conversation with an interventional cardiologist and an experienced cardiothoracic surgeon ● Procedure is performed in a center that meets all of the following criteria: ○ On-site heart valve surgery and interventional cardiology programs; and ○ Post-procedure intensive care unit with personnel experienced in managing individuals who have undergone open-heart valve procedures; and ○ Volume Requirements consistent with the Centers for Medicare and Medicaid Services (CMS); for additional information, refer to the corresponding CMS National Coverage Determination and the Society of Thoracic Surgeons/American College of Cardiology (STS/ACC) Transcatheter Valve Therapy (TVT) Registry. Transcatheter valve-in-valve (ViV) replacement within a failed bioprosthetic aortic valve is proven and medically necessary for individuals at high or prohibitive surgical risk (Predicted Risk of Mortality [PROM] score of ≥ 8%) when performed according to FDA labeled indications, contraindications, warnings and precautions. Note: Requests for transcatheter aortic heart valve replacement for low-flow/low-gradient aortic stenosis will be evaluated on a case-by-case basis. **Mitral** Transcatheter mitral valve repair is proven and medically necessary when used according to FDA labeled indications, contraindications, warnings and precautions in individuals with one of the following clinical indications for intervention: ● Primary (degenerative) mitral regurgitation (MR) when all of the following criteria are met:

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Transcatheter Heart Valve Procedures (continued)	Apr. 1, 2023		○ Moderate-to-severe or severe MR (grade ≥ 3); and ○ Symptomatic NYHA class III or IV; and ○ Prohibitive surgical risk as defined by ONE of the following: ▪ PROM score of ≥ 8% for individuals deemed likely to undergo mitral valve replacement; or ▪ PROM score of ≥ 6% for individuals deemed likely to undergo mitral valve repair; or ▪ Predicted risk of death or major morbidity at 1 year of over 50%; and ○ Care directed by a multidisciplinary heart team which includes a heart failure specialist, interventional cardiologist and cardiothoracic surgeon experienced in the evaluation and treatment of heart failure and mitral valve disease. • Secondary (functional) MR when all of the following criteria are met: ○ Moderate-to-severe or severe MR (grade ≥ 3) with left ventricular ejection fraction (LVEF) ≥ 20 and ≤ 50; and ○ Symptomatic NYHA class II –IV (ambulatory); and ○ Optimal evidence-based management which includes pharmacologic therapy plus cardiac resynchronization therapy as indicated; and ○ High surgical risk (PROM score of ≥ 8%); and ○ Care directed by a multidisciplinary heart team which includes a heart failure specialist, interventional cardiologist and cardiothoracic surgeon experienced in the evaluation and treatment of heart failure and mitral valve disease. **Pulmonary** Transcatheter pulmonary heart valve replacement, using the Melody™ or Sapien valves, is proven and medically necessary, when used according to FDA labeled indications, contraindications, warnings and precautions, in individuals with right ventricular outflow tract (RVOT) dysfunction with one of the following clinical indications for intervention: • Moderate or greater pulmonary regurgitation; and/or • Pulmonary stenosis with a mean RVOT gradient ≥ 35 mmHg

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Transcatheter Heart Valve Procedures (continued)	Apr. 1, 2023		The following transcatheter heart valve devices and/or procedures are unproven and not medically necessary due to insufficient evidence of efficacy: • Cerebral protection devices (e.g., Sentinel™) • Mitral valve repair, reconstruction or replacement, except where noted above • Tricuspid valve repair, reconstruction or replacement • Valve-in-Valve (ViV) replacement within a failed bio-prosthesis for mitral, pulmonary, or tricuspid valves • Transcatheter pulmonary heart valve replacement using the Harmony™ valve

Upper Extremity Myoelectric Prosthetic Devices	Apr. 1, 2023	Title Change/Template Update
		• Relocated and reformatted content previously included in the Coverage Determination Guideline titled *Prosthetic Devices, Wigs, Specialized, Microprocessor or Myoelectric Limbs*
		• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans
		• Changed policy type classification from "Coverage Determination Guideline" to "Medical Policy"
		• Added *Application* section to indicate this Medical Policy applies to:
		  ○ All UnitedHealthcare Commercial benefit plans
		  ○ Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Nevada, and New York
			An upper extremity Myoelectric Prosthetic for amputations above the wrist is proven and Medically Necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Prosthetics, Myoelectric, Upper Extremity, Above the Wrist (Custom) - UHG.
			
			Click here to view the InterQual® criteria.
			
			An upper extremity Myoelectric Prosthetic hand, partial-hand, or artificial digit(s) for amputations below the wrist is Medically Necessary when the following criteria are met:
			• Member has a traumatic or surgical amputation below the wrist or a congenital missing or dysfunctional hand or finger; and
			• Prosthetic replaces all or part of a missing limb; and
			• Prosthetic will help the member regain or maintain function; and
			• Member is evaluated for his/her individual needs by a healthcare professional with the qualifications and training to make an evaluation under the supervision of the ordering physician; and
			• Member is willing and able to participate in the training for the use of the prosthetic; and
			• Member is able to operate the stimulator of the computerized prosthetic or microprocessor; and

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

Upper Extremity Myoelectric Prosthetic Devices
(continued)
	Apr. 1, 2023	**Related Policies**
		• Added reference link to the Medical Policy titled *Lower Extremity Prosthetics*
		Coverage Rationale
		• Revised language to indicate:
		  ○ An upper extremity Myoelectric Prosthetic for amputations above the wrist is proven and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Prosthetics, Myoelectric, Upper Extremity, Above the Wrist (Custom) - UHG
		  ○ An upper extremity Myoelectric Prosthetic hand, partial-hand, or artificial digit(s) for amputations below the wrist is medically necessary when the following criteria are met:
		  ▪ Member has a traumatic or surgical amputation below the wrist or a congenital missing or dysfunctional hand or finger; and
		  ▪ Prosthetic replaces all or part of a missing limb; and
		  ▪ Prosthetic will help the member regain or maintain
			• Functional assessment (including Activities Of Daily Living (ADLs) and Instrumental ADLs (IADLs)) evaluation and expected rehabilitation potential; and
			• Remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a Myoelectric Prosthetic Device (usually 3-5 muscle groups must be activated to use a computerized hand), no external switch; and
			• Ordering physician authorizes the final prosthetic proposal
			
			Myoelectric Prosthetic components for hand, partial-hand, and artificial digits below the wrist are considered not Medically Necessary in members who do not meet the criteria above.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Upper Extremity Myoelectric Prosthetic Devices (continued)	Apr. 1, 2023	function; and ▪ Member is evaluated for his/her individual needs by a healthcare professional with the qualifications and training to make an evaluation under the supervision of the ordering physician; and ▪ Member is willing and able to participate in the training for the use of the prosthetic; and ▪ Member is able to operate the stimulator of the computerized prosthetic or microprocessor; and ▪ Functional assessment (including Activities Of Daily Living (ADLs) and Instrumental ADLs (IADLs)) evaluation and expected rehabilitation potential; and ▪ Remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a Myoelectric Prosthetic Device (usually 3-5 muscle groups must be activated to use a computerized hand), no	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Upper Extremity Myoelectric Prosthetic Devices (continued)	Apr. 1, 2023	external switch; and ▪ Ordering physician authorizes the final prosthetic proposal ○ Myoelectric prosthetic components for hand, partial-hand, and artificial digits below the wrist are considered not medically necessary in members who do not meet the criteria above **Documentation Requirements** ● Updated list of HCPCS codes with associated documentation requirements; removed L6000, L6010, L6020, L6050, L6055, L6120, L6130, L6200, L6205, L6310, L6320, L6350, L6360, L6370, L6400, L6450, L6570, L6580, L6582, L6584, L6586, L6588, L6590, L6624, L6638, L6648, L6693, L6707, L6885, L6900, L6905, L6910, L6920, L6930, L6940, L6950, L6960, L6965, L6970, L7040, L7170, L7185, L7186, and L7499 ● Updated list of *Required Clinical Information* to reflect/include: ○ *Vendor Coversheet* with the narrative describing the request ○ Vendor invoice listing the HCPCS codes, make/ model	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Upper Extremity Myoelectric Prosthetic Devices (continued)	Apr. 1, 2023	description, indicate if the item is right or left; include, make, model, and pricing for unlisted codes ○ Other healthcare professional notes, if applicable (i.e., occupational therapist) ○ Current prescription ○ Professional qualification and training of the healthcare professional who performed the member evaluation ○ Physician office notes including documentation of: ▪ History related to the prosthetic request ▪ Co-morbidities ▪ Specify absent limb including the date, level and etiology of amputation ▪ Documentation of handedness ▪ Physical examination to include residual limb length and limb volume stability, skin integrity of residual limb, examination of contralateral limb, manual muscle testing and ROM examination ▪ Describe limitations to Activities Of Daily Living (ADLs) and Instrumental	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Upper Extremity Myoelectric Prosthetic Devices (continued)	Apr. 1, 2023	ADLs (IADLs) without the prosthetic ▪ Prosthetist notes to include medical justification for each of the requested prosthetic components; if applicable, documentation should include a description of the current prosthesis, including the age and components of the current prosthetic arm ▪ Motivation to use device ▪ Member ability to tolerate prosthetic weight ▪ Member willingness and ability to participate in the training for the use of the prothesis (i.e., prosthetic rehabilitation) ▪ Member cognitive ability to operate prosthetic ▪ Reason myoelectric device is being requested ▪ Microvolt threshold and outcome of myotesting results ▪ Environment in which the device will be used ▪ Outcome of myoelectric prosthetic testing device ▪ Member ability to access	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Upper Extremity Myoelectric Prosthetic Devices (continued)	Apr. 1, 2023	services and care related to prosthetic ○ Specify whether the prosthetic is an initial, replacement, preparatory or definitive or a request to upgrade ○ Rehabilitation plan ○ Final prosthetic proposal from ordering physician ○ For replacement prosthesis, also include: ▪ Age of the current prosthesis ▪ Reason for replacement ▪ Estimated cost of adjustment or repair if applicable ○ For a socket replacement, include age of the current socket, reason for replacement, and comparative residual limb measurements showing a change in residual limb size, what adjustments have been made to the current socket to improve fit **Definitions** ● Added definition of: ○ Activities of Daily Living (ADLs) ○ Instrumental Activities of Daily Living (IADLs) ○ Prosthesis ● Removed definition of:	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Upper Extremity Myoelectric Prosthetic Devices (continued)	Apr. 1, 2023	○ Prosthetic Device ○ Upper Limb Prosthetic Categories • Updated definition of: ○ Medically Necessary ○ Myoelectric Prosthetic ○ Prosthetist Applicable Codes • Added HCPCS codes L7360, L7364, L7366, L7367, and L7368 • Removed HCPCS codes L6000, L6010, L6020, L6050, L6055, L6100, L6110, L6120, L6130, L6200, L6205, L6250, L6300, L6310, L6320, L6350, L6360, L6370, L6380, L6382, L6384, L6386, L6388, L6400, L6450, L6500, L6550, L6570, L6580, L6582, L6584, L6586, L6588, L6590, L6600, L6605, L6610, L6615, L6616, L6620, L6623, L6624, L6625, L6628, L6630, L6635, L6637, L6638, L6640, L6641, L6642, L6645, L6646, L6647, L6648, L6650, L6655, L6660, L6665, L6670, L6672, L6675, L6676, L6684, L6689, L6690, L6691, L6692, L6693, L6703, L6704, L6706, L6707, L6708, L6709, L6711, L6712, L6713, L6714, L6721, L6722, L6805, L6810, L6885, L6895, L6900, L6905, L6910, L6915,	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Upper Extremity Myoelectric Prosthetic Devices (continued)	Apr. 1, 2023	L6920, L6930, L6940, L6950, L6965, L6970, L7040, L7170, L7185, L7186, L7402, L7405, L7499, L7510, L7520, L7600, L7700, L8415, L8435, L8485, L8499, L8881, and L9900 Supporting Information • Added *Description of Services*, *Benefit Considerations*, *Clinical Evidence*, and *FDA* sections • Updated *References* section to reflect the most current information	

Replaced		
Policy Title	**Effective Date**	**Summary of Changes**
Surgical Treatment for Spine Pain	Apr. 1, 2023	• Policy replaced; refer to the Medical Policies titled: ○ Interspinous Fusion and Decompression Devices ○ Minimally Invasive Spine Surgery Procedures ○ Spinal Fusion and Decompression

New

Policy Title	Effective Date	Coverage Rationale
Hemgenix® (Etranacogene Dezaparvovec-Drlb)	Mar. 1, 2023	Hemgenix (etranacogene dezaparvovec-drlb) has been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Refer to the Medical Benefit Drug Policy titled Review at Launch for New to Market Medications for additional details. **Hemophilia B (i.e., Congenital Factor IX Deficiency, Christmas Disease)** Hemgenix is proven and medically necessary for the treatment of Hemophilia B (congenital Factor IX deficiency) when all of the following criteria are met: • Patient is 18 years of age or older; and • One of the following: ○ Both of the following: ▪ Diagnosis of severe hemophilia B; and ▪ Documentation of endogenous Factor IX levels less than 1% of normal Factor IX (< 0.01 IU/mL) or ○ All of the following: ▪ Diagnosis of moderately severe hemophilia B; and ▪ Documentation of endogenous Factor IX levels ≥ 1% ≤ 2% (greater than or equal to 0.01 IU/mL to less than or equal to 0.02 IU/mL); and ▪ One of the following: – Patient has current or historical life-threatening hemorrhage; or – Patient has repeated, serious spontaneous bleeding episodes and • Patient currently uses Factor IX prophylaxis therapy; and • Patient has had a minimum of 150 exposure days to prophylactic therapy with a Factor IX agent; and • Patient does not have a history of inhibitors to Factor IX; and • Patient does not screen positive for active Factor IX inhibitors as defined as greater than or equal to 0.6 Bethesda units [BU] prior to administration of Hemgenix; and • Liver health assessments including enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin)] and hepatic ultrasound and elastography are performed to rule out radiological liver abnormalities and/or sustained liver enzyme elevations; and • All of the following: ○ Documentation that the patient has been evaluated for the presence of preexisting neutralizing antibodies to the adenovirus vector (e.g., AAV-5) used to deliver the therapy; and ○ Documentation that the patient does not have anti-AAV antibody (e.g., AAV-5) titers exceeding 1:678; and

New		
Policy Title	**Effective Date**	**Coverage Rationale**
Hemgenix® (Etranacogene Dezaparvovec-Drlb) (continued)	Mar. 1, 2023	○ Patient will be enrolled in the CSL Behring study to measure pre-existing anti-AAV5 neutralizing antibodies and • One of the following: ○ Patient is not HIV positive; or ○ Patient is HIV positive and is well controlled with anti-viral therapy (i.e., CD4 + counts > 200/µL) and • The patient's hepatitis B surface antigen is negative; and • One of the following: ○ Patient's hepatitis C virus (HCV) antibody is negative; or ○ Patient's HCV antibody is positive, and the patient's HCV RNA is negative and • The patient is not currently using antiviral therapy for hepatitis B or C; and • Patient has not previously received treatment with Hemgenix (etranacogene dezaparvovec-drlb); and • Hemgenix is delivered by or in consultation with a Hemophilia Treatment Center (HTC); and • Hemgenix dosing is in accordance with the United States Food and Drug Administration approved labeling; and • Authorization will be issued for a single-use intravenous infusion only
Spevigo® (Spesolimab-Sbzo)	Feb. 1, 2023	Spevigo (spesolimab-sbzo) injection for intravenous use has been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Refer to the policy titled Review at Launch for New to Market Medications for additional details. **Generalized Pustular Psoriasis (GPP)** Spevigo is proven for the treatment of generalized pustular psoriasis flares when all of the following criteria are met: • Diagnosis of generalized pustular psoriasis (GPP); and • Patient has a GPP flare; and • Spevigo is dosed according to U.S. Food and Drug Administration labeled dosing for GPP flares; and • Total dose of Spevigo does not exceed two doses per single GPP flare; Note: If the patient has been treated with Spevigo for a previous GPP flare, then a new (different) GPP flare may be treated with up to two doses of Spevigo. and • Authorization will be for no more than 21 days. Spevigo is medically necessary for the treatment of generalized pustular psoriasis flares when all of the following criteria are met:

New		
Policy Title	**Effective Date**	**Coverage Rationale**

Spevigo® (Spesolimab-Sbzo)
(continued)
	Feb. 1, 2023	• Diagnosis of generalized pustular psoriasis (GPP) based on both of the following
		  ○ Presence of primary, sterile, macroscopically visible pustules on non-acral skin
		  ○ Pustulation is not restricted to psoriatic plaques
		and
		• One of the following:
		  ○ Patient has a moderate to severe GPP flare based on one of the following:
		  ▪ Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 3 (moderate)
		  ▪ Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation subscore ≥ 2 (mild)
		  ▪ Erythema and pustules cover ≥ 5% of body-surface area
		  ▪ New appearance or worsening of pustules
		  or
		  ○ All of the following:
		  ▪ Patient has already received one initial dose of Spevigo for a current GPP flare; and
		  ▪ Documentation that the patient requires a second dose of Spevigo in order to treat persistent GPP flare symptoms including one of the following:
		  – GPPPGA total score ≥ 2
		  – GPPPGA pustulation subscore ≥ 2
		  – Fever
		  – Asthenia
		  – Myalgia
		  – Elevated C-reactive protein
		  – Leukocytosis with peripheral blood neutrophilia (above the upper limit of normal [ULN])
		  and
		  ▪ The second dose of Spevigo is to be administered no sooner than one week after the initial dose of Spevigo
		and
		• Patient is not receiving Spevigo in combination with any of the following:
		  ○ Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cosentyx (secukinumab), Stelara (ustekinumab)]
		  ○ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
		  ○ Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
		and
		• Spevigo is dosed according to U.S. Food and Drug Administration labeled dosing for GPP flares; and
		• Total dose of Spevigo does not exceed two doses per single GPP flare;

New		
Policy Title	**Effective Date**	**Coverage Rationale**
Spevigo® (Spesolimab-Sbzo) (continued)	Feb. 1, 2023	Note: If the patient has been treated with Spevigo for a previous GPP flare, then a new (different) GPP flare may be treated with up to two doses of Spevigo. and • Prescribed by a dermatologist; and • Authorization will be for no more than 21 days. Spevigo (Spesolimab-sbzo) is unproven and not medically necessary for the treatment of the following conditions and situations: • Administration in excess of 2 doses per single GPP flare • Atopic dermatitis • Crohn´s disease • Hidradenitis suppurativa • Palmoplantar pustulosis • Plaque psoriasis • Prevention of GPP flares • Ulcerative colitis
Tzield™ (Teplizumab-Mzwv)	Feb. 1, 2023	Tzield has been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Refer to the Medical Benefit Drug Policy titled Review at Launch for New to Market Medications for additional details. Tzield, administered as a one-time 14-day course of therapy, is proven to delay the onset of stage 3 type 1 diabetes in patients that meet the following criteria: • Diagnosis of stage 2 type 1 diabetes confirmed by all of following: ○ At least two positive pancreatic islet autoantibodies ○ Dysglycemia without overt hyperglycemia using an oral glucose tolerance test (OGTT) ○ Clinical history of patient does not suggest type 2 diabetes and • Dosing is in accordance with the United States Food and Drug Administration approved labeling; and • Patient has not been previously treated with Tzield; and • Authorization will be issued for no more than 14 doses Tzield is medically necessary when all of the following criteria are met: • Diagnosis of stage 2 type 1 diabetes confirmed by all of the following:

New

Policy Title	Effective Date	Coverage Rationale
Tzield™ (Teplizumab-Mzwv) (continued)	Feb. 1, 2023	○ At least two of the following pancreatic islet autoantibodies: ▪ Glutamic acid decarboxylase 65 (GAD) autoantibodies ▪ Insulin autoantibody (IAA) ▪ Insulinoma-associated antigen 2 autoantibody (IA-2A) ▪ Zinc transporter 8 autoantibody (ZnT8A) ▪ Islet cell autoantibody (ICA) and ○ Dysglycemia without overt hyperglycemia on an oral glucose tolerance test (OGTT) defined by one of the following: ▪ Fasting blood glucose > 110mg/dL and < 126 mg/dL; or ▪ 2-hour post-prandial plasma glucose level ≥ 140 mg/dL and < 200 mg/dL; or ▪ 30-, 60-, or 90-minute post-prandial glucose level ≥ 200 mg/dL and ○ Clinical history of patient does not suggest type 2 diabetes and ● Prescribed by an endocrinologist; and ● Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ● Patient has not been previously treated with Tzield; and ● Authorization will be issued for no more than 14 doses

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ilumya® (Tildrakizumab-Asmn)	Mar. 1, 2023	Coverage Rationale ● Revised list of: ○ Biologic DMARDs the patient must not receive in combination with Ilumya; replaced "*Humira* (adalimumab)" with "adalimumab" ○ Preferred biologic products to which the patient has a history of failure, contraindication, or intolerance; replaced "Humira	Ilumya to be used as a self-administered, subcutaneous injection for the treatment of plaque psoriasis should be obtained under the pharmacy benefit. Ilumya (tildrakizumab) is proven for provider administration for the treatment of moderate to severe plaque psoriasis when the following criteria are met: ● For initial therapy: ○ Diagnosis of moderate to severe plaque psoriasis; and ○ Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug; physician must submit explanation; and ○ Patient is not receiving Ilumya in combination with any of the following: ▪ Biologic DMARD [e.g., Enbrel (etanercept), adalimumab, Cimzia

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Ilumya® (Tildrakizumab-Asmn) (continued)	Mar. 1, 2023	(adalimumab)" with "Humira *or* *Amjevita* (adalimumab)"	(certolizumab), Simponi (golimumab)] ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)] ▪ Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Initial authorization will be for no longer than 12 months. ● For continuation of therapy: ○ Documentation of positive clinical response to Ilumya therapy; and ○ Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug; physician must submit explanation; and ○ Patient is not receiving Ilumya in combination with any of the following: ▪ Biologic DMARD [e.g., Enbrel (etanercept), adalimumab, Cimzia (certolizumab), Simponi (golimumab)] ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)] ▪ Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] 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. Ilumya (tildrakizumab) is medically necessary for provider administration for the treatment of moderate to severe plaque psoriasis when the following criteria are met: ● For initial therapy, submission of medical records (e.g., chart notes, laboratory values) documenting all of the following: ○ Diagnosis of chronic moderate to severe plaque psoriasis; and ○ Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis; and ○ One of the following:

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Ilumya® (Tildrakizumab-Asmn) (continued)	Mar. 1, 2023		▪ Both of the following: – History of failure, contraindication, or intolerance to one of the following topical therapies: • Corticosteroids (e.g., betamethasone, clobetasol, desonide) • Vitamin D analogs (e.g., calcitriol, calcipotriene) • Tazarotene • Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus) • Anthralin • Coal tar and – History of failure to a 3-month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced or ▪ Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of plaque psoriasis [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Tremfya (guselkumab), Enbrel (etanercept)]. and ○ History of failure, contraindication, or intolerance to two of the following preferred biologic products: *(for Medicare reviews, refer to the CMS section [of the policy]*)* ▪ Humira or Amjevita (adalimumab) ▪ Stelara (ustekinumab) ▪ Tremfya (guselkumab) ▪ Cimzia (certolizumab) ▪ Skyrizi (risankizumab) ▪ Enbrel (etanercept) and ○ One of the following: *(for Medicare reviews, refer to the CMS section [of the policy]*)*

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ilumya® (Tildrakizumab-Asmn) (continued)	Mar. 1, 2023		▪ History of a 6-month trial of Cosentyx (secukinumab) with moderate clinical response yet residual disease activity; or ▪ Both of the following: – History of intolerance or adverse event to Cosentyx – Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Ilumya and ○ Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug; physician must submit explanation; and ○ Patient is not receiving Ilumya in combination with any of the following: ▪ Biologic DMARD [e.g., adalimumab, Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept), Enbrel (etanercept)] ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)] ▪ Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Prescribed by or in consultation with a dermatologist; and ○ Initial authorization will be for no longer than 12 months. ● For continuation of therapy: ○ Documentation of positive clinical response to Ilumya therapy; and ○ Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug. Physician must submit explanation; and ○ Patient is not receiving Ilumya in combination with any of the following: ▪ Biologic DMARD [e.g., Enbrel (etanercept), adalimumab, Cimzia (certolizumab), Simponi (golimumab)] ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ilumya® (Tildrakizumab-Asmn) (continued)	Mar. 1, 2023		▪ Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] 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.
Infliximab (Avsola®, Inflectra®, Remicade®, & Renflexis®)	Mar. 1, 2023	Coverage Rationale *Sarcoidosis* • Revised coverage criteria for initial therapy; replaced criterion requiring "infliximab is dosed no higher than 10 mg/kg, administered at week 0, 2, *6, and every 8* weeks thereafter" with "infliximab is dosed no higher than 10 mg/kg, administered at week 0, 2, *then once every 4 to 6* weeks thereafter" Supporting Information • Updated *Clinical Evidence*, *FDA*, *CMS*, and *References* sections to reflect the most current information	This policy refers to the following infliximab products: • Avsola® (infliximab-axxq) • Inflectra® (infliximab-dyyb) • Remicade® (infliximab) • Renflexis® (infliximab-abda) • Any FDA-approved infliximab biosimilar product not listed here* *Any U.S. Food and Drug Administration approved and launched infliximab biosimilar product not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare. Refer to the policy for complete details.
Leqvio® (Inclisiran)	Mar. 1, 2023	Coverage Rationale • Revised coverage criteria for initial therapy; replaced criterion allowing coverage when "LDL-C between *70* mg/dL and 99 mg/dL with ASCVD while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days or 120 days prior to starting Leqvio therapy" with "LDL-C between *55* mg/dL and 99 mg/dL with ASCVD while on	Leqvio (inclisiran) is proven and medically necessary for the treatment of heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) in patients who meet all of the following criteria: • For initial therapy, all of the following: ○ Diagnosis of one of the following: ▪ Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: – Both of the following: • Pre-treatment LDL-C greater than or equal to 190 mg/dL (greater than or equal to 155 mg/dL if less than 16 years of age); and

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Leqvio® (Inclisiran) (continued)	Mar. 1, 2023	maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days or 120 days prior to starting Leqvio therapy" **Supporting Information** • Updated *References* section to reflect the most current information	• One of the following: ○ Family history of myocardial infarction in first-degree relative < 60 years of age; or ○ Family history of myocardial infarction in second-degree relative < 50 years of age; or ○ Family history of LDL-C greater than or equal to 190 mg/dL in first- or second-degree relative; or ○ Family history of heterozygous or homozygous familial hypercholesterolemia in first- or second-degree relative; or ○ Family history of tendinous xanthomata and/or arcus cornealis in first- or second degree relative or – Both of the following: • Pre-treatment LDL-C greater than or equal to 190 mg/dL (greater than or equal to 155 mg/dL if less than 16 years of age); and • One of the following: ○ Functional mutation in LDL, apoB, or PCSK9 gene; or ○ Tendinous xanthomata; or ○ Arcus cornealis before age 45 or ▪ Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: – Acute coronary syndromes; or – History of myocardial infarction; or – Stable or unstable angina; or – Coronary or other arterial revascularization; or – Stroke; or – Transient ischemic attack; or – Peripheral arterial disease presumed to be of atherosclerotic origin and

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Leqvio® (Inclisiran) (continued)	Mar. 1, 2023		○ One of the following: ▪ Patient has been receiving at least 12 consecutive weeks of high intensity statin therapy [i.e. atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a high intensity statin at maximally tolerated dose or ▪ Both of the following: – Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e. more than 2 weeks) symptoms: • Myalgia (muscle symptoms without CK elevations); or • Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN]) and – Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin therapy [i.e. atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin ≥ 10 mg, pravastatin ≥ 10 mg, lovastatin 20-40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 20-40 mg up to 40mg twice daily or Livalo (pitavastatin) ≥ 1 mg] and will continue to receive a low-intensity or moderate-intensity statin at maximally tolerated dose or ▪ Patient is unable to tolerate low or moderate-, and high-intensity statins as evidenced by one of the following: – One of the following intolerable and persistent (i.e. more than 2 weeks) symptoms for low or moderate-, and high-intensity statins: • Myalgia (muscle symptoms without CK elevations); or • Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN]) or – Patient has a labeled contraindication to all statins

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Leqvio® (Inclisiran) (continued)	Mar. 1, 2023		or – Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations > 10 times ULN and ○ One of the following: ▪ One of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days or 120 days prior to starting Leqvio therapy: – LDL-C ≥ 100 mg/dL with ASCVD; or – LDL-C ≥ 130 mg/dL without ASCVD or ▪ Both of the following: – One of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days or 120 days prior to starting Leqvio therapy: • LDL-C between 55 mg/dL and 99 mg/dL with ASCVD; or • LDL-C between 100 mg/dL and 129 mg/dL without ASCVD and – One of the following: • Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia®) therapy as adjunct to maximally tolerated statin therapy; or • Patient has a history of contraindication, or intolerance to ezetimibe and ○ Used as an adjunct to a low-fat diet and exercise; and ○ Leqvio will not be used in combination with PCSK9 inhibitor therapy; and ○ Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided; and

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Leqvio® (Inclisiran) (continued)	Mar. 1, 2023		○ Leqvio dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Initial authorization will be for no more than 12 months. • For continuation of therapy, all of the following: ○ Documentation of a positive clinical response to therapy from pre-treatment baseline (e.g., achieved LDL-C goal of < 100 mg/dL or achieved a 50% reduction in LDL-C levels); and ○ Patient continues to receive statin at maximally tolerated dose (unless patient has an inability to take statins) in combination with Leqvio; and ○ Patient is continuing a low-fat diet and exercise regimen; and ○ Leqvio will not be used in combination with PCSK9 inhibitor therapy; and ○ Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided; and ○ Leqvio dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Reauthorization will be for no more than 12 months.
Maximum Dosage and Frequency	Mar. 1, 2023	**Related Policies** • Added reference link to the Medical Benefit Drug Policy titled *Skyrizi® (Risankizumab-Rzaa)* **Coverage Rationale** • Revised list of applicable drug products; added: ○ Bevacizumab-adcd (Vegzelma®) ○ Risankizumab-rzaa (Skyrizi®) ○ Vutrisiran (Amvuttra™)	This policy provides information about the maximum dosage per administration and dosing frequency for certain medications administered by a medical professional. Most medications have a maximum dosage and frequency based upon body surface area or patient weight or a set maximal dosage and frequency independent of patient body size. • abatacept (Orencia®) • aflibercept (Eylea®) • atezolizumab (Tecentriq®) • avelumab (Bavencio®) • bevacizumab (Avastin®) • bevacizumab-adcd (Vegzelma®) • bevacizumab-awwb (Mvasi™)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Maximum Dosage and Frequency (continued)	Mar. 1, 2023	*Maximum Allowed Quantities by HCPCS Units* • Added: Amvuttra (vutrisiran) ○ Maximum Dosage Per Administration: 25 mg ○ HCPCS Code: J0225 ○ Maximum Allowed: 25 HCPCS units (1 mg per unit) Skyrizi (risankizumab-rzaa) ○ Maximum Dosage Per Administration: 600 mg ○ HCPCS Code: J2327 ○ Maximum Allowed: 600 HCPCS units (1 mg per unit) *Maximum Allowed Quantities for National Drug Code (NDC) Billing* • Added: Amvuttra (vutrisiran) ○ NDC: 71336-1003-01 ○ How Supplied: 25 mg/0.5 mL PFS ○ Maximum Allowed: 0.5 mL Skyrizi (risankizumab-rzaa) ○ NDC: 71336-1003-01 ○ How Supplied: 00074-5015-01 ○ Maximum Allowed: 10 mL Vegzelma (bevacizumab-adcd) ○ For NDCs 32228-0011-01 and 32228-0011-02: ▪ How Supplied: 100 mg/4 mL vials	• bevacizumab-bvzr (Zirabev®) • bevacizumab-maly (Alymsys®) • brolucizumab-dbll (Beovu®) • cemiplimab-rwlc (Libtayo®) • certolizumab pegol (Cimzia®) • denosumab (Prolia® & Xgeva®) • durvalumab (Imfinzi®) • eculizumab (Soliris®) • emicizumab-kxwh (Hemlibra®) • golimumab (Simponi Aria®) • infliximab (Remicade®) • infliximab-axxq (Avsola™) • infliximab-dyyb (Inflectra®) • infliximab-abda (Renflexis®) • ipilimumab (Yervoy®) • nivolumab (Opdivo®) • omalizumab (Xolair®) • patisiran (Onpattro®) • pegaptanib sodium (Macugen®) • pegfilgrastim (Neulasta®) • pegfilgrastim-apgf (Nyvepria™) • pegfilgrastim-cbqv (Udenyca®) • pegfilgrastim-jmdb (Fulphila™) • pegfilgrastim-bmez (Ziextenzo®) • pembrolizumab (Keytruda®) • ranibizumab (Lucentis®) • ranibizumab-nuna (Byooviz™) • ranibizumab-eqrn (Cimerli™) • ravulizumab-cwvz (Ultomiris®) • risankizumab-rzaa (Skyrizi®) • rituximab (Rituxan®) • rituximab-pvvr (Ruxience™) • rituximab-abbs (Truxima®)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Maximum Dosage and Frequency (continued)	Mar. 1, 2023	▪ Maximum Allowed: 12 mL ○ For NDCs 32228-0011-03 and 32228-0011-04: ▪ How Supplied: 400 mg/16 mL vials ▪ Maximum Allowed: 96 mL *Maximum Allowed Frequencies* ● Added: Amvuttra (vutrisiran) ○ Diagnosis: Polyneuropathy from hATTR amyloidosis ○ Maximum Frequency: Administered once every 3 months Skyrizi (risankizumab-rzaa) ○ Diagnosis: Crohn's disease ○ Maximum Frequency: Administered intravenously (IV) initially at week 0, week 4, and week 8, then administered subcutaneously at week 12, and once every 8 weeks thereafter Vegzelma (bevacizumab-adcd) ○ Diagnosis: Oncology ○ Maximum Frequency: Administered once every 2 weeks Applicable Codes ● Added HCPCS codes J0225 and J2327 ● Added NDCs 00074-5015-01,	● rituximab-arrx (Riabni™) ● rituximab and hyaluronidase (Rituxan Hycela®) ● testosterone cypionate (Depo-Testosterone®) ● testosterone enanthate ● testosterone pellets (Testopel®) ● testosterone undecanoate (Aveed®) ● tildrakizumab-asmn (Ilumya™) ● tocilizumab (Actemra®) ● trastuzumab (Herceptin®) ● trastuzumab-anns (Kanjinti™) ● trastuzumab-dkst (Ogivri™) ● trastuzumab-dttb (Ontruzant®) ● trastuzumab-pkrb (Herzuma®) ● trastuzumab-qyyp (Trazimera™) ● ustekinumab (Stelara®) ● vedolizumab (Entyvio®) ● vutrisiran (Amvuttra™) ● zoledronic acid (zoledronic acid, Reclast®) The use of medications included in this policy when given within the maximum dosage and/or frequency based upon body surface area or patient weight or a set of maximal dosage and/or frequency independent of patient body size are proven when used according to labeled indications or when otherwise supported by published clinical evidence. The medications included in this policy when given beyond maximum dosages and/or frequency based upon body surface area or patient weight or a set maximal dosage independent of patient body size are not supported by package labeling or published clinical evidence and are unproven. This policy creates an upper dose limit based on the clinical evidence and the 95th percentile for adult body weight (140 kg) and body surface area (2.71 meters^2) in the U.S. (adult male, 30 to 39 years, Fryar, 2021). In some cases, the

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Maximum Dosage and Frequency (continued)	Mar. 1, 2023	32228-0011-01, 32228-0011-02, 32228-0011-03, 32228-0011-04, and 71336-1003-01 Supporting Information • Updated *References* section to reflect the most current information	maximum allowed units and/or vials may exceed the upper level limit as defined within this policy due to an individual patient body weight > 140 kg or body surface area > 2.71 meters. Refer to the policy for complete details.
RNA-Targeted Therapies (Amvuttra™ and Onpattro®)	Mar. 1, 2023	Coverage Rationale *Amvuttra (Vutrisiran)* • Revised coverage criteria for: Initial Therapy ○ Replaced criterion requiring "the patient has a baseline neuropathy impairment score (NIS) ≥ *10* and ≤ 130" with "the patient has a baseline neuropathy impairment score (NIS) ≥ *5* and ≤ 130" Continuation of Therapy ○ Replaced criterion requiring "the patient continues to have a NIS score ≥ *10* and ≤ 130" with "the patient continues to have a NIS score ≥ *5* and ≤ 130" Supporting Information • Updated *Clinical Evidence* section to reflect the most current information	Amvuttra (vutrisiran) and Onpattro (patisiran) are proven for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis. Amvuttra (vutrisiran) is medically necessary for the treatment of the polyneuropathy of hATTR amyloidosis in patients who meet all of the following criteria: • For initial therapy, all of the following: ○ Both of the following: ▪ Diagnosis of hATTR amyloidosis with polyneuropathy ▪ Documentation that the patient has a pathogenic TTR mutation (e.g., V30M) and ○ Documentation of one of the following: ▪ Patient has a baseline polyneuropathy disability (PND) score ≤ IIIb ▪ Patient has a baseline familial amyloid polyneuropathy (FAP) Stage 1 or 2 ▪ Patient has a baseline neuropathy impairment score (NIS) ≥ 5 and ≤ 130 ▪ Patient has a baseline Karnofsky performance status (KPS) score ≥ 60% and ○ Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.); and ○ Patient has not had a liver transplant; and ○ Patient is not receiving Amvuttra in combination with any of the

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
RNA-Targeted Therapies (Amvuttra™ and Onpattro®) (continued)	Mar. 1, 2023		following: ▪ RNA interference agents [e.g., Onpattro (patisiran), Tegsedi (inotersen)] ▪ Transthyretin stabilizers [e.g., Vyndaqel (tafamidis meglumine) or Vyndamax (tafamidis)] and ○ Prescribed by or in consultation with a neurologist; and ○ Dosing is in accordance with the US Food and Drug Administration prescribing information; and ○ Initial authorization is for no more than 12 months. ● For continuation of therapy, all of the following: ○ Patient has previously received treatment with Amvuttra and ○ Documentation of one of the following: ▪ Patient continues to have a PND score ≤ IIIb ▪ Patient continues to have a FAP stage 1 or 2 ▪ Patient continues to have a NIS score ≥ 5 and ≤ 130 ▪ Patient continues to have a KPS score ≥ 60% and ○ Documentation that the patient has experienced a positive clinical response to Amvuttra (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.); and ○ Patient is not receiving Amvuttra in combination with any of the following: ▪ RNA interference agents [e.g., Onpattro (patisiran), Tegsedi (inotersen)] ▪ Transthyretin stabilizers [e.g., Vyndaqel (tafamidis meglumine) or Vyndamax (tafamidis)] and ○ Prescribed by or in consultation with a neurologist; and ○ Dosing is in accordance with the US Food and Drug Administration prescribing information; and ○ Authorization is for no more than 12 months.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
RNA-Targeted Therapies (Amvuttra™ and Onpattro®) (continued)	Mar. 1, 2023		Onpattro (patisiran) are medically necessary for the treatment of the polyneuropathy of hATTR amyloidosis in patients who meet all of the following criteria: • For initial therapy, all of the following: ○ Both of the following: ▪ Diagnosis of hATTR amyloidosis with polyneuropathy ▪ Documentation that the patient has a pathogenic TTR mutation (e.g., V30M) and ○ Documentation of one of the following: ▪ Patient has a baseline polyneuropathy disability (PND) score ≤ IIIb ▪ Patient has a baseline familial amyloid polyneuropathy (FAP) Stage 1 or 2 ▪ Patient has a baseline neuropathy impairment score (NIS) ≥ 5 and ≤ 130 and ○ Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.); and ○ Patient has not had a liver transplant; and ○ Patient is not receiving Onpattro in combination with any of the following: ▪ RNA interference agents [e.g., Amvuttra (vutrisiran), Tegsedi (inotersen)]] ▪ Transthyretin stabilizers [e.g., Vyndaqel (tafamidis meglumine) or Vyndamax (tafamidis)] and ○ Prescribed by or in consultation with a neurologist; and ○ Dosing is in accordance with the US Food and Drug Administration prescribing information; and ○ Initial authorization is for no more than 12 months. • For continuation of therapy, all of the following: ○ Patient has previously received treatment with Onpattro; and

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
RNA-Targeted Therapies (Amvuttra™ and Onpattro®) (continued)	Mar. 1, 2023		○ Documentation of one of the following: ▪ Patient continues to have a PND score ≤ IIIb ▪ Patient continues to have a FAP Stage 1 or 2 ▪ Patient continues to have a NIS score ≥ 5 and ≤ 130 and ○ Documentation that the patient has experienced a positive clinical response to requested drug (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.); and ○ Patient is not receiving Onpattro in combination with any of the following: ▪ RNA interference agents [e.g., Amvuttra (vutrisiran), Tegsedi (inotersen)] ▪ Transthyretin stabilizers [e.g., Vyndaqel (tafamidis meglumine) or Vyndamax (tafamidis)] and ○ Prescribed by or in consultation with a neurologist; and ○ Dosing is in accordance with the US Food and Drug Administration prescribing information; and ○ Authorization is for no more than 12 months. Onpattro (patisiran) is unproven and not medically necessary for the treatment of: ● Sensorimotor or autonomic neuropathy not related to hATTR amyloidosis ● Primary or leptomeningeal amyloidosis

Coverage Determination Guideline Updates

Replaced		
Policy Title	**Effective Date**	**Summary of Changes**
Prosthetic Devices, Wigs, Specialized, Microprocessor or Myoelectric Limbs	Apr. 1, 2023	• Policy replaced; refer to the: ○ Medical Policies titled: ▪ Breast Reconstruction for breast prosthesis ▪ Lower Extremity Prosthetics ▪ Upper Extremity Myoelectric Prosthetic Devices ○ Member specific benefit plan document for: ▪ Ear, eye, facial, and nose prosthesis ▪ Wigs

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 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 Medical Policies, Medical Benefit Drug Policies, Coverage Determination Guidelines, and Utilization Review Guidelines is available at UHCprovider.com > Policies and Protocols > Commercial Policies > Medical & Drug Policies and Coverage Determination Guidelines.