UnitedHealthcare®

November 2019

medical policy update bulletin

Medical Policy, Medical Benefit Drug Policy & Coverage Determination Guideline Updates

In This Issue

Medical Policy Updates

Page

REVISED

Medical Benefit Drug Policy Updates

TAKE NOTE

REVISED

Coverage Determination Guideline (CDG) Updates

UPDATED

REVISED

Utilization Review Guideline (URG) Updates

UPDATED

REVISED

UnitedHealthcare®

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			

Articular Cartilage Defect Repairs	Jan. 1, 2020	**Title Change/Template Update**
		• Reorganized and renamed policy; combined content previously included in the Medical Policies titled:
		  ○ *Autologous Chondrocyte Transplantation in the Knee*
		  ○ *Osteochondral Grafting*
		• Added *Documentation Requirements* section
		Coverage Rationale
		• Revised coverage guidelines for:
		Autologous Chondrocyte Transplantation (ACT)
		  ○ Replaced coverage criterion requiring "[patient is an] *adult individual* younger than age 55" with "[patients is an] *individual* younger than age 55"
		  ○ Updated list of unproven and not medically necessary indications; replaced:
		  ▪ "Osteoarthritis" with "*treatment of cartilage damage associated with generalized* osteoarthritis"
		  ▪ "*Unstable* knee" with "*joint instability of the* knee"
		  ▪ "Total meniscectomy" with "previous total meniscectomy"
		Osteochondral Autograft and Allograft Transplantation
		  ○ Replaced language indicating "osteochondral allograft transplantation *using human*
			Autologous chondrocyte transplantation (ACT) is proven and medically necessary for treating individuals with a single symptomatic full-thickness articular cartilage defect when ALL of the following criteria are met:
			• Defect is caused by acute or repetitive trauma;
			• Defect is greater than 2 squared cm;
			• Individual has defect in the articular cartilage of the femoral condyle (medial, lateral, or trochlea);
			• Individual has failed to respond to conservative treatment such as physical therapy, braces, and/or nonsteroidal anti-inflammatory drugs (NSAIDs);
			• Individual has had an inadequate response to a prior arthroscopic or other surgical repair procedure (e.g., debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft); and
			• Individual younger than age 55
			
			(ACT) is unproven and not medically necessary for treating individuals with the following indications due to insufficient evidence of efficacy:
			• Cartilage defects in locations other than the femoral condyle of the knee
			• Growth plates have not closed
			• Partial-thickness defects
			• History of multiple defects
			• History of defects of the patella
			• Osteochondritis dissecans
			• Previous history of cancer in the bones, cartilage, fat or muscle of the treated limb
			• Treatment of cartilage damage associated with generalized osteoarthritis
			• Joint instability of the knee
			• Previous total meniscectomy
			• Inflammatory diseases of the joint
			
			Osteochondral autograft and allograft transplantation is proven and medically necessary for treating cartilage defects of the knee when ALL of the following criteria are met:
			• Considered unsuitable candidate for total knee replacement
			• Individual must be capable and willing to participate in post-operative physical rehabilitation program
			• Individual who has achieved mature skeletal growth with documented

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Articular Cartilage Defect Repairs *(continued)*	Jan. 1, 2020	*cadaver tissue* is proven and medically necessary for treating cartilage defects of the knee when criteria are met" with "osteochondral allograft transplantation is proven and medically necessary for treating cartilage defects of the knee when criteria are met" ○ Replaced coverage criterion requiring: ▪ "Willingness to *comply with* rehabilitation following surgery" with "*individual must be capable and* willing to *participate in* post-operative *physical* rehabilitation *program*" ▪ "*Presence of* debilitating symptoms *that significantly* limit ambulation *and failed conventional* medical treatment (including physical therapy and/or bracing techniques) and/or prior surgical treatment" with "*persistent* symptoms of debilitating *knee pain* limiting ambulation *that have not been relieved by conservative* medical treatment (including physical therapy and/or bracing techniques) and/or prior surgical	closure of growth plates • Minimal to absent degenerative changes in surrounding articular cartilage (Outerbridge Grade II or less) • Normal alignment or correctable varus or valgus deformities • Persistent symptoms of debilitating knee pain limiting ambulation that have not been relieved by conservative medical treatment (including physical therapy and/or bracing techniques) and/or prior surgical treatment • Symptomatic focal full-thickness articular cartilage defect **Microfracture repair to treat full and partial thickness chondral defects of the knee is proven and medically necessary when ALL of the following criteria are met**: • Symptomatic focal cartilage defects (<2-4 cm^2) of the weight-bearing femoral condyles, tibial plateau, trochlea, and patella (identified by magnetic resonance imaging (MRI), arthrogram, or arthroscopy) • Outerbridge Grade 3-4 cartilage lesions **Focal articular cartilage repair is unproven and not medically necessary for treating individuals with any of the following due to insufficient evidence of efficacy**: • Osteochondral autograft and allograft transplantation for **all** other indications than those listed above • Minced articular cartilage repair (allograft or autograft) for treating osteochondral defects of the knee • Cryopreserved viable osteochondral allograft products (e.g., Cartiform) • Microfracture repair of the knee with any of the following indications: ○ Misalignment of the knee ○ Osteoarthritis ○ Systemic immune-mediated disease, disease-induced arthritis, or cartilage disease ○ Unwilling or unable to follow rehabilitation protocol

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Articular Cartilage Defect Repairs *(continued)*	Jan. 1, 2020	treatment" • Added language to indicate: ***Microfracture Repair*** ○ Microfracture repair to treat full and partial thickness chondral defects of the knee is proven and medically necessary when all of the following criteria are met: ▪ Symptomatic focal cartilage defects (<2-4 cm^2) of the weight-bearing femoral condyles, tibial plateau, trochlea, and patella [identified by magnetic resonance imaging (MRI), arthrogram, or arthroscopy] ▪ Outerbridge Grade 3-4 cartilage lesions ***Focal Articular Cartilage Repair*** ○ Focal articular cartilage repair is unproven and not medically necessary for treating individuals with any of the following due to insufficient evidence of efficacy: ▪ Cryopreserved viable osteochondral allograft products (e.g., Cartiform) ▪ Microfracture repair of the knee with any of the following indications: - Misalignment of the knee	

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Articular Cartilage Defect Repairs *(continued)*	Jan. 1, 2020	- Osteoarthritis - Systemic immune-mediated disease, disease-induced arthritis, or cartilage disease - Unwilling or unable to follow rehabilitation protocol **Definitions** • Added definition of: ○ Allograft *(procedure)* ○ Allograft Discs ○ Allografts *(items)* ○ Autografts ○ Microfracture ○ Osteochondral Autograft Transfer System (OATS) *(relocated from Description of Services)* ○ Osteochondral Autologous Transplant (OAT) • Updated definition of *(relocated from Description of Services)*: ○ Autologous Chondrocyte Transplantation (ACT) ○ Juvenile Cartilage Allograft Tissue Implantation ○ Minced Cartilage Repair ○ Mosaicplasty ○ Osteochondral Allograft (OCA) ○ Outerbridge Classification of Articular Lesions by Severity **Applicable Codes** • Added CPT code 29879 **Supporting Information** • Updated *Description of Services*,	

UnitedHealthcare®

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Articular Cartilage Defect Repairs *(continued)*	Jan. 1, 2020	*Clinical Evidence*, *CMS*, and *References* sections to reflect the most current information	
Computed Tomographic Colonography	Jan. 1, 2020	**Template Update** • Added *Documentation Requirements* section **Coverage Rationale** • Revised list of proven and medically necessary indications; replaced "as a screening test for colon cancer" with "as a screening test for colon cancer *for average risk individuals*" • Revised list of unproven and not medically necessary indications; replaced "as a diagnostic tool for *Crohn's disease"* with "as a diagnostic tool for *inflammatory bowel disease*" **Supporting Information** • Updated *Clinical Evidence*, *CMS*, and *References* sections to reflect the most current information	**The following is proven and medically necessary**: • Computed tomographic colonography for **any** of the following: ○ As a diagnostic tool for individuals on anticoagulation therapy ○ As a diagnostic tool for symptomatic individuals who are unable to undergo or are unable to tolerate a complete colonoscopy ○ As a screening test for colon cancer for average risk individuals **The following is unproven and not medically necessary due to insufficient evidence of efficacy**: • Computed tomographic colonography as a diagnostic tool for the following conditions: ○ Diverticulitis ○ Inflammatory bowel disease
Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation	Jan. 1, 2020	**Coverage Rationale** • Added language to indicate percutaneous electrical nerve field stimulation (PENFS) is unproven and not medically necessary **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	**Functional electrical stimulation (FES) is proven and medically necessary as a component of a comprehensive rehabilitation program in members with lower limb paralysis due to spinal cord injury (SCI) when all of 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;

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			

Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation *(continued)*	Jan. 1, 2020		• 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 the following indications:
			• Disuse muscle atrophy if:
			  ○ The nerve supply to the muscle is intact; and
			  ○ The disuse muscle atrophy is not of neurological origin but results from other conditions including but not limited to casting, splinting or contractures
			• To improve wrist and finger function and prevent or correct shoulder subluxation in persons with partial paralysis following stroke
			
			The following are unproven and not medically necessary due to insufficient evidence of efficacy:
			• Dorsal root ganglion (DRG) stimulation
			• 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)
			• Peripheral subcutaneous field stimulation (PSFS) or peripheral nerve field stimulation (PNFS)
			• Pulsed electrical stimulation (PES)
			• Scrambler Therapy (ST)

Genetic Testing for Hereditary Cancer	Dec. 1, 2019	**Coverage Rationale** • Revised coverage criteria for **genetic testing for *BRCA1* and *BRCA2* for individuals *without* a personal history of a related cancer**; replaced criterion requiring "at least *two*	Genetic counseling is strongly recommended prior to these tests in order to inform persons being tested about the advantages and limitations of the test as applied to a unique person. **Hereditary Breast and Ovarian Cancer (*BRCA1/BRCA2*)** **Genetic testing for *BRCA1* and *BRCA2* for individuals with a personal history of a related cancer is proven and medically necessary in the**

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Genetic Testing for Hereditary Cancer *(continued)*	Dec. 1, 2019	Close Blood Relatives with a BRCA-Related Cancer" with "at least *one* Close Blood Relatives with a BRCA-Related Cancer" **Definitions** • Updated definition of "BRCA-Related Cancers" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	**following situations**: • Individuals with a *BRCA 1/2* pathogenic mutation detected in tumor tissue; or • Individuals with a personal history of pancreatic cancer; or • Men with a personal history of Breast Cancer; or • Men with a personal history of prostate cancer in any of the following situations: ○ At least one Close Blood Relative who has a *BRCA1* or *BRCA2* mutation; or ○ Metastatic prostate cancer; or ○ High risk prostate cancer (Gleason Score at least 7) with at least one Close Blood Relative with a BRCA-Related Cancer; or ○ At least two Close Blood Relatives with BRCA-Related Cancer; or ○ Ashkenazi Jewish ancestry; or ○ An unknown or Limited Family History • Women with a personal history of Ovarian Cancer; or • Women with a personal history of Breast Cancer in any of the following situations: ○ Metastatic Breast Cancer; or ○ Breast Cancer diagnosed at age 45 or younger; or ○ An additional Breast Cancer primary (prior diagnosis or bilateral cancer); or ○ Triple-Negative Breast Cancer diagnosed at age 60 or younger; or ○ At least one Close Blood Relative who has a *BRCA1* or *BRCA2* mutation; or ○ Ashkenazi Jewish ancestry; or ○ At least one Close Blood Relative with a BRCA-Related Cancer; or ○ An unknown or Limited Family History **Genetic testing for *BRCA1* and *BRCA2* for individuals *without* a personal history of a related cancer is proven and medically necessary in the following situations**: • A known *BRCA1*/*BRCA2* mutation in a Close Blood Relative; or • At least one Close Blood Relative with a BRCA-Related Cancer; or • Ashkenazi Jewish ancestry and at least one Close Blood Relative with a BRCA-Related Cancer **Genetic testing for *BRCA1* and/or *BRCA2* is unproven and not medically necessary for all other indications including**:

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Genetic Testing for Hereditary Cancer *(continued)*	Dec. 1, 2019		• Screening for cancer risk for individuals not listed in the proven indications above; or • Risk assessment of other cancers; or • Confirmation of direct to consumer genetic testing without meeting **any** of the proven indications above **Multi-Gene Hereditary Cancer Panel Testing Criteria** **Genetic testing with a Multi-Gene hereditary cancer Panel in individuals with an indication for testing for hereditary Breast and Ovarian cancer is proven and medically necessary if all of the following criteria are met**: • The suspected hereditary cancer syndromes can be diagnosed by testing of two or more genes included in the specific hereditary cancer Panel; and • The individual meets at least one of the criteria for Hereditary Breast and Ovarian Cancer (*BRCA1/BRCA2*) (see above section); and • The individual has a family history or personal history that is strongly suggestive of **more than one** hereditary cancer syndrome including at least one of the following: o A personal history of at least two different cancers (e.g., Breast and Ovarian); or o A personal history of cancer diagnosed at age 40 or younger; or o A personal history of cancer and at least one Close Blood Relative with a cancer associated with Lynch Syndrome; or o At least one Close Blood Relative diagnosed with a BRCA-Related Cancer at age 40 or younger; or o At least three Close Blood Relatives diagnosed with any cancer **Genetic testing with a Multi-Gene hereditary cancer Panel in individuals with an indication for testing for hereditary colorectal cancer is proven and medically necessary in the following situations**: • The suspected hereditary cancer syndromes can be diagnosed by testing of two or more genes included in the specific hereditary cancer Panel; and • The individual has a personal or family history with at least one of the following criteria for Hereditary Colorectal Cancer/Lynch Syndrome-Associated Cancer or colorectal polyposis syndrome: o A personal history of cancer associated with Lynch Syndrome; or o A personal history of cancer where tumor testing results demonstrate

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Genetic Testing for Hereditary Cancer *(continued)*	Dec. 1, 2019		that the cancer was MSI-high or had immunohistochemical staining showing the absence of one or more mismatch repair proteins (*MLH1, MSH2, MSH6* or *PMS2*); or ○ A personal history of colorectal polyposis with at least 10 adenomatous polyps, at least 2 hamartomatous polyps or at least 5 serrated polyps proximal to the sigmoid colon; or ○ At least one 1st degree Blood Relative with a cancer associated with Lynch Syndrome; or ○ At least one Close Blood Relative with a cancer associated with Lynch Syndrome diagnosed at age 50 or younger; or ○ At least one Close Blood Relative with at least two cancers associated with Lynch Syndrome; or ○ Two or more Close Blood Relatives with a cancer associated with Lynch Syndrome; or ○ At least one Close Blood Relative with a clinical diagnosis of Familial Adenomatous Polyposis, Attenuated Familial Adenomatous Polyposis, Juvenile Polyposis Syndrome or Peutz-Jeghers Syndrome; or ○ A PREMM5, MMRpro or MMRpredict Score of 2.5% or greater for having a Lynch syndrome gene mutation **Genetic testing with a Multi-Gene hereditary cancer Panel in individuals without an indication for testing for hereditary Breast and Ovarian cancer or colorectal cancer is proven and medically necessary in the following situations**: • The suspected hereditary cancer syndromes can be diagnosed by testing of two or more genes included in the specific hereditary cancer Panel; and • The results of testing will directly impact this individual's medical management; and • The individual has a family history or personal history that is strongly suggestive of **more than one** hereditary cancer syndrome as outlined below: ○ A personal history of at least two different cancers (e.g., Breast and colon); or ○ A personal history of cancer diagnosed at age 40 or younger; or ○ A personal history of cancer and at least one Close Blood Relative with a cancer associated with Lynch Syndrome; or ○ At least one Close Blood Relative diagnosed with a BRCA-Related Cancer at age 40 or younger; or

UnitedHealthcare®

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Genetic Testing for Hereditary Cancer *(continued)*	Dec. 1, 2019		○ At least three Close Blood Relatives diagnosed with any cancer **Genetic testing with a Multi-Gene hereditary cancer Panel in individuals diagnosed with cancer at age 18 or younger is proven and medically necessary**. **Multi-Gene hereditary cancer Panels are unproven and not medically necessary for all other indications**.
Skin and Soft Tissue Substitutes	Jan. 1, 2020	**Coverage Rationale** • Revised list of unproven and not medically necessary skin and soft tissue substitutes; added: ○ AlloGen™ ○ Amnio Wrap2™ ○ Amnion Bio™ ○ Artacent® Cord ○ Ascent™ ○ AxoBioMembrane™ ○ Axolotl™ Ambient or Axolotl Cryo ○ Axolotl Graft or Axolotl DualGraft ○ BellaCell HD™ ○ BioWound™, BioWound Plus, or BioWound Xplus ○ Cellesta Duo ○ Cellesta Cord ○ DermACELL AWM® or DermACELL AWM Porous ○ Fluid Flow™ ○ Fluid GF™ ○ Kerasorb® ○ Membrane Graft™ ○ Membrane Wrap™ ○ MyOwn Skin™ ○ Novafix™ ○ ProgenaMatrix™ ○ Surederm™ ○ SurGraft™	**<u>TransCyte™</u>** **TransCyte is proven and medically necessary for treating surgically excised Full-Thickness Thermal Burn wounds and deep Partial-Thickness Thermal Burn wounds before autograft placement**. **TransCyte is unproven and not medically necessary for all other indications due to insufficient evidence of efficacy**. **<u>Other Skin and Soft Tissue Substitutes</u>** **The following skin and soft tissue substitutes are unproven and not medically necessary for any indication* due to insufficient evidence of efficacy**: • Affinity® • AlloGen™ • AlloSkin™ • AlloWrap® • Amnio Wound™ • Amnio Wrap2™ • AmnioArmor™ • AmnioBand® • AMNIOEXCEL®, AMNIOEXCEL Plus, or BioDExcel™ • AmnioFix® • AMNIOMATRIX® or BioDMatrix™ • Amnion Bio™ • Architect® • Artacent® Cord • Artacent Wound or Artacent AC • ArthroFLEX® • Ascent™ • AxoBioMembrane™ • Axolotl™ Ambient or Axolotl Cryo

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Skin and Soft Tissue Substitutes *(continued)*	Jan. 1, 2020	○ SurgiCORD™ ○ SurgiGRAFT-DUAL ○ WoundFix™, WoundFix Plus, or WoundFix Xplus **Applicable Codes** • Added HCPCS codes Q4205, , Q4206, Q4208, Q4209, Q4210, Q4211, Q4212, Q4213, Q4214, Q4215, Q4216, Q4217, Q4218, Q4219, Q4220, Q4221, Q4222, and Q4226 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	• Axolotl Graft or Axolotl DualGraft • BellaCell HD™ • bio-ConneKt® • BioDfence™ or BioDFence DryFlex™ • Bioskin™ • Bioskin Flow • Biovance® • BioWound™, BioWound Plus, or BioWound Xplus • Cellesta™ or Cellesta Duo • Cellesta Cord • Cellesta Flowable Amnion • CLARIX® • CLARIX FLO® • Coll-e-Derm™ • Conexa™ • CorMatrix® • Cygnus™ • Cymetra™ • Cytal™ • DermACELL®*, DermACELL AWM® or DermACELL AWM Porous (*see asterisked note below when DermACELL is used during breast reconstruction*) • Derma-Gide™ • DermaPure™ • DermaSpan™ • Dermavest® or Plurivest® • EpiCord® • EpiFix® • Excellagen® • E-Z Derm® • FlowerAmnioFlo™ or FlowerFlo™ • FlowerAmnioPatch™ or FlowerPatch™ • FlowerDerm™ • Fluid Flow™ • Fluid GF™ • GammaGraft™ • Genesis Amniotic Membrane • Grafix® • GrafixPL®

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Skin and Soft Tissue Substitutes *(continued)*	Jan. 1, 2020		• Grafix PRIME® • GrafixPL PRIME® • Guardian • Helicoll™ • hMatrix® • Hyalomatrix® • Integra® Flowable Wound Matrix • InteguPly® • Interfyl™ • Keramatrix® • Kerasorb® • Kerecis™ Omega3 • Keroxx™ • Matrion™ • MatriStem® • Mediskin™ • Membrane Graft™ • Membrane Wrap™ • MemoDerm™ • MIRODERM™ • MyOwn Skin™ • NeoPatch™ • NEOX® • NEOX FLO® • Novachor™ • Novafix™ • NuShield® • PalinGen® Amniotic Tissue Allograft and PalinGen Flow products • PriMatrix® • ProgenaMatrix™ • ProMatrX™ • PuraPly®, PuraPly AM, or PuraPly XT • Repriza® • Restorigin™ • Revita™ • Revitalon® • SkinTE™ • STRATTICE™ • Stravix™ or StravixPL™

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Skin and Soft Tissue Substitutes *(continued)*	Jan. 1, 2020		• Surederm™ • SurGraft™ • SurgiCORD™ • SurgiGRAFT™ • SurgiGRAFT-DUAL • Talymed® • TenSIX® • TheraSkin® • TranZgraft® • TruSkin™ • WoundEx® • WoundEx™ Flow • WoundFix™, WoundFix Plus, or WoundFix Xplus • XCM BIOLOGIC® Tissue Matrix • XWRAP™ *Refer to the Coverage Determination Guideline titled *Breast Reconstruction Post Mastectomy* for information about coverage for skin and soft tissue substitutes used during post mastectomy breast reconstruction procedures.
Vagus and External Trigeminal Nerve Stimulation	Dec. 1, 2019	**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 implemented on **Dec. 1, 2019**. **Title Change** • Previously titled *Vagus Nerve Stimulation* **Coverage Rationale** • Revised coverage criteria for proven and medically necessary use of implantable vagus nerve stimulators for treating epilepsy; replaced criterion requiring "the individual is not a *surgical* candidate or has failed *a surgical intervention*" with "the individual	**Implantable vagus nerve stimulators are proven and medically necessary for treating epilepsy in individuals with ALL of the following** (see below for implants that allow detection and stimulation of increased heart rate): • Medically refractory epileptic seizures with failure of two or more trials of single or combination antiepileptic drug therapy or intolerable side effects of antiepileptic drug therapy; and • The individual is not a candidate for epilepsy surgery, has failed epilepsy surgery, or refuses epilepsy surgery after Shared Decision Making discussion; and • No history of left or bilateral cervical vagotomy. The U.S. Food and Drug Administration (FDA) identifies a history of left or bilateral cervical vagotomy as a contraindication to vagus nerve stimulation **Implantable vagus nerve stimulators are unproven and not medically necessary for treating ALL other conditions due to insufficient evidence of efficacy**. These conditions include but are not limited to: • Alzheimer's disease • Anxiety disorder

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Vagus and External Trigeminal Nerve Stimulation *(continued)*	Dec. 1, 2019	is not a candidate *for epilepsy surgery*, has failed *epilepsy surgery*, *or refuses epilepsy surgery after Shared Decision Making discussion*" • Revised list of unproven and not medically necessary indications: ○ Added external or transcutaneous (nonimplantable) trigeminal nerve stimulation devices (e.g., Monarch® eTNS System, Cefaly®) for preventing or treating all conditions, including but not limited to: ▪ Attention deficit hyperactivity disorder (ADHD) ▪ Depression ▪ Epilepsy ▪ Headache ○ Updated list of examples of vagus nerve stimulation implants that allow detection and stimulation of increased heart rate; added "SenTiva™ Model 1000" **Documentation Requirements** • Updated documentation requirements to reflect changes to the *Coverage Rationale* **Definitions** • Added definition of "Shared Decision Making" **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, *CMS*, and	• Autism spectrum disorder • Back and neck pain • Bipolar disorder • Bulimia • Cerebral palsy • Chronic pain syndrome • Cluster headaches • Depression • Fibromyalgia • Heart failure • Migraines • Morbid obesity • Narcolepsy • Obsessive-compulsive disorder • Paralysis agitans • Sleep disorders • Tourette's syndrome **The following are unproven and not medically necessary due to insufficient evidence of efficacy**: • Vagus nerve stimulation implants that allow detection and stimulation of increased heart rate (e.g., AspireSR™ Model 106, SenTiva™ Model 1000) for treating epilepsy • Transcutaneous (nonimplantable) vagus nerve stimulation (e.g., gammaCore® for headaches) for preventing or treating all indications • External or transcutaneous (nonimplantable) trigeminal nerve stimulation devices (e.g., Monarch® eTNS System, Cefaly®) for preventing or treating **all** conditions including but not limited to: ○ Attention deficit hyperactivity disorder (ADHD) ○ Depression ○ Epilepsy ○ Headache **Note**: For vagus nerve blocking for the treatment of obesity, refer to the Medical Policy titled *Bariatric Surgery*.

UnitedHealthcare®

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Vagus and External Trigeminal Nerve Stimulation *(continued)*	Dec. 1, 2019	*References* sections to reflect the most current information	
Visual Information Processing Evaluation and Orthoptic and Vision Therapy	Dec. 1, 2019	**Coverage Rationale** • Added language to indicate Pharmacologic Penalization Therapy is proven and medically necessary for treating Amblyopia **Definitions** • Added definition of "Pharmacologic Penalization Therapy" **Supporting Information** • Updated *Clinical Evidence*, *CMS*, and *References* sections to reflect the most current information	**The following are proven and medically necessary**: • Occlusion Therapy or Pharmacologic Penalization Therapy for treating Amblyopia • Orthoptic Therapy or Vision Therapy for treating Convergence Insufficiency • Prism Adaptation Therapy for treating Esotropia **The following are unproven and not medically necessary due to insufficient evidence of efficacy**: • Orthoptic Therapy or Vision Therapy for treating **all** other indications not listed above • Virtual perception therapy for treating any type of learning disability or language disorder • Vision Restoration Therapy (VRT) for treating visual field deficits following stroke or neurotrauma • Visual information processing to diagnose reading or learning disabilities

Medical Benefit Drug Policy Updates

Take Note

IMPLEMENTATION DELAYED FOR MEDICAL BENEFIT DRUG POLICY UPDATES

Implementation of the changes associated with the following **Medical Benefit Drug Policies**, previously announced for an **Oct. 1 2019** effective date, has been delayed until further notice:

- Actemra® (Tocilizumab) Injection for Intravenous Infusion
- Benlysta® (Belimumab)
- Cimzia® (Certolizumab Pegol) *(New)*
- Orencia® (Abatacept) Injection for Intravenous Infusion
- Simponi Aria® (Golimumab) Injection for Intravenous Infusion

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Botulinum Toxins A and B	Dec. 1, 2019	**Template Update** • Reorganized policy template; relocated *Background* and *FDA* sections **Coverage Rationale** • Revised medical necessity criteria: ***General Requirements*** ○ Added criterion for **initial therapy** requiring "botulinum toxin administration is no more frequent than every 12 weeks, regardless of diagnosis" ***Diagnosis-Specific Requirements*** ○ Removed criterion for **migraine headaches** requiring "botox will not be used in combination with CGRP antagonists [i.e., Aimovig (erenumab), Ajovy (fremanezumab), Emgality (galcanezumab)]" **Supporting Information** • Updated *Clinical Evidence*, *FDA*,	This policy refers to the following botulinum toxin types A and B: • Dysport® (abobotulinumtoxinA) • Xeomin® (incobotulinumtoxinA) • Botox® (onabotulinumtoxinA) • Myobloc® (rimabotulinumtoxinB) Refer to the policy for complete details on the coverage guidelines for *Botulinum Toxins A and B*.

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Botulinum Toxins A and B *(continued)*	Dec. 1, 2019	*CMS*, and *References* sections to reflect the most current information	
Clotting Factors, Coagulant Blood Products & Other Hemostatics	Nov. 1, 2019	**Coverage Rationale** • Revised coverage criteria for **emicizumab-kxwh [Hemlibra]**; added criterion requiring one of the following: ○ Patient is less than 7 years of age; or ○ Patient is 7 years of age or older and cannot self-inject and does not have a caretaker who can be trained to administer emicizumab; *or* ○ *Patient is receiving Hemlibra from a contracted hemophilia treatment center*	Refer to the policy for complete details on the coverage guidelines for *Clotting Factors, Coagulant Blood Products & Other Hemostatics*.
Erythropoiesis-Stimulating Agents	Jan. 1, 2020	**Template Update** • Reorganized policy template; relocated *Background* and *FDA* sections **Coverage Rationale** • Added language to indicate: ***Medical Necessity Plans*** ○ Coverage for Retacrit is contingent on criteria in the *Diagnosis-Specific Criteria* section of the policy; prior authorization is not required ○ Coverage for Epogen or Procrit is contingent on *Medical Necessity Criteria* and *Diagnosis-Specific Criteria* sections of the policy; in order to continue coverage, members already	This policy addresses the following erythropoiesis-stimulating agents (ESAs): • Aranesp® (darbepoetin alfa) • Epogen® (epoetin alfa) • Mircera® (methoxy polyethylene glycol-epoetin beta [MPG-epoetin beta]) • Procrit® (epoetin alfa) • Retacrit™ (epoetin alfa) **Medical Necessity Plans** **Coverage for Retacrit is contingent on criteria in the Diagnosis-Specific Criteria section.** Prior authorization is not required. **Coverage for Epogen or Procrit is contingent on Medical Necessity Criteria and Diagnosis-Specific Criteria.** In order to continue coverage, members already on these products will be required to change therapy to Retacrit unless they meet the criteria below. ***Medical Necessity Criteria*** Treatment with Epogen or Procrit is medically necessary for the indications specified in this policy when **one** the criteria below are met:

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Erythropoiesis-Stimulating Agents *(continued)*	Jan. 1, 2020	on these products will be required to change therapy to Retacrit unless they meet the *Medical Necessity Criteria* section of the policy ○ Treatment with Epogen or Procrit is medically necessary for the indications specified in this policy when one of the criteria below are met: ▪ Both of the following: - History of a trial of adequate dose and duration of Retacrit, resulting in minimal clinical response; and - Physician attests that, in their clinical opinion, the clinical response would be expected to be superior than experienced with Retacrit or ▪ Both of the following: - History of failure, contraindication, or intolerance to Retacrit; and - Physician attests that, in their clinical opinion, the same failure, contraindication, or intolerance would not be expected to	• **Both** of the following: ○ History of a trial of adequate dose and duration of Retacrit, resulting in minimal clinical response; **and** ○ Physician attests that, in their clinical opinion, the clinical response would be expected to be superior than experienced with Retacrit. **or** • **Both** of the following: ○ History of failure, contraindication, or intolerance to Retacrit; **and** ○ Physician attests that, in their clinical opinion, the same failure, contraindication, or intolerance would not be expected to occur with Epogen or Procrit. **Non-Medical Necessity Plans** Retacrit, Epogen, or Procrit is to be approved contingent on the coverage criteria in the Diagnosis-Specific Criteria section. **Diagnosis-Specific Criteria** "ESAs" will be used to refer to all erythropoiesis stimulating agents, unless otherwise specified. For the purposes of the *Coverage Rationale*, all hematocrit (Hct) values are either pretreatment (for the first 4-6 weeks of therapy) or obtained during treatment to assess ongoing titration and safety. **Anemia Due to Chronic Kidney Disease** ***Patients Receiving Dialysis*** **ESAs are proven for the treatment of anemia of chronic kidney disease (CKD) when ALL of the following criteria are met**: • Patient is on dialysis; **and** • Hematocrit is less than 30% at initiation of therapy. **ESAs are unproven to treat anemia of CKD in patients on dialysis for a hematocrit greater than or equal to 33%.** ***Patients NOT Receiving Dialysis*** **ESAs are proven for the treatment of anemia of chronic kidney disease (CKD) when ALL of the following criteria are met:** • Patient is **not** on dialysis; **and**

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Erythropoiesis-Stimulating Agents *(continued)*	Jan. 1, 2020	occur with Epogen or Procrit ***Non-Medical Necessity Plans*** ○ Retacrit, Epogen, or Procrit is to be approved contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section of the policy **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	• Hematocrit less than 30% at initiation of therapy; **and** • The rate of hematocrit decline indicates the likelihood of requiring a red blood cell (RBC) transfusion; **and** • Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. **ESAs are unproven to treat anemia of CKD in patients NOT on dialysis for a hematocrit greater than 30%.** **Anemia Due to Cancer Chemotherapy** **Aranesp, Epogen, Procrit, and Retacrit are proven when used to treat anemia in cancer chemotherapy when BOTH of the following criteria are met:** • Hematocrit less than 30% at initiation of therapy; **and** • There is a minimum of two additional months of planned chemotherapy. **Mircera is unproven for the treatment of anemia due to cancer chemotherapy.** **ESAs are unproven to treat anemia in patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.** **ESAs are unproven to treat anemia in patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion.** **Anemia Associated with Myelodysplastic Disease** **Aranesp, Epogen, Procrit, and Retacrit are proven to treat anemia associated with myelodysplastic disease (MDS) when BOTH of the following criteria are met:** • **One** of the following: A. Serum erythropoietin level ≤ 500 mUnits/mL; **or** B. Hematocrit is less than or equal to 30% at the initiation of therapy **and** • For **continuation of therapy**, the hematocrit remains less than 36%. **Anemia Associated with Zidovudine Treatment in HIV-Infected**

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Erythropoiesis-Stimulating Agents *(continued)*	Jan. 1, 2020		**Patients** **Epogen, Procrit, and Retacrit are proven to treat anemia in HIV-infected patients when BOTH of the following criteria are met:** • Patient is receiving zidovudine administered at ≤ 4200 mg/week; **and** • Endogenous serum erythropoietin level ≤ 500 mUnits/mL; **and** • Hematocrit is less than 30% at initiation of therapy. **Anemia in Patients with Hepatitis C with Ribavirin and Interferon Therapy** **Epogen, Procrit, and Retacrit are proven to treat anemia associated with hepatitis C virus infection when ALL of the following criteria are met:** • Patient is receiving ribavirin and interferon therapy; **and** • Hematocrit is less than or equal to 30% at initiation of therapy; **and** • For **continuation of therapy**, the hematocrit remains less than 36%. **Preoperative Use for Reduction of Allogeneic Blood Transfusions in Surgery Patients** **Epogen, Procrit, and Retacrit are proven perioperatively to reduce the need for allogeneic blood transfusions when ALL of the following criteria are met:** • Perioperative Hct is greater than 30% and less than or equal to 39%; **and** • Patient is at high risk for blood loss during surgery; **and** • Patient is unable or unwilling to donate autologous blood; **and** • Surgery procedure is elective, noncardiac, and nonvascular. **ESAs are unproven for patients who are willing to donate autologous blood pre-operatively or in patient undergoing cardiac or vascular surgery**. **Additional Information** For the purposes of this policy, a conversion factor of 3 should be used to estimate hematocrit when *only* the hemoglobin is measured, e.g., hemoglobin of 10 g/dL is approximately equal to a hematocrit of 30%, a hemoglobin of 11 g/dL is approximately equal to a hematocrit of 33%, and a hemoglobin of 12 g/dL is approximately equal to a hematocrit of 36%.

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Erythropoiesis-Stimulating Agents *(continued)*	Jan. 1, 2020		**Unproven** **ESAs are unproven for**: • Patients undergoing curative chemotherapy. For information regarding use of ESAs in patients receiving cancer chemotherapy, refer to information in the National Comprehensive Cancer Network (NCCN) Practice Guideline, Cancer- and Chemotherapy-Induced Anemia, as referenced in the *Professional Societies* section of the policy. • Patients with cancer receiving hormonal agents, biologic products or radiotherapy (unless also receiving concomitant myelosuppressive chemotherapy). • Patients who require an immediate correction of anemia as a substitute for RBC transfusions. • Patients undergoing cardiac or vascular surgery. • Patients scheduled for surgery who will donate autologous blood. • Patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure • Patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion.

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Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
UPDATED			
Breast Reduction Surgery	Nov. 1, 2019	**Coverage Rationale** • Removed language pertaining to "potential required documentation" **Documentation Requirements** • Updated documentation requirements for reduction mammoplasty to include language relocated from *Coverage Rationale* section	
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
REVISED			

Preventive Care Services	Dec. 1, 2019	**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 implemented on **Dec. 1, 2019**.
		
		Applicable Codes: Preventive Care Services
		Hepatitis B Virus Infection Screening
		• Updated service description for **Pregnant Women**:
		  ○ Removed June 2009 USPSTF "A" rating
		  ○ Added July 2019 USPSTF "A" rating to indicate the USPSTF recommends screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit
		Newborn Screenings
		• Updated service description; removed July 2008 USPSTF "B" rating
		• Removed list of applicable CPT/HCPCS codes for **Hearing Screening**: 92551, 92558, 92585, 92586, 92587, 92588,
			Refer to the policy for complete details on the coverage guidelines for *Preventive Care Services*.

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	
UPDATED			

Preventive Care Services *(continued)*	Dec. 1, 2019	and V5008
		Osteoporosis Screening
		• Updated list of applicable CPT codes; removed 77078
		Screening for Visual Impairment in Children
		• Updated service description/Bright Futures recommendation to indicate:
		  ○ Visual acuity screening is recommended for age 4 and 5 years, as well as in cooperative 3 year olds
		  ○ Instrument-based screening is recommended for age 12 and 24 months, in addition to the well visits at age 3 through 5 years
		• Revised preventive benefit instructions/age limit guidelines to indicate:
		  ○ **Visual acuity screening (CPT code 99173)**:
		  ▪ Up to age 21 years (ends on 22nd birthday): Does not have diagnosis code requirements for preventive benefits to apply
		  ○ **Instrument-based screening (CPT codes 99174 and 99177)**:
		  ▪ Age 1 to 5 (ends on 6th birthday): Does not have diagnosis code requirements for preventive benefits to apply
		  ▪ Age 6 to 21 years (ends	

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	
UPDATED			
Preventive Care Services *(continued)*	Dec. 1, 2019	on 22nd birthday): Refer to the Medical Policy titled *Omnibus Codes* for allowable diagnoses ***Hearing Tests (Bright Futures)*** • Updated list of applicable codes: ○ Added CPT/HCPCS codes 92558, 92585, 92586, 92587, 92588, and V5008 ○ Added ICD-10 diagnosis codes Z00.00 and Z00.01 • Revised preventive benefit instructions/age limit guidelines to indicate: ○ Ages 0-90 days: Does not have diagnosis code requirements for the preventive benefit to apply ○ Ages 91 days to 21 years (ends on 22nd birthday): Requires one of the diagnosis codes listed in [the *Hearing Tests (Bright Futures)* row of the policy]	

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Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Coverage Rationale
UPDATED		
Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) Scan – Site of Service	Nov. 1, 2019	**Title Change** • Previously titled *Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) Scan – Site of Care* **Template Update** • Added *Documentation Requirements* section **Supporting Information** • Removed *Clinical Evidence* section • Updated *References* section to reflect the most current information; no change to *Coverage Rationale* or *Applicable Codes*

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Outpatient Surgical Procedures – Site of Service	Nov. 1, 2019	**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 amended guidelines to be applied on **Nov. 1, 2019**. **Related Policies** • Updated list of related policies **Coverage Rationale** • Replaced language indicating "certain *elective* procedures performed in a hospital outpatient department are considered medically necessary for an individual who meets any of the criteria [listed in the policy]" with "certain *planned surgical* procedures performed in a hospital outpatient department are considered medically necessary for an individual who meets any of the criteria [listed in the policy]" • Revised medical necessity criteria; added criterion requiring "[the individual is] less	UnitedHealthcare members may choose to receive surgical procedures in an ambulatory surgical center (ASC) or other locations. We are conducting site of service medical necessity reviews, however, to determine whether the outpatient hospital department is medically necessary, in accordance with the terms of the member's benefit plan. If the outpatient hospital department is not considered medically necessary, this location will not be covered under the member's plan. **Certain planned surgical procedures performed in a hospital outpatient department are considered medically necessary for an individual who meets ANY of the following criteria**: • Advanced liver disease (MELD Score > 8) • Advance surgical planning determines an individual requires overnight recovery and care following a surgical procedure • Anticipated need for transfusion • Bleeding disorder requiring replacement factor or blood products or special infusion products to correct a coagulation defect • Brittle Diabetes • Cardiac arrhythmia (symptomatic arrhythmia despite medication) • Chronic obstructive pulmonary disease (COPD) (FEV1 <50%) • Coronary artery disease ([CAD]/peripheral vascular disease [PVD]) (ongoing cardiac ischemia requiring medical management recently placed [within 1 year] drug eluting stent) • Developmental stage or cognitive status warranting use of a hospital outpatient department • End stage renal disease ([hyperkalemia above reference range] peritoneal or hemodialysis) • History of cerebrovascular accident (CVA) or transient ischemic attack

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Coverage Rationale	
UPDATED			

Outpatient Surgical Procedures – Site of Service *(continued)*	Nov. 1, 2019	than 19 years of age"
		• Revised language pertaining to the inability to access an ambulatory surgical center:
		  ○ Replaced reference to "*elective* surgical procedure" with "*planned* surgical procedure"
		  ○ Added language to clarify *any one* of the listed situations are considered medically necessary
		• Revised language pertaining to the *Planned Surgical Procedures List* to indicate site of service medical necessity reviews will be conducted for the surgical procedures [listed in the policy] only when performed in an outpatient hospital setting
		Documentation Requirements
		• Added requirement for medical notes documenting physician privileging information related to the need for the use of the hospital outpatient department
		Applicable Codes
		• Reformatted content
		• Added ~~1,105~~ 919 CPT/HCPCS codes (see list for details; revised Nov. 1, 2019)
		Supporting Information
		• Updated *References* section to reflect the most current information
			(TIA) (recent event [< 3 months])
			• History of myocardial infarction (MI) (recent event [< 3 months])
			• Individuals with drug eluting stents (DES) placed within one year or bare metal stents (BMS) or plain angioplasty within 90 days unless acetylsalicylic acid and antiplatelet drugs will be continued by agreement of surgeon, cardiologist and anesthesia
			• Less than 19 years of age
			• Ongoing evidence of myocardial ischemia
			• Poorly Controlled asthma (FEV1 < 80% despite medical management)
			• Pregnancy
			• Prolonged surgery (> 3 hours)
			• Resistant hypertension (Poorly Controlled)
			• Severe valvular heart disease
			• Sleep apnea (moderate to severe Obstructive Sleep Apnea (OSA)
			• Uncompensated chronic heart failure (CHF) (NYHA class III or IV)
			
			A planned surgical procedure performed in a hospital outpatient department is considered medically necessary if there is an inability to access an ambulatory surgical center for the procedure due to ANY one of the following:
			• There is no geographically accessible ambulatory surgical center that has the necessary equipment for the procedure; or
			• There is no geographically accessible ambulatory surgical center available at which the individual's physician has privileges; or
			• An ASC's specific guideline regarding the individual's weight or health conditions that prevents the use of an ASC
			
			Planned Surgical Procedures List
			Site of service medical necessity reviews will be conducted for surgical procedures on the *Applicable Codes List* only when performed in an outpatient hospital setting.

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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, Utilization Review Guideline, and Quality of Care 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 and/or documentation review requirements 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 or documentation review requirements; 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 and/or documentation review requirements

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

Tips for using the Medical Policy Update Bulletin

- From the table of contents, click the policy title to be directed to the corresponding policy update summary.
- From the policy updates table, click the policy title to view a complete copy of a new, updated, or revised policy.

The complete library of UnitedHealthcare Medical Policies, Medical Benefit Drug Policies, CDGs, URGs, and QOCGs is available at **UHCprovider.com** > *Policies and Protocols > Commercial Policies > Medical & Drug Policies and Coverage Determination Guidelines.*