UnitedHealthcare®

July 2018

medical policy update bulletin

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

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.*

***Where information in this bulletin conflicts with applicable state and/or federal law, UnitedHealthcare follows such applicable federal and/or state law.**

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

Overview

This bulletin provides complete details on UnitedHealthcare Medical Policy, Medical Benefit Drug Policy, Coverage Determination Guideline (CDG), Utilization Review Guideline (URG), and/or Quality of Care Guideline (QOCG) updates. The inclusion of a health service (e.g., test, drug, device or procedure) in this bulletin indicates only that UnitedHealthcare has recently adopted 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. In the event of an inconsistency or conflict between the information provided in this bulletin and the posted policy, the provisions of the posted policy will prevail. 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.

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

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.

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

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.

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Utilization Review Guideline (URG) Updates

UPDATED

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		

Bronchial Thermoplasty	Jul. 1, 2018	• Updated coverage rationale:
		  ○ Replaced language indicating "[the listed service] is unproven *and* not medically necessary" with "[the listed service] is unproven *and/or* not medically necessary"
		  ○ Replaced reference to "patients" with "individuals"
		• Updated supporting information to reflect the most current clinical evidence, FDA information, and references

Cardiovascular Disease Risk Tests	Jul. 1, 2018	• Updated list of applicable CPT codes to reflect quarterly code edits; added 0052U

Cytological Examination of Breast Fluids for Cancer Screening	Jul. 1, 2018	• Updated coverage rationale:
		  ○ Replaced language indicating "[the listed services] are unproven *and* not medically necessary" with "[the listed services] are unproven *and/or* not medically necessary"
		  ○ Replaced reference to "*patient* selection criteria" with "selection criteria"
		• Updated supporting information to reflect the most current clinical evidence, FDA information, and references

Home Traction Therapy	Jul. 1, 2018	• Updated coverage rationale:
		  ○ Replaced language indicating "[the listed service] is unproven *and* not medically necessary" with "[the listed service] is unproven *and/or* not medically necessary"
		  ○ Replaced reference to "patient" with "member"
		• Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references

Light and Laser Therapy for Cutaneous Lesions and Pilonidal Disease	Jul. 1, 2018	• Updated coverage rationale:
		  ○ Replaced language indicating:
		  ▪ "[The listed service] is proven *and* medically necessary" with "[the listed service] is proven *and/or* medically necessary"
		  ▪ "[The listed services] are unproven *and* not medically necessary" with "[the listed services] are unproven *and/or* not medically necessary"
		  ○ Replaced reference to "patient" with "member"
		• Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references

Magnetic Resonance Spectroscopy (MRS)	Jul. 1, 2018	• Updated coverage rationale:
		  ○ Replaced language indicating "[the listed service] is unproven *and* not medically necessary" with "[the listed service] is unproven *and/or* not medically necessary"
		  ○ Replaced reference to "patients" with "individuals"
		• Updated supporting information to reflect the most current clinical evidence, FDA information, and references

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		

Meniscus Implant and Allograft	Jul. 1, 2018	• Updated coverage rationale:
		  ○ Replaced language indicating:
		  ▪ "[The listed service] is proven *and* medically necessary" with "[the listed service] is proven *and/or* medically necessary"
		  ▪ "[The listed service] is unproven *and* not medically necessary" with "[the listed service] is unproven *and/or* not medically necessary"
		  ○ Replaced references to "patient" with "individual"
		• Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references

Obstructive Sleep Apnea Treatment	Jul. 1, 2018	• Updated coverage rationale; replaced reference to "patients" with "individuals" • Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references

Total Artificial Heart	Aug. 1, 2018	• Updated coverage rationale:
		  ○ Replaced language indicating "[the listed service] is proven *and* medically necessary" with "[the listed service] is proven *and/or* medically necessary"
		  ○ Replaced reference to "patients" with "members"
		• Updated list of applicable CPT codes; removed 33929
		• Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references

Umbilical Cord Blood Harvesting and Storage for Future Use	Jul. 1, 2018	• Updated benefit considerations; replaced language indicating "examples [of long term storage excluded from coverage] include, but are not limited to, *long term storage of* blood, blood products*, sperm, eggs* and *any other body parts*" with "examples [of long term storage excluded from coverage] include, but are not limited to, *cryopreservation of tissue,* blood and blood products" • Updated coverage rationale; replaced language indicating "[the listed service] is unproven *and* not medically necessary" with "[the listed service] is unproven *and/or* not medically necessary" • Updated supporting information to reflect the most current clinical evidence, FDA information, and references

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			

Apheresis	Aug. 1, 2018	• Reorganized and revised coverage rationale:
		  ○ Replaced reference to "patients" with "individuals"
		  ○ Replaced language indicating:
			Therapeutic apheresis is proven and/or medically necessary for treating or managing the following conditions/diagnoses:
			• ABO incompatible heart transplantation in children less than 40 months of age (only as second line therapy)
			• ABO incompatible major hematopoietic stem cell/bone marrow transplant (only as second line therapy)

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Apheresis *(continued)*	Aug. 1, 2018	▪ "[The listed service] is proven *and* medically necessary" with "[the listed service] is proven *and/or* medically necessary" ▪ "[The listed service] is unproven *and* not medically necessary" with "[the listed service] is unproven *and/or* not medically necessary" ○ Modified list of conditions/ diagnoses for which treatment/management with therapeutic Apheresis is proven and/or medically necessary: ▪ Added: - ABO incompatible kidney transplantation, A²/A²B into B, deceased donor - ABO incompatible liver transplantation, desensitized ABOi, deceased donor - Cardiac transplantation, desensitization - Cardiac transplantation, recurrent rejection - Coagulation factor inhibitors, autoantibody via Immunoadsorption (IA)	• ABO incompatible kidney transplantation (only as second line therapy) ○ Antibody mediated rejection, living donor (LD) desensitization ○ A²/A²B into B, deceased donor • ABO incompatible liver transplantation, desensitized ABOi, deceased donor • Acute inflammatory demyelinating polyneuropathy (Guillain-Barré syndrome), primary treatment • Acute liver failure (requiring high volume plasma exchange) • Age-related macular degeneration, dry • ANCA-associated rapidly progressive glomerulonephritis (Granulomatosis with polyangiitis; and Microscopic Polyangiitis) ○ Dialysis dependent ○ Diffuse alveolar hemorrhage (DAH) • Anti-glomerular basement membrane disease(Goodpasture's syndrome) ○ Dialysis independent ○ DAH • Cardiac transplantation ○ Recurrent rejection ○ Desensitization • Chronic inflammatory demyelinating polyneuropathy • Coagulation factor inhibitors, autoantibody via immunoadsorption (IA) • Cutaneous T-cell lymphoma; mycosis fungoides; Sezary syndrome, erythrodermic • Familial hypercholesterolemia ○ Homozygous ○ Heterozygous (only as second line therapy) • Focal segmental glomerulosclerosis, recurrent in transplanted kidney (only as second line therapy) • Graft-versus-host disease, ○ Acute, skin and non-skin ○ Chronic, non-skin ○ Chronic, skin (only as second line therapy) • Hereditary hemochromatosis • Hyperleukocytosis, symptomatic • Hyperlipoproteinemia • Hyperviscosity in monoclonal gammopathies • Idiopathic dilated cardiomyopathy, NYHA class II-IV, via IA • Inflammatory bowel disease, via adsorptive cytapheresis • Lung transplantation, bronchiolitis obliterans syndrome

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			

Apheresis *(continued)*	Aug. 1, 2018	- Graft-versus-host disease, acute, skin and non-skin
		- Inflammatory bowel disease, via Adsorptive Cytapheresis
		- Lung transplantation, bronchiolitis obliterans syndrome
		- N-methyl D-aspartate receptor antibody encephalitis
		- Paraproteinemic polyneuropathies via Therapeutic Plasma Exchange (TPE), anti-MAG
		- Paraproteinemic polyneuropathies via Therapeutic Plasma Exchange (TPE), multifocal motor
		- Progressive multifocal leukoencephalopathy associated with natalizumab
		- Pruritus due to hepatobiliary diseases
		- Systemic lupus erythematosus nephritis
		- Thrombotic microangiopathy, complement mediated, MCP mutations
			• Multiple sclerosis
			  ○ Acute CNS inflammatory, demyelinating
			  ○ Relapsing form with steroid resistant exacerbations (only as second line therapy)
			• Myasthenia gravis
			• Neuromyelitis optica spectrum disorders, acute (Devic's syndrome) (only as second line therapy)
			• *N*-methyl D-aspartate receptor antibody encephalitis
			• Paraproteinemic polyneuropathies via Therapeutic Plasma Exchange (TPE)
			  ○ Anti-MAG
			  ○ Multifocal motor
			  ○ IgG/IgA
			  ○ IgM
			• Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS exacerbation)
			• Peripheral vascular diseases
			• Polycythemia vera; erythrocytosis
			• Progressive multifocal leukoencephalopathy associated with natalizumab
			• Pruritus due to hepatobiliary diseases
			• Renal transplantation, ABO compatible
			  ○ Antibody mediated rejection
			  ○ Desensitization, living donor
			• Rheumatoid arthritis, refractory (only as second line therapy)
			• Sickle cell disease
			  ○ Acute stroke or multiorgan failure
			  ○ Acute chest syndrome, severe (only as second line therapy)
			  ○ Primary or secondary stroke prevention
			  ○ Prevention of transfusional iron overload
			• Systemic lupus erythematosus nephritis
			• Thrombotic microangiopathy, complement mediated
			  ○ MCP mutations
			• Thrombotic microangiopathy, Shiga toxin mediated
			  ○ Absence of severe neurological symptoms
			• Thrombotic thrombocytopenic purpura
			• Vasculitis
			  ○ Behet's disease (adsorption granulocytapheresis)
			  ○ Idiopathic PAN (TPE)
			  ○ EGPA (TPE)

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Apheresis *(continued)*	Aug. 1, 2018	- Thrombotic microangiopathy, Shiga toxin mediated, absence of severe neurological symptoms - Vasculitis, Behet's disease (adsorption granulocytapheresis) - Vasculitis, EGPA (TPE) - Vasculitis, idiopathic PAN (TPE) - Wilson's disease, fulminant ▪ Removed: - Babesiosis - Cardiac allograft rejection - Cardiac allograft rejection prophylaxis - Cardiac allograft rejection, recurrent - Cryoglobulinemia - Hyperleukocytosis, leukostasis - Lung allograft rejection - Renal transplantation, desensitization, living or deceased donor recipients, positive crossmatch due to donor specific HLA antibody ▪ Replaced: - "Hyperviscosity in monoclonal	• Wilson's disease, fulminant **Therapeutic apheresis including plasma exchange, plasmapheresis, or photopheresis is unproven and/or not medically necessary for treating or managing the following conditions/diagnoses, including but not limited to**: • ABO incompatible liver transplantation, antibody mediated rejection • Acute disseminated encephalomyelitis • Acute inflammatory demyelinating polyneuropathy (Guillain-Barré syndrome), after IVIG • 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; warm autoimmune hemolytic anemia (WAIHA); cold agglutinin disease • Babesiosis • Burn shock resuscitation • Cardiac neonatal lupus • Cardiac transplantation o Antibody mediated rejection o Rejection prophylaxis • Catastrophic antiphospholipid syndrome • Chronic focal encephalitis (Rasmussen's encephalitis) • Coagulation factor inhibitors, o Alloantibody (via IA) o Autoantibody (via TPE or IA) • Complex regional pain syndrome • Cryoglobulinemia • Cutaneous T-cell lymphoma; mycosis fungoides; Sézary syndrome, non-erythrodermic • Dermatomyositis/polymyositis • Erythropoietic porphyria, liver disease • Focal segmental glomerulosclerosis, native kidney, steroid resistant

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			

Apheresis *(continued)*	Aug. 1, 2018	gammopathies, *symptomatic*" and "hyperviscosity in monoclonal gammopathies, *treatment of symptoms*" with "hyperviscosity in monoclonal gammopathies"
		- "ABO incompatible major hematopoietic stem cell transplant *(marrow)*" with "ABO incompatible major hematopoietic stem cell/*bone marrow* transplant"
		- "ANCA-associated rapidly progressive glomerulonephritis *(Wegener's Granulomatosis)*" with "ANCA-associated rapidly progressive glomerulonephritis *(Granulomatosis with polyangiitis; and Microscopic Polyangiitis), diffuse alveolar hemorrhage (DAH)*"
		- "Anti-glomerular basement membrane disease (Goodpasture's syndrome)" with "anti-glomerular
			• Hashimoto's encephalopathy
			• HELLP syndrome
			• Hematopoietic stem cell transplantation, HLA desensitized (major or minor HPC(A))
			• Hemolytic uremic syndrome
			• Hemophagocytic lymphohistiocytosis
			• Henoch-Schonlein purpura
			• Heparin induced thrombocytopenia and thrombosis
			• Hyperleukocytosis, prophylaxis
			• Hypertriglyceridemic pancreatitis
			• Immune thrombocytopenia
			• Immunoglobulin A nephropathy
			• Inflammatory bowel disease, via Extracorporeal Photopheresis
			• Lambert-Eaton myasthenic syndrome
			• Lung transplantation
			  ○ Antibody mediated rejection
			  ○ Desensitization
			• Malaria
			• Multiple sclerosis (unless noted above as proven)
			• Myeloma cast nephropathy
			• Nephrogenic systemic fibrosis
			• Neuromyelitis optica spectrum disorders, maintenance
			• Overdose, venoms, and poisoning
			• Paraneoplastic neurologic syndromes
			• Paraproteinemic polyneuropathy (unless noted above as proven)
			• Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (Sydenham's chorea, severe)
			• Pemphigus vulgaris
			• Phytanic acid storage disease (Refsum's disease)
			• Post transfusion purpura
			• Prevention of RhD alloimmunization after RBC exposure
			• Psoriasis
			• Red cell alloimmunization in pregnancy
			• Renal transplantation, ABO compatible, desensitized, deceased donor
			• Scleroderma (systemic sclerosis)
			• Sepsis with multiorgan failure
			• Sickle cell disease, non-acute (unless noted above as proven)
			• Stiff-person syndrome
			• Sudden sensorineural hearing loss

Medical Policy Updates

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REVISED			
Apheresis *(continued)*	Aug. 1, 2018	basement membrane disease (Goodpasture's syndrome)*, DAH*" - "Focal segmental glomerulosclerosis, recurrent" with "focal segmental glomerulosclerosis, recurrent *in transplanted kidney*" - "Idiopathic dilated cardiomyopathy, NYHA class II-IV" with "idiopathic dilated cardiomyopathy, NYHA class II-IV*, via IA*" - "Myasthenia gravis*, moderate-severe*" with "myasthenia gravis" - "Paraproteinemic polyneuropathies, IgG/IgA" with "paraproteinemic polyneuropathies *via Therapeutic Plasma Exchange (TPE)*, IgG/IgA" - "Paraproteinemic polyneuropathies, IgM" with "paraproteinemic polyneuropathies *via Therapeutic Plasma Exchange (TPE)*, IgM"	• Systemic lupus erythematosus, severe • Thrombocytosis • Thrombotic microangiopathy (unless noted above as proven) • Thyroid storm • Toxic epidermal necrolysis • Vasculitis (unless noted above as proven) • Voltage gated potassium channel antibodies There is insufficient evidence to conclude that apheresis, plasma exchange, plasmapheresis, immunoadsorption, or photopheresis is beneficial for health outcomes such as decreased morbidity and mortality rates in individuals with disorders other than those listed as proven. **Note**: Please see the *Description of Services* section of the policy for information regarding all apheresis-based procedures.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Apheresis *(continued)*	Aug. 1, 2018	- "Renal transplantation antibody mediated rejection" with "renal transplantation, *ABO compatible,* antibody mediated rejection" - "Renal transplantation desensitization, living donor" with "renal transplantation, *ABO compatible,* desensitization, living donor" - "Sickle cell disease, acute chest syndrome" with "sickle cell disease, acute chest syndrome, *severe*" - "Sickle cell disease, *treatment of* acute stroke or multiorgan failure" with "sickle cell disease, acute stroke or multiorgan failure" ▪ Removed first or secondary line of therapy indicators for: - ABO incompatible kidney transplantation, antibody mediated rejection, living donor (LD) desensitization	

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Apheresis *(continued)*	Aug. 1, 2018	- Anti-glomerular basement membrane disease (Goodpasture's syndrome), DAH - Chronic inflammatory demyelinating polyneuropathy - Cutaneous T-cell lymphoma; mycosis fungoides; Sezary syndrome, erythrodermic - Familial hypercholesterol-emia, homozygous - Focal segmental glomerulosclerosis, recurrent in transplanted kidney - Hyperviscosity in monoclonal gammopathies - Myasthenia gravis - Paraproteinemic polyneuropathies via Therapeutic Plasma Exchange (TPE), IgG/IgA - Paraproteinemic polyneuropathies via Therapeutic Plasma Exchange (TPE), IgM - Renal transplantation, ABO compatible, antibody mediated rejection - Sickle cell disease,	

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Apheresis *(continued)*	Aug. 1, 2018	acute stroke or multiorgan failure - Sickle cell disease, prevention of transfusional iron overload - Sickle cell disease, primary or secondary stroke prevention - Thrombotic thrombocytopenic purpura ○ Modified list of conditions/diagnoses for which treatment/management with therapeutic Apheresis, including plasma exchange, Plasmapheresis, or photopheresis, is unproven and/or not medically necessary: ▪ Added: - Cardiac transplantation, rejection prophylaxis ▪ Removed: - ANCA-associated rapidly progressive glomerulonephritis, with diffuse alveolar hemorrhage (DAH) (Granulomatosis with polyangiitis; and Microscopic Polyangiitis) - Familial hypercholesterolemia, homozygous with small blood	

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Apheresis *(continued)*	Aug. 1, 2018	volume - Hyperviscosity in monoclonal gammopathies, prophylaxis for rituximab - IgG/IgA or IgM type of paraproteinemic polyneuropathy treated with Immunoadsorption - Myasthenia gravis, pre-thymectomy - N-methyl D-aspartate receptor antibody encephalitis - Polycythemia vera, secondary erythrocytosis ▪ Replaced: - "Coagulation factor inhibitors" with "coagulation factor inhibitors*: alloantibody (via IA), autoantibody (via TPE or IA)*" - "Hematopoietic stem cell transplantation*,* HLA desensitized *or ABO incompatible* [major or minor HPC(A)]" with "hematopoietic stem cell transplantation, HLA desensitized [major or minor HPC(A)]" - "Inflammatory bowel	

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Apheresis *(continued)*	Aug. 1, 2018	disease" with "inflammatory bowel disease*, via Extracorporeal Photopheresis*" - "Lung transplantation" with "lung transplantation*: antibody mediated rejection, desensitization*" - "Paraproteinemic polyneuropathy*, multiple indications* (unless noted [in the policy] as proven)" with "paraproteinemic polyneuropathy (unless noted [in the policy] as proven)" - "Systemic lupus erythematosus, severe" with "systemic lupus erythematosus*, severe*" - "Thrombotic microangiopathy*, all indications*" with "thrombotic microangiopathy *(unless noted [in the policy] as proven)*" - "Vasculitis" with "vasculitis *(unless noted [in the policy] as proven)*"	

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Apheresis *(continued)*	Aug. 1, 2018	• Updated supporting information to reflect the most current clinical evidence, FDA information, and references	
Cochlear Implants	Aug. 1, 2018	• Revised coverage rationale: **Cochlear Implantation (Non-Hybrid)** ○ Replaced reference to "bilateral or unilateral cochlear implantation" with "bilateral or unilateral cochlear implantation *(non-hybrid)"* ○ Updated coverage criteria; added language to indicate a hearing aid trial is not required in an individual with a concern for meningitis-related cochlear ossification **Hybrid Cochlear Implantation** ○ Removed language indicating cochlear hybrid implants are unproven and/or not medically necessary for treating hearing loss ○ Added language to indicate: ▪ When used according to FDA labeled indications, contraindications, warnings and precautions, hybrid cochlear implantation is proven and/or medically necessary for treating individuals who meet all of the following criteria: - Diagnosis of bilateral	**Cochlear Implantation (Non-Hybrid)** **When used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions, bilateral or unilateral cochlear implantation (non-hybrid) is proven and/or medically necessary for treating individuals who meet ALL of the following criteria:** • Diagnosis of bilateral prelingual or postlingual moderate-to-profound sensorineural hearing impairment; and • Limited benefit from appropriate hearing (or vibrotactile) aids. A hearing aid trial is not required in an individual with a concern for meningitis-related cochlear ossification; and • Ability to follow or participate in a program of aural rehabilitation; and • Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation; and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system; and • No contraindications to surgery. Refer to the *U.S. Food and Drug Administration (FDA)* section of the policy for indications for each cochlear implant device. Specific criteria vary with the device. **Hybrid Cochlear Implantation** **When used according to FDA labeled indications, contraindications, warnings and precautions, hybrid cochlear implantation is proven and/or medically necessary for treating individuals who meet ALL of the following criteria:** • Diagnosis of bilateral severe to profound sensorineural hearing loss in the mid to high frequencies with residual low-frequency hearing sensitivity; and • Ability to follow or participate in a program of aural rehabilitation; and • Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system; and • No contraindications to surgery.

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Cochlear Implants *(continued)*	Aug. 1, 2018	severe to profound sensorineural hearing loss in the mid to high frequencies with residual low-frequency hearing sensitivity; and - Ability to follow or participate in a program of aural rehabilitation; and - Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system; and - No contraindications to surgery ▪ Refer to the *U.S. Food and Drug Administration (FDA*) section of the policy for indications for hybrid cochlear implant devices; specific criteria vary with the device • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	Refer to the *U.S. Food and Drug Administration (FDA)* section of the policy for indications for hybrid cochlear implant devices. Specific criteria vary with the device.

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes	Aug. 1, 2018	• Revised coverage rationale; removed language indicating continuous glucose monitoring using an implantable glucose sensor is investigational due to lack of U.S. Food and Drug Administration (FDA) approval • Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references	**Insulin Delivery** **External insulin pumps that deliver insulin by continuous subcutaneous infusion are proven and/or medically necessary for treating individuals with type 1 or insulin-requiring type 2 diabetes**. For applicable clinical coverage criteria, see MCG™ Care Guidelines, 22nd edition, 2018, Insulin Infusion Pump ACG:A-0339 (AC). **Note**: Programmable disposable external insulin pumps (e.g., Omnipod) are considered clinically equivalent to standard insulin pumps. **Nonprogrammable transdermal insulin delivery systems (e.g., V-Go) are unproven and/or not medically necessary for treating individuals with diabetes**. There is insufficient evidence in the clinical literature demonstrating the safety and efficacy of transdermal insulin delivery in the management of individuals with diabetes. **Implantable insulin pumps are investigational, unproven and/or not medically necessary for treating individuals with diabetes**. No implantable insulin pumps have received U.S. Food and Drug Administration (FDA) approval at this time. While some preliminary studies reported improved glycemic control and fewer episodes of hypoglycemia in carefully selected individuals, complications such as catheter blockage and infection were observed. Larger, randomized controlled trials are needed to determine the long-term impact of implantable insulin pumps on diabetes management. **Insulin infuser ports are unproven and/or not medically necessary for insulin delivery in individuals with diabetes**. There is insufficient evidence demonstrating that the use of insulin infuser ports results in improved glycemic control beyond what can be achieved by using standard insulin delivery methods. In addition, an increase in complications, such as infection at the port site, has been reported when using these devices. Further well-designed, large-scale randomized controlled trials are needed to establish the safety and efficacy of these devices. See the *Description of Services* section of the policy for further details on the various types of insulin delivery systems.

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes *(continued)*	Aug. 1, 2018		**Continuous Glucose Monitoring** **Short-term (3-7 days) continuous glucose monitoring by a healthcare provider for diagnostic purposes is proven and/or medically necessary for managing individuals with diabetes**. **Long-term continuous glucose monitoring for personal use at home is proven and/or medically necessary for managing individuals with type 1 diabetes who have demonstrated adherence to a physician ordered diabetic treatment plan and are on an intensive insulin regimen (3 or more insulin injections per day or insulin pump therapy)**. **Long-term continuous glucose monitoring for personal use at home is unproven and/or not medically necessary for managing individuals with type 2 diabetes or gestational diabetes**. There is insufficient evidence that the use of long-term continuous glucose monitoring leads to improvement of glycemic control in individuals with type 2 or gestational diabetes. **Continuous glucose monitoring using an implantable glucose sensor (e.g., Eversense) is unproven and/or not medically necessary for managing individuals with diabetes.** There is insufficient published clinical evidence to conclude that the use of continuous glucose monitoring using an implantable gluocose sensor leads to an improvement in glycemic control. The small sample sized studies lack adequate controls, randomization and blinding. **Continuous glucose monitoring using a noninvasive device is investigational, unproven and/or not medically necessary for managing individuals with diabetes due to lack of FDA approval**. There are no commercially available noninvasive systems at this time. There is insufficient published clinical evidence to assess the safety and efficacy of continuous glucose monitoring using a noninvasive device.
Laser Interstitial Thermal Therapy	Aug. 1, 2018	• Revised coverage rationale: ○ Replaced language indicating "[the listed service] is unproven *and* not medically necessary" with "[the listed	**Laser interstitial thermal therapy is considered unproven and/or not medically necessary for treating ANY condition or diagnosis, including but not limited to**: • Bone tumors • Brain tumors

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Laser Interstitial Thermal Therapy *(continued)*	Aug. 1, 2018	service] is unproven *and/or* not medically necessary" ○ Updated list of applicable conditions/diagnoses: ▪ Added "bone tumors" ▪ Replaced "prostate *cancer*" with "prostate *tumors*" • Updated list of applicable CPT codes; added 53899 • Updated supporting information to reflect the most current clinical evidence and references	• Breast tumors (i.e., benign or malignant) • Epilepsy (e.g., drug-resistant epilepsy, focal cortical dysplasias, mesial temporal lobe epilepsy) • Prostate tumors • Radiation necrosis There is insufficient published evidence in the clinical literature supporting the safety and efficacy of this minimally invasive surgical procedure. Further studies are needed to determine whether such treatment is beneficial for health outcomes.
Total Artificial Disc Replacement for the Spine	Sep. 1, 2018	• Revised coverage rationale: **Cervical Artificial Disc Replacement** ○ Updated coverage statements to clarify intervertebral disc replacement prosthetics must be FDA-approved ○ Replaced language indicating: ▪ "[The listed services] are proven *and* medically necessary" with "[the listed services] are proven *and/or* medically necessary" ▪ "[The listed service] is unproven *and* not medically necessary" with "[the listed service] is unproven *and/or* not medically necessary" ○ Replaced reference(s) to: ▪ "Patient(s)" and "persons" with	**Cervical artificial total disc replacement with an FDA-approved prosthetic intervertebral disc for Degenerative cervical Disc Disease with symptomatic intractable radiculopathy and/or myelopathy is proven and/or medically necessary in a skeletally mature individual when at least ONE of the following criteria is met**: • Herniated disc • Osteophyte formation **AND both of the following**: • Documented individual history of neck and/or upper extremity pain and/or a functional/neurological deficit associated with the cervical level to be treated • Failed at least six weeks of non-operative treatment prior to implantation (only applicable for elective surgery; emergent surgery does not require prior non-operative treatment) **Cervical artificial disc replacement with an FDA-approved prosthetic intervertebral disc is proven and/or medically necessary for treating symptoms of Degenerative Disc Disease at one level even if they have radiological evidence of Degenerative Disc Disease at multiple levels**. Radiologic evidence of Degenerative Disc Disease is common in individuals who are middle aged and older and does not necessarily correlate with clinical symptoms. **Cervical artificial total disc replacement with an FDA-approved**

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Total Artificial Disc Replacement for the Spine *(continued)*	Sep. 1, 2018	"individual(s)" ▪ "Neck and/or *arm* pain" with "neck and/or *upper extremity* pain" **Lumbar Artificial Disc Replacement** ○ Removed language indicating lumbar artificial total disc replacement is unproven and not medically necessary for treating single or multiple level degenerative disc disease in skeletally mature patients ○ Added language to indicate: ▪ Lumbar artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and/or medically necessary for treating single level Degenerative Disc Disease with symptomatic intractable discogenic low back pain in a skeletally mature individual when all of the following criteria are met: - Advanced Degenerative Disc Disease (DDD) in only one vertebral level between L3 and S1 characterized by moderate to severe Degenerative Disease with Modic changes (defined as	**prosthetic intervertebral disc is proven and/or medically necessary for treating symptomatic contiguous two level Degenerative Disc Disease in skeletally mature individuals when used according to U.S. Food and Drug Administration (FDA) labeled indications**. Note: Not all cervical artificial discs have FDA labeling for contiguous two level Degenerative Disc Disease. Only cervical artificial discs FDA labeled for contiguous two level disease are proven and medically necessary for this indication. Refer to the *FDA* section of the policy. **Cervical artificial disc replacement at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent) performed at the same surgical setting is unproven and/or not medically necessary**. This is commonly referred to as a hybrid surgery. There is insufficient published clinical evidence in peer-reviewed medical literature demonstrating the safety and efficacy of combination cervical spine surgery at multiple adjacent or non-adjacent levels. **Lumbar artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and/or medically necessary for treating single level Degenerative Disc Disease with symptomatic intractable discogenic low back pain in a skeletally mature individual when ALL of the following criteria are met**: • Advanced Degenerative Disc Disease (DDD) in only one vertebral level between L3 and S1 characterized by moderate to severe Degenerative Disease with Modic changes (defined as peridiscal bone signal above and below the disc space in question) confirmed on current complex imaging studies (i.e., computerized tomography [CT] scan or magnetic resonance imaging [MRI]) • Symptoms correlate with imaging findings • No more than Grade 1 Spondylolisthesis at the involved level or any listhesis at two or more lumbar segments • Presence of symptoms for at least one year • Failed at least 6 months of conservative treatment just prior to implantation of artificial disc. Conservative treatment shall include all of the following, unless contraindicated: physical therapy, anti-inflammatory medications, analgesics, muscle relaxants, and epidural steroid injections • Age 18 to 60 years

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Total Artificial Disc Replacement for the Spine *(continued)*	Sep. 1, 2018	peridiscal bone signal above and below the disc space in question) confirmed on current complex imaging studies (i.e., computerized tomography [CT] scan or magnetic resonance imaging [MRI]) - Symptoms correlate with imaging findings - No more than Grade 1 Spondylolisthesis at the involved level or any listhesis at two or more lumbar segments - Presence of symptoms for at least one year - Failed at least 6 months of conservative treatment just prior to implantation of artificial disc; conservative treatment shall include all of the following, unless contraindicated: physical therapy, anti-inflammatory medications, analgesics, muscle relaxants, and	• Favorable face to face psychological evaluation confirming candidacy for surgery • There are no contraindications to lumbar artificial total disc replacement, including, but not limited to the following: ○ Moderate or severe facet arthropathy or pars defect at the operative level on a preoperative MRI scan, CT scan or plain radiograph ○ Lumbosacral spinal fracture ○ Scoliosis of the lumbosacral spine ○ Active systemic infection or infection localized to the site of implantation ○ Tumor in the peritoneum, retroperitoneum or site of implantation ○ Osteoporosis or osteopenia as defined by recent (within one year) DEXA scan ○ Previous lumbar spine surgery, spinal stenosis or radicular compression syndromes or radiculopathy, especially due to disc herniation ○ Vascular, urological, or other peritoneal or retroperitoneal pathology that may preclude safe and adequate anterior spine exposure as required for the surgery **Lumbar artificial total disc replacement at more than one spinal level is unproven and/or not medically necessary.** There is insufficient published clinical evidence demonstrating the safety and efficacy of lumbar artificial total disc replacement at multiple adjacent or non-adjacent levels. Further research from larger, well-designed studies is needed to evaluate the safety and long-term effectiveness. **Lumbar artificial total disc replacement is unproven and/or not medically necessary with a history of prior lumbar fusion or when combined with a lumbar fusion at any level.** There is insufficient published clinical evidence to conclude that lumbar artificial total disc replacement is safe and effective when combined with a lumbar fusion. **Lumbar artificial total disc replacement is unproven and/or not medically necessary for treating ANY other indication.**

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Total Artificial Disc Replacement for the Spine *(continued)*	Sep. 1, 2018	epidural steroid injections - Age 18 to 60 years - Favorable face to face psychological evaluation confirming candidacy for surgery - There are no contraindications to lumbar artificial total disc replacement, including, but not limited to the following: • Moderate or severe facet arthropathy or pars defect at the operative level on a preoperative MRI scan, CT scan or plain radiograph • Lumbosacral spinal fracture • Scoliosis of the lumbosacral spine • Active systemic infection or infection localized to the site of implantation • Tumor in the peritoneum, retroperitoneum or site of	

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Total Artificial Disc Replacement for the Spine *(continued)*	Sep. 1, 2018	implantation • Osteoporosis or osteopenia as defined by recent (within one year) DEXA scan • Previous lumbar spine surgery, spinal stenosis or radicular compression syndromes or radiculopathy, especially due to disc herniation • Vascular, urological, or other peritoneal or retroperitoneal pathology that may preclude safe and adequate anterior spine exposure as required for the surgery ▪ Lumbar artificial total disc replacement at more than one spinal level is unproven and/or not medically necessary ▪ Lumbar artificial total disc replacement is unproven and/or not medically necessary with a history of prior lumbar fusion or when combined	

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Total Artificial Disc Replacement for the Spine *(continued)*	Sep. 1, 2018	with a lumbar fusion at any level ▪ Lumbar artificial total disc replacement is unproven and/or not medically necessary for treating any other indication [not listed as proven/medically necessary in the policy] • Added definition of: ○ Degenerative Disc Disease (DDD) ○ Grade 1 Spondylolisthesis • Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references	

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Coverage Rationale
NEW		
Ilumya™ (Tildrakizumab)	Jul. 1, 2018	Ilumya, for subcutaneous injection, is obtained under the pharmacy benefit when self-administered, and is indicated in the treatment of plaque psoriasis. **Initial Therapy** **Ilumya (tildrakizumab) is proven for provider administration for the treatment of moderate to severe plaque psoriasis when the following criteria are met:** I. Diagnosis of moderate to severe plaque psoriasis; **and** II. 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** III. Patient is not receiving Ilumya in combination with **any** of the following: A. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] B. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] C. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] **and** IV. Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** V. Initial authorization 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:** I. **Submission of medical records** (e.g., chart notes, laboratory values) documenting **all** of the following: A. Diagnosis of chronic moderate to severe plaque psoriasis; **and** B. Greater than or equal to 5 % body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis; **and** C. **Both** of the following: 1. History of failure, contraindication, or intolerance to **one** of the following topical therapies: a. Corticosteroids (e.g., betamethasone, clobetasol, desonide) b. Vitamin D analogs (e.g., calcitriol, calcipotriene) c. Tazarotene d. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus) e. Anthralin f. Coal tar **and** 2. History of contraindication, intolerance, or failure of a 3 month trial of methotrexate; **and** D. History of failure, contraindication, or intolerance to **two** of the following preferred biologic products: 1. Humira (adalimumab) 2. Stelara (ustekinumab) 3. Tremfya (guselkumab) **and**

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Coverage Rationale
NEW		
Ilumya™ (Tildrakizumab) *(continued)*	Jul. 1, 2018	E. **One** of the following: 1. History of a 6 month trial of Cosentyx (secukinumab) with moderate clinical response yet residual disease activity **or** 2. **Both** of the following: a. History of intolerance or adverse event to Cosentyx b. Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Ilumya **and** F. 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** G. Patient is not receiving Ilumya in combination with **any** of the following: 1. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)] 2. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] 3. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] **and** H. Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** I. Initial authorization will be for no longer than 12 months. **Continuation Therapy** **Ilumya (tildrakizumab) will be reauthorized for provider administration based on all of the following criteria:** I. Documentation of positive clinical response to Ilumya therapy; **and** II. 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** III. Patient is not receiving Ilumya in combination with **any** of the following: A. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] B. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] C. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] **and** IV. Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** V. Reauthorization will be for no longer than 12 months.
Parsabiv™ (Etelcalcetide)	Jul. 1, 2018	**Initial Therapy** **Parsabiv (etelcalcetide) is proven for the treatment of secondary hyperparathyroidism with chronic kidney disease when the following criteria are met:** I. Diagnosis of secondary hyperparathyroidism with chronic kidney disease; **and**

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Coverage Rationale
NEW		
Parsabiv™ (Etelcalcetide) *(continued)*	Jul. 1, 2018	II. Patient is on dialysis; **and** III. Patient is not receiving Parsabiv (etelcalcetide) in combination with Sensipar (cinacalcet hydrochloride); **and** IV. Prescribed by or in consultation with an endocrinologist or nephrologist; **and** V. Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** VI. Initial authorization will be for no longer than 12 months. **Parsabiv (etelcalcetide) is medically necessary for the treatment of secondary hyperparathyroidism with chronic kidney disease when the following criteria are met:** I. Diagnosis of secondary hyperparathyroidism with chronic kidney disease; **and** II. Patient is on dialysis; **and** III. **All** of the following: A. History of failure, contraindication, or intolerance to **one** phosphate binder (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.); **and** B. History of failure, contraindication, or intolerance to **one** vitamin D analog (e.g., calcitriol, Hectorol, Zemplar, etc.); **and** C. History of failure of maximum tolerated dosage, adverse reaction, or contradiction to Sensipar (cinacalcet hydrochloride); **and** IV. Patient is not receiving Parsabiv (etelcalcetide) in combination with Sensipar (cinacalcet hydrochloride); **and** V. Prescribed by or in consultation with an endocrinologist or nephrologist; **and** VI. Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** VII. Initial authorization will be for no longer than 12 months. **Continuation Therapy** **Parsabiv (etelcalcetide) will be reauthorized based on all of the following criteria:** I. Documentation of a reduction in serum calcium from baseline; **and** II. Patient is not receiving Parsabiv (etelcalcetide) in combination with Sensipar (cinacalcet hydrochloride); **and** III. Prescribed by or in consultation with an endocrinologist or nephrologist; **and** IV. Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** V. Reauthorization will be for no longer than 12 months.
Self-Administered Medications	Jul. 1, 2018	This Medical Benefit Drug Policy is to support benefit plan language to exclude from medical coverage those medications that are determined as "self-administered" by the patient for whom the drug is prescribed. A medication may be determined "**self-administered**" and will **not be covered under the medical benefit** when the following evidence is taken into consideration: I. Medication is **not** typically administered or directly supervised by a qualified provider or licensed/certified health professional in an outpatient setting; **and** II. Medication does **not** require continuous or periodic monitoring immediately before, during, or after

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Coverage Rationale
NEW		
Self-Administered Medications *(continued)*	Jul. 1, 2018	administration by a qualified provider or licensed/certified health professional in an outpatient setting; **and** III. Route of administration (e.g., oral, topical, rectal, subcutaneous or some intramuscular injections); **and** IV. Dosage form (e.g., prefilled syringe, auto-injector, tablet, capsule, suppository); **and** V. Acuity of condition (e.g., chronic disease); **and** VI. Frequency of administration; **and** VII. The medication is **not** specifically allowed under the medical benefit; **and** VIII. Standards of medical practice allowing for self-administration (e.g., self-infused hemophilia factor); **and** IX. Evaluation of any established medical literature or compendia including but not limited to: A. FDA approved prescribing information B. Manufacturer provided medical literature C. Peer reviewed medical literature D. Evidence-based practice guidelines E. Self-administration utilization statistics F. Compendia (e.g., IBM Micromedex® DRUGDEX®, Clinical Pharmacology)

Policy Title	Effective Date	Summary of Changes
UPDATED		
Brineura™ (Cerliponase Alfa)	Jul. 1, 2018	• Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or lists of applicable codes
Buprenorphine (Probuphine® & Sublocade™)	Jul. 1, 2018	• Updated list of applicable HCPCS codes: ○ Added Q9991* and Q9992* ○ Removed J3490 *(*quarterly code edit)*
Clotting Factors and Coagulant Blood Products	Jul. 1, 2018	• Updated list of applicable HCPCS codes: ○ Added Q9995* ○ Removed J3590 *(*quarterly code edit)*
Luxturna™ (Voretigene Neparvovec-Rzyl)	Jul. 1, 2018	• Updated list of applicable HCPCS codes: ○ Added C9032* ○ Removed C9399 *(*quarterly code edit)*
Off-Label/Unproven Specialty Drug Treatment	Jul. 1, 2018	• Updated supporting information to reflect the most current references; no change to coverage rationale

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Oncology Medication Clinical Coverage	Jul. 1, 2018	• Changed policy title; previously titled *Oncology Medication Clinical Coverage Policy* • Updated list of related policies; added reference link to the policy titled: ○ *Denosumab (Prolia® & Xgeva®)* ○ *White Blood Cell Colony Stimulating Factors* • Updated coverage rationale; modified *Additional Information* pertaining to National Comprehensive Cancer Network (NCCN) Guidelines: ○ Replaced language indicating: ▪ "[These] are a comprehensive set of *67* guidelines" with "[these] are a comprehensive set of *71* guidelines" ▪ "The guidelines are developed and updated by *52* volunteer panels, composed of more than *1,200* clinicians and oncology researchers representing the 27 NCCN Member Institutions and their affiliates" with "the guidelines are developed and updated by *54* volunteer panels, composed of more than *1,275* clinicians and oncology researchers representing the 27 NCCN Member Institutions and their affiliates"
Synagis® (Palivizumab)	Jul. 1, 2018	• Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or lists of applicable codes

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Pectus Deformity Repair	Jul. 1, 2018	• Updated coverage rationale; replaced reference to: ○ "Functional/physiological deficit" with "functional *or* physiological deficit" ○ "Functional/Physical" with "Functional *or* Physical Impairment" ○ "Functional/psychological consequences" with "functional *or* psychological consequences" • Updated definition of: ○ Functional or Physical or Physiological Impairment ○ Reconstructive Procedures ○ Sickness
Private Duty Nursing Services (PDN)	Jul. 1, 2018	• Routine review; no content changes
Rhinoplasty and Other Nasal Surgeries	Jul. 1, 2018	• Updated coverage rationale; replaced language indicating "repair of nasal vestibular stenosis or alar collapse is considered reconstructive and medically necessary when other causes have been *eliminated* as the primary cause of nasal obstruction" with "repair of nasal vestibular stenosis or alar collapse is considered reconstructive and medically necessary when other causes have been *ruled out* as the primary cause of nasal obstruction" • Updated definition of: ○ External Nasal Valve ○ Functional or Physical or Physiological Impairment ○ Reconstructive Procedures • Updated supporting information to reflect the most current references

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Breast Repair/ Reconstruction Not Following Mastectomy	Aug. 1, 2018	• Revised coverage rationale; added language to indicate removal of a breast implant and capsulectomy is covered, regardless of the indication for the initial implant placement, for treatment of anaplastic lymphoma of the breast when there is pathologic confirmation of the diagnosis by cytology or biopsy • Updated definitions: ○ Added definition of	**Indications for Coverage** If the member's condition meets the Women's Health and Cancer Rights Act (WHCRA) criteria, please refer to the Coverage Determination Guideline titled Breast Reconstruction Post Mastectomy. ***Criteria for a Coverage Determination as Reconstructive*** **Removal of breast implants with capsulectomy/capsulotomy for symptomatic capsular contracture is considered reconstructive when the following criteria are met**: • Baker grade III or IV capsular contracture ○ *Baker Grading System for Capsular Contracture*: ▪ Grade I – Breast is soft without palpable thickening ▪ Grade II – Breast is a little firm but no visible changes in

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Breast Repair/ Reconstruction Not Following Mastectomy *(continued)*	Aug. 1, 2018	"Anaplastic Lymphoma" ○ Modified definition of "Reconstructive Procedures" • Updated supporting information to reflect the most current references	appearance ▪ Grade III – Breast is firm and has visible distortion in shape ▪ Grade IV – Breast is hard and has severe distortion or malposition in shape; pain/discomfort may be associated with this level of capsule contracture (ASPS, 2005) • Limited movement leading to an inability to perform tasks that involve reaching or abduction. Examples include retrieving something from overhead, combing one's hair, reaching out or above to grab something to stabilize oneself. **Removal of a deflated saline breast implant shell is considered cosmetic unless the implants were done post mastectomy**. (See Coverage Determination Guideline titled Breast Reconstruction Post Mastectomy.) **Correction of inverted nipples is considered reconstructive when one of the following criteria are met**: • Member meets the Women's Health and Cancer Rights Act (WHCRA) criteria (see Coverage Determination Guideline titled Breast Reconstruction Post Mastectomy for details); or • Documented history of chronic nipple discharge, bleeding, scabbing or ductal infection. **Note**: Correction of congenital inverted nipples may be covered based on a state mandate or the member specific benefit plan document. See the definition of *Congenital Anomaly*. **Breast reconstruction done for Poland Syndrome (see *Definitions* section of the policy) is reconstructive**. Although no Functional Impairment may exist for the breast reconstruction for Poland Syndrome, this has been deemed reconstructive surgery. **Removal of a ruptured silicone gel breast implant is covered regardless of the indication for the initial implant placement**. Removal of a breast implant and capsulectomy is covered, regardless of the indication for the initial implant placement, for treatment of anaplastic lymphoma of the breast when there is pathologic confirmation of the diagnosis by cytology or biopsy.

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			

Breast Repair/ Reconstruction Not Following Mastectomy *(continued)*	Aug. 1, 2018		***Additional Information***
			Tissue protruding at the end of a scar ("dog ear"/standing cone), painful scars or donor site scar revisions must be reviewed to determine if the procedure meets reconstructive guidelines.
			
			Coverage Limitations and Exclusions
			Some states require benefit coverage for services that UnitedHealthcare considers Cosmetic Procedures, such as repair of external congenital anomalies in the absence of a Functional Impairment. Please refer to the member specific benefit plan document.
			• Cosmetic Breast Procedures are excluded from coverage. Examples include but are not limited to:
			  ○ Replacement of an existing breast implant if the earlier breast implant was performed as a cosmetic procedure. (Replacement of an existing breast implant is considered reconstructive if the initial breast implant followed mastectomy. See Coverage Determination Guideline titled Breast Reconstruction Post Mastectomy.)
			  ○ Breast reduction surgery that is determined to be a cosmetic procedure. This exclusion does not apply to breast reduction surgery which we determine is requested to treat a physiologic functional impairment or to coverage required by the Women's Health and Cancer Right's Act.
			  ○ Breast surgery only for the purpose of creating symmetrical breasts except when post mastectomy.
			  ○ Breast prosthetics or replacement following a cosmetic breast augmentation.
			• Revision of a prior reconstructed breast due to normal aging does not meet the definition of a covered reconstructive health service.

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Office Based Program	July 1, 2018	• Routine review; no content changes