UnitedHealthcare®

February 2016

medical policy update bulletin

Medical Policy, 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, Drug Policy, and Coverage Determination Guideline (CDG) 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, Drug Policy, and Coverage Determination Guideline (CDG) Updates

Overview

This bulletin provides complete details on UnitedHealthcare Medical Policy, Drug Policy, and Coverage Determination Guideline (CDG) updates. The appearance of a service 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 service or procedure. 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 an enrollee for services not covered by the applicable benefit plan unless first obtaining the enrollee's written consent, acknowledging that the service is not covered by the benefit plan and that they will be billed directly for the service.

A complete library of Medical Policies, Drug Policies, and Coverage Determination Guidelines (CDGs) is available at **UnitedHealthcareOnline.com** > *Tools & Resources > Policies, Protocols and Guides > 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 service, procedure, test, or device

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 procedural codes and/or services previously outlined 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 service or procedure 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.

In This Issue

Medical Policy Updates

Page

NEW

- Functional Endoscopic Sinus Surgery (FESS) - Effective May 1, 2016 4

UPDATED

- Bone or Soft Tissue Healing and Fusion Enhancement Products - Effective Feb. 1, 2016 4
- Fecal Calprotectin - Effective Feb. 1, 2016 9
- Home Hemodialysis - Effective Feb. 1, 2016 9
- Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins - Effective Feb. 1, 2016 10
- Transcranial Magnetic Stimulation - Effective Feb. 1, 2016..... 12

Drug and Biologics Policy Updates

UPDATED

- Alemtuzumab - Effective Feb. 1, 2016 & Mar. 1, 2016..... 14

Coverage Determination Guideline (CDG) Updates

REVISED

- Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/ Replacements - Effective Mar. 1, 2016 17
- Emergency Health Services and Urgent Care Center Services - Effective Mar. 1, 2016..... 17

Medical Policy Updates

NEW

Policy Title	Effective Date	Coverage Rationale

Functional Endoscopic Sinus Surgery (FESS)	May 1, 2016	**Please Note:** Medical necessity reviews will also include site of service (SOS), per the member's benefit plan. Please refer to the Site of Service Utilization Review Guideline for additional information on SOS reviews for these services.
		
		Functional endoscopic sinus surgery (FESS) is medically necessary for one or more of the following:
		• Patients with chronic rhinosinusitis (defined as rhinosinusitis lasting longer than 12 weeks) with both of the following:
		  ○ Chronic rhinosinusitis is confirmed on computed tomography (CT) scan by one or more of the following:
		  ▪ mucosal thickening
		  ▪ bony remodeling
		  ▪ bony thickening or
		  ▪ obstruction of the ostiomeatal complex
		  ▪ opacified sinus
		  ○ Symptoms persist despite medical therapy with one or more of the following:
		  ▪ Nasal lavage
		  ▪ Antibiotic therapy, if bacterial infection is suspected
		  ▪ Intranasal corticosteroids
		• Mucocele documented on CT scan
		• Complications of sinusitis such as abscess
		• Tumor documented on CT scan (such as polyposis or malignancy)
		• Recurrent acute rhinosinusitis (RARS)
		
		Drug eluting stents or drug eluting implants are unproven and not medically necessary for maintaining sinus ostial patency after sinus surgery.
		The evidence is insufficient to determine whether drug eluting sinus stents or drug eluting implants improve outcomes when used postoperatively following endoscopic sinus surgery. Further randomized clinical trials are needed that compare the devices to postoperative care without the device to determine whether they can improve postoperative outcomes for patients undergoing endoscopic sinus surgery.

UPDATED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Bone or Soft Tissue Healing and Fusion Enhancement Products	Feb. 1, 2016	• Updated coverage rationale; added language pertaining to clinical evidence/study findings for cell-based products to indicate: ○ Evidence in the published scientific literature has not demonstrated an improved	**Bone graft materials used in spinal fusion surgery can be categorized into the following domains:** • Autografts • Allografts including (cadaver bone graft) • Amniotic tissue membrane • Demineralized Bone Matrix (DBM) • Bone Morphogenetic Proteins (BMP)

Medical Policy Updates

UPDATED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Bone or Soft Tissue Healing and Fusion Enhancement Products *(continued)*	Feb. 1, 2016	health outcome benefit over standard therapies ○ Well-designed, large randomized comparative clinical trials are needed to demonstrate the efficacy and safety of mesenchymal stem cell (MSC) therapy for orthopedic indications • Updated definitions: ○ Revised definition of "allograft" ○ Added definition of "anorganic bone graft materials" ○ Removed definition of "xenografts" • Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references	• Ceramic-based products • Cell-based products • Platelet-Rich Plasma **Autografts** **Autografts are proven and medically necessary for bone fusion enhancement**: Autografts harvest bone for grafting from the person undergoing surgery. The harvested bone is typically retrieved from the patient's own tibia, fibula or iliac crest and then placed at the surgery site. **Allografts** **Demineralized bone matrix (DBM) is a type of allograft and is proven and medically necessary** for bone fusion enhancement. DBM is human bone processed with hydrochloric acid to remove mineral content. **Allografts are proven and medically necessary for bone fusion enhancement**. Allografts harvest bone for grafting from a person other than the surgical candidate. Cadaver bone is one type of allograft. **Amniotic Tissue Membrane** **The use of amniotic membrane products in the treatment of spine disease or in spine surgery is unproven and not medically necessary due to insufficient clinical evidence of safety and/or efficacy in published peer-reviewed medical literature.** Evidence is limited to animal studies only. No current clinical trials with humans were identified. There is limited evidence that amniotic tissue membrane improves health outcomes when used in lumbar spine fusion. Long term safety and efficacy have not been established. **Bone Morphogenetic Proteins (BMP)** **Bone Morphogenetic Protein-2 (rhBMP-2)** **Note:** As indicated in the Clinical Evidence section below, the use of bone morphogenic protein as an adjunct to spinal fusion surgery may be associated with significant adverse events. Thus, before using bone morphogenic protein, the physician should engage in a shared decision-

Medical Policy Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Bone or Soft Tissue Healing and Fusion Enhancement Products *(continued)*	Feb. 1, 2016		making process with the patient, discussing the potential advantages, harms and alternatives to the use of bone morphogenic protein as an adjunct to spinal fusion surgery. **Infuse® Bone Graft is proven and medically necessary for the enhancement of bone healing and/or fusion of the lumbar spine in patients who meet all of the following criteria**: • Implanted via an anterior approach and used in conjunction with an Infuse Bone Graft fusion device Infuse Bone Graft fusion devices include: ○ Infuse bone graft/LT-Cage ○ Infuse bone graft/Lumbar Tapered Fusion Device ○ Infuse bone graft/InterFix™ threaded fusion device ○ Infuse bone graft/Inter Fix™ RP threaded fusion device • Skeletally mature patient (18 years of age or older or radiographic evidence of epiphyseal closure) with degenerative disc disease at one level from L4–S1 • No more than Grade I spondylolisthesis at the involved level • Failure of at least 6 months of non-operative treatment **Infuse® Bone Graft is unproven and not medically necessary for all other indications including but not limited to the following:** • Enhancement of bone healing and/or fusion of the lumbar spine via a posterior approach. • Treatment of cervical spine or any other area with or without use of other devices including the PEEK device. • Known contraindications including: ○ hypersensitivity to recombinant human Bone Morphogenetic Protein-2, bovine Type I collagen or to other components of the formulation ○ Pregnancy ○ Active infection at operative site or patient has an allergy to titanium or titanium alloy • Planned use of grafting in the vicinity of a resected or extant tumor • Skeletally immature patient (younger than 18 years of age or 18 years of age or older with no radiographic evidence of epiphyseal closure) **Note:** The Infuse Bone Graft is also known as bone morphogenic, or morphogenetic protein-2, BMP-2. Posterolateral or posterior lumbar interbody fusion utilizing Infuse Bone Graft

Medical Policy Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Bone or Soft Tissue Healing and Fusion Enhancement Products *(continued)*	Feb. 1, 2016		has not received FDA approval. Available studies have demonstrated increased adverse events with the posterior approach. The safety and effectiveness of Infuse Bone Graft in the cervical spine have not been demonstrated. There is insufficient clinical evidence to support the use of Infuse Bone Graft with devices made of PEEK or other biocompatible materials. In addition, Infuse Bone Graft has not been approved by the FDA for use with PEEK cages. **When used according to U.S. Food and Drug Administration (FDA) indications, the Infuse/MASTERGRAFT™ Posterolateral Revision Device system is proven and medically necessary in patients who meet all of the following criteria:** • Implanted via a posterolateral approach • Presence of symptomatic posterolateral lumbar spine pseudoarthrosis • Skeletally mature patient (older than 21 years of age or radiographic evidence of epiphyseal closure) • Treatment of 2 or more levels of the lumbar spine • Autologous bone and/or bone marrow harvest is not feasible or is not expected to promote fusion. These patients are diabetics and smokers. **The Infuse/MASTERGRAFT™ Posterolateral Revision Device system is unproven and not medically necessary for all other indications including the following:** • Known contraindications including: ○ hypersensitivity to recombinant human Bone Morphogenetic Protein-2, bovine Type I collagen or to other components of the formulation ○ Known active malignancy or patients undergoing treatment for a malignancy ○ Pregnancy ○ Active infection at operative site • Planned use of grafting in the vicinity of a resected or extant tumor • Skeletally immature patient (younger than 21 years of age or no radiographic evidence of epiphyseal closure) • Infuse/MASTERGRAFT Posterolateral Revision Device system has not received FDA approval for any other indications except those indicated as proven. The safety and effectiveness of Infuse/MASTERGRAFT Posterolateral Revision Device system has not been demonstrated for other conditions in studies published in peer-reviewed literature.

Medical Policy Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Bone or Soft Tissue Healing and Fusion Enhancement Products *(continued)*	Feb. 1, 2016		**Bone Morphogenetic Protein-7 (BMP-7)** **OP-1 Implant and OP-1 Putty are unproven and not medically necessary for the enhancement of bone healing and/or fusion with or without use of other devices (including the PEEK device).** Use of BMP7 has not demonstrated accelerated healing. Available studies have been limited by substantial loss of study participants at follow-up as well as by short follow-up times. **Ceramic-Based Products** Ceramic-based products **such as beta tricalcium phosphate (b-TCP), calcium phosphate, calcium sulfate and bioactive glass, used alone or in combination with other grafts including bone marrow aspirate are unproven and not medically necessary for the enhancement of bone healing and/or fusion.** Only very weak conclusions about effectiveness of ceramic-based products may be drawn from studies because of small sample size, lack of control or comparison groups in most studies. The absence of a formal assessment of clinical outcomes in most studies limits the conclusions that can be drawn about the place of b-TCP in bone healing and fusion. Furthermore, definitive patient selection criteria have not been established for the use of b-TCP bone void fillers. **Note:** For additional information on ceramic-based products please see definition section. **Cell-Based Products** **Cell based products such as mesenchymal stem cells (MSC), are unproven and not medically necessary for the enhancement of bone healing.** Evidence in the published scientific literature has not demonstrated an improved health outcome benefit over standard therapies. Well-designed, large randomized comparative clinical trials are needed to demonstrate the efficacy and safety of MSC therapy for orthopedic indications. **Platelet-Rich Plasma** **Platelet-rich plasma (e.g., autologous platelet derived growth factor) is unproven and not medically necessary when used to enhance bone or soft tissue healing.**

Medical Policy Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Bone or Soft Tissue Healing and Fusion Enhancement Products *(continued)*	Feb. 1, 2016		Evidence in the published scientific literature is inconsistent and does not lend strong support to the clinical utility of using PRP to augment bone or soft tissue healing. **OptiMesh®** **The OptiMesh deployable grafting system is unproven and not medically necessary.** There is insufficient evidence that the use of OptiMesh will improve structural support of the vertebrae. Further studies are needed to evaluate safety and efficacy of this grafting system.
Fecal Calprotectin	Feb. 1, 2016	• Updated supporting information to reflect the most current clinical evidence, CMS information, and references; no change to coverage rationale or list of applicable codes	**Fecal measurement of calprotectin is unproven and not medically necessary for the diagnosis and management of all conditions including but not limited to the following:** • **Inflammatory bowel disease (IBD) including ulcerative colitis and Crohn's disease** • **Colorectal cancer** There is insufficient evidence that fecal calprotectin is effective as a biomarker for the diagnosis and management of intestinal disease. Before fecal calprotectin can be incorporated into routine clinical practice, studies in larger and diverse groups of patients will be needed to further clarify its role in clinical decision making and its effect on the outcome of treatment of the condition for which it is being used.
Home Hemodialysis	Feb. 1, 2016	• Updated coverage rationale; corrected reference to the *Medicare Benefit Policy Manual Chapter 11, Section 30.2* ***Home Dialysis*** *Training* • Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references	**Home hemodialysis (HHD) is a proven therapy as an alternative to facility-based hemodialysis for patients with end-stage renal disease and medically necessary when the following criteria are met:** • Patient is stable on dialysis with no evidence of complex skilled interventions being necessary during treatments • Patient or non-professional caregiver has the ability to perform and maintain home hemodialysis and has received comprehensive training regarding proper protocol. • Absence of complications and significant concomitant disease that would cause home hemodialysis to be unsafe or unsuitable • Presence of well-functioning vascular access **Professional staff-assisted home hemodialysis is medically necessary**

Medical Policy Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Home Hemodialysis *(continued)*	Feb. 1, 2016		**as an alternative to facility-based hemodialysis for patients with end-stage renal disease who meet ALL of the following criteria:** • Patient is stable on dialysis and not at increased risk as a result of having the procedure performed outside a dialysis center venue; and • Patient has well-functioning vascular access; and • Patient has medical contraindications to leaving home for hemodialysis; and • Patient or non-professional caregiver is not capable of performing home hemodialysis • Staff assisted home hemodialysis protocols generally match those provided in the hemodialysis center (i.e., at least 3 times per week, 3-4 hour treatments). The exact dialysis therapy employed is determined on an individual basis by the attending nephrologist. See the Medicare Benefit Policy Manual Chapter 11, Section 30.2 Home Dialysis Training. Available at: https://www.cms.gov/manuals/Downloads/bp102c11.pdf Accessed November 5, 2015.
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins	Feb. 1, 2016	• Clarified coverage limitations and exclusions; replaced language indicating: ○ "Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures" with "procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures *and therefore excluded from coverage*" ○ "Spider veins and/or telangiectasias are considered to be cosmetic	**I. Varicose Vein Ablative and Stripping Procedures:** A. **Radiofrequency ablation, endovenous laser ablation, stripping, ligation and excision of the great saphenous vein and small saphenous veins are considered reconstructive and medically necessary when ALL of the following criteria are present (1, 2, 3 and 4):** 1. **Junctional Reflux** (see definition section): a. Ablative therapy for the great or small saphenous veins will be considered reconstructive and therefore medically necessary only if junctional reflux is demonstrated in these veins; or b. Ablative therapy for accessory veins will be considered reconstructive and medically necessary only if anatomically related persistent junctional reflux is demonstrated after the great or small saphenous veins have been removed or ablated. 2. **Member must have one of the following functional impairments:** a. Skin ulceration; or b. Documented episode(s) of frank bleeding of the varicose vein due to erosion of/or trauma to the skin; or

Medical Policy Updates

UPDATED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins *(continued)*	Feb. 1, 2016	and therefore excluded from coverage" with "*Treatments for* spider veins and/or telangiectasias are considered to be cosmetic and therefore excluded from coverage" ○ "Endovenous ablation (radiofrequency and/or laser) of either reticular or telangiectatic veins is not reconstructive and not medically necessary" with "Endovenous ablation (radiofrequency and/or laser) of either reticular or telangiectatic veins is not reconstructive and not medically necessary *and therefore excluded from coverage*" • Updated coverage rationale; replaced references to "endomechanical ablation" with "endovenous mechanochemical ablation (MOCA)" • Updated definitions; added definition of "duplicate saphenous vein" • Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references	c. Documented superficial thrombophlebitis or documented venous stasis dermatitis; or d. Moderate to severe pain causing functional/physical impairment. 3. **Venous Size:** a. The great saphenous vein must be 5.5 mm or greater when measured at the proximal thigh immediately below the saphenofemoral junction via duplex ultrasonography b. The small saphenous vein or accessory veins must measure 5 mm or greater in diameter immediately below the appropriate junction. 4. **Duration of reflux, in the standing or reverse Trendelenburg position that meets the following parameters:** a. Greater than or equal to 500 milliseconds (ms) for the great saphenous, small saphenous or principle tributaries b. Perforating veins > 350 ms c. Some duplex ultrasound readings will describe this as moderate to severe reflux which will be acceptable. B. **Ablation of perforator veins is considered reconstructive and medically necessary when the following criteria are present:** 1. Evidence of perforator venous insufficiency measured by recent duplex ultrasonography report (see criteria above); and 2. Perforator vein size is 3.5 mm or greater; and 3. Perforating vein lies beneath a healed or active venous stasis ulcer. C. **Endovenous mechanochemical ablation (MOCA) of varicose veins using a percutaneous infusion catheter is unproven and not medically necessary for treating venous reflux.** There is insufficient evidence in the clinical literature supporting the safety and efficacy of MOCA for treating varicose veins. Further results from large, well-designed studies are needed to support the clinical utility of this approach. **II. Ligation Procedures:** A. **Ligation of the great saphenous vein at the saphenofemoral junction, as a stand-alone procedure, is unproven and not medically necessary for treating venous reflux.** Ligation performed without stripping or ablation is associated with high long-term recurrence rates due to neovascularization.

Medical Policy Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins *(continued)*	Feb. 1, 2016		B. **Ligation of the small saphenous vein at the saphenopopliteal junction, as a stand-alone procedure, is unproven and not medically necessary for treating venous reflux.** Ligation performed without stripping or ablation is associated with high long-term recurrence rates due to neovascularization. C. **Ligation at the saphenofemoral junction, as a stand-alone procedure, is proven and medically necessary, when used to prevent the propagation of an active clot to the deep venous system in patients with ascending superficial thrombophlebitis who fail or are intolerant of anticoagulation therapy.** D. **Ligation at the saphenofemoral junction, as an adjunct to radiofrequency ablation or endovenous laser ablation of the main saphenous veins, is unproven and not medically necessary for treating venous reflux.** Published clinical evidence has not demonstrated that the addition of saphenofemoral ligation to endovenous ablation procedures provides an additive benefit in resolving venous reflux or preventing varicose vein recurrence. Endovenous ablation is a clinically effective therapy for treating venous reflux. Adding ligation to the procedure adds clinical risk without adding clinical benefit.
Transcranial Magnetic Stimulation	Feb. 1, 2016	• Updated reference links to related policies • Updated coverage rationale; modified language pertaining to coverage guidelines for treatment of behavioral disorders: ○ Added reference link to the Optum Behavioral Solutions Coverage Determination Guideline titled *Transcranial Magnetic Stimulation (TMS)* ○ Removed reference link to the Optum Behavioral Solutions Technology	**Transcranial magnetic stimulation is unproven and not medically necessary for treating all medical (i.e., non-behavioral) conditions including the following:** • Chronic neuropathic pain • Dystonia • Epilepsy • Headaches • Parkinson's disease • Stroke • Tinnitus For behavioral disorders, refer to the Optum Behavioral Solutions Coverage Determination Guideline titled *Transcranial Magnetic Stimulation (TMS)* at Optum Provider Express > Clinical Resources > Guidelines/Policies/Manuals > Coverage Determination Guidelines.

Medical Policy Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Transcranial Magnetic Stimulation *(continued)*	Feb. 1, 2016	Assessments titled *NeuroStar Transcranial Magnetic Stimulation Therapy for Major Depression* and *Brainsway Deep TMS for Major Depression* • Updated supporting information to reflect the most current clinical evidence, CMS information, and references	Some studies have examined the use of transcranial magnetic stimulation for treating disorders such as pain, dystonia, epilepsy, headaches, Parkinson's disease, stroke, and tinnitus. However, because of limited studies and small sample size there is insufficient data to conclude that transcranial magnetic stimulation is beneficial for treating these conditions. **Navigated transcranial magnetic stimulation (nTMS) is unproven and not medically necessary for treatment planning or for diagnosing motor neuron diseases or neurological disorders.** There is limited information from the peer-reviewed published medical literature to conclude that navigated transcranial magnetic stimulation is an effective clinical diagnostic test. Most published studies involve a small number of patients. Randomized controlled trials with large populations are needed to evaluate how this test can reduce clinical diagnostic uncertainty or impact treatment planning.

Drug and Biologics Policy Updates

UPDATED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Alemtuzumab	Feb. 1, 2016	**Notice of Correction**: The following summary of changes has been modified. Revisions to the policy update announcement previously appearing in the Medical Policy Update Bulletin are outlined in red below. • Updated list of applicable HCPCS codes to reflect annual code edits: ○ Added J0202 ○ Removed ~~J9019~~ J9010 and Q9979	This drug policy will only be updated for ***non-oncology indications***. Please refer to the Oncology Medication Clinical Coverage Policy for updated information based on the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium for oncology indications associated with Campath (alemtuzumab) only. Campath (alemtuzumab) is **proven** for the treatment of:* 1. Patients undergoing peripheral blood stem cell (PBSC) and/or bone marrow transplantation 2. Patients undergoing solid organ transplantation * Effective September 4th, 2012, Campath (alemtuzumab) will no longer be available commercially, but will be provided through the Campath Distribution Program free of charge. Additional details about this program may be found at www.campath.com. UnitedHealthcare will not provide coverage of Campath in relapsing-remitting multiple sclerosis (RRMS). Lemtrada (alemtuzumab) is **proven and medically necessary** for treatment of relapsing-remitting multiple sclerosis when **all** of the following criteria are met: 1. Diagnosis of relapsing-remitting multiple sclerosis (RRMS) **AND** 2. **One** of the following: a. **Treatment-naïve to alemtuzumab:** (1) Patient has history of failure following a trial for at least 4 weeks **or** history of intolerance or contraindication to **two** of the following: (a) interferon β-1a (Avonex® or Rebif®) (b) interferon β-1b (Betaseron® or Extavia®) (c) glatiramer acetate (Copaxone®) (d) dimethyl fumarate (Tecfidera®) (e) teriflunomide (Aubagio®) (f) fingolimod (Gilenya®) (g) peginterferon beta-1a (Plegridy™) **AND** (2) Patient has not been previously treated with alemtuzumab **AND**
Alemtuzumab	Mar. 1, 2016	• Removed reference link to Drug Policy titled *Oncology Medication Clinical Coverage Policy* • Updated list of applicable ICD-9 diagnosis codes associated with deleted code J9010; removed V42.0, V42.1, V42.6, V42.7, V42.81, V42.82, V42.83, and V42.84 • Updated list of applicable ICD-10 diagnosis codes: ○ Replaced G35.0 with G35 (multiple sclerosis) ○ Removed Z94.0, Z94.1, Z94.3, Z94.2, Z94.4, Z94.81, Z94.84, Z94.83, and Z94.82 (codes associated with deleted code J9010)	

Drug and Biologics Policy Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Alemtuzumab *(continued)*	Mar. 1, 2016		(3) Patient is not receiving alemtuzumab in combination with another disease modifying agent (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, or teriflunomide) **AND** (4) Initial dosing is administered: 12 mg intravenously daily for 5 consecutive days **AND** (5) Regimen is administered only once within 12 months **OR** b. **Treatment-experienced with alemtuzumab:** (1) Patient has previously received treatment with alemtuzumab **AND** (2) Patient is not receiving alemtuzumab in combination with another disease modifying agent (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, or teriflunomide) **AND** (3) Retreatment dosing is administered: 12 mg intravenously daily for 3 consecutive days **AND** (4) Regimen is administered only once within 12 months Coverage of Lemtrada is limited up to two treatment courses (5 day initial and 3 day end course). Requests for additional doses/courses beyond two courses will not be approved. UnitedHealthcare will not provide coverage of Lemtrada for indications other than relapsing-remitting multiple sclerosis RRMS. Alemtuzumab is **unproven** for the treatment of: 1) Rheumatoid arthritis 2) Autoimmune neutropenia 3) Autoimmune hemolytic anemia 4) Pure red cell aplasia 5) Immune thrombocytopenic purpura 6) Evans syndrome 7) Autoimmune pancytopenia **Centers for Medicare and Medicaid Services (CMS):**

Drug and Biologics Policy Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Alemtuzumab *(continued)*	Mar. 1, 2016		Medicare does not have a National Coverage Determination (NCD) for alemtuzumab (Campath®). Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for Alemtuzumab (Campath®) and Chemotherapy Drugs and their Adjuncts. In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf. (Accessed October 1, 2014)

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/ Replacements	Mar. 1, 2016	• Revised coverage rationale: ○ Updated indications for coverage for ventilators; replaced reference to HCPCS code E0464 (expired 12/31/2015) with E0466 ○ Modified list of coverage limitations and exclusions; added language to indicate batteries are excluded unless specifically stated as covered in the enrollee specific benefit document	Refer to the policy for complete details on the coverage guidelines for Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements.
Emergency Health Services and Urgent Care Center Services	Mar. 1, 2016	• Revised coverage rationale/additional information; modified language pertaining to cost sharing if/when an urgent care center is part of a larger facility (e.g., hospital) to indicate: ○ If the enrollee leaves the urgent care center for services in other parts of the same facility (e.g., radiology department services) and then returns to the urgent care center for discharge, *a separate cost share may be applied, depending on the plan design* ▪ For example, if the enrollee has a fractured arm and is brought from the urgent care center to the radiology department of that same facility for an x-ray, and	Refer to the policy for complete details on the coverage guidelines for Emergency Health Services and Urgent Care Center Services.

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Emergency Health Services and Urgent Care Center Services	Mar. 1, 2016	is then returned to the urgent care center for discharge, *a separate cost share may be applied* ▪ Refer to the enrollee specific benefit document for cost sharing details	