UnitedHealthcare®

May 2015

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.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ablative Treatment for Spinal Pain	May 1, 2015	• Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references; no change to coverage rationale or list of applicable codes	**Thermal radiofrequency ablation of facet joint nerves is proven and medically necessary for chronic cervical, thoracic and lumbar pain when confirmed by:** • Temperature 60 degrees Celsius or more; • Duration of ablation 40 - 90 seconds; • Positive response to medial branch block injection at the side and level of the proposed ablation; **and** • Confirmation of needle placement by fluoroscopic guided imaging **Thermal radiofrequency ablation is proven and medically necessary:** • When performed at a frequency of six months or longer (maximum of 2 times over a 12 month period); **and** • Provided there has been a 50% or greater documented reduction in pain for 10 to 12 weeks **Thermal radiofrequency ablation is unproven and not medically necessary:** • When performed more frequently than every six months; or • When there has been no significant improvement after medial branch block injection Ablation procedures performed more frequently than every 6 months increase the risk of adverse events without improving the clinical outcome. Documentation requirements for the aforementioned procedures must include: • Temperature of administration of procedure • Duration of ablation • Specific identification of side and level of medial branch blocks • Specific cervical, thoracic and/or lumbar ablated by side and level • Percentage of pain relief with prior ablation if applicable • Duration of improvement from previous ablation if applicable. **Thermal radiofrequency ablation is unproven and not medically necessary for the treatment of all other causes of spinal pain including but not limited to the following:** • Diabetic neuropathy • Sacroiliac pain

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Ablative Treatment for Spinal Pain *(continued)*	May 1, 2015		• Complex regional pain syndrome or regional pain disorders and syndromes in the absence of spinal pain • Definitive clinical and/or imaging findings identifying a condition requiring surgical treatment • Identified specific causes of spinal pain (e.g., disc herniation) requiring definitive treatment Studies of radiofrequency ablation for other conditions were limited, uncontrolled, and insufficient to support conclusions regarding efficacy or duration of effect. Additional well-designed, longer-term randomized controlled trials are required to evaluate the safety and efficacy of radiofrequency ablation and to compare this technique with other medical or surgical therapies for pain. **The following ablation procedures are unproven and not medically necessary for the treatment of spinal pain:** • Pulsed radiofrequency therapy of the facet nerves of the cervical, thoracic, or lumbar region, sacral nerve root or dorsal root ganglion. • Radiofrequency ablation with temperature less than 60 degrees Celsius • Endoscopic radiofrequency ablation (rhizotomy) • Cryoablation (cryodenervation, cryoneurolysis, cryosurgery, or cryoanesthesia) • Chemical ablation (including but not limited to alcohol, phenol or sodium morrhuate • Laser ablation (including pulsed, continuous, or low level) There is insufficient evidence to establish the efficacy of the ablation therapies bulleted immediately above to reduce or relieve spinal pain. Studies are limited by small sample size and lack of long term follow-up. Additional well designed studies are needed to establish the efficacy of these procedures.
Cochlear Implants	June 1, 2015	• Updated benefit considerations; added language for *Essential Health Benefits for Individual and Small Group* plans to indicate: ○ For plan years beginning on	**When used according to U.S. Food and Drug Administration (FDA) labeled indications, bilateral or unilateral cochlear implantation is proven and medically necessary for patients who meet all of the following criteria:** • Diagnosis of bilateral prelingual or postlingual moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate

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Cochlear Implants *(continued)*	June 1, 2015	or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs") ○ Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans ○ The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee specific benefit document to determine benefit coverage • Updated list of applicable CPT codes; removed 92601, 92602, 92603, and 92604 • Updated supporting information to reflect the most current	hearing (or vibrotactile) aids; • Ability to follow or participate in a program of aural rehabilitation; • 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; • No contraindications to surgery See the *U.S. Food and Drug Administration (FDA)* section of the policy for FDA indications for each cochlear implant device. Specific criteria vary with the device. **Cochlear hybrid implants are unproven and not medically necessary for hearing loss.** There is insufficient evidence in the clinical literature demonstrating the safety and efficacy of cochlear hybrid implants in the management of patients with severe hearing loss. Published evidence has shown that there is a potential risk of low frequency hearing loss as a result of cochlear hybrid implant surgery. Studies are needed to verify that benefits are likely to outweigh the risks of cochlear hybrid implantation and to determine which group of patients would benefit most from this device.

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Cochlear Implants *(continued)*	June 1, 2015	clinical evidence, FDA and CMS information, and references; no change to coverage rationale	
Computerized Dynamic Posturography	May 1, 2015	• Updated coverage rationale; modified/clarified language pertaining to clinical evidence/study findings to indicate: ○ Overall, there is weak evidence in the peer-reviewed literature regarding the efficacy of computerized dynamic posturography (CDP) for evaluating vestibular disorders ○ There is a lack of well-designed, randomized controlled trials (RCTs) with blinded assessments to demonstrate the diagnostic utility of CDP compared with standard tests ○ Furthermore, there is insufficient evidence demonstrating consistent and beneficial effects of CDP testing on patient-relevant outcomes ○ Therefore, CDP is considered unproven and not medically necessary • Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references; no change to coverage rationale or list of applicable codes	**Computerized dynamic posturography (CDP) testing, also called balance board testing or equilibrium platform testing (EPT), is unproven and not medically necessary for evaluating balance disorders.** Overall, there is weak evidence in the peer-reviewed literature regarding the efficacy of CDP for evaluating vestibular disorders. There is a lack of well-designed, randomized controlled trials (RCTs) with blinded assessments to demonstrate the diagnostic utility of CDP compared with standard tests. Furthermore, there is insufficient evidence demonstrating consistent and beneficial effects of CDP testing on patient-relevant outcomes. Therefore, CDP is considered unproven and not medically necessary.

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Epidural Steroid and Facet Injections for Spinal Pain	June 1, 2015	• Updated list of applicable ICD-10 diagnosis codes for facet injections (preview draft effective 10/01/15); added M47.021, M47.022, M47.029, S22.000A, S22.001A, S22.002A, S22.008A, S22.009A, S22.010A, S22.011A, S22.012A, S22.018A, S22.019A, S22.020A, S22.021A, S22.022A, S22.028A, S22.029A, S22.030A, S22.031A, S22.032A, S22.038A, S22.039A, S22.040A, S22.041A, S22.042A, S22.048A, S22.049A, S22.050A, S22.051A, S22.052A, S22.058A, S22.059A, S22.060A, S22.061A, S22.062A, S22.068A, S22.069A, S22.070A, S22.071A, S22.072A, S22.078A, S22.079A, S22.080A, S22.081A, S22.082A, S22.088A, S22.089A, S32.000A, S32.001A, S32.002A, S32.008A, S32.009A, S32.010A, S32.011A, S32.012A, S32.018A, S32.019A, S32.020A, S32.021A, S32.022A, S32.028A, S32.029A, S32.030A, S32.031A, S32.032A, S32.038A, S32.039A, S32.040A, S32.041A, S32.042A, S32.048A, S32.049A, S32.050A, S32.051A, S32.052A, S32.058A, S32.059A, S32.10XA, S32.110A, S32.111A, S32.112A, S32.119A, S32.120A, 32.121A, S32.122A, S32.129A, S32.130A, S32.131A, S32.132A, S32.139A, S32.14XA, S32.15XA, S32.16XA, S32.17XA, S32.19XA and S32.2XXA • Updated supporting information to reflect the most current	**Epidural steroid injections in this policy apply to the lumbar spine only. This section does not address cervical injections.** **The facet joint injections section of this policy addresses multiple sites, and is not limited to the lumbar spine.** **The use of ultrasound guidance for epidural steroid injection(s) and facet joint injection(s) is unproven and not medically necessary.** There is insufficient clinical evidence regarding its safety and/or efficacy in published peer-reviewed medical literature. The available published evidence for ultrasound guidance for epidural and facet injections is limited to a small feasibility study and a cadaver study. **Epidural Steroid Injections** **Epidural steroid injection is proven and medically necessary for the treatment of acute and sub-acute sciatica or radicular pain of the low back caused by spinal stenosis, disc herniation or degenerative changes in the vertebrae.** Epidural steroid injections have a clinically established role in the short-term management of low back pain when the following two criteria are met: • The pain is associated with symptoms of nerve root irritation and/or low back pain due to disc extrusions and/or contained herniations; and • The pain is unresponsive to conservative treatment, including but not limited to pharmacotherapy, exercise or physical therapy **Epidural steroid injection is unproven and not medically necessary for all other indications of the lumbar spine.** There is a lack of evidence from randomized controlled trials indicating that epidural steroid injections effectively treat patients with lumbar pain not associated with sciatica or radicular pain. ***Note:*** *This policy does not apply to obstetrical epidural anesthesia utilized during labor and delivery.* **Facet Joint Injections** **Diagnostic facet joint injection and/or facet nerve block (e.g., medial branch block) is proven and medically necessary to localize the**

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Epidural Steroid and Facet Injections for Spinal Pain *(continued)*	June 1, 2015	description of services, clinical evidence, FDA and CMS information, and references; no change to coverage rationale	**source of pain to the facet joint in persons with spinal pain. Therapeutic facet joint injection is unproven and not medically necessary for the treatment of chronic spinal pain.** Clinical evidence about the very existence of facet joint syndrome is conflicting, and evidence from studies is inadequate regarding the superiority of periodic facet joint injections compared to placebo in relieving chronic spinal pain. (pain lasting more than 3 months). **Additional Information** Facet joint injection, as a **diagnostic procedure** prior to radiofrequency ablation, is not recommended in patients with: • Neurologic abnormalities • More than one pain syndrome • Definitive clinical and/or imaging findings pointing to a specific diagnosis other than facet joint syndrome • Previous spinal surgery at the clinically suspected levels
Gait Analysis	June 1, 2015	• Added benefit considerations language for *Essential Health Benefits for Individual and Small Group* plans to indicate: ○ For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs") ○ Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs;	**Gait analysis for surgical or clinical decision-making is unproven and not medically necessary.** The available clinical evidence does not establish that gait analysis benefits health outcomes. The evidence is too limited to draw definitive conclusions regarding the role of gait analysis in the continuum of care. Evidence that includes clinical outcome results from randomized controlled trials is needed.

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Gait Analysis *(continued)*	June 1, 2015	however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans ○ The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee specific benefit document to determine benefit coverage • Updated supporting information to reflect the most current clinical evidence, CMS information, and references; no change to coverage rationale or list of applicable codes	
Glaucoma Surgical Treatments	May 1, 2015	• Updated supporting information to reflect the most current clinical evidence, CMS information, and references; no change to coverage rationale or lists of applicable codes	**Glaucoma drainage devices, such as the ExPRESS™ mini glaucoma shunt, Molteno implant, Baerveldt tube shunt, Krupin Eye Valve, or the Ahmed glaucoma valve implant, are proven and medically necessary for treatment of refractory glaucoma when there is intolerance, contraindication, or failure of topical or oral medication, when used according to U.S. Food and Drug Administration (FDA) labeled indications.** **The iStent® Trabecular Micro-Bypass Stent System is proven and medically necessary when used in combination with cataract surgery to treat mild to moderate open-angle glaucoma and a cataract in adults currently being treated with ocular hypotensive medication. Glaucoma drainage devices, such as Eyepass, DeepLight SOLX® Gold**

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Glaucoma Surgical Treatments *(continued)*	May 1, 2015		**Shunt and other shunts that do not have FDA approval are investigational and unproven and not medically necessary for the treatment of glaucoma.** Clinical evidence is limited to small studies; therefore, additional studies are needed to establish the safety and efficacy of these devices. **Canaloplasty is proven and medically necessary for the treatment of primary open-angle glaucoma.** **Viscocanalostomy is unproven and not medically necessary for the treatment of glaucoma**. Evidence from the majority of available randomized controlled trials indicates that viscocanalostomy is not as effective as trabeculectomy in reducing intraocular pressure (IOP). **Transciliary fistulization is unproven and not medically necessary for the treatment of glaucoma.** Further studies are needed to evaluate long-term safety and efficacy in comparison to established filtering procedures. The currently available published data are insufficient to draw any conclusion regarding health outcomes of transciliary fistulization for the treatment of glaucoma.

Hepatitis Screening	June 1, 2015	• Added reference link to policy titled *Preventive Care Services*
		• Updated list of applicable ICD-9 diagnosis codes:
		  ○ Added 631.0 and 631.8
		  ○ Removed 631
		• Updated list of applicable ICD-10 diagnosis codes (preview draft effective 10/01/15):
		  ○ Added M08.442 and Z11.4
		• Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references
			Hepatitis screening for "at risk" persons for acute and chronic infections is proven and medically necessary for:
			• Persons with a history of sexually transmitted infections (STI)
			• Men who have sexual relations with men
			• Persons with multiple sexual partners
			• Persons who have experienced Intercourse with trauma
			• Human Immunodeficiency Virus (HIV) infected persons
			• Persons who have history of using injection and non-injection illicit drugs
			• Persons born in regions or who have traveled to countries with high or intermediate prevalence of hepatitis A virus (HAV) or hepatitis B virus (HBV) infection
			• All pregnant women including those with a sexually transmitted infection (STI)
			• Persons who have received blood transfusion or organ transplantation before July 1992
			• Recipient of clotting factor concentrates made before 1987

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Hepatitis Screening *(continued)*	June 1, 2015		• Hemodialysis patients • Patients prior to initiating TNF blocker immunosuppressive therapy • Patients needing immunosuppressive or cytotoxic therapy • Patients with signs and symptoms of liver disease/elevated liver enzymes (abnormal ALT/AST) • Patients with positive test for anti-hepatitis C virus (HCV) • Patients with clotting factor disorders • Patients with history of working with non-human primates susceptible to HAV infection • Infants born to HBV or HCV positive mothers (do not test before 18 months of age) • US born infants whose parents were born in regions with high rates of Hepatitis B • Sexual partners of infected persons • Household, needle sharing or secondary contacts of HbsAg positive persons • Health care and public safety workers at risk for occupational exposure to blood or blood contaminated body fluids • Residents and staff of facilities for developmentally disabled persons • Persons with known exposure to HCV (health care workers after needle sticks involving HCV positive blood or recipients of blood or organs from a donor who later tested HCV positive) • Donors of blood, plasma, organs, tissue or semen **Hepatitis screening is proven and medically necessary for one-time screening for HCV infection for adults born between 1945-1965, whether or not risk factors have been identified.**
In Utero Fetal Surgery	May 1, 2015	• Updated supporting information to reflect the most current description of services, clinical evidence, and references; no change to coverage rationale or lists of applicable codes	**Intrauterine fetal surgery is proven and medically necessary for the following diagnoses and procedures:** 1. Congenital cystic adenomatoid malformation (CCAM) and extralobar pulmonary sequestration (EPS): fetal lobectomy or thoracoamniotic shunt placement for CCAM and thoracoamniotic shunt placement for EPS 2. Sacrococcygeal teratoma (SCT): SCT resection 3. Urinary tract obstruction (UTO): urinary decompression via vesicoamniotic shunt placement 4. Twin-twin transfusion syndrome: fetoscopic laser surgery

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In Utero Fetal Surgery *(continued)*	May 1, 2015		5. Twin reversed arterial perfusion (TRAP): ablation or occlusion of anastomotic vessels (e.g., laser coagulation or radiofrequency ablation) 6. Myelomeningocele (MMC) repair **Intrauterine fetal surgery is unproven and not medically necessary for the following:** 1. Congenital diaphragmatic hernia (CDH) There is insufficient evidence that in utero correction of CDH improves health outcomes for fetuses with CDH compared with standard postnatal surgery. Consistent improvements in survival following in utero fetal surgery have not been observed. 2. Congenital heart disease (CHD) There is insufficient evidence that in utero fetal surgery for complex heart disease improves health outcomes or survival.
Manipulative Therapy	May 1, 2015	• Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references; no change to coverage rationale or lists of applicable codes	**Manipulative therapy is proven and medically necessary for treatment of musculoskeletal disorders, except as noted below.** **Manipulative therapy is unproven and not medically necessary for treatment of:** • Non-musculoskeletal disorders (e.g., asthma, otitis media, infantile colic, etc) • Prevention/maintenance/custodial care • Internal organ disorders (e.g., gallbladder, spleen, intestinal, kidney, or lung disorders) • Temporomandibular Joint (TMJ) Disorder • Scoliosis correction • Craniosacral therapy (cranial manipulation/Upledger technique) • Manipulative services that utilize nonstandard techniques such as applied kinesiology technique, NUCCA, network and neural organizational technique The role of manipulation for the above has not been established in scientific literature. A beneficial impact on health outcomes, e.g., improved physical function, durable pain relief, has not been established. **Manipulative therapy is unproven and not medically necessary when ANY of the following apply:** 1. The patient's condition has returned to the pre-symptom state.

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Manipulative Therapy *(continued)*	May 1, 2015		2. Little or no improvement is demonstrated within 30 days of the initial visit despite modification of the treatment plan. 3. Concurrent manipulative therapy, for the same or similar condition, provided by another health professional whether or not the healthcare professional is in the same professional discipline. This policy does not address manipulation under anesthesia; refer to the policy titled Manipulation Under Anesthesia.
Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD)	June 1, 2015	• Updated list of applicable CPT codes; added 43289 (no change to coverage rationale)	**Endoscopic therapies are unproven and not medically necessary for the treatment of gastroesophageal reflux disease (GERD).** Endoscopic therapies include: 1. Radiofrequency energy • Stretta System 2. Endoscopic plication or suturing • Bard EndoCinch Endoscopic Suturing System • Endoscopic Suturing Device (ESD) • Surgical Endoscopic Plication System (EPS) • EsophyX™ System with SerosaFuse™ Fastener (transoral incisionless fundoplication procedure) 3. Injection or implantation techniques • Gatekeeper Reflux Repair System • Plexiglas (polymethylmethacrylate [PMMA]) procedure • Durasphere® The safety and efficacy of endoscopic therapies for the treatment of GERD have not been established in the published medical literature. Current studies are generally of small to moderate size, lack adequate control or comparison groups, and provide only short-term follow-up. Well-designed clinical trials with long-term follow up are required to establish that endoscopic therapies benefit health outcomes in patients with GERD by eliminating symptoms, preventing recurrence of symptoms or progression of disease, healing esophagitis, and reducing or eliminating the need for pharmacologic therapy. **The LINX™ Reflux Management System is unproven and not**

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Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) *(continued)*	June 1, 2015		**medically necessary for the treatment of GERD.** The safety and efficacy of this system has not been established in the peer-reviewed medical literature. Available studies are hampered by a number of limitations, including small study size, lack of statistical power, lack of controls or comparators, and lack of long-term follow-up. See the Medical Policy titled Bariatric Surgery for information regarding transoral endoscopic surgery (such as transoral gastroplasty [TOGA®], StomaphyX, and Restorative Obesity Surgery, Endoluminal [ROSE] procedure) for the treatment of obesity.
Obstructive Sleep Apnea Treatment	May 1, 2015	• Updated coverage rationale; removed and relocated content/language pertaining to frequency and severity of obstructive events to the *Definitions* section of the policy • Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references; no change to coverage rationale or lists of applicable codes	**Nonsurgical Treatment** **Removable oral appliances are proven and medically necessary for treating obstructive sleep apnea (OSA) as documented by polysomnography.** Refer to the Medical Policy titled Attended Polysomnography for Evaluation of Sleep Disorders for further information. For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 19th edition, 2015, Oral Appliances (Mandibular Advancement Devices), A-0341 (ACG). **Removable oral appliances are unproven and not medically necessary for treating central sleep apnea.** This type of sleep apnea is caused by impaired neurological function, and these devices are designed to manage physical obstructions. **Nasal dilator devices are unproven and not medically necessary for treating obstructive sleep apnea (OSA).** There is insufficient clinical evidence supporting the safety and efficacy of nasal dilators for treating OSA. Results from available studies indicate that therapeutic response is variable among the participants. Further research from larger, well-designed studies is needed to evaluate the effectiveness of the device compared with established treatments for OSA, to determine its long-term effectiveness and to determine which patients would benefit from this therapy. **Surgical Treatment** **The following surgical procedures are proven and medically necessary for treating obstructive sleep apnea as documented by**

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Obstructive Sleep Apnea Treatment *(continued)*	May 1, 2015		**polysomnography.** Refer to the medical policy titled Attended Polysomnography for Evaluation of Sleep Disorders for further information. Also see the *Definitions* section of the policy for information on the definitions and severity of OSA. • **Uvulopalatopharyngoplasty (UPPP)** For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 19th edition, 2015, Uvulopalatopharyngoplasty (UPPP), A-0245 (ACG). • **Maxillomandibular advancement surgery (MMA)** For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 19th edition, 2015, Maxillomandibular Osteotomy and Advancement, A-0248 (ACG). • **Multilevel procedures whether done in a single surgery or phased multiple surgeries.** There are a variety of procedure combinations, including mandibular osteotomy and genioglossal advancement with hyoid myotomy (GAHM). For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 19th edition, 2015, Mandibular Osteotomy, A-0247 (ACG). **Radiofrequency ablation of the soft palate and/or tongue base is proven and medically necessary for treating mild to moderate obstructive sleep apnea as documented by polysomnography.** Refer to the medical policy titled Attended Polysomnography for Evaluation of Sleep Disorders for further information. In addition to the criteria listed above, radiofrequency ablation of the soft palate and/or tongue base is medically necessary for patients who fail to improve with or cannot tolerate an adequate trial of continuous positive airway pressure (CPAP) or another device, including bi-level positive airway pressure (BiPAP), auto-titrating positive airway pressure (APAP) and/or oral appliances. **The following surgical procedures are unproven and not medically necessary for treating obstructive sleep apnea:** • Laser-assisted uvulopalatoplasty (LAUP) • Palatal implants • Lingual suspension - also referred to as tongue stabilization, tongue

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Obstructive Sleep Apnea Treatment *(continued)*	May 1, 2015		stitch or tongue fixation • Transoral robotic surgery (TORS) • Implantable hypoglossal nerve stimulation There is insufficient evidence to conclude that laser-assisted uvulopalatoplasty (LAUP) results in improved apnea-hypopnea index (AHI) or secondary outcomes. Some studies saw a worsening of symptoms as well as increased complications. Results of studies provide preliminary but inconsistent evidence that palatal implants benefit patients with mild to moderate OSA. However, the magnitude of the benefits has been small; the largest randomized controlled trial (RCT) found that average OSA worsened in spite of treatment; and the available studies involved ≤ 1 year of patient monitoring after treatment. Additional studies are needed to determine the role of palatal implants in the management of OSA There is insufficient evidence to support the safety, efficacy and long-term outcomes of lingual suspension in the treatment of OSA. The published peer-reviewed medical literature includes a few small, uncontrolled studies with short-term follow-up. Large, controlled studies, with long-term follow-up, comparing lingual suspension to established procedures are necessary. There is insufficient evidence to support the safety, efficacy and long-term outcomes of transoral robotic surgery (TORS) in the treatment of OSA. Large, controlled studies, with long-term follow-up, comparing TORS to established procedures are necessary. There is insufficient evidence to support the safety, efficacy and long-term outcomes of hypoglossal nerve stimulation in the treatment of OSA. The optimal patient selection criteria for the use of hypoglossal nerve stimulation have not been defined. Randomized controlled trials or comparative effectiveness trials with long-term follow-up, comparing hypoglossal nerve stimulation to established procedures are necessary to evaluate the effectiveness of this technology. Follow-up polysomnography should be performed following surgery to evaluate response to treatment (Kushida et al., 2006; Ferguson et al., 2006). Refer to the medical policy titled Attended Polysomnography for Evaluation of Sleep Disorders for further information.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Occipital Neuralgia and Headache Treatment	June 1, 2015	• Added benefit considerations language for *Essential Health Benefits for Individual and Small Group* plans to indicate: ○ For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs") ○ Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans ○ The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee specific benefit document to determine benefit coverage • Updated supporting information	**Injection of local anesthetics and/or steroids, used as occipital nerve blocks, is proven and medically necessary for the treatment of pain due to malignancy involving the head and neck.** **Injection of local anesthetics and/or steroids, used as occipital nerve blocks, is unproven and not medically necessary for the diagnosis and treatment of occipital neuralgia or headaches including migraine and cervicogenic headaches.** There is insufficient evidence that greater occipital nerve blocks can be used as a specific diagnostic test for occipital neuralgia or headaches. The efficacy of local injection therapies for occipital neuralgia or cervicogenic headache and other headaches has not been established in well-designed clinical trials. See the Drug Policy titled Botulinum Toxin A and B for information regarding the use of botulinum toxin for treatment of headaches. **Surgery including but not limited to the following is unproven and not medically necessary for the treatment of occipital neuralgia or cervicogenic headache:** • Occipital neurectomy • Partial posterior intradural C1-C3 rhizotomy • Rhizotomy of C1-C3 spinal dorsal roots • Surgical decompression of second cervical nerve root and ganglion • Surgical decompression of the greater occipital nerve The available evidence is insufficient to conclude that surgery is an effective treatment for occipital neuralgia or cervicogenic-headaches. The long-term efficacy of surgical procedures for occipital neuralgia or cervicogenic headaches has not been established in well-designed clinical trials. **Occipital neurectomy or surgical nerve decompression is unproven and not medically necessary for the treatment of headaches.** The available evidence is insufficient to conclude that occipital neurectomy or nerve decompression including decompression of the supraorbital, supratrochlear, zygomaticotemporal, or greater occipital nerves is an effective treatment for headaches. The long-term efficacy of these procedures for headaches has not been established in well-designed clinical trials.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Occipital Neuralgia and Headache Treatment *(continued)*	June 1, 2015	to reflect the most current clinical evidence, FDA and CMS information, and references; no change to coverage rationale or list of applicable codes	**Radiofrequency ablation (thermal or pulsed) or denervation is unproven and not medically necessary for the treatment of occipital neuralgia or headaches including migraine, cluster and cervicogenic headache.** The available evidence from published studies is not sufficient to conclude that radiofrequency ablation or denervation is an effective treatment for occipital neuralgia or headaches. Well-designed studies are needed to evaluate the potential advantages of radiofrequency ablation for these conditions and to identify which patients would benefit from this procedure. **Neurostimulation or electrical stimulation is unproven and not medically necessary for the treatment of occipital neuralgia or headaches including migraine, cluster and cervicogenic headache.** The available studies were limited and had significant methodological flaws, making it difficult to draw conclusions regarding the efficacy of electrical stimulation for the treatment of headache or occipital neuralgia. There are no well-designed randomized controlled studies in the medical literature comparing neurostimulation to established treatment options or a sham procedure. Studies on larger populations with longer follow-up are needed to establish the benefits of neurostimulation and electrical stimulation for treating these conditions.
Prolotherapy for Musculoskeletal Indications	May 1, 2015	• Routine review; no change to coverage rationale or lists of applicable codes	**Prolotherapy is unproven and not medically necessary.** The available studies are limited to those that include short to medium term follow-up with no significant functional improvement compared to placebo. Additional studies are needed to further define treatment parameters and to determine whether a clinically significant improvement is achieved.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes	Apr. 22, 2015	• Revised coverage rationale: ○ Updated language pertaining to insulin delivery to indicate external insulin pumps that deliver insulin by continuous subcutaneous infusion are proven and medically necessary for the	**Insulin Delivery** **External insulin pumps that deliver insulin by continuous subcutaneous infusion are proven and medically necessary for the following:** • Patients with type 1 diabetes • Patients with type 2 diabetes who currently perform ≥4 insulin injections and ≥4 blood glucose measurements daily

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Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes *(continued)*	April 22, 2015	following: ▪ Patients with type 1 diabetes ▪ Patients with type 2 diabetes who currently perform ≥4 insulin injections and ≥4 blood glucose measurements daily ○ Added language to indicate short-term (3-7 days) continuous glucose monitoring by a healthcare provider for diagnostic purposes is proven and medically necessary for patients with diabetes ○ Replaced language indicating: ▪ "Long-term continuous glucose monitoring *(greater than 72 hours), alone or in combination with an external insulin pump,* is proven and medically necessary as a supplement to self-monitoring of blood glucose (SMBG) for patients with type 1 diabetes who meet listed criteria" with "long-term continuous glucose monitoring *for personal use at home* is proven and medically necessary as a supplement to self-monitoring of blood	For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 19th edition, 2015, Insulin Infusion Pump ACG:A-0339 (AC). **Note:** Programmable disposable external insulin pumps are considered equivalent to standard insulin pumps. **Nonprogrammable transdermal insulin delivery systems are unproven and not medically necessary for treating patients with diabetes.** There is insufficient evidence in the clinical literature demonstrating the safety and efficacy of transdermal insulin delivery in the management of patients with diabetes. **Implantable insulin pumps are investigational, unproven and not medically necessary.** 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 patients, 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 not medically necessary for insulin delivery in patients 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. **Continuous Glucose Monitors with or without Combined Insulin Pumps** **Short-term (3-7 days) continuous glucose monitoring by a**

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes *(continued)*	Apr. 22, 2015	glucose (SMBG) for patients with type 1 diabetes who meet listed criteria" ▪ "Long-term continuous glucose monitoring is unproven and not medically necessary for patients with type 2 diabetes or gestational diabetes" with "long-term continuous glucose monitoring *for personal use at home* is unproven and not medically necessary for patients with type 2 diabetes or gestational diabetes" ○ Removed language indicating: ▪ Devices classified by the U.S. Food and Drug Administration (FDA) as an artificial pancreas are unproven and not medically necessary - Study results fail to provide conclusive evidence that artificial pancreas devices lead to improved health outcomes, such as improved glycemic control or delay in diabetes-related complications, in patients with	**healthcare provider for diagnostic purposes is proven and medically necessary for patients with diabetes.** **Long-term continuous glucose monitoring for personal use at home is proven and medically necessary as a supplement to self-monitoring of blood glucose (SMBG) for patients with type 1 diabetes who meet EITHER of the following criteria AND have demonstrated adherence to a physician ordered diabetic treatment plan:** • Have been unable to achieve optimum glycemic control as defined by the most current version of the American Diabetes Association (ADA) *Standards of Medical Care in Diabetes*; or • Have experienced hypoglycemia unawareness and/or frequent episodes of hypoglycemia **Long-term continuous glucose monitoring for personal use at home is unproven and not medically necessary for patients 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 patients with type 2 or gestational diabetes. For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 19th edition, 2015, Continuous Glucose Monitoring ACG:A-0126 (AC). **Remote Glucose Monitoring** **Remote glucose monitoring is unproven and not medically necessary for managing patients with diabetes.** There is insufficient evidence in the clinical literature to conclude that remote glucose monitoring demonstrates improvement in clinical outcomes.

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Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes *(continued)*	April 22, 2015	diabetes - Larger, randomized controlled trials are needed to determine the long-term impact of these devices on diabetes management ▪ As part of the ongoing effort to improve diabetes care, the National Diabetes Education Program, the American Association of Clinical Endocrinology and others have recommended the term "A1c" be used for GHB or hemoglobin A1c (HbA1c) measurement in health care practice to avoid confusion • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	
Gene Expression Tests	June 1, 2015	• Reformatted and revised coverage rationale: ○ Added language to indicate gene expression tests are unproven and not medically necessary for: ▪ Predicting tumor aggressiveness and guiding disease management in patients with newly diagnosed prostate cancer (e.g.,	**Oncology Indications** ***Thyroid Cancer*** Multi-panel gene expression tests (e.g., Afirma®) are proven and medically necessary for assessing thyroid nodules that are not clearly benign or malignant based on fine-needle aspiration biopsy results alone. **Gene expression tests are unproven and not medically necessary for the following:** ***Cancer of Unknown Primary*** • Identifying tissue of origin in difficult to diagnose cancers (e.g., ResponseDX Tissue of Origin® or CancerTYPE ID®)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gene Expression Tests *(continued)*	June 1, 2015	Oncotype DX® Prostate Cancer Assay and Prolaris®) ▪ Predicting risk of recurrence and metastasis and guiding disease management following radical prostatectomy (e.g., Decipher® Prostate Cancer Classifier) ○ Replaced language indicating "gene expression tests are unproven and not medically necessary for *assessing cardiovascular risk* (e.g., Corus® CAD)" with "gene expression tests are unproven and not medically necessary for *predicting the likelihood of obstructive coronary artery disease* (e.g., Corus® CAD)" • Updated list of applicable CPT codes; added 81479 and 81599 • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	***Colon Cancer*** • Predicting the likelihood of colon cancer recurrence (e.g., Oncotype DX® Colon Cancer Assay) ***Multiple Myeloma*** • Guiding therapy in patients with multiple myeloma (e.g., MyPRS®) ***Prostate Cancer*** • Predicting tumor aggressiveness and guiding disease management in patients with newly diagnosed prostate cancer (e.g., Oncotype DX® Prostate Cancer Assay and Prolaris®) • Predicting risk of recurrence and metastasis and guiding disease management following radical prostatectomy (e.g., Decipher® Prostate Cancer Classifier) ***Uveal Melanoma*** • Predicting metastatic risk of uveal melanoma (e.g., DecisionDx-UM) There is insufficient evidence in the clinical literature demonstrating that these tests have a role in clinical decision-making or have a beneficial effect on health outcomes. Further studies are needed to determine the clinical utility of these tests. **Non-Oncology Indications** ***Coronary Artery Disease*** **Gene expression tests are unproven and not medically necessary for predicting the likelihood of obstructive coronary artery disease (e.g., Corus® CAD).** There is insufficient evidence in the clinical literature demonstrating that this test has a role in clinical decision-making or has a beneficial effect on health outcomes. Further studies are needed to determine the clinical utility of this test.
Omnibus Codes	June 1, 2015	• Revised coverage guidelines for VeriStrat® serum test: ○ Changed coverage status for CPT code 84999 [Unlisted chemistry procedure (when	Refer to the policy for complete details on the coverage guidelines for Omnibus Codes.

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Omnibus Codes *(continued)*	June 1, 2015	used to report VeriStrat)] from "unproven" to "proven in certain circumstances" ○ Revised coverage rationale to indicate the VeriStrat serum-based biomarker test (serum proteomic profiling, using mass spectrometry) is proven for guiding treatment decisions in patients with advanced non-small cell lung cancer (NSCLC) being considered for second-line therapy with an epidermal growth factor receptor (EGFR) inhibitor, such as erlotinib, and whose EGFR mutation status is wild-type (no mutation detected) or unknown ○ Updated supporting information to reflect the most current clinical evidence and references	

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Ambulance Services	June 1, 2015	• Updated coverage rationale/indications for coverage: ○ Added language to indicate the enrollee specific benefit document should be checked for prior authorization and notification requirements ○ Removed language indicating enrollee pre-service notification/prior authorization is not required for emergency ambulance services	Refer to the CDG for complete details on the coverage guidelines for Ambulance Services.
Blepharoplasty, Blepharoptosis, and Brow Ptosis Repair	May 1, 2015	• Updated coverage rationale; removed definition of "reconstructive procedures" for California plan members (addressed in *Definitions* section of the policy)	Refer to the CDG for complete details on the coverage guidelines for Blepharoplasty, Blepharoptosis, and Brow Ptosis Repair.
Cosmetic and Reconstructive Procedures	June 1, 2015	• Updated list of applicable CPT codes: ○ Added most current *CPT Assistant* newsletter listings for additional coding guidelines for flap procedures and adjacent tissue transfer or rearrangement ○ Relocated 36468 [single or multiple injections of sclerosing solutions, spider veins (telangiectasia), limb or trunk] to list of codes that "may be cosmetic; review is	**Benefit Document Language** Before using this guideline, please check the enrollee specific benefit document and any federal or state mandates, if applicable. **Essential Health Benefits for Individual and Small Group** For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by

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Cosmetic and Reconstructive Procedures *(continued)*	June 1, 2015	required to determine if considered cosmetic or reconstructive" (previously listed as "cosmetic")	state basis. As such, when using this guideline, it is important to refer to the enrollee specific benefit document to determine benefit coverage. **Indications for Coverage** 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 enrollee's plan specific documents. **Criteria for a Procedure to be considered Reconstructive and Medically Necessary:** 1. There is documentation that the physical abnormality and/or physiological abnormality is causing a functional impairment (as defined in the *Definitions* section of the policy) that requires correction. 2. The proposed treatment is of proven efficacy; and is deemed likely to significantly improve or restore the patient's physiological function. **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 enrollee's plan specific documents. 1. Cosmetic Procedures are excluded from coverage. Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures. The fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure. 2. Any procedure that does not meet the reconstructive criteria above in the *Indications for Coverage* section above.

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Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements	May 1, 2015	• Added coding guidelines to indicate: ○ UnitedHealthcare has adopted the requirements and intent of the National Correct Coding Initiative ○ The Centers for Medicare & Medicaid Services (CMS) has contracted with Noridian to manage Pricing, Data and Coding (PDAC) for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) ○ This notice is to confirm UnitedHealthcare has established the PDAC as its definitive source for correct coding and coding clarification.	Refer to the CDG for complete details on the coverage guidelines for Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gender Dysphoria (Gender Identity Disorder) Treatment	June 1, 2015	• Changed policy title; previously titled *Gender Identity Disorder/Gender Dysphoria Treatment* • Updated plan document guidelines; added language to indicate: ○ The terms "treatment for gender dysphoria", "gender identity disorder treatment", "sex transformation surgery", "sex change", "sex reversal", "gender change", "transsexual surgery",	**Benefit Document Language** Before using this guideline, please the check the enrollee specific benefit document and any federal or state mandates, if applicable. **Essential Health Benefits for Individual and Small Group** For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by

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Gender Dysphoria (Gender Identity Disorder) Treatment *(continued)*	June 1, 2015	"transgender surgery" and "sex or gender reassignment" are used interchangeably throughout this document, and, for purposes of this document, are intended to have the same meaning ○ Throughout this document, the abbreviation WPATH refers to an advocacy group called the World Professional Association for Transgender Health; WPATH notations in this policy refer to the publication, Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7th Version ○ The eligibility qualifications for continuous hormone therapy and surgical treatment of gender dysphoria are in addition to the plan's overall eligibility requirements as shown in the plan document ○ Plans may cover, or exclude, surgical or non-surgical treatment for gender dysphoria; when deciding coverage, the enrollee's specific benefit document must be referenced • Revised coverage criteria for **non-surgical treatment of**	state basis. As such, when using this guideline, it is important to refer to the enrollee specific benefit document to determine benefit coverage. Treatment for Gender dysphoria is sometimes referred to as: gender identity disorder treatment, sex transformation surgery, sex change, sex reversal, gender change, transsexual surgery, transgender surgery and sex or gender reassignment. **These terms are used interchangeably throughout this document, and, for purposes of this document, are intended to have the same meaning.** Throughout this document the abbreviation WPATH refers to an advocacy group called the World Professional Association for Transgender Health. WPATH notations in this policy refer to the publication, *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7th Version.* The Eligibility Qualifications for continuous hormone therapy and surgical treatment of gender dysphoria are in addition to the plan's overall eligibility requirements as shown in the enrollee specific benefit document. **Note:** Plans may cover, or exclude, surgical or non-surgical treatment for gender dysphoria. When deciding coverage, the enrollee' specific benefit document must be referenced: **NON-SURGICAL TREATMENT OF GENDER DYSPHORIA** Plans may cover non-surgical treatment for gender dysphoria. If there is a difference between an enrollee specific benefit document and the information below, the enrollee specific benefit document should be used for making benefit determinations. For plans that cover non-surgical treatment of gender dysphoria, please note the following Covered Services, and Limitations and Exclusions, sections below. **Covered Services** (for plans that cover non-surgical treatment of gender dysphoria): If a plan covers non-surgical treatment for gender dysphoria, the following non-surgical treatments are covered: 1. **Psychotherapy** for gender dysphoria and associated co-morbid

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Gender Dysphoria (Gender Identity Disorder) Treatment *(continued)*	June 1, 2015	**gender dysphoria**: ○ Added language to indicate: ▪ If there is a difference between the information provided in an enrollee's plan document and this guideline, the enrollee's plan document should be used for making benefit determinations ▪ For plans that cover non-surgical treatment of gender dysphoria, refer to the *Covered Services and Limitations* and *Exclusions* sections of the policy ○ Revised list of **covered services (for plans that cover non-surgical treatment of gender dysphoria)** to reflect/include: ▪ Psychotherapy for gender dysphoria and associated co-morbid psychiatric diagnoses [Note: If mental health services are not covered on the UnitedHealthcare plan (for example when mental health services are carved out of the plan design) the UnitedHealthcare plan will not cover psychotherapy for	psychiatric diagnoses. **Note**: If mental health services are not covered on the UHC plan (for example when mental health services are carved out of the plan design) the UHC plan will not cover psychotherapy for gender dysphoria. 2. **Continuous Hormone Replacement Therapy** – hormones of the desired gender. Hormones injected by a medical provider (for example hormones injected during an office visit) are covered by the medical plan. Benefits for these injections vary depending on the plan design. Oral and self-injected hormones from a pharmacy are not covered under the medical plan. Refer to the Outpatient Prescription Drug Rider, or SPD for self-funded plans, for specific prescription drug product coverage and exclusion terms. Eligibility Qualifications for Continuous Hormone Replacement Therapy The covered person must meet **all** of the following eligibility qualifications for hormone replacement: • Persistent, well-documented gender dysphoria (see definition of Gender Identity Disorder below); **and** • Capacity to make a fully informed decision and to consent for treatment; **and** • Age of majority in a given country. **Note**: WPATH guidelines address age of majority in a given country. For the purposes of this guideline, the age of majority is age 18. However, this refers to chronological age not biological age. Where approval or denial of benefits is based solely on the age of the individual a case-by-case medical director review is necessary; **and** • If significant medical or mental health concerns are present, they must be reasonably well-controlled. 3. **Laboratory testing** to monitor the safety of continuous hormone therapy. **Coverage Limitations and Exclusions** Certain non-surgical treatments are not covered. Examples that apply to this exclusion include, but are not limited to: 1. Treatment received outside of the United States.

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Gender Dysphoria (Gender Identity Disorder) Treatment *(continued)*	June 1, 2015	gender dysphoria] ▪ Continuous hormone replacement therapy (hormones of the desired gender): - Hormones injected by a medical provider (for example hormones injected during an office visit) are covered by the medical plan; benefits for these injections vary depending on the plan design - Oral and self-injected hormones from a pharmacy are not covered under the medical plan - Refer to the Outpatient Prescription Drug Rider, or SPD for self-funded plans, for specific prescription drug product coverage and exclusion terms - Eligibility qualifications for continuous hormone replacement therapy; the covered person	2. Non-surgical treatments that are not listed in the *Covered Services* section above. 3. Reproduction services including, but not limited to: sperm preservation in advance of hormone treatment or gender dysphoria surgery, cryopreservation of fertilized embyros, oocyte preservation, surrogate parenting, donor eggs, donor sperm and host uterus. (See the Reproduction exclusion in the enrollee specific benefit document.) 4. Drugs* for hair loss or growth. 5. Drugs* for sexual performance for patients that have undergone genital reconstruction. 6. Drugs* for cosmetic purposes. 7. Hormone therapy except as described in the *Covered Services* section above. 8. Pubertal suppression therapy is considered unsafe in managing children and adolescents with gender identity dysphoria and is, therefore, not covered. See the policy titled Lupron Depot / Lupron Depot-Ped (leuprolide acetate) for Non-Oncology Use 9. Voice therapy. 10. Services that exceed the maximum dollar limit on the plan. 11. Transportation, meals, lodging or similar expenses. * The drugs exclusions listed above apply to drugs administered by a provider in a medical setting (including, but not limited to: office, outpatient, or inpatient facility). For drugs obtained at a pharmacy, check with the pharmacy plan administrator for information on covered and excluded drugs. **Note the following**: 1. Certain plans may have a different list of exclusions. Check the enrollee specific benefit document before making a determination. 2. Additional exclusions are listed in the *surgical treatment* section below. **SURGICAL TREATMENT FOR GENDER DYSPHORIA** Most plans exclude coverage for surgical treatment for gender dysphoria. However, certain self-funded plans may include a benefit that covers surgical treatment for gender dysphoria. Please refer to the enrollee specific benefit document to verify coverage. If there is a difference between an enrollee specific benefit document and the information below,

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Gender Dysphoria (Gender Identity Disorder) Treatment *(continued)*	June 1, 2015	must meet all of the following eligibility qualifications for hormone replacement: a. Persistent, well-documented gender dysphoria; and b. Capacity to make a fully informed decision and to consent for treatment; and c. Age of majority in a given country (Note: WPATH guidelines address age of majority in a given country and for the purposes of this guideline, the age of majority is age 18; however, this refers to chronological age not biological age. Where approval or denial of benefits is based solely on the age of the individual a case-by-case medical director review is necessary); and d. If significant medical or mental health concerns are present, they must be reasonably well-	the enrollee specific benefit document should be used for making benefit determinations. For plans that **cover** surgical treatment for gender dysphoria, please note the following: **Covered Surgical Treatment for Gender Dysphoria:** If a plan covers surgical treatment for gender dysphoria, the following are covered when the Eligibility Qualifications for Surgery are met below: 1. **Genital Surgery** (by various techniques which must be appropriate to each patient), including: complete hysterectomy; orchiectomy; penectomy; vaginoplasty; vaginectomy; clitoroplasty; labiaplasty; salpingo-oophorectomy; metoidioplasty; scrotoplasty; urethroplasty; placement of testicular prosthesis; phalloplasty 2. **Surgery to change specified secondary sex characteristics, specifically**: • Thyroid chondroplasty (removal or reduction of the Adam's Apple); and • Bilateral mastectomy; and • Augmentation mammoplasty (including breast prosthesis if necessary) if the Physician prescribing hormones and the surgeon have documented that breast enlargement after undergoing hormone treatment for 18 months is not sufficient for comfort in the social role. 3. **Related Services**: In addition to the surgeon fees, the benefit applies to the services related to the surgery, including but not limited to: anesthesia, laboratory testing, pathology, radiologic procedures, hospital and facility fees, and/or surgical center fees. Eligibility Qualifications for Surgery The following criteria apply to genital surgery, and to surgery to change specified secondary sex characteristics listed above. It is our expectation that surgery be performed by a qualified provider at a facility with a history of treating individuals with gender identity disorder. If a plan covers surgical treatment for gender dysphoria, the Covered Person must meet **all** of the following eligibility qualifications prior to surgery: 1. Persistent, well-documented gender dysphoria (see definition of Gender Identity Disorder below); **and**

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Gender Dysphoria (Gender Identity Disorder) Treatment *(continued)*	June 1, 2015	controlled - Laboratory testing to monitor the safety of continuous hormone therapy ○ Revised list of **coverage limitations and exclusions for non-surgical treatment of gender dysphoria**; added language to clarify the following surgical treatments are not covered: ▪ Non-surgical treatments that are not listed in the *Covered Services* section of the policy ▪ Reproduction services including, but not limited to sperm preservation in advance of hormone treatment or gender dysphoria surgery, cryopreservation of fertilized embyros, oocyte preservation, surrogate parenting, donor eggs, donor sperm and host uterus (see the *Reproduction exclusion* in the enrollee specific plan document) • Revised coverage criteria for **surgical treatment for gender dysphoria** ○ Added language to indicate: ▪ Certain self-funded plans may include a	2. Capacity to make a fully informed decision and to consent for treatment; **and** 3. Age of majority in a given country. **Note**: WPATH* guidelines address age of majority in a given country. For the purposes of this guideline, the age of majority is age 18. However, this refers to chronological age, not biological age. Where approval or denial of benefits is based solely on the age of the individual a case-by-case medical director review is necessary, **and** 4. If significant medical or mental health concerns are present, these must be reasonably well-controlled; **and** 5. The covered person must complete 12 months of successful continuous full time real life experience in the desired gender, **and** 6. The covered person may be required to complete continuous hormone therapy (for those without contraindications). In consultation with the patient's physician, this should be determined on a case-by-case basis through the Notification process; and 7. The treatment plan must conform to identifiable external sources including the World Professional Association for Transgender Health Association (WPATH) standards, and/or evidence-based professional society guidance. <u>Clarifications for Breast/Chest Surgery</u> In addition to the Eligibility Qualifications listed above, please note the following: 1. **A biologic female** patient that is only requesting a **bilateral mastectomy**: • Does not need to complete hormone therapy in order to qualify for the mastectomy. • Although not a requirement for coverage, UnitedHealthcare recommends that the patient complete at least **3 months of psychotherapy** before having the mastectomy. 2. **A biologic male** patient that is only requesting a **breast augmentation:** • If able to take female hormones, the patient should take the female hormones for at least **12 – 24 months*** before being considered for bilateral breast augmentation since the patient may achieve adequate breast development without surgery. • Although not a requirement for coverage, UnitedHealthcare

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gender Dysphoria (Gender Identity Disorder) Treatment *(continued)*	June 1, 2015	benefit that covers surgical treatment for gender dysphoria; refer to the enrollee specific benefit document to verify coverage ▪ If there is a difference between the information provided in an enrollee's plan document and this guideline, the enrollee's plan document should be used for making benefit determinations ○ Revised **eligibility qualifications for surgery (for plans that cover surgical treatment for gender dysphoria)** ▪ Revised coverage criteria for genital surgery/surgery to change specified secondary sex characteristics to reflect/include the following (prior to surgery): - Persistent, well-documented gender dysphoria (see definition of "gender identity disorder"); and - Capacity to make a fully informed decision and to consent for	recommends that the patient complete at least **3 months of psychotherapy** before having the breast augmentation. * 12 months is listed by WPATH v7, whereas, 2 years is listed by, *Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline (2009)* **Note the following:** 1. Certain plans may have a different list of Covered Services for Treatment of Gender Identity Disorder and may not cover all services listed above. Check the enrollee specific benefit document to determine. 2. Benefits are limited to one sex transformation reassignment per lifetime which may include several staged procedures. 3. Check the enrollee specific benefit document for any applicable prior authorization or notification requirements, or limits and maximum dollar amounts to this coverage. 4. Sterilization surgery is not required in order to receive the covered services under this benefit. **Excluded Services for Surgical Treatment of Gender Dysphoria:** The following are **not** covered even if the plan includes coverage for surgical treatment for gender dysphoria: 1. Treatment received outside of the United States. 2. Reversal of genital surgery or reversal of surgery to revise secondary sex characteristics. 3. Voice modification surgery. 4. Facial feminization surgery, including but not limited to: facial bone reduction, face "lift", facial hair removal, and certain facial plastic reconstruction. 5. Suction-assisted lipoplasty of the waist. 6. Rhinoplasty (except if rhinoplasty criteria are met; see the CDG titled Rhinoplasty, Septoplasty, and Repair of Vestibular Stenosis) 7. Blepharoplasty (except if blepharoplasty criteria are met; see the CDG titled Blepharoplasty, Blepharoptosis, and Brow Ptosis Repair) 8. Abdominoplasty (except if abdominoplasty criteria are met; see the CDG titled Panniculectomy and Body Contouring Procedures) 9. Breast reduction (except if breast reduction criteria are met; see the CDG titled Breast Reduction Surgery

Coverage Determination Guideline (CDG) Updates

REVISED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gender Dysphoria (Gender Identity Disorder) Treatment *(continued)*	June 1, 2015	treatment; and - Age of majority in a given country (Note: WPATH guidelines address age of majority in a given country and for the purposes of this guideline, the age of majority is age 18; however, this refers to chronological age, not biological age. Where approval or denial of benefits is based solely on the age of the individual a case-by-case medical director review is necessary); and - If significant medical or mental health concerns are present, these must be reasonably well-controlled; and - The covered person must complete 12 months of successful continuous full time real life experience in the desired gender, and - The covered person may be required to complete	10. For plans that do not cover surgical treatment of gender dysphoria, surgical treatments for gender dysphoria are not covered even if considered to be medically necessary by the prescribing physician or other health practitioner. 11. For plans that cover surgical treatment of gender dysphoria, coverage does not apply to enrollees that do not meet the criteria listed in the *Eligibility Qualifications for Surgery* section above. **Note the following**: 1. Certain plans may have a different list of exclusions. Check the enrollee specific benefit document before making a determination. 2. Additional exclusions are listed in the *non-surgical treatment* section above.

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Gender Dysphoria (Gender Identity Disorder) Treatment *(continued)*	June 1, 2015	continuous hormone therapy (for those without contraindications); in consultation with the patient's physician, this should be determined on a case-by-case basis through the notification process; and - The treatment plan must conform to identifiable external sources including the World Professional Association for Transgender Health Association (WPATH) standards, and/or evidence-based professional society guidance ▪ Revised **clarifications for breast/chest surgery**; added language to indicate: - For a biologic male patient that is only requesting a breast augmentation, if able to take female hormones, the patient should take the female hormones for at	

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Gender Dysphoria (Gender Identity Disorder) Treatment *(continued)*	June 1, 2015	least 12 – 24 months* before being considered for bilateral breast augmentation since the patient may achieve adequate breast development without surgery [**12 months is listed by WPATH v7, whereas, 2 years is listed by, Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline (2009)]* ▪ Added notation to clarify the benefit plan document should be checked for any applicable *prior authorization or notification requirements,* or limits and maximum dollar amounts • Revised list of **excluded services for surgical treatment of gender dysphoria;** added language to clarify the following services are not covered (even if the plan includes coverage for surgical treatment for gender dysphoria: ○ Breast reduction (except if breast reduction criteria are	

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Gender Dysphoria (Gender Identity Disorder) Treatment *(continued)*	June 1, 2015	met; see the policy titled *Breast Reduction Surgery*) ○ For plans that do not cover surgical treatment of gender dysphoria, surgical treatments for gender dysphoria are not covered even if considered to be medically necessary by the prescribing physician or other health practitioner ○ For plans that cover surgical treatment of gender dysphoria, coverage does not apply to enrollees that do not meet the criteria listed in the *Eligibility Qualifications for Surgery* section of the policy	
Preventive Care Services	May 1, 2015	• Revised list of applicable procedure codes for **Preventive Care Services** ○ ***Immunizations*** ▪ Updated list of applicable CPT codes for HPV; added 90651(Gardasil9®) ▪ Updated list of applicable CPT codes for Meningococcal; added 90620 and 90621 ▪ Updated claims edit criteria; added benefit age limits for: - CPT codes 90620 and 90621: Ages 10 years and up	Refer to the CDG for complete details on the coverage guidelines for Preventive Care Services.

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	May 1, 2015	- CPT code 90651: Ages 9-26 years (ends on 27th birthday)	

Utilization Review Guideline (URG) Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Utilization Management Guiding Principles**
Propranolol Treatment for Infantile Hemangiomas: Inpatient Protocol	May 1, 2015	• Updated utilization management guiding principles; removed information pertaining to medical necessity plans (no change to coverage guidelines) • Updated supporting information to reflect the most current references	**Essential Health Benefits for Individual and Small Group** For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee specific benefit document to determine benefit coverage. **Introduction** This clinical guideline addresses the use of oral propranolol for the treatment of infantile hemangiomas (IH) and the need for up to a two day inpatient stay to monitor certain patients for heart rate, blood pressure and glycemic control. However, the mechanism of action of propranolol on IH is yet to be clearly defined. Some of the proposed hypotheses include vasoconstriction, decreased renin production, inhibition of angiogenesis, and stimulation of apoptosis. 1. Oral propranolol is proven for the treatment of infantile hemangiomas (IH). 2. The physicians and facility providing care must follow a written protocol. 3. A two day inpatient length of stay in a licensed acute care hospital is medically necessary for the treatment of patients 2 months or younger: a. Medical management is highly individualized and treatment with oral propranolol is considered in the presence of ulceration, impairment, of a vital function, (ocular compromise or airway obstruction), or risk of permanent disfigurement b. Newborns (up 2 months or age) may be admitted to an inpatient setting for 48 hours with oral propranolol c. Children over 2 months of age with medical problems that require closer monitoring when initiating propranolol (e.g. SGA, prematurity requiring apnea monitoring, cardiac disease) are treated as inpatients for the same 2 day protocol unless the medical issues require longer monitoring. In that event, comorbidities requiring a

Utilization Review Guideline (URG) Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Utilization Management Guiding Principles**
Propranolol Treatment for Infantile Hemangiomas: Inpatient Protocol *(continued)*	May 1, 2015		longer stay must be identified, with an anticipated length of inpatient stay. d. Any requests for an extension of the inpatient stay beyond two days must be clinically reviewed.