



April 2017

medical policy update **bulletin**

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

UnitedHealthcare respects the expertise of the physicians, health care professionals, and their staff who participate in our network. Our goal is to support you and your patients in making the most informed decisions regarding the choice of quality and cost-effective care, and to support practice staff with a simple and predictable administrative experience. The Medical Policy Update Bulletin was developed to share important information regarding UnitedHealthcare Medical Policy, Medical Benefit Drug Policy, Coverage Determination Guideline, Utilization Review Guideline, and Quality of Care Guideline updates.*

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

Overview

This bulletin provides complete details on UnitedHealthcare Medical Policy, Medical Benefit Drug Policy, Coverage Determination Guideline (CDG), Utilization Review Guideline (URG), and/or Quality of Care Guideline (QOCG) updates. The 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 a member for services not covered by the applicable benefit plan unless first obtaining the member's written consent, acknowledging that the service is not covered by the benefit plan and that they will be billed directly for the service.



The complete library of UnitedHealthcare Medical Policies, Medical Benefit Drug Policies, CDGs, URGs, and QOCGs is available at 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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UPDATED			
Chelation Therapy for Non-Overload Conditions	Apr. 1, 2017	<ul style="list-style-type: none"> Updated supporting information to reflect the most current clinical evidence, FDA information and references; no change to coverage rationale or list of applicable codes 	<p>Chelation for heavy metal toxicity and overload conditions (e.g., iron, copper, lead, aluminum) is proven and medically necessary and not addressed in this policy.</p> <p>Chelation therapy is unproven and not medically necessary for the treatment of "mercury toxicity" from dental amalgam fillings. Randomized controlled trials do not identify a causal association between amalgam fillings and various systemic symptoms and disorders attributed to mercury.</p> <p>Chelation therapy is unproven and not medically necessary for the treatment of chronic, progressive diseases (not involving heavy metal toxicity or overload conditions) and other disorders including but not limited to:</p> <ul style="list-style-type: none"> Alzheimer's disease Apoplectic coma Autism spectrum disorder Cancer Cardiovascular disease Chronic fatigue syndrome Chronic renal insufficiency Defective hearing Diabetes Diabetic ulcer Cholelithiasis Gout Erectile dysfunction Multiple sclerosis Osteoarthritis Osteoporosis Parkinson's disease Raynaud's disease Renal calculus Rheumatoid arthritis Schizophrenia Scleroderma Snake venom poisoning Varicose veins Vision disorders (glaucoma, cataracts, etc.)

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UPDATED			
Chelation Therapy for Non-Overload Conditions (continued)	Apr. 1, 2017		Much of the evidence supporting chelation treatment for other chronic progressive disease is based on testimonials and single-case studies. Thus, there still is no scientific evidence that demonstrates any benefit from this form of therapy.
Cognitive Rehabilitation	Apr. 1, 2017	<ul style="list-style-type: none"> Updated definition of “coma” 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 	<p>Cognitive rehabilitation is proven and medically necessary for the treatment of traumatic brain injury (TBI) and brain injury due to stroke, aneurysm, anoxia, encephalitis, brain tumors, and brain toxins when the patient can actively participate in the program (e.g., is not comatose or a vegetative or minimally conscious state which precludes such active engagement).</p> <p>The treatment regimen usually includes one of the following modalities:</p> <ul style="list-style-type: none"> Specific interventions for functional communication deficits, including pragmatic conversational skills, or Compensatory memory strategy training. <p>Cognitive rehabilitation is unproven and not medically necessary for the treatment of cerebral palsy, Down syndrome, Alzheimer's disease, attention deficit hyperactivity disorder, developmental disorders such as autism, schizophrenia and Parkinson's disease.</p> <p>Evidence in the published, peer-reviewed, medical literature to support the use of cognitive rehabilitation for these conditions is limited and conflicting. Available studies also contain design flaws including small study samples, lack of comparison groups and lack of long-term follow-up.</p> <p>Coma stimulation is unproven and not medically necessary for the treatment of comatose patients or patients in a vegetative or minimally conscious state who have sustained a brain injury due to limited evidence with overall poor quality in methodology and design, and diversity in reporting outcome measures.</p>
Embolization of the Ovarian and Iliac Veins for Pelvic Congestion Syndrome	Apr. 1, 2017	<ul style="list-style-type: none"> Updated supporting information to reflect the most current clinical evidence, CMS information and references; no change to coverage rationale or lists of applicable codes 	<p>Embolization of the ovarian or internal iliac veins is considered unproven and not medically necessary for treating pelvic congestion syndrome.</p> <p>The body of evidence in the peer-reviewed medical literature regarding embolization of the ovarian or internal iliac veins for the treatment of pelvic congestion syndrome is insufficient and poor quality. Additional well-designed randomized controlled trials are necessary to establish the relative safety and efficacy of the embolization procedure as a treatment of pelvic</p>

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UPDATED			
Embolization of the Ovarian and Iliac Veins for Pelvic Congestion Syndrome (continued)	Apr. 1, 2017		congestion syndrome.
Fecal DNA Testing	Apr. 1, 2017	<ul style="list-style-type: none"> Updated supporting information to reflect the most current clinical evidence, CMS information and references; no change to coverage rationale or list of applicable codes 	<p>Fecal DNA testing for colorectal cancer screening and/or monitoring is unproven and not medically necessary.</p> <p>There is insufficient published evidence in the clinical literature supporting the diagnostic accuracy of fecal DNA tests to screen for colorectal cancer in asymptomatic, average-risk patients. The gold standard for colorectal cancer screening is optical colonoscopy. There is insufficient published evidence comparing fecal DNA testing to optical colonoscopy. In fact, there is insufficient published clinical evidence that fecal DNA testing reduces the likelihood of mortality from colorectal cancer.</p>
Thermography	Apr. 1, 2017	<ul style="list-style-type: none"> Reformatted and reorganized policy; transferred content to new template Updated supporting information to reflect the most current clinical evidence, FDA information and references; no change to coverage rationale or list of applicable codes 	<p>Thermography (including digital infrared thermal imaging, temperature gradient studies, and magnetic resonance (MR) thermography) is unproven and not medically necessary.</p> <p>There is insufficient evidence to conclude that thermography has a beneficial impact on health outcomes. The available evidence is limited and weak, and standards for image evaluation and cut-off values that would allow clinical recommendations based on this technology have not been established.</p>
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Ablative Treatment for Spinal Pain	May 1, 2017	<ul style="list-style-type: none"> Revised coverage rationale: <ul style="list-style-type: none"> Updated coverage criteria for thermal radiofrequency ablation of facet joint nerves; replaced reference to: <ul style="list-style-type: none"> “Chronic cervical pain” with “chronic cervical (C3-4 and below) pain” 	<p>Thermal radiofrequency ablation of facet joint nerves is proven and medically necessary for chronic cervical (C3-4 and below), thoracic and lumbar pain when confirmed by:</p> <ul style="list-style-type: none"> Positive response to medial branch block at the side and level of the proposed ablation Confirmation of needle placement by fluoroscopic guided imaging Operative notes document: <ul style="list-style-type: none"> Temperature 60 degrees celsius or more Duration of ablation at least 40 seconds

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REVISED			
Ablative Treatment for Spinal Pain (continued)	May 1, 2017	<ul style="list-style-type: none"> ▪ “Medial branch block injection” with “medial branch block” ○ Added language to clarify repeat thermal radiofrequency ablation of the same facet joint <i>nerves</i> is proven and medically necessary when criteria are met ○ Updated documentation requirements; replaced criterion requiring documentation of: <ul style="list-style-type: none"> ▪ “Temperature of administration of procedure” with “temperature of procedure” ▪ “Specific <i>cervical, thoracic and/or lumbar ablated by side and level</i>” with “specific <i>identification of side and level of ablation</i>” • Updated supporting information to reflect the most current description of services, clinical evidence, FDA information and references 	<p>A repeat thermal radiofrequency ablation of the same facet joint nerves is proven and medically necessary when:</p> <ul style="list-style-type: none"> • Performed at a frequency of six months or longer (maximum of 2 times over a 12 month period); and • There has been a 50% or greater documented reduction in pain for 10 to 12 weeks following the previous ablation. <p>Thermal radiofrequency ablation of facet joint nerves is unproven and not medically necessary:</p> <ul style="list-style-type: none"> • When there has been no positive response to medial branch block injection; or • When performed more frequently than every six months. <p>For additional information regarding frequency guidelines, refer to the <i>Professional Societies</i> section of the policy.</p> <p>Documentation requirements for the aforementioned procedures must include:</p> <ul style="list-style-type: none"> • Temperature of procedure • Duration of ablation • Specific identification of side and level of medial branch blocks • Specific identification of side and level of ablation Percentage of pain relief with prior ablation if applicable • Duration of improvement from previous ablation if applicable <p>Thermal radiofrequency ablation is unproven and not medically necessary for treating ALL other pain indications including but not limited to:</p> <ul style="list-style-type: none"> • Diabetic neuropathy • Sacroiliac pain • 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 <p>Studies of radiofrequency ablation for other conditions were limited, uncontrolled, and insufficient to support conclusions regarding efficacy or</p>

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Ablative Treatment for Spinal Pain <i>(continued)</i>	May 1, 2017		<p>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.</p> <p>The following ablation procedures are unproven and not medically necessary for treating spinal pain:</p> <ul style="list-style-type: none"> • Pulsed radiofrequency therapy of the facet nerves of the cervical, thoracic, or lumbar region, sacral nerve root or dorsal root ganglion • 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) <p>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, retrospective and case series studies. The clinical value needs to be examined in well-designed, randomized controlled trials with large sample size and long term follow-up.</p>
Bariatric Surgery	Jun. 1, 2017	<ul style="list-style-type: none"> • Updated list of related policies; added reference link to policy titled <i>Obstructive Sleep Apnea Treatment</i> • Revised coverage rationale: <ul style="list-style-type: none"> ○ Updated list of required comorbidities for Class II obesity in adults; replaced "cardiopulmonary problems [e.g., documented obstructive sleep apnea (OSA) confirmed on polysomnography with an AHI or RDI of ≥ 30 (as defined by AASM Task Force Sleep1999;22:667-89)]" with "cardiopulmonary problems as a result of 	<p>The following bariatric surgical procedures are proven in adults for treating extreme obesity:</p> <ul style="list-style-type: none"> • Gastric bypass (Roux-en-Y; gastrojejunal anastomosis) • Adjustable gastric banding (laparoscopic adjustable silicone gastric banding) – Refer to the <i>U.S. Food and Drug Administration</i> section of the policy • Gastric sleeve procedure (also known as laparoscopic vertical gastrectomy or laparoscopic sleeve gastrectomy) • Vertical banded gastroplasty (gastric banding; gastric stapling) • Biliopancreatic bypass (Scopinaro procedure) • Biliopancreatic diversion with duodenal switch <p>Bariatric surgery using one of the procedures identified above (primary, secondary or revisions) for treating weight loss is medically necessary when ALL of the following criteria are met:</p> <ul style="list-style-type: none"> • Class III obesity (extreme obesity) [body mass index (BMI) > 40 kg/m²]; or • Class II obesity (BMI 35-39.9 kg/m²) in the presence of one or more of

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Bariatric Surgery (continued)	Jun. 1, 2017	<p><i>another disease process, including but not limited to documented obstructive sleep apnea (OSA) confirmed on polysomnography with an AHI or RDI of ≥ 30"</i></p> <ul style="list-style-type: none"> ○ Updated medical necessity criteria for bariatric surgical procedures in adolescents: <ul style="list-style-type: none"> ▪ Replaced criterion requiring "Class III obesity (extreme obesity) [body mass index (BMI) > 40 kg/m²]" with "Class III obesity (extreme obesity) [body mass index (BMI) > 40 kg/m²] with mild obstructive sleep apnea" ▪ Removed criterion requiring "cardiopulmonary problems [e.g., documented obstructive sleep apnea (OSA) confirmed on polysomnography with an AHI or RDI of ≥ 30 (as defined by AASM Task Force Sleep1999;22:667-89)]" ▪ Added criterion requiring "BMI 35-39.9 kg/m² with moderate to severe obstructive sleep apnea" ○ Replaced language indicating "bariatric surgery for treating gynecological abnormalities, 	<p>the following co-morbidities:</p> <ul style="list-style-type: none"> ○ Type 2 diabetes; or ○ Cardiovascular disease [e.g., stroke, myocardial infarction, poorly controlled hypertension (systolic blood pressure-greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite pharmacotherapy)]; or ○ History of coronary artery disease with a surgical intervention such as cardiopulmonary bypass or percutaneous transluminal coronary angioplasty; or ○ Cardiopulmonary problems as a result of another disease process, including but not limited to documented obstructive sleep apnea (OSA) confirmed on polysomnography with an AHI or RDI of ≥ 30; or ○ History of cardiomyopathy; <p>AND</p> <ul style="list-style-type: none"> • The individual must also meet the following criteria: <ul style="list-style-type: none"> ○ Documentation of a motivated attempt of weight loss through a structured diet program, prior to bariatric surgery, which includes physician or other health care provider notes and/or diet or weight loss logs from a structured weight loss program for a minimum of 6 months; and ○ Psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges that may contribute to a poor postoperative outcome. <p>The bariatric surgical procedures identified above are medically necessary in adolescents for treating extreme obesity and who have:</p> <ul style="list-style-type: none"> • Achieved greater than 95% of estimated adult height based on documented individual growth pattern; and • A minimum Tanner stage of 4; and • Meet the following medical necessity criteria: <ul style="list-style-type: none"> ○ Class III obesity (extreme obesity) [body mass index (BMI) > 40 kg/m²] with mild obstructive sleep apnea; or ○ Class II obesity (BMI 35-39.9 kg/m²) in the presence of one or more of the following co-morbidities: <ul style="list-style-type: none"> ▪ Type 2 diabetes; or ▪ Cardiovascular disease [e.g., stroke, myocardial infarction, poorly controlled hypertension (systolic blood pressure-greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite pharmacotherapy)]; or

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Bariatric Surgery (continued)	Jun. 1, 2017	<p>osteoarthritis, gallstones, urinary stress incontinence, gastroesophageal reflux (including for Barrett’s esophagus or gastroparesis) or other obesity- associated diseases that generally do not lead to life threatening consequences is unproven and not medically necessary” with “Bariatric surgery as the primary treatment for gynecological abnormalities, osteoarthritis, gallstones, urinary stress incontinence, gastroesophageal reflux (including for Barrett’s esophagus or gastroparesis) or other obesity- associated diseases that generally do not lead to life threatening consequences is unproven and not medically necessary”</p> <ul style="list-style-type: none"> ○ Modified language pertaining to clinical evidence/study findings to indicate: <ul style="list-style-type: none"> ▪ There is insufficient published clinical evidence to support bariatric surgery for the definitive treatment of gynecological abnormalities, osteoarthritis, gallstones, urinary stress incontinence or as treatment for gastroesophageal reflux and other obesity- 	<ul style="list-style-type: none"> ▪ History of coronary artery disease with a surgical intervention such as cardiopulmonary bypass or percutaneous transluminal coronary angioplasty; or ▪ BMI 35-39.9 kg/m²with moderate to severe obstructive sleep apnea; or ▪ History of cardiomyopathy; <p>AND</p> <ul style="list-style-type: none"> ○ The individual must also meet the following criteria: <ul style="list-style-type: none"> ▪ Documentation of a motivated attempt of weight loss through a structured diet program, prior to bariatric surgery, which includes physician or other health care provider notes and/or diet or weight loss logs from a structured weight loss program for a minimum of 6 months; and ▪ Psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges that may contribute to a poor postoperative outcome. <p>Note: See additional information in the <i>Description of Services</i> section for growth and BMI charts.</p> <p>Bariatric surgical procedures in a person who has not attained an adult level of physical development and maturation are unproven and not medically necessary.</p> <p>Potential safety issues must be addressed in studies with sufficient sample size and adequate follow-up times necessary to demonstrate the impact of the surgery on physical, sexual and reproductive maturation and the long term improvement of co-morbidities in this age group.</p> <p>Bariatric surgery as the primary treatment for gynecological abnormalities, osteoarthritis, gallstones, urinary stress incontinence, gastroesophageal reflux (including for Barrett’s esophagus or gastroparesis) or other obesity-associated diseases that generally do not lead to life threatening consequences is unproven and not medically necessary.</p> <p>There is insufficient published clinical evidence to support bariatric surgery for the definitive treatment of gynecological abnormalities, osteoarthritis, gallstones, urinary stress incontinence or as treatment for gastroesophageal reflux and other obesity-associated diseases. Bariatric surgery will frequently ameliorate symptoms of these co-morbidities; however, the primary purpose</p>

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Bariatric Surgery <i>(continued)</i>	Jun. 1, 2017	<p>associated diseases</p> <ul style="list-style-type: none"> ▪ Bariatric surgery will frequently ameliorate symptoms of these co-morbidities; however, the primary purpose of bariatric surgery in obese persons is to achieve weight loss • Updated definitions: <ul style="list-style-type: none"> ○ Modified definition of “extreme obesity” ○ Added definition of “obstructive sleep apnea (OSA)” • Updated supporting information to reflect the most current clinical evidence and references 	<p>of bariatric surgery in obese persons is to achieve weight loss.</p> <p>Robotic-assisted gastric bypass surgery is proven as equivalent but not superior to other types of minimally invasive bariatric surgery.</p> <p>Surgical adjustment or alteration of a prior bariatric procedure is proven and medically necessary for complications of the original surgery, such as stricture, obstruction, pouch dilatation, erosion, or band slippage when the complication causes abdominal pain, inability to eat or drink or causes vomiting of prescribed meals.</p> <p>The following procedures are unproven and not medically necessary for treating obesity:</p> <ul style="list-style-type: none"> • Transoral endoscopic surgery • Mini-gastric bypass (MGB) or laparoscopic mini-gastric bypass (LMGBP) • Gastric electrical stimulation with an implantable gastric stimulator (IGS) • VBLOC® vagal blocking therapy • Intragastric balloon • Laparoscopic greater curvature plication, also known as total gastric vertical plication • Stomach aspiration therapy (AspireAssist®) • Bariatric artery embolization (BAE) <p>Further studies are needed to determine the safety and efficacy of these procedures as a treatment option for obesity.</p> <p>Gastrointestinal liners (EndoBarrier®) are investigational, unproven and not medically necessary for treating obesity. Gastrointestinal liners have not received FDA approval. Their long-term efficacy has not been demonstrated.</p>
Chromosome Microarray Testing	May 1, 2017	<ul style="list-style-type: none"> • Revised coverage rationale; replaced references to “comparative genomic hybridization microarray testing” with “genome-wide comparative genomic hybridization microarray testing” • Updated supporting information to reflect the most current 	<p>Genome-wide comparative genomic hybridization microarray testing or single nucleotide polymorphism (SNP) chromosomal microarray analysis is proven and medically necessary for evaluating an embryo/fetus in the following cases:</p> <ul style="list-style-type: none"> • Women undergoing invasive prenatal testing (i.e., amniocentesis, chorionic villus sampling or fetal tissue sampling) • Intrauterine fetal demise or stillbirth <p>Genome-wide comparative genomic hybridization microarray testing</p>

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Chromosome Microarray Testing <i>(continued)</i>	May 1, 2017	description of services, clinical evidence, FDA and CMS information, and references	<p>or single nucleotide polymorphism (SNP) chromosomal microarray analysis is proven and medically necessary for evaluating patients with one or more of the following:</p> <ul style="list-style-type: none"> Multiple anomalies not specific to a well-delineated genetic syndrome and cannot be identified by a clinical evaluation alone Non-syndromic developmental delay/intellectual disability Autism spectrum disorders <p>Genome-wide comparative genomic hybridization microarray testing and single nucleotide polymorphism (SNP) chromosomal microarray analysis are unproven and not medically necessary for all other patient populations and conditions including but not limited to the following:</p> <ul style="list-style-type: none"> Preimplantation genetic diagnosis or screening in embryos Diagnosis, management, and prognosis of cancer <p>There is insufficient evidence in the clinical literature demonstrating that genome-wide comparative genomic hybridization (CGH) microarray testing or single nucleotide polymorphism (SNP) chromosomal microarray analysis has a role in clinical decision-making or has a beneficial effect on health outcomes for other conditions such as preimplantation genetic diagnosis or screening in embryos or aiding diagnosis or tumor classification or determining the most appropriate treatment and establishing an accurate prognosis for cancer. Further studies are needed to determine the analytic validity, clinical validity and clinical utility of this test for indications other than those listed above as proven.</p> <p>Genetic Counseling</p> <p>Genetic counseling is strongly recommended prior to this test in order to inform persons being tested about the advantages and limitations of the test as applied to a unique person.</p>
Cochlear Implants	Jun. 1, 2017	<ul style="list-style-type: none"> Reformatted and reorganized policy; transferred content to new template Updated benefit considerations; replaced language indicating: <ul style="list-style-type: none"> "If benefits exist for a cochlear implant, the 	<p>When used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions, bilateral or unilateral cochlear implantation is proven and medically necessary for treating patients who meet ALL of the following criteria:</p> <ul style="list-style-type: none"> Diagnosis of bilateral prelingual or postlingual moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate

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Cochlear Implants (continued)	Jun. 1, 2017	<p>external components (i.e., speech processor, microphone, and transmitter coil) are considered durable medical equipment (DME), and the implantable components are considered under the medical-surgical benefit(s) with "if benefits exist for a cochlear implant, the external components (i.e., speech processor, microphone, and transmitter coil) are considered <i>under the durable medical equipment (DME) benefit</i>, and the implantable components are considered under the medical-surgical benefit"</p> <ul style="list-style-type: none"> ○ "The member specific benefit plan document must be referenced to determine <i>the DME benefits for repair or replacement of external components</i>" with "the member specific benefit plan document must be referenced to determine <i>if there are DME benefits for repair or replacement of external components</i>" ○ "Frequency modulated (FM) systems do not prevent, diagnose or treat a sickness or injury, and are not integral to the cochlear implant itself" with "frequency modulated (FM) 	<p>hearing (or vibrotactile) aids; and</p> <ul style="list-style-type: none"> • Ability to follow or participate in a program of aural rehabilitation; and • Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system; and • No contraindications to surgery. <p>Refer to the <i>U.S. Food and Drug Administration (FDA)</i> section of the policy for indications for each cochlear implant device. Specific criteria vary with the device.</p> <p>Cochlear hybrid implants are unproven and not medically necessary for treating hearing loss.</p> <p>There is insufficient high quality evidence in the published 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.</p>

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Cochlear Implants <i>(continued)</i>	Jun. 1, 2017	<p>systems do not prevent, diagnose or treat a sickness or injury, and are not integral to <i>the function of the cochlear implant itself</i>"</p> <ul style="list-style-type: none"> Revised coverage rationale: <ul style="list-style-type: none"> Replaced reference to "U.S. Food and Drug Administration (FDA) labeled indications" with "U.S. Food and Drug Administration (FDA) labeled indications, <i>contraindications, warnings, and precautions</i>" Modified language pertaining to clinical evidence/study findings to indicate there is insufficient <i>high quality</i> evidence in the <i>published</i> clinical literature demonstrating the safety and efficacy of cochlear hybrid implants in the management of patients with severe hearing loss Added definition of "degree of hearing loss" Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references 	
Neurophysiologic Testing	May 1, 2017	<ul style="list-style-type: none"> Reorganized and revised coverage rationale for nerve conduction studies; modified language to clarify nerve conduction studies with or without late responses (e.g., F- 	<p><u>Electromyography (EMG)</u></p> <p>Surface electromyography (SEMG) is unproven and not medically necessary.</p> <p>There is limited and insufficient evidence to support the use of SEMG. Studies varied considerably in SEMG instrumentation, SEMG protocol, and diagnostic algorithm. Depending on the study's SEMG approach, diagnostic</p>

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Neurophysiologic Testing (continued)	May 1, 2017	<p>wave and H-reflex tests) are proven and medically necessary when:</p> <ul style="list-style-type: none"> ○ Performed <i>in conjunction with needle electromyography</i> for any of the listed known or suspected disorders ○ Performed <i>without needle electromyography</i> for patients who have any of the listed known or suspected disorders with any of the following clinical indications: <ul style="list-style-type: none"> ▪ Patients treated with anticoagulants; or ▪ Patients with lymphedema; or ▪ Patients being evaluated for carpal tunnel syndrome • Removed list of applicable ICD-10 diagnosis codes 	<p>performance ranged from poor to fair. Further research is needed to standardize SEMG approaches and diagnostic algorithms, increase diagnostic performance, and to assess the role of SEMG in clinical practice.</p> <p>Macroelectromyography (macro-EMG) testing is unproven and not medically necessary. There is limited and insufficient evidence to support the use of macro-EMG. Additional studies are needed to establish how this test improves diagnostic capabilities and physician decision-making.</p> <p><u>Nerve Conduction Studies</u> <i>Nerve Conduction Studies Performed in Conjunction with Needle Electromyography</i> Nerve conduction studies with or without late responses (e.g., F-wave and H-reflex tests) are proven and medically necessary when performed in conjunction with needle electromyography for any of the following known or suspected disorders:</p> <ul style="list-style-type: none"> • Peripheral nerve entrapment syndromes • Generalized neuropathies • Hereditary, metabolic, or degenerative polyneuropathy • Plexopathy (acquired disorder in tissue along nerves that causes motor and sensory dysfunction) • Neuromuscular junction disorders • Myopathies • Motor neuron disease • Spine disorder with nerve root impingement symptoms • Cervical, thoracic, and/or lumbosacral radiculopathy • Guidance for botulinum toxin injection for spasmodic dysphonia or segmental dystonia when it is difficult to isolate affected muscles • Traumatic nerve lesions <p><i>Nerve Conduction Studies Performed without Needle Electromyography</i> Nerve conduction studies with or without late responses (e.g., F-wave and H-reflex tests) are proven and medically necessary when performed without needle electromyography for patients who have any of the above known or suspected disorders with any of the following clinical indications:</p> <ul style="list-style-type: none"> • Patients treated with anticoagulants; or

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Neurophysiologic Testing (continued)	May 1, 2017		<ul style="list-style-type: none"> • Patients with lymphedema; or • Patients being evaluated for carpal tunnel syndrome <p>The American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) states that it is in the best interest of patients, in the majority of situations, for the needle EMG and the NCS examination to be conducted and interpreted on-site in real time. According to the AANEM, the use of the term “real time” with regard to nerve conduction studies indicates that information from the history and physical examinations are integrated, the specific and tailored electrodiagnostic (EDX) study is performed, and the analysis of the waveforms are all done at the same time and while the patient is present in the EDX laboratory (AANEM, Proper Performance and Interpretation of Electrodiagnostic Studies, 2014; AANEM, What does ‘On Site’ and ‘Real Time’ Mean?, 2014).</p> <p>Nerve conduction studies are unproven and not medically necessary for all conditions other than those listed above as proven. There is limited and insufficient evidence to conclude that nerve conduction studies are beneficial for health outcomes in patients with disorders other than those listed above as proven.</p> <p>Non-invasive automatic, portable, or automated point of care nerve conduction monitoring systems (e.g., the NC-stat® System, the Brevio® NCS-Monitor, and the Advance™ System) that test only distal motor latencies and conduction velocities are unproven and not medically necessary for the purpose of electrodiagnostic testing. Studies of these devices are primarily small case series comparing portable with conventional nerve conduction studies in the same patient. Studies that did use controls did not always report the patients' conditions. Large, robust randomized, controlled studies are needed to prove the safety and efficacy of this technology.</p> <p><u>Physiologic Recording of Tremor</u> Physiologic recording of tremor using accelerometers is unproven and not medically necessary. There is insufficient evidence and too few studies to conclude that these devices improve therapeutic responses for the purpose of decreasing tremor in patients with tremor. Well-designed controlled studies are needed to determine the usefulness of these devices.</p>

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Neurophysiologic Testing (continued)	May 1, 2017		<p><u>Quantitative Sensory Testing</u> Quantitative sensory testing, including monofilament testing, pressure-specified sensory testing, computer assisted sensory examinations, and current perception threshold (CPT) testing is unproven and not medically necessary. Definitive conclusions for current perception threshold (CPT) testing cannot be drawn due to evidence that is inconsistent. Furthermore, in the absence of other testing, CPT tests do not include sensory nerve conduction amplitudes or other critical data to reach conclusions on diagnoses. Further research is needed to validate the clinical utility of pressure-specified sensory testing.</p> <p><u>Visual Evoked Potentials for Glaucoma</u> Visual evoked potential testing is unproven and not medically necessary for diagnosing and evaluating glaucoma. Visual evoked potentials (VEPs) show some promise as a tool for diagnosing glaucoma, but definitive conclusions cannot be drawn due to evidence that is limited and inconsistent. Evidence regarding the use of VEP testing for monitoring progression in patients at risk for glaucoma is too limited to allow evaluation of sensitivity or positive predictive value. VEP has not been shown to be as good as or better than standard visual testing in managing patients with glaucoma.</p> <p>This policy does not address intraoperative neurophysiologic testing.</p>

Coverage Determination Guideline (CDG) Updates

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UPDATED			
Infertility Services	May 1, 2017	<ul style="list-style-type: none"> Removed list of applicable codes; added reference link to the Medical Policy titled <i>Infertility Diagnosis and Treatment</i> for coding information 	<p>Indications for Coverage</p> <p>Therapeutic (medical or surgical) procedures to correct a physical condition, which is the underlying cause of the infertility, are a covered health service (e.g., for the treatment of a pelvic mass or pelvic pain, thyroid disease, pituitary lesions, etc.).</p> <p>Infertility services include the following:</p> <ul style="list-style-type: none"> Ovulation induction (or controlled ovarian stimulation); Insemination procedures: Artificial Insemination (AI) and Intra Uterine Insemination (IUI); Assisted Reproductive Technologies (ART). <p>In addition, the infertility treatments above must be provided under the direction of a physician and the member must meet all of the following:</p> <ul style="list-style-type: none"> Have failed to achieve a Pregnancy after a year of regular, unprotected intercourse if the woman is under age 35, or after six months, if the woman is over age 35; Be under age 44, if female; Have infertility that is not related to voluntary sterilization or failed reversal of voluntary sterilization. <p>A member with an infertility benefit that is using a surrogate/gestational carrier because of a known medical cause of infertility (this does not include a member who has had a voluntary sterilization or a failed reversal of a sterilization procedure) will have coverage for the following services. These services will be paid per the member's coverage.</p> <ul style="list-style-type: none"> Female member's ovary stimulation and retrieval of eggs are covered when a member is using a surrogate (host uterus). Please note: The implantation of eggs or oocytes or donor sperm into a host uterus is not covered even if the member has the infertility benefit. Male member retrieval of sperm. <p>When applying the infertility benefit, consider the following:</p> <ul style="list-style-type: none"> Female Infertility: Infertility caused by a problem that results in the inability to produce an egg, if an embryo is unable to travel to the womb, or there is a process that prevents use of the womb for reproduction. Male Infertility: Infertility caused by problems due to inability to ejaculate or insufficient number or motility of sperm.

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UPDATED			
Infertility Services (continued)	May 1, 2017		<p>Please check the member specific benefit plan document for inclusion or exclusion.</p> <p>Some states mandate benefit coverage for infertility services. Please check state mandates.</p> <p><u>Benefit Limitations and Exclusions</u></p> <ul style="list-style-type: none"> Assisted Reproductive Technologies, ovulation induction and insemination procedures are excluded from coverage unless the member has a benefit for infertility and the criteria listed in the Indications for Coverage has been met. When the plan has a benefit for infertility services, in-vitro fertilization when it is not used as an Assisted Reproductive Technology for the treatment of infertility is not a covered health service. This would include but is not limited to elective fertility preservation, embryo accumulation/banking. When a plan does not have a benefit for infertility services, in-vitro fertilization regardless of the reason for the treatment is excluded. Surrogate parenting including fees incurred for the use of a surrogate/gestational carrier (i.e., host uterus). Donor eggs - All aspects of a donor egg cycle including stimulation, retrieval, fertilization, embryo culture and embryo transfer (fresh or frozen) are excluded from coverage unless otherwise specified in the plan language. Donor sperm - The cost of procurement and storage of donor sperm is excluded. However, the thawing and insemination are covered if the member has an infertility benefit that allows for artificial donor insemination. Additional Information: As a standard, coverage is provided for maternity services (prenatal, delivery and postnatal pregnancy). If a female member is pregnant and functioning as a surrogate, coverage would be provided for the maternity related care. Coverage is not provided for maternity services for a surrogate that is not a member. Please check the member specific benefit plan document. Tests or procedures for infertility that are unproven. Refer to the Medical Policy titled <i>Infertility Diagnosis and Treatment</i>. Advanced Reproductive Technology Services (IVF, GIFT, ZIFT, PROS, and TET) requested for reasons other than infertility, must be reviewed in accordance with the member specific benefit plan document (case by

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Infertility Services (continued)	May 1, 2017		<p>case determination).</p> <ul style="list-style-type: none"> • Infertility treatment when the cause of the infertility was a procedure that produces sterilization, e.g., vasectomy or tubal ligation. (Check the member specific benefit plan document). • Expenses for donor sperm, ovum or oocytes (eggs) or embryos. • Storage and retrieval of all reproductive materials. Examples include eggs, sperm, testicular tissue and ovarian tissue. For example, preservation of reproductive materials prior to cancer treatments and elective preservation of reproductive materials are not covered. This includes all services related, including but not limited to drug therapy, retrieval, cryopreservation and storage. • Cryopreservation except if specifically included in the member specific benefit plan document. Cryopreservation and other forms of preservation of reproductive materials, e.g., sperm, oocytes (eggs), embryos or ovarian. • Self- injectable drugs for infertility. Refer to the exclusion for self-injectable drugs in the member specific benefit plan document. • Any Infertility services or supplies beyond the benefit maximum (dollars or procedures).
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Blepharoplasty, Blepharoptosis and Brow Ptosis Repair	Jun. 1, 2017	<ul style="list-style-type: none"> • Revised coverage rationale: <ul style="list-style-type: none"> ○ Replaced references to "color photographs" with "clear color photographs" ○ Updated coverage criteria for upper eyelid blepharoplasty; replaced language indicating: <ul style="list-style-type: none"> ▪ "The color photograph must show the extra skin, but not the lid margin, <i>taped up</i> to show it reverses the visual field obstruction, and/or lateral hooding present" with "clear color 	<p>Indications for Coverage</p> <p>Some states require benefit coverage for services that UnitedHealthcare considers cosmetic procedures, such as repair of external congenital anomalies in the absence of a functional impairment. Please refer to the member specific benefit plan document.</p> <p>Criteria for a Coverage Determination that Surgery is Reconstructive and Medically Necessary</p> <p>The following must be available when requested by UnitedHealthcare:</p> <ul style="list-style-type: none"> • Best corrected visual acuity in both eyes, all patients (except pediatrics) • Eye exam (chief complaint, HPI) • Clear color photographs (eye level, frontal with patient looking straight ahead, light reflex visible and centered) • Peripheral or superior visual fields automated, reliable (refer to the <i>Definitions</i> section of the policy), un-taped/taped are preferable. Note the following:

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Blepharoplasty, Blepharoptosis and Brow Ptosis Repair (continued)	Jun. 1, 2017	<p>photographs must show <i>that the extra skin is the primary cause of visual field obstruction</i>; the extra skin, but not the lid margin, is <i>elevated</i> to show it reverses the visual field obstruction, and lateral hooding (<i>if present</i>) <i>resolves</i>"</p> <ul style="list-style-type: none"> ▪ "Automated peripheral or superior visual field testing, with the <i>eyelids</i> taped and un-taped, showing improvement of 30% or more <i>in number of points seen</i> [is required]" with "automated peripheral or superior visual field testing, with the <i>eyelid skin</i> taped and un-taped, showing improvement of 30% or more [is required]" ○ Updated coverage criteria for upper eyelid blepharoptosis repair; replaced language indicating "upper eyelid blepharoptosis repair is considered reconstructive and medically necessary when other causes of ptosis are ruled out" with "upper eyelid blepharoptosis repair is considered reconstructive and medically necessary when other <i>treatable</i> causes of ptosis 	<ul style="list-style-type: none"> ○ In situations where computerized visual field testing is not available, we will accept manual visual field testing. ○ In situations where visual field testing is not possible, see section below: "When Patient is Not Capable of Visual Field Testing." <p>Note: The visual fields and color photographs must be consistent.</p> <p>If multiple procedures are requested, the following criteria must be met:</p> <ul style="list-style-type: none"> • All criteria for each individual procedure must be met; and • Visual field testing shows visual impairment which can't be addressed by one procedure alone; and • Color photograph findings are consistent with visual field findings. <p>Upper eyelid blepharoplasty (CPT 15822 and 15823) is considered reconstructive and medically necessary when the following criteria are present:</p> <ul style="list-style-type: none"> • Ptosis has been ruled out as the primary cause of visual field obstruction; and • Clear color photographs must show that the extra skin is the primary cause of visual field obstruction. The extra skin, but not the lid margin, is elevated to show it reverses the visual field obstruction; and lateral hooding (if present) resolves; and • The patient must have a Functional/Physical Impairment complaint directly related to an abnormality of the eyelid(s); and • Excess skin (dermatochalasis/blepharochalasis) touches the lashes; and • Automated peripheral or superior visual field testing, with the eyelid skin taped and un-taped, showing improvement of 30% or more. <ul style="list-style-type: none"> ○ In situations where computerized visual field testing is not available, we will accept manual visual field testing. ○ In situations where visual field testing is not possible, see section below: "When Patient is Not Capable of Visual Field Testing." <p>Note: Extended blepharoplasty may be indicated for blepharospasm (eyelids are forced shut) when the following two criteria are met:</p> <ul style="list-style-type: none"> • Debilitating symptoms (e.g., pain); and • Conservative treatment has been tried and failed, or is contraindicated (e.g., Botox®). <p>Upper eyelid blepharoptosis repair (CPT 67901–67909) is considered</p>

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Blepharoplasty, Blepharoptosis and Brow Ptosis Repair <i>(continued)</i>	Jun. 1, 2017	<ul style="list-style-type: none"> are ruled out” ○ Updated coverage criteria for brow ptosis: <ul style="list-style-type: none"> ▪ Replaced language indicating “a second photograph [is required] with the brow <i>taped up</i> that eliminates the visual field defect” with “a second photograph [is required] with the brow <i>elevated</i> that eliminates the visual field defect” ▪ Revised list of examples of brow lift procedures to include supra-ciliary, mid-forehead, coronal, or pretrichial direct brow lift vs. browpexy or internal brow lift ○ Updated coverage criteria for entropion (eyelid turned inward); removed criterion requiring “conservative treatments have been tried and failed” ○ Updated coverage criteria for canthoplasty/canthopex: <ul style="list-style-type: none"> ▪ Removed criterion requiring “conservative treatments have been tried and failed” ▪ Replaced criterion requiring “<i>simple</i> repair of ectropion or entropion will not correct condition” with “repair of ectropion or entropion will not correct 	<p>reconstructive and medically necessary when the following criteria are present:</p> <ul style="list-style-type: none"> • The patient must have a Functional/Physical Impairment complaint directly related to the position of the eyelid(s); and • Other treatable causes of ptosis are ruled out (e.g., recent Botox® injections, myasthenia gravis when applicable); and • Eyelid droop (upper eyelid ptosis) and an MRD-1 of 2.0 mm or less; and • The MRD is documented in clear color photographs with patient looking straight ahead and light reflex centered on the pupil; and • Automated peripheral or superior visual field testing, with the eyelids taped and un-taped, showing improvement of 30% or more improvement in the number of points seen. <ul style="list-style-type: none"> ○ In situations where computerized visual field testing is not available, we will accept manual visual field testing. ○ In situations where visual field testing is not possible, see section below: “When Patient is Not Capable of Visual Field Testing.” <p>Note: For children under age 10 years, ptosis repair is covered to prevent amblyopia. Visual field testing is not required, but color photographs are required.</p> <p>Brow ptosis (CPT 67900) is considered reconstructive and medically necessary when the following criteria are present:</p> <ul style="list-style-type: none"> • Other causes have been eliminated as the primary cause for the visual field obstruction (e.g., Botox® treatments within the past six (6) months); and • Patient must have a functional complaint related to brow ptosis. Brow ptosis must be documented in two color photographs. One showing the eyebrow below the bony superior orbital rim, and a second photograph with the brow elevated that eliminates the visual field defect; and <ul style="list-style-type: none"> ○ Automated peripheral and superior visual field testing, with differential taping (eyebrow and eyebrow + eyelid) showing 30% or more improvement in total number of points seen with the eyebrow taped up. In situations where computerized visual field testing is not available, we will accept manual visual field testing. ○ In situations where visual field testing is not possible, see section below: “When Patient is Not Capable of Visual Field Testing.” • Documentation indicating the specific brow lift procedure (e.g., supra-ciliary, mid forehead or coronal, pretrichial, direct brow lift vs browpexy,

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Blepharoplasty, Blepharoptosis and Brow Ptosis Repair <i>(continued)</i>	Jun. 1, 2017	<p>condition”</p> <ul style="list-style-type: none"> Updated coverage criteria for repair of floppy eyelid syndrome (FES); replaced criterion requiring “color photos that clearly document floppy eyelid syndrome; <i>the photographs must clearly demonstrate both of the [listed criteria]</i>” with “<i>clear color photographs that clearly document floppy eyelid syndrome and demonstrate both of the [listed criteria]</i>” 	<p>internal brow lift).</p> <p>Note: For Browpexy/internal brow lift, see Coverage Limitations and Exclusions.</p> <p>Eyelid surgery with an anophthalmic socket (has no eyeball) is considered reconstructive and medically necessary when both of the following criteria are present:</p> <ul style="list-style-type: none"> Patient has an anophthalmic condition; and Patient is experiencing difficulties fitting or wearing an ocular prosthesis. <p>Lower eyelid blepharoplasty (CPT 15820 and 15821) is usually cosmetic, however, is considered reconstructive and medically necessary only when all of the following criteria are present:</p> <ul style="list-style-type: none"> There is documented facial nerve damage; and Clear color photographs document the pathology; and Patient is unable to close the eye due to the lower lid dysfunction; and Functional impairment including both of the following: <ul style="list-style-type: none"> Documented uncontrolled tearing or irritation; and Conservative treatments tried and failed. <p>Ectropion (eyelid turned outward) (CPT 67914 through 67917) or punctal eversion is considered reconstructive and medically necessary when all of the following criteria are present:</p> <ul style="list-style-type: none"> Clear color photographs document the pathology; and Corneal or conjunctival injury with both of the following criteria: <ul style="list-style-type: none"> Subjective symptoms include either: <ul style="list-style-type: none"> Pain or discomfort; or Excess tearing; and Any one of the following: <ul style="list-style-type: none"> Exposure keratitis; and/or Keratoconjunctivitis; and/or Corneal ulcer <p>Entropion (eyelid turned inward) (CPT 67921–67924) is considered reconstructive and medically necessary when all of the following criteria are present:</p> <ul style="list-style-type: none"> Clear color photographs must document the following: <ul style="list-style-type: none"> Lid turned inward; and

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Blepharoplasty, Blepharoptosis and Brow Ptosis Repair <i>(continued)</i>	Jun. 1, 2017		<ul style="list-style-type: none"> ○ At least one of the following: <ul style="list-style-type: none"> ▪ Trichiasis; or ▪ Irritation of cornea or conjunctiva; and ○ Subjective symptoms including either of the following: <ul style="list-style-type: none"> ▪ Excessive tearing; or ▪ Pain or discomfort <p>Lid retraction surgery (CPT 67911) is considered reconstructive and medically necessary when all of the following criteria are present:</p> <ul style="list-style-type: none"> • Other causes have been eliminated as the reason for the lid retraction such as use of dilating eye drops, glaucoma medications; and • Clear color photographs document the pathology; and • There is functional impairment (such as 'dry eyes', pain/discomfort, tearing, blurred vision); and • Tried and failed conservative treatments; and • In cases of thyroid eye disease two or more Hertel measurements at least 6 months apart with the same base measurements are unchanged. <p>Canthoplasty/canthopexy (CPT 21280, 21282, 67950, 67961, 67966) is considered reconstructive and medically necessary when all of the following criteria are present:</p> <ul style="list-style-type: none"> • Functional impairment; and • Clear color photographs document the pathology; and • Repair of ectropion or entropion will not correct condition; and • At least one of the following patient complaints is present: <ul style="list-style-type: none"> ○ Epiphora (excess tearing) not resolved by conservative measures; or ○ Corneal dryness unresponsive to lubricants; or ○ Corneal ulcer. <p>Repair of floppy eyelid syndrome (FES) (CPT 67961 and 67966) is considered reconstructive and medically necessary when all of the following are present when documented and confirmed by history and examination:</p> <ul style="list-style-type: none"> • Subjective symptoms must include eyelids spontaneously "flipping over" when they sleep due to rubbing on the pillow, AND one of the following: <ul style="list-style-type: none"> ○ Eye pain or discomfort; or ○ Excess tearing; or ○ Eye irritation, ocular redness and discharge • Physical Examination that documents the following:

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Blepharoplasty, Blepharoptosis and Brow Ptosis Repair <i>(continued)</i>	Jun. 1, 2017		<ul style="list-style-type: none"> ○ Eyelash Ptosis; and ○ Significant upper eyelid laxity; and ○ Presence of Giant Papillary Conjunctivitis; or ○ Corneal findings such as: <ul style="list-style-type: none"> ▪ Superficial Punctate Erosions (SPK); or ▪ Corneal abrasion (documentation of a history of corneal abrasion or recurrent erosion syndrome is considered sufficient); or ▪ Microbial Keratitis • Clear color photographs that clearly document floppy eyelid syndrome and demonstrate both of the following: <ul style="list-style-type: none"> ○ Lids must be everted in the photographs; and ○ Conjunctival surface (underbelly) of the lids must clearly demonstrate Giant Papillary Conjunctivitis • Documentation that conservative treatment has been tried and failed, examples may include: <ul style="list-style-type: none"> ○ Ocular lubricants both drops (daytime) and ointments (bedtime); or ○ Short trial of antihistamines; or ○ Topical steroid drops; or ○ Eye Shield and/or Taping the lids at bedtime • Other causes of the eye findings have been ruled out, examples may include: <ul style="list-style-type: none"> ○ Allergic conjunctivitis ○ Atopic keratoconjunctivitis ○ Blepharitis ○ Contact lens (CL) complication ○ Dermatochalasis ○ Ectropion ○ GPC (giant papillary conjunctivitis) that is not related to FES ○ Ptosis of the lid(s) ○ Superior limbic keratoconjunctivitis (SLK) <p>When Patient Is Not Capable of Visual Field Testing</p> <p>Visual field testing is not required when the patient is not capable of performing a visual field test. The following are some examples:</p> <ul style="list-style-type: none"> • If the patient is a child 12 years old or under • If the patient has intellectual disabilities (previously known as mental retardation) or some other severe neurologic disease

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Blepharoplasty, Blepharoptosis and Brow Ptosis Repair <i>(continued)</i>	Jun. 1, 2017		<p><u>Coverage Limitations and Exclusions</u></p> <p>Some states require benefit coverage for services that UnitedHealthcare considers cosmetic procedures, such as repair of external congenital anomalies in the absence of a functional impairment. Please refer to the member specific benefit plan document.</p> <p>Cosmetic Procedures are excluded from coverage:</p> <ul style="list-style-type: none"> 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. Any procedure that does not meet the reconstructive criteria above in the Indications for Coverage section. Browpexy/internal brow lift is not designed to improve function. It is considered a cosmetic procedure and is not a covered service.

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Utilization Management Guiding Principles
REVISED			
Specialty Medication Administration – Site of Care Review Guidelines	May 1, 2017	<ul style="list-style-type: none"> • Revised coverage rationale: <ul style="list-style-type: none"> ○ Updated list of applicable specialty medications requiring healthcare provider administration; replaced: <ul style="list-style-type: none"> ▪ “Infliximab (Remicade® lyophilized concentrate for intravenous use)” with “infliximab (Remicade®)” ▪ “Tocilizumab (Actemra® injection for intravenous use)” with “tocilizumab (Actemra®)” ○ Updated review criteria for outpatient hospital facility-based intravenous medication infusion site of care selection: <ul style="list-style-type: none"> ▪ Added language to indicate submission of medical records detailing at least one of the listed criteria is required ▪ Replaced criterion requiring “continuing experience of adverse events that cannot be mitigated by pre-medications” with “continuing experience of adverse events that cannot be mitigated by pre-medications <i>or infusion rate adjustments</i>” ▪ Added criteria requiring: <ul style="list-style-type: none"> - Difficulty establishing and maintaining 	<p><u>Introduction</u></p> <p>This guideline addresses the criteria for consideration of allowing hospital outpatient facility specialty medication infusion services. This includes claim submission for hospital based services with the following CMS/AMA Place of Service codes:</p> <ul style="list-style-type: none"> • 22 On Campus-Outpatient Hospital, and • 19 Off Campus-Outpatient Hospital. <p>Alternative sites of care, such as non-hospital outpatient infusion, physician office, ambulatory infusion or home infusion services are well accepted places of service for medication infusion therapy. If a patient does not meet criteria for outpatient hospital facility infusion, alternative sites of care may be used.</p> <p>This policy applies to these specialty medications that require healthcare provider administration:</p> <ul style="list-style-type: none"> • Abatacept (Orencia®) • Eculizumab (Soliris®) • Eteplirsen (Exondys 51™) • Golimumab (Simponi® Aria™) • Infliximab (Remicade®) • Infliximab-dyyb (Inflectra™) • Tocilizumab (Actemra®) • Vedolizumab (Entyvio®) <p><u>Review Criteria for Site of Care Selection</u></p> <p>Outpatient hospital facility-based intravenous medication infusion is medically necessary for persons who meet any of the following criteria (submission of medical records is required, detailing at least ONE of the following):</p> <ul style="list-style-type: none"> • Medically unstable based upon submitted clinical history; or • Initial medication infusion of or re-initiation after more than 6 months following discontinuation of therapy; or • Previous experience of a severe adverse event following infusion. Examples include but are not limited to anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure; or • Continuing experience of adverse events that cannot be mitigated by pre-medications or infusion rate adjustments; or

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Specialty Medication Administration – Site of Care Review Guidelines (continued)	May 1, 2017	<p>patent vascular access</p> <ul style="list-style-type: none"> - Homecare or infusion provider has deemed that the patient, home caregiver, or home environment is not suitable for home infusion therapy <ul style="list-style-type: none"> • Updated supporting information to reflect the most current references 	<ul style="list-style-type: none"> • Physically and/or cognitively impaired AND no home caregiver available; or • Difficulty establishing and maintaining patent vascular access; or • Homecare or infusion provider has deemed that the patient, home caregiver, or home environment is not suitable for home infusion therapy. <p>Additional Information Medical necessity criteria for administration of intravenous infusion therapy at home are addressed in MCG™ Care Guidelines, 21st edition, 2017, Home Infusion Therapy, CMT: CMT-0009(SR).</p> <p>Benefit Considerations This guideline applies to members with 2011 COC or Summary Plan Document with benefits available for health care services if medically necessary and have been approved for the requested medication clinical use.</p> <p>This guideline applies to UnitedHealthcare Commercial plans. This guideline does not apply to Medicare or Medicaid plans.</p> <p>Supporting Information and Clinical Evidence Background Home infusion as a place of service is well established and accepted by physicians. A 2010 home infusion provider survey by the National Home Infusion Association reported providing 1.24 million therapies to approximately 829,000 patients, including 129,071 infusion therapies of specialty medications.</p> <p>Clinical Evidence MCG™ Care Guidelines, 21st edition, 2017, Home Infusion Therapy, CMT: CMT-0009(SR) addresses criteria for home infusion therapy. Clinical patient characteristics for home suitability include: clinical stability, no need for close observation or daily nurse care, and reliable venous access. Additional criteria for home environment, infusion plan and patient ability to participate in care are summarized.</p> <p>Professional Societies The American Academy of Allergy Asthma and Immunology has published guidelines for the suitability of patients to receive treatment in various care</p>

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Specialty Medication Administration – Site of Care Review Guidelines (continued)	May 1, 2017		<p>setting including clinical characteristics of patients needing a high level of care in the hospital outpatient facility which includes patient characteristics: previous serious infusion reaction such as anaphylaxis, seizure, myocardial infarction, or renal failure, immune globulin therapy naïve, continual experience of moderate or serious infusion related adverse reactions, physical or cognitive impairment.</p> <p>The Hunter Syndrome European Expert Council: European recommendations for the diagnosis and multidisciplinary management of a rare disease published an article reviewing the collective experiences with agalsidase beta home infusion therapy and outlines how safe, patient-centered homecare can be organized in enzyme replacement therapy for patients with Fabry disease. Criteria include that “Patients must have received ERT in hospital for 3-6 months; if patients have previously had IRRs, they must be under control with premedication, and they must not have had an IRR in the 2-8 weeks before homecare is approved and premedication must be given. If a patient has significant respiratory disease (%FVC, 40% or less; or evidence of serious obstructive airway disease), homecare may not be suitable.”</p> <p>The Agency for Healthcare Research and Quality (AHRQ) publication on Enzyme Replacement Therapy states, “Home infusion of ERT was initially studied in patients with type I Gaucher disease. It has been reported as an option for patients with Fabry disease, MPS I, and MPS II, and MPS VI. However, patients with infantile Pompe disease may not be able to transfer to home care because of an increased risk for serious adverse events during an infusion. In general, the outcomes measured in these studies and the follow-up durations were similar to those reported by disease in the clinical studies summarized under Guiding Question 3. Safety was the main focus of most home infusion studies, as the patients had already been receiving ERT in a more controlled setting.”</p> <p><u>Medication or Condition Specific Studies</u></p> <p>In a trial evaluating patients with paroxysmal nocturnal hemoglobinuria, after initial 2-5 doses of eculizumab (Soliris), 79 patients received continued infusion with every 14 days in the home setting for the duration of the study – 1-98 months, mean duration of 39 months. The survival of patients treated with eculizumab was not different from age- and sex-matched normal controls (P = .46) but was significantly better than 30 similar patients managed before eculizumab (P = .030). Three patients on eculizumab, all</p>

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Specialty Medication Administration – Site of Care Review Guidelines <i>(continued)</i>	May 1, 2017		returning to the home infusion program. No severe adverse events (palpitations, blood pressure instability, hyperemia, respiratory symptoms) occurred during home infusions. In the carefully selected patients, infliximab infusions administered at home were safe and are cost-effective. Patients and families preferred home infusions, since time missed from school and work was reduced.