UnitedHealthcare®

November 2016

medical policy update bulletin

Medical Policy, Drug Policy & Coverage Determination Guideline Updates

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

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

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

Overview

This bulletin provides complete details on UnitedHealthcare Medical Policy, Drug Policy, and Coverage Determination Guideline (CDG) updates. The appearance of a service or procedure in this bulletin indicates only that UnitedHealthcare has recently adopted a new policy and/or updated, revised, replaced or retired an existing policy; it does not imply that UnitedHealthcare provides coverage for the service or procedure. In the event of an inconsistency or conflict between the information provided in this bulletin and the posted policy, the provisions of the posted policy will prevail. Note that most benefit plan documents exclude from benefit coverage health services identified as investigational or unproven/not medically necessary. Physicians and other health care professionals may not seek or collect payment from 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.

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

Tips for using the Medical Policy Update Bulletin:

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

Policy Update Classifications

New

New clinical coverage criteria and/or documentation review requirements have been adopted for a service, procedure, test, or device

Updated

An existing policy has been reviewed and changes have not been made to the clinical coverage criteria or documentation review requirements; however, items such as the clinical evidence, FDA information, and/or list(s) of applicable codes may have been updated

Revised

An existing policy has been reviewed and revisions have been made to the clinical coverage criteria and/or documentation review requirements

Replaced

An existing policy has been replaced with a new or different policy

Retired

The procedural codes and/or services previously outlined in the policy are no longer being managed or are considered to be proven/medically necessary and are therefore not excluded as unproven/not medically necessary services, unless coverage guidelines or criteria are otherwise documented in another policy

Note: The absence of a policy does not automatically indicate or imply coverage. As always, coverage for a service or procedure must be determined in accordance with the member's benefit plan and any applicable federal or state regulatory requirements. Additionally, UnitedHealthcare reserves the right to review the clinical evidence supporting the safety and effectiveness of a medical technology prior to rendering a coverage determination.

In This Issue

Medical Policy Updates

Page

NEW

UPDATED

REVISED

Drug and Biologics Policy Updates

NEW

REVISED

Coverage Determination Guideline (CDG) Updates

NEW

REVISED

RETIRED/REPLACED

Medical Policy Updates

NEW		
Policy Title	**Effective Date**	**Coverage Rationale**
Electric Tumor Treatment Field Therapy	Jan. 1, 2017	**The use of U.S. Food and Drug Administration (FDA) approved devices to generate electric tumor treatment fields (TTF) to treat histologically-confirmed supratentorial glioblastoma (known also as glioblastoma multiforme [GBM] or World Health Organization [WHO] grade IV astrocytoma) is proven and medically necessary as adjunctive therapy when used according to FDA labeled indications, contraindications, warnings and precautions, and when ALL of the following criteria are met**: • Initial treatment with debulking surgery or biopsy followed by chemoradiation with concomitant temozolomide and radiotherapy has been completed; and • Individual has Karnofsky Performance Status (KPS) score of ≥60; and • Individual or caregiver has been trained and is willing and able to apply the device daily; and • Individual is willing to wear the device at least 18 hours daily. When all of the above criteria are met, an initial 3 months of electric TTF therapy will be approved. Subsequent approval(s) for continuation of TTF is based on: • Evidence of no documented disease progression by MRI imaging done at a minimum of every 2-4 months. This includes a completed MRI scan with report submitted as part of any request for continuation of TTF treatment; and • KPS score of ≥60; and • Documentation that the individual and/or caregiver have been applying the device daily; and • Documentation that the patient has been wearing the device at least 18 hours daily. **The use of devices to generate electric tumor treatment fields (TTF) is considered investigational, unproven, and not medically necessary when the criteria above are not met and for all other indications**. The FDA has not approved the use of electric tumor treatment field devices for indications other than GBM. Further studies are needed to determine the safety and long-term efficacy of electric tumor treatment field therapy for other types of cancer. **Computer software used for therapeutic radiology clinical treatment planning in conjunction with electric tumor treatment field therapy is unproven and not medically necessary**. There is insufficient evidence to establish the efficacy of these products in the long-term outcomes of patients receiving electric tumor treatment field therapy.
Gender Dysphoria Treatment	Jan. 1, 2017	**Note:** This medical policy does not apply to individuals with ambiguous genitalia or disorders of sexual development. **Gender reassignment surgery may be indicated for individuals who provide the following documentation:** • A written psychological assessment from at least one qualified behavioral health provider experienced in treating gender dysphoria*, is needed for breast surgery. The assessment must document that an individual meets **all** of the following criteria:

Medical Policy Updates

NEW		
Policy Title	**Effective Date**	**Coverage Rationale**
Gender Dysphoria Treatment *(continued)*	Jan. 1, 2017	○ Persistent, well-documented gender dysphoria ○ Capacity to make a fully informed decision and to consent for treatment ○ Must be at least 18 years of age (age of majority) ○ If significant medical or mental health concerns are present, they must be reasonably well controlled. • A written psychological assessment from at least two qualified behavioral health providers experienced in treating gender dysphoria*, who have independently assessed the individual, is required for genital surgery. The assessment must document that an individual meets **all** of the following criteria: ○ Persistant, well-documented gender dysphoria ○ Capacity to make a fully informed decision and to consent for treatment ○ Must be at least 18 years of age (age of majority) ○ If significant medical or mental health concerns are present, they must be reasonably well controlled ○ Complete at least 12 months of successful continuous full-time real-life experience in the desired gender ○ Complete 12 months of continuous cross-sex hormone therapy appropriate for the desired gender (unless medically contraindicated). • Treatment plan that includes ongoing follow-up and care by a qualified behavioral health provider experienced in treating gender dysphoria*. *See the Optum Coverage Determination Guideline titled *Gender Dysphoria* for provider qualification criteria (to access this guideline, go to: Optum Provider Express > Clinical Resources > Guidelines/Policies/Manuals > Coverage Determination Guidelines). **When the above criteria are met, the following gender reassignment surgical procedures are medically necessary and covered as a proven benefit:** ***Male-to-Female (MtF)*** • Clitoroplasty (creation of clitoris) • Labiaplasty (creation of labia) • Orchiectomy (removal of testicles) • Penectomy (removal of penis) • Urethroplasty (reconstruction of female urethra) • Vaginoplasty (creation of vagina) ***Female-to-Male (FtM)*** • Bilateral mastectomy or breast reduction* • Hysterectomy (removal of uterus) • Metoidioplasty (creation of penis, using clitoris) • Penile prosthesis • Phalloplasty (creation of penis) • Salpingo-oophorectomy (removal of fallopian tubes and ovaries)

Medical Policy Updates

NEW		
Policy Title	**Effective Date**	**Coverage Rationale**
Gender Dysphoria Treatment *(continued)*	Jan. 1, 2017	• Scrotoplasty (creation of scrotum) • Testicular prostheses • Urethroplasty (reconstruction of male urethra) • Vaginectomy (removal of vagina) • Vulvectomy (removal of vulva) ∗ Bilateral mastectomy or breast reduction may be done as a stand-alone procedure, without having genital reconstruction procedures. In those cases, the individual does not need to complete hormone therapy prior to procedure. **Certain ancillary procedures, including but not limited to the following, are considered cosmetic and not medically necessary, when performed as part of gender reassignment**: • Abdominoplasty - also see the Coverage Determination Guideline titled Panniculectomy and Body Contouring Procedures) • Blepharoplasty - also see the Coverage Determination Guideline titled Blepharoplasty, Blepharoptosis and Brow Ptosis Repair) • Body contouring (e.g., fat transfer, lipoplasty, panniculectomy) - also see the Coverage Determination Guideline titled Panniculectomy and Body Contouring Procedures • Breast enlargement, including augmentation mammaplasty and breast implants • Brow lift • Calf implants • Cheek, chin and nose implants • Injection of fillers or neurotoxins – also see the Drug Policy titled Botulinum Toxins A and B • Face/forehead lift and/or neck tightening • Facial bone remodeling for facial feminization • Hair removal (e.g., electrolysis or laser) • Hair transplantation • Lip augmentation • Lip reduction • Liposuction (suction-assisted lipectomy) – also see the Coverage Determination Guideline titled Panniculectomy and Body Contouring Procedures • Mastopexy • Pectoral implants for chest masculinization • Rhinoplasty – also see the Coverage Determination Guideline titled Rhinoplasty and Other Nasal Surgeries • Skin resurfacing (e.g., dermabrasion, chemical peels, laser) • Thyroid cartilage reduction/reduction thyroid chondroplasty/trachea shave (removal or reduction of the Adam's apple) • Voice modification surgery (e.g., laryngoplasty, glottoplasty or shortening of the vocal cords) • Voice lessons and voice therapy

Medical Policy Updates

NEW

Policy Title	Effective Date	Coverage Rationale
Percutaneous Vertebroplasty and Kyphoplasty	Dec. 1, 2016	**Percutaneous vertebroplasty and kyphoplasty are proven and medically necessary for treating severe debilitating pain in cervical, thoracic or lumbar vertebral bodies within 4 months of pain onset that has failed to respond to optimal medical therapy (e.g. acetaminophen, non-steroidal anti-inflammatory drugs [NSAIDS], narcotic analgesics, braces, physical therapy, etc.) for the following indications:** • Osteoporotic vertebral compression fracture • Steroid-induced vertebral fracture • Osteolytic metastatic disease involving a vertebral body • Multiple myeloma involving a vertebral body • Vertebral hemangioma with aggressive features • Unstable fractures due to osteonecrosis (e.g., Kummel disease) **AND** computed tomography (CT) or magnetic resonance imaging (MRI) has ruled out other causes of spinal pain, including but not limited to: • Foraminal stenosis • Facet arthropathy • Herniated intervertebral disk • Other spinal degenerative disease • Other significant coexistent spinal or bony pain generators **AND** the following are not present: • Clinical evidence of spinal cord compression as confirmed by CT or MRI; or • Significant vertebral collapse or destruction (i.e., vertebra reduced to less than one-third of its original height) as confirmed by CT or MRI; or • Healed VCF as confirmed by CT or MRI; or • Lesions of the sacrum or coccyx (see the Medical Policy titled Surgical Treatment for Spine Pain for additional information on percutaneous sacral augmentation); or • Asymptomatic vertebral compression fractures (VCFs); or • VCFs responding appropriately to conservative therapy **Percutaneous vertebroplasty and kyphoplasty are unproven and not medically necessary for treating indications other than those listed above due to inadequate clinical evidence of safety and/or efficacy in published, peer-reviewed literature.**

UPDATED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Hip Resurfacing Arthroplasty	Nov. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated supporting information to reflect the most current	**Hip resurfacing arthroplasty (HRA) with U.S. Food and Drug Administration (FDA) approved devices is proven and medically necessary for treating hip disease in patients who are younger than age 65 and who meet ALL of the following criteria**: • Have chronic, persistent pain and/or disability,

Medical Policy Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Hip Resurfacing Arthroplasty *(continued)*	Nov. 1, 2016	description of services, clinical evidence, FDA and CMS information, and references; no change to coverage rationale or lists of applicable codes	• Are otherwise fit and active, • Have normal proximal femoral bone geometry and bone quality, and • Would otherwise receive a conventional primary total hip replacement (THR), but are likely to live longer than a conventional THR is expected to last. **Hip resurfacing arthroplasty (HRA) is unproven and not medically necessary for devices not approved by the FDA for treating patients who do not meet the above criteria**. There is a lack of evidence that outcomes after HRA are equivalent or superior to those of THR in other patient populations.
Proton Beam Radiation Therapy	Nov. 1, 2016	• Updated coverage rationale; added language to clarify proton beam radiation therapy is proven and medically necessary for *treating* the [listed] indications • Updated supporting information to reflect the most current clinical evidence, CMS information, and references	**Proton beam radiation therapy is proven and medically necessary for treating the following indications**: • Intracranial arteriovenous malformations (AVMs) • Ocular tumors, including intraocular/uveal melanoma (includes the iris, ciliary body and choroid) • Skull-based tumors (e.g., chordomas, chondrosarcomas or paranasal sinus tumors) **Proton beam radiation therapy is unproven and not medically necessary for treating ALL other indications, including but not limited to**: • Age-related macular degeneration (AMD) • Bladder cancer • Brain and spinal cord tumors • Choroidal hemangioma • Esophageal cancer • Gynecologic cancers • Head and neck cancers • Hepatocellular carcinoma • Lung cancer • Lymphomas • Pancreatic cancer • Prostate cancer • Vestibular tumors (e.g., acoustic neuroma or vestibular schwannoma) There is limited clinical evidence that directly compares proton beam therapy (PBT) with other types of radiation therapy. Current published evidence does

Medical Policy Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Proton Beam Radiation Therapy *(continued)*	Nov. 1, 2016		not allow for any definitive conclusions about the safety and efficacy of proton beam therapy to treat conditions other than those noted above as proven and medically necessary. **Proton beam radiation therapy used in conjunction with intensity-modulated radiation therapy (IMRT) is unproven and not medically necessary**. Clinical evidence is insufficient to support the combined use of these technologies in a single treatment plan. Comparative effectiveness studies including randomized controlled trials are needed to demonstrate the safety and long-term efficacy of combined therapy.

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Attended Polysomnography for Evaluation of Sleep Disorders	Dec. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Reorganized and revised coverage rationale: ○ Added language to indicate home sleep apnea testing (HSAT), using a portable monitor, is medically necessary for evaluating adults with suspected OSA ○ Revised coverage criteria for the following services to indicate: **Attended Full-Channel Nocturnal Polysomnography** ▪ Attended full-channel nocturnal polysomnography performed in a healthcare facility or laboratory setting is medically necessary for	**Home sleep apnea testing (HSAT), using a portable monitor, is medically necessary for evaluating adults with suspected OSA.** Where HSAT is indicated, an auto-titrating continuous positive airway pressure (APAP) device is an option to determine a fixed PAP pressure. **Attended full-channel nocturnal polysomnography, performed in a healthcare facility or laboratory setting, is medically necessary for evaluating individuals with suspected OSA when:** • Results of previous HSAT are negative, indeterminate or technically inadequate to make a diagnosis of OSA OR • Patient is a child or adolescent (i.e., less than 18 years of age) OR • Patient is known to have one or more of the following comorbid medical conditions that prohibits the use of a HSAT: ○ Significant chronic pulmonary disease as defined by a forced expiratory volume (FEV_1) % predicted of <60 (Pellegrino et al., 2005) ○ Progressive neuromuscular disease/neurodegenerative disorder (examples include, but are not limited to, Parkinson's disease, myotonic dystrophy, amyotrophic lateral sclerosis, multiple sclerosis with associated pulmonary disease, history of stroke with persistent neurological sequelae) ○ Moderate to severe heart failure (New York Heart Association class III or IV) ○ Body mass index (BMI) >50 (DeMaria et al., 2007; Blackstone and

Medical Policy Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Dec. 1, 2016	evaluating individuals with suspected OSA when: - Results of previous HSAT are negative, indeterminate or technically inadequate to make a diagnosis of OSA, or - Patient is a child or adolescent (i.e., less than 18 years of age), or - Patient is known to have one or more of the following comorbid medical conditions that prohibits the use of a HSAT: • Significant chronic pulmonary disease as defined by a forced expiratory volume (FEV_1) % predicted of <60 • Progressive neuromuscular disease/neurode generative disorder (examples include, but are not limited to, Parkinson's disease,	Cortés, 2010) ○ Obesity hypoventilation syndrome ○ Documented ongoing epileptic seizures in the presence of symptoms of sleep disorder Also see Repeat Testing section below. **When a diagnosis of OSA has been excluded or adequately treated, attended full-channel nocturnal polysomnography, performed in a healthcare facility or laboratory setting, is medically necessary for evaluating symptomatic individuals suspected of having one (1) or more of the following conditions:** • Severe chronic periodic limb movement disorder (PLMD) (not leg movements associated with another disorder such as sleep disordered breathing) • Restless legs syndrome (RLS)/Willis-Ekbom disease that has not responded to treatment • Parasomnia with documented disruptive, violent or potentially injurious sleep behavior suspicious of rapid eye movement sleep behavior disorder (RBD) • Narcolepsy, once other causes of excessive sleepiness have been ruled out **(Also see MSLT section below)** • Central sleep apnea **Attended full-channel nocturnal polysomnography, performed in a healthcare facility or laboratory setting is not medically necessary for diagnosing ANY of the following conditions:** • Circadian rhythm disorders • Depression • Insomnia There is insufficient published clinical evidence that evaluation of the above disorders with polysomnography (PSG) in the absence of symptoms of sleep disorder leads to better health outcomes. **Actigraphy is not medically necessary for evaluating sleep-related breathing and circadian rhythm disorders.** A review of the evidence does not establish the effectiveness of actigraphy as a stand-alone tool for the diagnosis of OSA. In addition, definitive patient

Medical Policy Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Dec. 1, 2016	myotonic dystrophy, amyotrophic lateral sclerosis, multiple sclerosis with associated pulmonary disease, history of stroke with persistent neurological sequelae) • Moderate to severe heart failure (New York Heart Association class III or IV) • Body mass index (BMI) >50 • Obesity hypoventilation syndrome • Documented ongoing epileptic seizures in the presence of symptoms of sleep disorder (Also see *Attended Repeat Testing* section of the policy) ▪ When a diagnosis of OSA has been excluded or adequately treated, attended full-channel nocturnal polysomnography performed in a healthcare facility or	selection criteria for the use of actigraphy devices for the diagnosis of sleep apnea have not been established. The evidence regarding the use of actigraphy for the evaluation of circadian rhythm disorders is of low quality; therefore, the clinical utility cannot be established. **Daytime Sleep Studies** **Multiple sleep latency testing (MSLT) is medically necessary for evaluating individuals with suspected narcolepsy when other causes of excessive sleepiness have been excluded.** For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 20th edition, 2016, Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT), A-0146 (AC). **Maintenance of wakefulness testing (MWT) is medically necessary for evaluating individuals whose inability to remain awake constitutes a safety issue, or for assessing response to treatment in individuals with narcolepsy or idiopathic hypersomnia.** For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 20th edition, 2016, Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT), A-0146 (AC). **Multiple sleep latency testing (MSLT) and the maintenance of wakefulness test (MWT) are not medically necessary for evaluating OSA, insomnia or circadian rhythm disorders.** Available published evidence is insufficient to demonstrate improved management of these conditions through the use of MSLT. Published evidence is limited to poorly controlled studies. **An abbreviated daytime sleep study (PAP-Nap), to acclimate individuals to PAP and its delivery, is not medically necessary.** Further results from large, prospective studies are needed to assess the clinical value of this test. **Attended PAP Titration** **A split-night sleep study, performed in a healthcare facility or laboratory setting, is medically necessary for diagnosis and PAP titration when an individual meets the above criteria for an attended sleep study.**

Medical Policy Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Dec. 1, 2016	laboratory setting is medically necessary for evaluating symptomatic individuals suspected of having **one (1) or more** of the following conditions: - Severe chronic periodic limb movement disorder (PLMD) (not leg movements associated with another disorder such as sleep disordered breathing) - Restless legs syndrome (RLS)/Willis-Ekbom disease that has not responded to treatment - Parasomnia with documented disruptive, violent or potentially injurious sleep behavior suspicious of rapid eye movement sleep behavior disorder (RBD) - Narcolepsy, once other causes of excessive sleepiness have been ruled out (also see the *Daytime Sleep Studies* section in	**When a split-night sleep study is inadequate or not feasible, a full-night study, performed in a healthcare facility or laboratory setting, is medically necessary for PAP titration when an individual meets the above criteria for an attended full-channel nocturnal polysomnography and has a confirmed diagnosis of OSA. (Also see Repeat Testing section below)** **Attended Repeat Testing** It may be necessary to perform repeat sleep studies. Where repeat testing is indicated, attended full-channel nocturnal polysomnography, performed in a healthcare facility or laboratory setting, is medically necessary for individuals who meet the above criteria for an attended sleep study. Repeat testing and repositioning/adjustments for oral sleep appliances can be done in the home unless the patient meets criteria for an attended sleep study.

Medical Policy Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Dec. 1, 2016	the policy) - Central sleep apnea ▪ Attended full-channel nocturnal polysomnography performed in a healthcare facility or laboratory setting is not medically necessary for diagnosing **any** of the following conditions: - Circadian rhythm disorders - Depression - Insomnia **Daytime Sleep Studies** ▪ Multiple sleep latency testing (MSLT) is medically necessary for evaluating individuals with suspected narcolepsy when other causes of excessive sleepiness have been excluded ▪ Maintenance of wakefulness testing (MWT) is medically necessary for evaluating individuals whose inability to remain awake constitutes a safety issue, or for assessing response to treatment in individuals with narcolepsy or idiopathic hypersomnia ▪ Multiple sleep latency testing (MSLT) and the	

Medical Policy Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Dec. 1, 2016	maintenance of wakefulness test (MWT) are not medically necessary for evaluating OSA, insomnia, or circadian rhythm disorders ▪ An abbreviated daytime sleep study (PAP-Nap), to acclimate individuals to PAP and its delivery, is not medically necessary **Attended PAP Titration** ▪ A split-night sleep study, performed in a healthcare facility or laboratory setting, is medically necessary for diagnosis and PAP titration when an individual meets the listed criteria for an attended sleep study ▪ When a split-night sleep study is inadequate or not feasible, a full-night study, performed in a healthcare facility or laboratory setting, is medically necessary for PAP titration when an individual meets the listed criteria for an attended full-channel nocturnal polysomnography and has a confirmed diagnosis of OSA (also	

Medical Policy Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Dec. 1, 2016	refer to the *Attended Repeat Testing* section of the policy) **Attended Repeat Testing** ▪ It may be necessary to perform repeat sleep studies; where repeat testing is indicated, attended full-channel nocturnal polysomnography performed in a healthcare facility or laboratory setting is medically necessary for individuals who meet the listed criteria for an attended sleep study ▪ Repeat testing and repositioning/adjustments for oral sleep appliances can be done in the home unless the patient meets criteria for an attended sleep study • Updated definitions: ○ Added definition of: ▪ Apnea ▪ Apnea hypopnea index (AHI) ▪ Central disorders of hypersomnolence ▪ Circadian rhythm sleep-wake disorders ▪ Home sleep apnea testing ▪ Hypersomnolence ▪ Hypopnea ▪ Monitoring time	

Medical Policy Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Dec. 1, 2016	▪ Positive airway pressure (PAP) ▪ Respiratory disturbance index (RDI) ▪ Respiratory effort-related arousal (RERA) ▪ Respiratory event index (REI) ○ Removed definition of: ▪ Disruptive snoring ○ Revised definition of: ▪ Actigraphy ▪ Central sleep apnea (CSA) ▪ Excessive sleepiness [somnolence, hypersomnia, excessive daytime sleepiness (EDS)] ▪ Insomnia ▪ Narcolepsy ▪ Obesity hypoventilation syndrome (OHS) ▪ Obstructive sleep apnea (OSA) ▪ Parasomnia ▪ Periodic limb movement arousal index (PLMAI) ▪ Periodic limb movement disorder (PLMD) ▪ Periodic limb movement index (PLMI) ▪ Periodic limb movements of sleep (PLMS) ▪ Rapid eye movement sleep behavior disorder (RBD) ▪ Restless legs syndrome (RLS)/Willis-Ekbom	

Medical Policy Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Dec. 1, 2016	disease • Updated and reformatted list of applicable CPT codes: ○ Added 95782, 95783, 95800, 95801, and 95806 ○ Removed descriptor classifying codes as "not medically necessary procedure codes" • Added list of applicable HCPCS codes: G0398, G0399, and G0400 • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	
Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC)	Nov. 1, 2016	• Reformatted and revised coverage rationale for BRCA testing criteria: ○ Replaced language indicating "BRCA1 and BRCA2 screening tests are proven and medically necessary for men and women without a personal history of breast or ovarian cancer with at least one of the listed familial risk factors *only when there are no family members affected with a BRCA associated cancer available for testing*" with "BRCA1 and BRCA2 screening tests are proven and medically necessary for men and women without a personal history of breast or ovarian cancer with at least	**Definitions** Please note, for the purpose of this policy: • Close blood relatives are defined as follows: ○ First degree relatives include parents, siblings and offspring ○ Second degree relatives include half-brothers/sisters, aunts/uncles, grandparents, grandchildren and nieces/nephews affected on the same side of the family ○ Third degree relatives include first cousins, great-aunts/uncles, great-grandchildren and great grandparents affected on same side of family • A breast cancer diagnosis includes either invasive carcinomas or non-invasive (in situ) ductal carcinoma types. • Ovarian cancer also includes fallopian tube cancers and primary peritoneal carcinoma. • Limited family history is defined as having fewer than two known first-degree or second-degree female relatives or female relatives surviving beyond 45 years of age on either or both sides of the family. (e.g., individual who is adopted) • Documentation of personal and family history, in the form of a pedigree drawing/diagram utilizing standardized nomenclature, should be in the contemporaneous medical records submitted with the testing request

Medical Policy Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Nov. 1, 2016	one of the listed familial risk factors" • Updated supporting information to reflect the most current references	(i.e., request form). • For the statements that include age guidelines, a person is considered to be 45 years of age up until the day before their 46th birthday, and a person is considered to be 50 years of age up until the day before their 51st birthday. • Two breast primary cancers include cancers appearing at the same time (synchronous) and one is not a metastasis of the other; or primary cancers developing at different times (metachronous or asynchronous). The tumors may be in one or two breasts. • Gleason scoring is a system of grading prostate cancer tissue based on how it looks under a microscope. Gleason scores range from 2 to 10 and indicate how likely it is that a tumor will spread. A low Gleason score means the cancer tissue is similar to normal prostate tissue and the tumor is less likely to spread. A high Gleason score means the cancer tissue is very different from normal and the tumor is more likely to spread. • HBOC-associated malignancies include prostate cancer (Gleason score ≥7), pancreatic cancer or melanoma. The presence of these malignancies does not necessarily justify BRCA testing. For example, a female with breast cancer over age 50 whose sister had melanoma at 40 and whose father has prostate cancer (Gleason score ≥7) would meet criteria. In another example, a female with breast cancer over age 50 whose maternal aunt had pancreatic cancer and whose paternal uncle had prostate cancer (Gleason score ≥7) would not meet criteria because the aunt and uncle are on different sides of the family. • Triple-negative breast cancer refers to any breast cancer that does not show expression of estrogen receptors (ER), progesterone receptors (PR) or HER2/neu. This subtype of breast cancer is clinically characterized as more aggressive and less responsive to standard treatment and is associated with poorer overall patient prognosis. It is diagnosed more frequently in younger women, women with *BRCA1* mutations and those belonging to African-American and Hispanic ethnic groups. • A founder mutation is a gene mutation observed with high frequency in a group that is or was geographically or culturally isolated, in which one or more of the ancestors was a carrier of the mutant gene. This phenomenon is often called a founder effect (National Cancer Institute website).

Medical Policy Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Nov. 1, 2016		**Genetic Counseling** For benefit plans that allow for medical necessity review, genetic counseling is required by an independent (not employed by a genetic testing lab) genetics provider prior to genetic testing for BRCA mutations in order to inform persons being tested about the benefits and limitations of a specific genetic test as applied to a unique person. Genetics providers employed by or contracted with a laboratory that are part of an integrated health system that routinely delivers health care services beyond the laboratory testing itself are considered independent. Genetic testing for BRCA mutations requires documentation of medical necessity by **one** of the following who has evaluated the member and intends to engage in post-test follow-up counseling: • Board-Eligible or Board-Certified Genetic Counselor (CGC) • Advanced Genetics Nurse (AGN-BC) • Genetic Clinical Nurse (GCN) • Advanced Practice Nurse in Genetics (APNG) • A Board-Eligible or Board-Certified Clinical Geneticist • A physician with experience in cancer genetics (Defined as providing cancer risk assessment on a regular basis and having received specialized ongoing training in cancer genetics. Educational seminars offered by commercial laboratories about how to perform genetic testing are not considered adequate training for cancer risk assessment and genetic counseling.) ***Documentation Requirements*** • Three generation pedigree • UnitedHealthcare genetic counseling attestation form **BRCA Testing Criteria** **Note**: National Comprehensive Cancer Network (NCCN) guidelines state that meeting one or more of these criteria warrants further personalized risk assessment, genetic counseling and consideration of genetic testing. Comprehensive *BRCA1*/*BRCA2* genetic testing includes sequencing of both *BRCA1* and *BRCA2* genes and analysis for large genomic rearrangements, either concurrently or sequentially. NCCN guidelines emphasize the need for comprehensive testing for individuals who meet the testing criteria for *BRCA1*/*BRCA2* and have no known familial *BRCA1*/*BRCA2* mutations who have undergone accurate risk assessment and genetic counseling.

Medical Policy Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**

Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC)
(continued)
	Nov. 1, 2016		**Personal History of Cancer**
			Personal History of Breast Cancer
			BRCA1 and *BRCA2* testing is proven and medically necessary for women **with a personal history** of breast cancer in the following situations and where gene testing results will impact medical management:
			• Breast cancer diagnosed at age 45 or younger with or without family history; or
			• Breast cancer diagnosed at age 50 or younger with:
			  ○ An additional primary breast cancer; or
			  ○ At least one close blood relative with breast cancer at any age; or
			  ○ At least one close blood relative with pancreatic cancer; or
			  ○ At least one close blood relative with prostate cancer (Gleason score ≥7; or
			  ○ An unknown or limited family history (see *Definitions* section of the policy for further clarification of limited family history).
			• Breast cancer diagnosed at any age with:
			  ○ At least one close blood relative with breast cancer diagnosed at age 50 or younger; or
			  ○ At least two close blood relatives on the same side of the family with breast cancer at any age; or
			  ○ At least one close blood relative with ovarian cancer at any age; or
			  ○ At least two close blood relatives on the same side of the family with pancreatic and/or prostate cancer (Gleason score ≥7) at any age; or
			  ○ Close male blood relative with breast cancer; or
			  ○ At least one close blood relative who has a *BRCA1* or *BRCA2* mutation (Testing should be targeted to the known *BRCA1*/*BRCA2* mutation in the family. Further *BRCA1*/*BRCA2* testing should only be pursued if the results are negative and the patient otherwise meets testing criteria); or
			  ○ Ashkenazi Jewish or ethnic groups associated with founder mutations. Testing for Ashkenazi Jewish founder-specific mutations should be performed first. Further *BRCA1*/*BRCA2* testing should only be pursued if the results are negative and the patient otherwise meets testing criteria without considering Ashkenazi Jewish ancestry.
			• Triple-negative breast cancer diagnosed at age 60 or younger.
			
			BRCA1 and *BRCA2* testing is proven and medically necessary for men **with a personal history** of breast cancer.

Medical Policy Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Nov. 1, 2016		***Personal History of Ovarian Cancer*** *BRCA1* and *BRCA2* testing is proven and medically necessary for women **with a personal history** of ovarian cancer. ***Personal History of Pancreatic Cancer*** *BRCA1* and *BRCA2* testing is proven and medically necessary for women and men **with a personal history** of pancreatic cancer at any age and at least one close blood relative on the same side of the family with ovarian cancer at any age or breast cancer (≤ age 50 years) or two relatives with breast, pancreatic and/or prostate cancer (Gleason score ≥7) at any age. *BRCA1* and *BRCA2* testing for Ashkenazi Jewish founder-specific mutations is proven and medically necessary for women and men **with a personal history** of pancreatic cancer and Ashkenazi Jewish ancestry. ***Personal History of Prostate Cancer*** *BRCA1* and *BRCA2* testing is proven and medically necessary for men **with a personal history** of prostate cancer (Gleason score ≥7) at any age and at least one close blood relative on the same side of the family with ovarian cancer at any age or breast cancer (≤ age 50 years) or two relatives with breast, pancreatic and/or prostate cancer (Gleason score ≥7) at any age. **No Personal History of Cancer** *BRCA1* and *BRCA2* screening tests are proven and medically necessary for men and women **without a personal history** of breast or ovarian cancer with **at least one** of the following familial risk factors: • At least one first- or second-degree blood relative meeting any of the criteria under Personal History of Cancer above; or • At least one third-degree blood relative with breast cancer and/or ovarian cancer who has at least 2 close blood relatives with breast cancer (at least one with breast cancer at age 50 or younger) and/or ovarian cancer; or • A known BRCA1/BRCA2 mutation in a blood relative (defined as first-, second- or third-degree relative). Testing should be targeted to the known *BRCA1/BRCA2* mutation in the family. Further *BRCA1/BRCA2* testing should only be pursued if the results are negative and the patient otherwise meets testing criteria. **Note**: NCCN guidelines state that significant limitations of interpreting test results for an individual without a cancer diagnosis should be

Medical Policy Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Nov. 1, 2016		discussed. If there are no living family members with breast or ovarian cancer available for testing, consider testing family members affected with other cancers associated with *BRCA1*/*BRCA2*, such as prostate cancer (Gleason score ≥7), pancreatic cancer or melanoma. Testing of individuals without a cancer diagnosis should only be considered when there is no affected family member available for testing (NCCN, 2016). **All Other Indications** *BRCA1* and/or *BRCA2* testing is unproven and not medically necessary for all other indications including: • Screening for breast or ovarian cancer risk for individuals not listed in the proven indications above or • Risk assessment of other cancers. Further evidence is needed to establish the clinical utility of testing in other populations.
Omnibus Codes	Dec. 1, 2016	• Revised coverage rationale; added language to indicate **cooled radiofrequency ablation (RFA) (CPT codes 22899, 27299, 27599, and 64999)** is unproven and not medically necessary for the treatment of pain of any etiology due to insufficient clinical evidence of safety and/or efficacy in published peer-reviewed medical literature	Refer to the policy for complete details on the coverage guidelines for Omnibus Codes.
Vagus Nerve Stimulation	Jan. 1, 2017	• Reformatted and reorganized policy; transferred content to new template • Updated list of related policies: ○ Added reference link to policy titled *Implanted Electrical Stimulator for Spinal Cord* ○ Removed reference link to	**Vagus nerve stimulation (VNS) is proven and medically necessary for treating epilepsy in patients with ALL of the following**: • Medically refractory epileptic seizures with failure of two or more trials of single or combination antiepileptic drug therapy or intolerable side effects of antiepileptic drug therapy; and • The patient is not a surgical candidate or has failed a surgical intervention; and • No history of left or bilateral cervical vagotomy. The U.S. Food and Drug Administration (FDA) identifies a history of left or bilateral cervical

Medical Policy Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Vagus Nerve Stimulation *(continued)*	Jan. 1, 2017	the United Behavioral Health New Technology Evaluation titled *Vagus Nerve Stimulation for Major Depressive Disorder* • Revised coverage rationale: ○ Replaced language indicating "vagus nerve stimulation (VNS) is proven and medically necessary for treating epilepsy in patients with medically refractory epileptic seizures" with "vagus nerve stimulation (VNS) is proven and medically necessary for treating epilepsy in patients with medically refractory epileptic seizures *with failure of two or more trials of single or combination antiepileptic drug therapy or intolerable side effects of antiepileptic drug therapy*" ○ Added language to indicate: ▪ Vagus nerve stimulation implants that allow detection and stimulation of increased heart rate (e.g., AspireSR™ Model 106) are unproven and not medically necessary for treating epilepsy ▪ There is limited evidence to determine if vagus nerve stimulation implants that allow detection and stimulation of increased heart rate	vagotomy as a contraindication to vagus nerve stimulation. It is an expectation that the physician have experience and expertise in the use of vagus nerve stimulation. **Vagus nerve stimulation implants that allow detection and stimulation of increased heart rate (e.g., AspireSR™ Model 106) are unproven and not medically necessary for treating epilepsy**. There is limited evidence to determine if vagus nerve stimulation implants that allow detection and stimulation of increased heart rate are beneficial for improving health outcomes in patients with epilepsy. Larger, long-term studies are needed to determine if this device is safe and effective. **Vagus nerve stimulation is unproven and not medically necessary for treating ALL other indications, including but not limited to**: • Alzheimer's disease • Anxiety disorder • Autism spectrum disorder • Back and neck pain • Bipolar disorder • Bulimia • Cerebral palsy • Chronic pain syndrome • Cluster headaches • Depression • Fibromyalgia • Heart failure • Migraines • Morbid obesity • Narcolepsy • Obsessive-compulsive disorder • Paralysis agitans • Sleep disorders • Tourette's syndrome Available studies on the use of vagus nerve stimulation for treating severe, major depression or bipolar disorder refractory to medical therapy contain methodological flaws such as lack of control group, small sample size, potential bias, lack of randomization and blinding and lack of statistical

Medical Policy Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Vagus Nerve Stimulation *(continued)*	Jan. 1, 2017	are beneficial for improving health outcomes in patients with epilepsy; larger, long-term studies are needed to determine if this device is safe and effective • Updated list of applicable CPT codes; removed 95970, 95974, and 95975 • Updated list of applicable HCPCS codes; revised description for L8680 • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	power analysis. There is a substantial placebo effect associated with depression treatments and the lack of data from prospective randomized controlled or comparative clinical studies considerably limits the conclusions that can be drawn from the available evidence. Furthermore, preliminary analysis of a randomized controlled trial did not find a statistically significant difference between sham and active VNS. Definitive patient selection criteria for vagus nerve stimulation (VNS) in patients with treatment-resistant depression have not yet been established, and significant predictors of response have also not been identified. Early research has examined the use of vagus nerve stimulation for additional indications. However, because of limited studies, small sample sizes and weak study designs, there is insufficient data to conclude that vagus nerve stimulation is safe and/or effective for treating these indications.

Drug and Biologics Policy Updates

NEW		
Policy Title	**Effective Date**	**Coverage Rationale**
Ocrevus® (Ocrelizumab)	Jan. 1, 2017	Please refer to the Oncology Medication Clinical Coverage Policy for updated information based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®) for oncology indications. Ocrelizumab is **proven** and **medically necessary** for the treatment of: 1. Primary progressive multiple sclerosis 2. Relapsing forms of multiple sclerosis Ocrelizumab is **unproven** and **not medically necessary** for the treatment of: 1. Lupus nephritis 2. Rheumatoid arthritis 3. Systemic Lupus Erythematosus
Probuphine® (Buprenorphine)	Jan. 1, 2017	Probuphine (buprenorphine) subdermal implant is **proven** and **medically necessary** for: 1. The maintenance treatment of **opioid dependence** in patients who meet **all** of the following criteria: a. Patient has achieved and sustained prolonged clinical stability on transmucosal buprenorphine **AND** b. Patient is currently maintained on a dose of 8mg per day or less of sublingual or transmucosal buprenorphine product equivalent [e.g., Subutex 8 mg or less, Suboxone (or generic equivalent) 8 mg/2 mg or less, Bunavail 4.2 mg/0.7 mg or less, or Zubsolv 5.7 mg/1.4 mg or less] **AND** b. Patient has been on a stable sublingual or transmucosal buprenorphine dose for six months or longer without any need for supplemental dosing or adjustments **AND** c. Prescriber meets DATA 2000 requirements and has been assigned a unique identification number specifc to the prescription of medication assisted therapy (DEA-X) **AND** d. Prescriber and/or the healthcare provider performing insertion has successfully completed a live training program specific to Probuphine insertion **AND** e. Submission of medical records (e.g., chart notes, laboratory values) documenting **One** of the following: (1) **Initial therapy with Probuphine** when meeting **all** of the following: (a) Patient has a viable site for implant on the upper arm (inner side of the upper arm about 8-10 cm (3-4 inches) above the medial epicondyle of the humerus in the sulcus between the biceps and triceps muscle). (b) Patient is participating in behavioral therapy/peer support program. (c) Patient will not be receiving supplemental sublingual or transmucosal buprenorphine. (d) Patient has not had an opioid-positive urine drug screen within the previous ninety days prior to insertion.* **OR** (2) **Continuation therapy with Probuphine** when meeting **all** of the following: (a) Patient has only had one Probuphine implant and has a viable, unused site in the contralateral arm. (b) Probuphine is not being inserted into a previously used arm or insertion site. (c) Probuphine is only to be used in a maximum of 2 insertions (once in each arm). (d) Patient shows no evidence of tampering, extraction, or attempted removal of the previous

Drug and Biologics Policy Updates

NEW		
Policy Title	**Effective Date**	**Coverage Rationale**
Probuphine® (Buprenorphine) *(continued)*	Jan. 1, 2017	Probuphine implant. (e) Patient has not had an opioid-positive urine drug screen since starting Probuphine therapy.* *Note: Patients screening positive for opioid use outside of an opioid dependence treatment regimen is evidence that the patient has not achieved or is no longer in susatained, prolonged, clinical stability with their treatment program. Use of Probuphine is not indicated in this population. Patients should use sublingual or transmucosal buprenorphine until the patient can achieve sustained, prolonged, clinical stability on a low-to-moderate dose (i.e., doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablet or generic equivalent). Probuphine is **unproven** and **not medically necessary** for: 1. Pain management 2. Patients who have not achieved and sustained prolonged clinical stability and tolerance to opioids for at least six months. 3. Patients who are maintained on sublinqual or transmucosal buprenorphine at doses greater than 8 mg per day. 4. Patients who are not participating in a treatment program that includes counseling and psychosocial support. 5. Patients who are recently tapered to a lower dose of sublingual or transmucosal buprenorphine for the sole purpose of transitioning to Probuphine. 6. Patients who are new entrants to opioid dependence treatment. 2. Patients who have already had one insertion in each arm. 3. Patient who do not have viable sites for insertion in the upper arm. 4. Patients who have an opioid-positive urine drug screen within the previous ninety days. 5. Patient is currently being treated for chronic pain requiring opioids.
Respiratory Interleukins (IL)	Jan. 1, 2017	This policy provides information about the use of certain specialty pharmacy medications administered by either the subcutaneous (SC) or intravenous (IV) route for severe asthmatic conditions. This policy refers to the following drug products, both of which are interleukin-5 (IL-5) antagonists: 1. Nucala® (mepolizumab) 2. Cinqair® (reslizumab) **Proven** **Nucala** for subcutaneous use is **proven** for add-on therapy for: 1. Patients who meet **both** of the following criteria: A. Has an eosinophilic phenotype B. Will be used as add-on maintenance therapy in the treatment of severe asthma **Additional information to support medical necessity review where applicable:** Nucala is **medically necessary** when **all** of the following criteria are met:

Drug and Biologics Policy Updates

NEW		
Policy Title	**Effective Date**	**Coverage Rationale**
Respiratory Interleukins (IL) *(continued)*	Jan. 1, 2017	A. Diagnosis of severe asthma **AND** B. Classification of asthma as uncontrolled or inadequately controlled as defined by at least **one** of the following: 1. Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20) **OR** 2. Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months **OR** 3. Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment) **OR** 4. Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal]) **AND** C. Asthma is an eosinophilic phenotype as defined by a baseline (pre-mepolizumab treatment) peripheral blood eosinophil level ≥ 150 cells/µL within the past 6 weeks **AND** D. Used in combination with **one** of the following: 1. **One** maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta$_2$-agonist (LABA) product [e.g., fluticasone propionate/salmeterol (Advair®), budesonide/formoterol (Symbicort®)] **OR** 2. Combination therapy including **both** of the following: a. **One** high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco®), mometasone furoate (Asmanex®), beclomethasone dipropionate (QVAR®)] **AND** b. **One** additional asthma controller medication [e.g., LABA - olodaterol (Striverdi®) or indacaterol (Arcapta®); leukotriene receptor antagonist – montelukast (Singulair®); theophylline] **AND** E. Patient is **not** receiving Nucala in combination with either of the following: 1. Xolair (omalizumab) 2. Cinqair (reslizumab) **AND** F. Nucala dosing for severe eosinophilic asthma is in accordance with the United States Food and Drug Administration approved labeling: 100mg subcutaneously once every 4 weeks **AND** G. Prescribed by or in consultation with a pulmonologist or allergist/immunologist **Cinqair** for intravenous use is **proven** for add-on therapy for: A. Patients who meet **both** of the following criteria: 1. Have an eosinophilic phenotype 2. Will be used as add-on maintenance therapy in the treatment of severe asthma **Additional information to support medical necessity review where applicable:** Cinqair is **medically necessary** when **all** of the following criteria are met: A. Diagnosis of severe asthma **AND** B. Classification of asthma as uncontrolled or inadequately controlled as defined by at least **one** of the following: 1. Poor symptom control (e.g., ACQ score consistently greater than 1.5 or ACT score consistently less than 20) **OR**

Drug and Biologics Policy Updates

NEW		
Policy Title	**Effective Date**	**Coverage Rationale**
Respiratory Interleukins (IL) *(continued)*	Jan. 1, 2017	2. Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months **OR** 3. Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment) **OR** 4. Airflow limitation (e.g., after appropriate bronchodilator withhold FEV1 less than 80% predicted [in the face of reduced FEV1/FVC defined as less than the lower limit of normal]) **AND** C. Asthma is an eosinophilic phenotype as defined by a baseline (pre-reslizumab) peripheral blood eosinophil level of ≥ 400 cells/µL within the past 4 weeks **AND** D. Used in combination with **one** of the following: 1. **One** maximally-dosed (appropriately adjusted for age) combination ICS/LABA product [e.g., fluticasone propionate/salmeterol (Advair®), budesonide/formoterol (Symbicort®)] **OR** 2. Combination therapy including **both** of the following: a. **One** high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco®), mometasone furoate (Asmanex®), beclomethasone dipropionate (QVAR®)] **AND** b. One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi®) or indacaterol (Arcapta®), leukotriene receptor antagonist – montelukast (Singulair®), theophylline] **AND** E. Patient is **not** receiving Cinqair in combination with either of the following: 1. Xolair (omalizumab) 2. Nucala (mepolizumab) **AND** F. Cinqair dosing for severe eosinophilic asthma is in accordance with the United States Food and Drug Administration approved labeling: 3 mg/kg intravenously once every 4 weeks **AND** G. Prescribed by or in consultation with a pulmonologist or allergist/immunologist **Reauthorization/Continuation of Care Criteria** For patients currently on Nucala or Cinqair for the treatment of severe eosinophilic asthma, authorization for continued use will be approved based on **all** of the following criteria: A. Documentation of positive clinical response (e.g., reduction in exacerbations) **AND** B. Used in combination with an ICS-containing controller medication **AND** C. **One** of the following: 1. Patient is **not** receiving Nucala in combination with either of the following: a. Xolair (omalizumab) b. Cinqair (reslizumab) **OR** 2. Patient is **not** receiving Cinqair in combination with either of the following: a. Xolair (omalizumab) b. Nucala (mepolizumab) **AND** D. **One** of the following: 1. Nucala dosing for severe eosinophilic asthma is in accordance with the United States Food and Drug Administration approved labeling: 100mg subcutaneously once every 4 weeks **OR** 2. Cinqair dosing for severe eosinophilic asthma is in accordance with the United States Food and Drug Administration approved labeling: 3 mg/kg intravenously once every 4 weeks **AND**

Drug and Biologics Policy Updates

NEW

Policy Title	Effective Date	Coverage Rationale
Respiratory Interleukins (IL) *(continued)*	Jan. 1, 2017	E. Prescribed by or in consultation with a pulmonologist or allergist/immunologist **Unproven** Nucala and Cinqair are **unproven and not medically necessary** in the following: A. Other eosinophilic conditions B. Acute bronchospasm C. Status asthmaticus D. Chronic obstructive pulmonary disease (COPD)

REVISED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gonadotropin Releasing Hormone Analogs	Jan. 1, 2017	• Reformatted and reorganized policy; transferred content to new template • Changed policy title; previously titled *Lupron Depot/Lupron Depot-Ped (Leuprolide Acetate)* • Updated list of related policies: ○ Removed reference link to Coverage Determination Guideline titled *Gender Dysphoria (Gender Identity Disorder) Treatment* ○ Added reference link to: ▪ Medical Policy titled *Gender Dysphoria Treatment* ▪ Optum Coverage Determination Guideline titled *Gender Dysphoria* • Updated benefit considerations: ○ Added language to indicate treatment for gender dysphoria is sometimes referred to as gender identity disorder treatment, sex transformation surgery, sex change, sex reversal,	Please refer to the Oncology Medication Clinical Coverage Policy for updated information based on the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®) for oncology indications. This policy refers to the following gonadotropin releasing hormone analog (GnRH analog) drug products: • Firmagon (degarelix) • Lupron Depot (leuprolide acetate) • Lupron Depot-Ped (leuprolide acetate) • Supprelin LA (histrelin acetate) • Trelstar (triptorelin pamoate) • Vantas (histrelin acetate) • Zoladex (goserelin acetate) For the coverage criteria below, in absence of specified drug products, the term "GnRH analogs" will be used in this policy where the coverage criteria apply to all products listed above. **Covered Indications** 1. **Central precocious puberty (Lupron Depot-Ped, Supprelin LA)** Lupron Depot-Ped, and Supprelin LA are **proven** for the treatment of Central precocious puberty. Additional information to support medical necessity review where applicable: Lupron Depot-Ped and Supprelin LA are **medically necessary** for the treatment of central precocious puberty when **all** of the following criteria

Drug and Biologics Policy Updates

REVISED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gonadotropin Releasing Hormone Analogs *(continued)*	Jan. 1, 2017	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 ○ Removed language indicating: ▪ 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 ▪ Plans may cover, or exclude, surgical or non-surgical treatment for gender dysphoria; when deciding coverage, the enrollee specific benefit document must be referenced • Revised coverage rationale: ○ Expanded list of applicable gonadotropin releasing hormone analog (GnRH analog) drug products to include: ▪ Firmagon (degarelix) ▪ Supprelin LA (histrelin acetate)	are met: a. Diagnosis of central precocious puberty (idiopathic or neurogenic) **AND** b. Onset of secondary sexual characteristics in **one** of the following: (1) Females ≤ 8 years of age (2) Males ≤ 9 years of age **AND** c. Confirmation of diagnosis as defined by **one** of the following: (1) Pubertal basal level of luteinizing hormone (based on laboratory reference ranges) (2) A pubertal luteinizing hormone response to a GnRH stimulation test (3) Bone age advanced one year beyond the chronological age Lupron Depot-Ped and Supprelin LA treatment should be discontinued at the appropriate age of onset of puberty at the discretion of the physician. Give consideration to discontinuing treatment before 11 years of age in girls and 12 years of age in boys. 2. **Endometriosis (Lupron Depot, Zoladex)** Lupron Depot and Zoladex are **proven** for the treatment of Endometriosis Additional information to support medical necessity review where applicable: Lupron Depot and Zoladex are **medically necessary** for the treatment of endometriosis when **all** of the following criteria are met: a. For **initial therapy**, **all** of the following**:** (1) Diagnosis of endometriosis **AND** (2) **One** of the following: (a) Contraindication, intolerance, or failure of initial treatment with **both** of the following: i. Oral contraceptives ii. Non-steroidal anti-inflammatory drugs (NSAIDs) **OR** (b) Patient has had surgical ablation to prevent recurrence **AND** (3) Initial treatment course is limited to a maximum of 6 months. b. For **retreatment**, **all** of the following **(Lupron Depot only)**: (1) Diagnosis of endometriosis **AND** (2) Recurrence of symptoms following an initial course of therapy **AND** (3) Concurrently to be used with add-back therapy (e.g., progestin,

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Gonadotropin Releasing Hormone Analogs *(continued)*	Jan. 1, 2017	▪ Trelstar (triptorelin pamoate) ▪ Vantas (histrelin acetate) ▪ Zoladex (goserelin acetate) ○ Added language to indicate: ▪ In the absence of a specified drug product, the term "GnRH analogs" will be used where the coverage criteria apply to all drug products listed ▪ This drug policy does not constitute medical advice and UnitedHealthcare does not make decisions about the kind of care a member should or should not receive; health care professionals are solely responsible for the care they deliver ○ Replaced references to "Lupron Depot" with "GnRH analogs" ○ Revised coverage guidelines for treatment of **central precocious puberty**: ▪ Expanded list of proven/medically necessary drug products to include Supprelin LA ▪ Updated medical necessity criteria; expanded criterion detailing options for confirmation of diagnosis to include pubertal basal	estrogen, or bone sparing agents) **AND** (4) Duration of both the initial and recurrent course of therapies is no longer than 12 months total. **Zoladex is not recommended for the retreatment of endometriosis, per FDA labelling.** The prescribing information for Lupron Depot and Zoladex state that the duration of initial treatment for endometriosis should be limited to 6 months. For Lupron Depot, for recurrence of symptoms, the prescriber should consider the impact to bone mineral density prior to retreatment. Leuprolide must be used in combination with add back therapy (e.g., norethindrone acetate) for 6 months; greater than one retreatment period is not recommended. Lupron Depot monotherapy is not recommended for retreatment. For Zoladex, there is no clinical data on the effect of treatment of benign gynecological conditions with Zoladex for periods in excess of 6 months. Retreatment with Zoladex cannot be recommended for the management of endometriosis. 3. **Endometrial thinning/dysfunctional uterine bleeding (Zoladex)** Zoladex is **proven** for endometrial thinning prior to endometrial ablation for dysfunctional uterine bleeding. Additional information to support medical necessity review where applicable: Zoladex is **medically necessary** for endometrial thinning when **all** of the following criteria are met: a. For use prior to endometrial ablation **AND** b. Other causes of symptoms or bleeding are ruled out **AND** c. Patient is to receive Zoladex 3.6mg implant **AND** d. Course of therapy is a maximum of two depots 4. **Fertility preservation** GnRH analogs are **proven** and **medically necessary** for the treatment of Fertility Preservation when all of the following criteria are met: a. **Both** of the following: (1) For use in pre-menopausal women **AND** (2) Patient is receiving a cytotoxic agent that is associated with

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Gonadotropin Releasing Hormone Analogs *(continued)*	Jan. 1, 2017	level of luteinizing hormone (based on laboratory reference ranges) ○ Revised coverage guidelines for treatment of **endometriosis**: ▪ Expanded list of proven/medically necessary drug products to include Zoladex ▪ Added language to indicate: - Initial treatment course is limited to a maximum of 6 months - Zoladex is not recommended for the retreatment of endometriosis, per FDA labelling and lack of clinical data on the effect of treatment of benign gynecological conditions for periods in excess of 6 months ▪ Added retreatment criteria for Lupron Depot ▪ Replaced reference to "norethindrone acetate" with "add back therapy (e.g., norethindrone acetate)" ○ Revised coverage guidelines for treatment of **uterine leiomyomata (fibroids)**;	causing primary ovarian insufficiency (premature ovarian failure) [e.g., Cytoxan (cyclophosphamide), procarbazine, vinblastine, cisplatin] GnRH therapy should be discontinued upon the completion of cytotoxic treatment. 5. **Uterine leiomyomata (fibroids) (Lupron Depot)** Lupron Depot is **proven** for the treatment of uterine leiomyomata (fibroids) Additional information to support medical necessity review where applicable: Lupron Depot is **medically necessary** for the treatment of uterine leiomyomata when **one** of the following criteria is met: a. **All** of the following: (1) For the treatment of uterine leiomyomata related anemia **AND** (2) Patient did not respond to iron therapy of one month duration **AND** (3) For use prior to surgery **OR** b. For use prior to surgery to reduce the size of fibroids to facilitate a surgical procedure (e.g., myomectomy, hysterectomy) The recommended duration of therapy for the treatment of uterine leiomyomata is ≤ 3 months. 6. **Gender dysphoria in adolescents** GnRH analogs **may be covered** for the treatment of Gender Dysphoria when **all** of the following criteria are met: a. Submission of medical records (e.g., chart notes, laboratory values) documenting **all** the following: 1. Diagnosis of gender dysphoria, according to the current DSM criteria, by a mental health professional with expertise in child and adolescent psychiatry; **AND** 2. **One** of the following: (a) Medication is prescribed by a pediatric endocrinologist; or (b) Medication is prescribed by a physician in consultation with a pediatric endocrinologist; **AND** 3. Patient has experienced puberty development to at least Tanner stage 2; **AND** 4. **One** of the following laboratory tests, based upon the laboratory

Drug and Biologics Policy Updates

REVISED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gonadotropin Releasing Hormone Analogs *(continued)*	Jan. 1, 2017	updated medical necessity criteria to clarify Lupron Depot is medically necessary for the treatment of *uterine leiomyomata related* anemia ○ Added coverage guidelines/criteria for: ▪ **Endometrial thinning/dysfunctional uterine bleeding (Zoladex)** ▪ **Gender dysphoria in adolescents** ○ Removed language indicating Lupron Depot is unproven and not medically necessary for puberty suppression in patients with gender identity disorder • Updated list of applicable HCPCS codes; added J3315, J9155, J9202, J9225, and J9226 • Removed list of applicable ICD-9 codes (discontinued Oct. 1, 2015) • Updated list of applicable ICD-10 diagnosis codes: ○ Added F64.1, F64.2, F64.8, F64.9, and N93.8 ○ Removed E23.0, Z51.11, and Z92.21 • Updated supporting information to reflect the most current background information, clinical evidence, FDA and CMS information, and references	reference range, confirming: (a) Pubertal levels of estradiol in females; or (b) Pubertal levels of testosterone in males; **AND** b. A Letter from the prescriber and/or formal documentation stating **all** of the following: 1. Patient has experienced pubertal changes that have resulted in an increase of their gender dysphoria that has significantly impaired psychological or social functioning; **AND** 2. Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment have been addressed or removed; **AND** 3. **Both** of the following: (a) Current enrollment, attendance, and active participation in psychological and social support treatment program; and (b) Patient will continue enrollment, attendance and active participation in psychological and social support throughout the course of treatment; **AND** 4. Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies. **Note:** Clinical evidence supporting the use of GnRH analogs for the treatment of gender dysphoria is limited and lacks long-term safety data. Statistically robust randomized controlled trials are needed to address the issue of whether the benefits outweigh the clinical risk in its use. **Disclaimer:** This Drug Policy does not constitute medical advice. UnitedHealthcare does not make decisions about the kind of care a member should or should not receive. Health care professionals are solely responsible for the care they deliver.

Coverage Determination Guideline (CDG) Updates

NEW		
Policy Title	**Effective Date**	**Coverage Rationale**
Infertility Services	Dec. 1, 2016	**Indications for Coverage** 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.). **Infertility services include the following:** • Ovulation induction (or controlled ovarian stimulation); • Insemination procedures: Artificial Insemination (AI) and Intra Uterine Insemination (IUI); • Assisted Reproductive Technologies (ART) In addition, the infertility treatments above must be provided under the direction of a physician and the member must meet all of the following: • 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 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. • 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 **When applying the infertility benefit consider the following**: • 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 Please check the member specific benefit plan document for inclusion or exclusion. Some states mandate benefit coverage for infertility services. Please check state mandates. **Benefit Limitations and Exclusions** • Assisted Reproductive Technologies, ovulation induction and insemination procedures are excluded from

Coverage Determination Guideline (CDG) Updates

NEW

Policy Title	Effective Date	Coverage Rationale
Infertility Services *(continued)*	Dec. 1, 2016	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 Infertility Diagnosis and Treatment. • 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 case determination). • 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).

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**

Breast Reconstruction Post Mastectomy	Jan. 1, 2017	• Updated list of related policies:
		  ○ Removed reference link to Coverage Determination Guideline titled *Gender Dysphoria (Gender Identity Disorder) Treatment* (retired Jan. 1, 2017)
		  ○ Added reference link to Medical Policy titled *Gender Dysphoria Treatment* (new policy effective Jan 1. 2017)
		• Revised coverage rationale; removed language indicating breast reconstruction may be covered under certain circumstances for the surgical treatment of gender dysphoria
			Indications for Coverage
			Breast reconstruction is covered for members who have a mastectomy with or without a diagnosis of cancer. Mastectomy includes partial (lumpectomy, tylectomy, quadrantectomy, and segmentectomy), simple, and radical. This benefit does not include aspirations, biopsy (open or core), excision of cysts, fibroadenomas or other benign or malignant tumors, aberrant breast tissue, duct lesions, nipple or areolar lesions, or treatment of gynecomastia.
			
			There is not a timeframe in which the member is required to have the reconstruction done post mastectomy under the Women's Health and Cancer Rights Act of 1998.
			
			In accordance with Federal and State mandates, the following services are covered:
			• Reconstruction of the breast on which the mastectomy was performed
			• Surgery and reconstruction of the other breast to produce a symmetrical appearance, including nipple tattooing
			• Prosthesis (implanted and/or external)
			• Treatment of physical complications of mastectomy, including lymphedema
			
			Various surgical techniques are used for breast reconstruction, including but not limited to:
			• Insertion of FDA approved breast implants and tissue expanders
			• Breast Implants and tissue expanders post mastectomy with or without skin substitutes, approved by the FDA, including but not limited to Alloderm, Allomax or FlexHD are a covered benefit
			• Transverse Rectus Abdominus Myocutaneous Flap (TRAM)
			• Latissimus Dorsi Flap (LD)
			• Deep Inferior Epigastric Perforator (DIEP) Flap
			• Gluteal Flap (GAP free flap)
			
			Refer to the *Definitions* section of this Coverage Determination Guideline (CDG) for breast reconstruction procedure definitions.
			
			If the original implant or reconstructive surgery was considered reconstructive surgery under the UnitedHealthcare benefit document, coverage may exist for removal, replacement, and/or reconstruction. If

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**

Breast Reconstruction Post Mastectomy *(continued)*	Jan. 1, 2017		the original implant or reconstructive surgery was considered reconstructive surgery under the UnitedHealthcare benefit document, then removal of a ruptured prosthesis is treating a "complication arising from a medical or surgical intervention." Removal or replacement of an implant that is not ruptured and unassociated with local breast complications may not be covered.
			
			Additional Information
			A gap exception may be granted if there is not an in-network provider able to provide the requested reconstructive procedure. Refer to the member specific benefit plan document for information regarding coverage from non-network providers.
			
			Treatments for Complications Post Mastectomy
			• Lymphedema:
			  ○ Complex Decongestive Physiotherapy (CDP) is covered for the complication of lymphedema post mastectomy
			  ○ Lymphedema pumps when required are covered (when covered these pumps are covered as Durable Medical Equipment)
			  ○ Compression lymphedema sleeves are covered (when covered, these sleeves are covered as a Prosthetic Device)
			  ○ Elastic bandages and wraps associated with covered treatments for the complications of lymphedema
			• Treatment of a post-operative infection(s)
			• Removal of a ruptured breast implant (either silicone or saline) is reconstructive for implants done post-mastectomy. Placement of a new breast implant will be covered if the original implantation was done post-mastectomy or for a covered reconstructive health service.
			
			Coverage Limitations and Exclusions
			Please refer to the member's state mandates and the member specific benefit plan document.
			• Insertion of breast implants or reinsertion of breast implants for the purpose of improving appearance is a cosmetic procedure unless covered under a state or federal mandate.
			  ○ If the breast reconstruction has been successfully completed post mastectomy and the member chooses to enlarge their breasts for cosmetic reasons, this is considered a cosmetic service and is not a covered health service.

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Breast Reconstruction Post Mastectomy *(continued)*	Jan. 1, 2017		• Breast reconstruction or scar revision after breast biopsy or removal of a cyst with or without a biopsy usually does not meet the definition of a covered reconstructive health service. Refer to the member specific benefit plan document and applicable state mandates. • Tissue protruding at the end of a scar ("dog ear"/standing cone), painful scars or donor site scar revisions must be reviewed to determine if the procedure meets reconstructive guidelines. • Liposuction other than to achieve breast symmetry during post mastectomy reconstruction is considered cosmetic and is not a covered health service. • Revision of prior reconstructed breast due to normal aging does not meet the definition of a covered reconstructive health service. • Unproven services.

Breast Repair/ Reconstruction Not Following Mastectomy	Jan. 1, 2017	• Reformatted and reorganized policy; transferred content to new template
		• Updated list of related policies:
		  ○ Removed reference link to Coverage Determination Guideline titled *Gender Dysphoria (Gender Identity Disorder) Treatment* (retired Jan. 1, 2017)
		  ○ Added reference link to Medical Policy titled *Gender Dysphoria Treatment* (new policy effective Jan 1. 2017)
		• Revised coverage rationale; removed language indicating breast reconstruction may be covered under certain circumstances for the surgical treatment of gender dysphoria
			Indications for Coverage
			If the member's condition meets the Women's Health and Cancer Rights Act (WHCRA) criteria, please refer to the Coverage Determination Guideline titled Breast Reconstruction Post Mastectomy.
			
			Criteria for a Coverage Determination as Reconstructive
			• Removal of breast implants with capsulectomy/capsulotomy for symptomatic capsular contracture is considered reconstructive when the following criteria are met:
			  ○ Baker grade III or IV capsular contracture;
			  Baker Grading System for Capsular Contracture:
			  ▪ Grade I – Breast is soft without palpable thickening
			  ▪ Grade II – Breast is a little firm but no visible changes in appearance
			  ▪ Grade III – Breast is firm and has visible distortion in shape
			  ▪ Grade IV – Breast is hard and has severe distortion or malposition in shape; pain/discomfort may be associated with this level of capsule contracture (ASPS, 2005)
			  ○ Limited movement leading to an inability to perform tasks that involve reaching or abduction. Examples include retrieving something from overhead, combing one's hair, reaching out or above to grab something to stabilize oneself.
			• Removal of a deflated saline breast implant shell is considered cosmetic unless the implants were done post mastectomy (see Coverage Determination Guideline titled Breast Reconstruction Post Mastectomy).

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**

Breast Repair/ Reconstruction Not Following Mastectomy *(continued)*	Jan. 1, 2017		• Correction of inverted nipples is considered reconstructive when one of the following criteria are met:
			  ○ Member meets the Women's Health and Cancer Rights Act (WHCRA) criteria (see Coverage Determination Guideline titled Breast Reconstruction Post Mastectomy for details); or
			  ○ Documented history of chronic nipple discharge, bleeding, scabbing or ductal infection.
			  Note: Correction of congenital inverted nipples may be covered based on a state mandate or the member specific benefit plan document. See Congenital Anomaly definition section.
			• Revision of a reconstructed breast (CPT code 19380) is considered reconstructive when the original reconstruction was done for mastectomy or other covered health service (see Applicable Codes section below for a list of codes that meet the criteria for a reconstructed breast).
			• Breast reconstruction done for Poland Syndrome (see definition section) is reconstructive. Although no functional impairment may exist for the breast reconstruction for Poland Syndrome, this has been deemed reconstructive surgery.
			• Removal of a ruptured silicone gel breast implant is covered regardless of the indication for the initial implant placement.
			
			Additional Information
			Tissue protruding at the end of a scar ("dog ear"/standing cone), painful scars or donor site scar revisions must be reviewed to determine if the procedure meets reconstructive guidelines.
			
			Coverage Limitations and Exclusions
			Some states require benefit coverage for services that UnitedHealthcare considers cosmetic procedures, such as repair of external congenital anomalies in the absence of a functional impairment. Please refer to the member specific benefit plan document.
			• Cosmetic Breast Procedures are excluded from coverage. Examples include but are not limited to:
			  ○ Replacement of an existing breast implant if the earlier breast implant was performed as a cosmetic procedure. (Replacement of an existing breast implant is considered reconstructive if the initial breast implant followed mastectomy**.** See Coverage Determination Guideline titled Breast Reconstruction Post Mastectomy.)
			  ○ Breast reduction surgery that is determined to be a cosmetic

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Breast Repair/ Reconstruction Not Following Mastectomy *(continued)*	Jan. 1, 2017		procedure. This exclusion does not apply to breast reduction surgery which we determine is requested to treat a physiologic functional impairment or to coverage required by the Women's Health and Cancer Right's Act. ○ Breast surgery only for the purpose of creating symmetrical breasts except when post mastectomy. ○ Breast prosthetics or replacement following a cosmetic breast augmentation. • Revision of a prior reconstructed breast due to normal aging does not meet the definition of a covered reconstructive health service.
Habilitative Services for Essential Health Groups	Jan. 1, 2017	• Revised coverage rationale/ indications for coverage: ○ Added language to indicate medically necessary, skilled, maintenance therapy is included in the habilitative services benefit; for information about skilled care, see the Coverage Determination Guideline titled *Skilled Care and Custodial Care Services* ○ Replaced language indicating "habilitative services received while in an inpatient setting, e.g., inpatient hospital, inpatient rehabilitation facility or skilled nursing facility, are *covered as part of that* benefit" with "habilitative services received while in an inpatient setting, e.g., inpatient hospital, inpatient rehabilitation facility or skilled nursing facility, are *part of the applicable inpatient setting* benefit"	**Indications for Coverage** Benefits for outpatient Habilitative Services include: • Physical therapy • Occupational therapy • Post-cochlear implant aural therapy • Cognitive rehabilitation therapy • Manipulative Treatment • Speech Therapy (see the Coverage Determination Guideline titled Speech Language Pathology Services) Medically necessary, skilled, maintenance therapy is included in the habilitative services benefit. For information about skilled care, see the Coverage Determination Guideline titled Skilled Care and Custodial Care Services. Certain plans may not include coverage for all of the above therapies. Please see the member specific benefit document for details. Certain state mandates may require that additional services be included within the defintion of Habilitative Services. [For example, with respect to the treatment of Autism and Autism Spectrum Disorder, Maryland includes behavioral health treatment (including applied behavioral analysis), and psychological care within the scope of habilitative service]. Please see the member specific benefit plan document and state mandate requirements for details. For plans that provide Essential Health Benefits, benefits are provided for Habilitative Services provided for Covered Persons with a disabling condition

Coverage Determination Guideline (CDG) Updates

REVISED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Habilitative Services for Essential Health Groups *(continued)*	Jan. 1, 2017	○ Updated language pertaining to habilitative services benefits for persons with a disabling condition who are covered by plans with Essential Health Benefits; removed "licensed nutritionist," "licensed social worker," and "licensed psychologist" from list of provider types who can administer habilitative services treatment on the same basis as a physician • Revised definition of: ○ Experimental or investigational service(s) ○ Habilitative services • Updated lists of applicable codes: ○ Added language to indicate the procedure codes listed in the policy only apply to habilitative services when billed with one of the listed habilitative diagnosis codes in the primary position on the claim ○ Updated list of applicable HCPCS codes for physical therapy; added S8990 ○ Updated list of applicable ICD-10 diagnosis codes; removed 506 codes (detailed on list attached below):  Habilitative ICD10 Dx Codes Removed.xls	when the following conditions are met: • The treatment is ordered by a Physician and is administered by a licensed speech-language pathologist, licensed audiologist, licensed occupational therapist, licensed physical therapist, Physician, or other provider who acts within the scope of his or her license will be considered on the same basis as a Physician. • The services must be provided in a physician's office or on an outpatient basis at a Hospital or Alternate Facility (such as health care facility that provides outpatient rehabilitative services). Certain states may require coverage of habilitative services in other locations. (For example, in Maryland, benefits for habilitative may not be denied on the sole basis that the services are received in the individual's educational setting.) Please see the member specific benefit document and state mandate requirements for details. We may require that a treatment plan be provided, request medical records, clinical notes, or other necessary data to allow us to substantiate that initial or continued medical treatment is needed. When the treating provider anticipates that continued treatment is or will be required to permit the Covered Person to achieve demonstrable progress, we may request a treatment plan consisting of diagnosis, proposed treatment by type, frequency, anticipated duration of treatment, the anticipated goals of treatment, and how frequently the treatment plan will be updated. Certain state mandates may limit the frequency for requesting plan treatment progress (for example Maryland is limited to no more than one request per year.) Please see the member specific benefit document and state mandate requirements for details. Coverage of Durable Medical Equipment and prosthetic devices, when used as a component of habilitative services, may require a separate review. Check the member specific benefit document. **Additional Information:** • Habilitative services received while in an **inpatient** setting, e.g., inpatient hospital, inpatient rehabilitation facility or skilled nursing facility are part of the applicable inpatient setting benefit. Depending on the inpatient setting, benefits are the same as the applicable inpatient benefit category (hospital inpatient, skilled nursing facility/inpatient rehabilitation facility benefit.)

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Habilitative Services for Essential Health Groups *(continued)*	Jan. 1, 2017	• Updated supporting information to reflect the most current references	• Eligible physical therapy and occupational therapy received in the home from a Home Health Agency is covered under the Home Health Care section of the plan. The Home Health Care benefit only applies to services that are rendered by a Home Health Agency. • Eligible physical therapy and occupational therapy received in the home from an independent physical or occupational therapist (a physical or occupational therapist that is not affiliated with a Home Health Agency) is covered under the Habilitative services benefit. • Cardiac and pulmonary therapy are covered under the Rehabilitation Services benefit. These are not Habilitative Services. **Coverage Limitations and Exclusions** • Coverage is excluded for services that are solely educational or vocational in nature or otherwise paid under state or federal law for purely educational services. A service that does not help the Covered Person to meet or maintain functional goals in a treatment plan within a prescribed time frame is not a habilitative service. • Coverage is excluded when the patient does not meet criteria for coverage as indicated in the *Indications for Coverage* section above and the member specific benefit document. • Coverage is excluded if the service is considered by UnitedHealthcare to be Unproven, Investigational or Experimental. • Coverage is excluded for Custodial care, respite care, day care, therapeutic recreation, vocational training and residential treatment. • In the absence of a disabling condition, services to improve general physical condition are excluded from coverage. • Coverage is excluded once the treatment plan goals are met. • Coverage is excluded for physiological modalities and procedures that result in similar or redundant therapeutic effects when performed on the same body region during the same visit or office encounter. An example includes, but is not limited to, the same day combined use of hot packs, ultrasound and iontophoresis in the treatment of strain. • Coverage is excluded for programs that do not require the supervision of Physician and/or a licensed therapy provider. • Coverage is excluded for work hardening. • Coverage is excluded for confinement, treatment, services or supplies that are required: a) only by a court of law, or b) only for insurance, travel, employment, and school or camp purposes. Please check the member specific benefit document and state mandates.

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Habilitative Services for Essential Health Groups *(continued)*	Jan. 1, 2017		• Coverage is excluded for services beyond any visit limits specified in the member specific benefit document. (Certain state mandates do not allow visit limits or limits on the number of hours of treatment. Please see the member specific benefit document and state mandate requirements for details.) • Coverage is excluded for gym and fitness club memberships and fees, health club fees, exercise equipment or supplies. • Biofeedback services are excluded on most plans. Please check the member specific benefit plan document.

RETIRED/REPLACED		
Policy Title	**Effective Date**	**Summary of Changes**
Gender Dysphoria (Gender Identity Disorder) Treatment	Jan. 1, 2017	• Coverage Determination Guideline retired; refer to the Medical Policy titled Gender Dysphoria Treatment for applicable coverage guidelines