August 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**

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.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Chemosensitivity and Chemoresistance Assays in Cancer	Aug. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated supporting information to reflect the most current clinical evidence, CMS information, and references; no change to coverage rationale or list of applicable codes	**Chemosensitivity assays and chemoresistance assays are unproven and not medically necessary for predicting response to chemotherapy in patients with cancer**. Results of the available studies fail to provide sufficient evidence that testing with chemoresistance and chemosensitivity assays leads to improved health outcomes in patients with cancer. To date, the majority of the available studies failed to demonstrate a survival benefit with chemotherapy regimens selected based on chemosensitivity and chemoresistance assays, compared with chemotherapy regimens selected based on traditional clinical factors. Well-designed randomized controlled trials (RCTs) are needed to determine the clinical utility of chemosensitivity and chemoresistance assays compared with traditional clinical factors to guide treatment selection and improve clinical outcomes including tumor response, time to progression and overall survival.
Discogenic Pain Treatment	Aug. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references; no change to coverage rationale or lists of applicable codes	**Thermal intradiscal procedures (TIPs) are unproven and not medically necessary for treating discogenic pain. TIPs include the following procedures**: • Intradiscal electrothermal therapy (IDET) • Intradiscal biacuplasty (IDB) • Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) • Percutaneous intradiscal annuloplasty **Percutaneous discectomy procedures are unproven and not medically necessary for treating discogenic pain. Percutaneous discectomy procedures include, but are not limited to, the following procedures**: • Nucleoplasty [percutaneous disc decompression (PDD) or percutaneous plasma discectomy] • Laser discectomy [laser disc decompression (PLDD); laser-assisted disc decompression (LADD); or percutaneous endoscopic discectomy, with or without laser (PELD)] • Yeung endoscopic spinal surgery (YESS) [arthroscopic microdiskectomy or percutaneous endoscopic diskectomy (PELD)] Overall, the evidence regarding the efficacy of TIPs and percutaneous discectomy procedures for the treatment of low back pain is insufficient to demonstrate beneficial health outcomes. Available clinical studies are weakened by the lack of randomization, lack comparator groups, and lack of long-term follow-up. Well-designed studies with larger patient populations are needed to evaluate the relative safety and effectiveness of these

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Discogenic Pain Treatment *(continued)*	Aug. 1, 2016		procedures. **Annulus fibrosus repair following spinal surgery is unproven and not medically necessary**. Further studies are needed to establish whether annulus fibrosus repair is beneficial for health outcomes in patients with low back pain following spinal surgery.
Electrical Bioimpedance for Cardiac Output Measurement	Aug. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references; no change to coverage rationale or list of applicable codes	**Electrical bioimpedance is unproven and not medical necessary for measuring cardiac output**. Definitive patient selection criteria for the use of electrical bioimpedance have not been established for measurement of cardiac output, primarily due to inadequate evidence regarding the impact of cardiac output monitoring on patient management or clinical outcomes. Further research is needed to confirm whether electrical bioimpedance can offer comparable clinical utility regarding cardiac function as thermodilution catheterization (TDC).
Magnetic Resonance Spectroscopy (MRS)	Aug. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or list of applicable codes	**Magnetic resonance spectroscopy (MRS) is unproven and not medically necessary.** There is a lack of evidence demonstrating that the use of MRS improves health outcomes such as increasing diagnosis rates, reducing the number of unnecessary biopsies, and improving care or treatment planning accuracy in patients with conditions such as psychiatric or neurological disorders, and prostate cancer. In addition, the techniques of acquiring the MRS spectra and interpreting the results are not well standardized. Further clinical trials that include well conducted randomized controlled trials and cohort studies are necessary to demonstrate the clinical usefulness of this procedure.
Spinal Ultrasonography	Aug. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated/clarified coverage rationale; replaced language indicating "spinal and paraspinal ultrasonography is proven and medically necessary in newborns and infants for *the evaluation of*	**Spinal and paraspinal ultrasonography is proven and medically necessary in newborns and infants for evaluating and managing suspected spinal disorders (e.g., congenital cord anomalies, spinal cord tumors, vascular malformations and birth-related trauma)**. **Spinal and paraspinal ultrasonography (including extremities, pelvis, or soft tissues of the head and neck) are unproven and not medically necessary for the following uses**: • To diagnose and manage spinal pain and radiculopathies

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Spinal Ultrasonography *(continued)*	Aug. 1, 2016	suspected spinal disorders" with "spinal and paraspinal ultrasonography is proven and medically necessary in newborns and infants for *evaluating and managing* suspected spinal disorders" • Updated supporting information to reflect the most current CMS information and references	• To guide rehabilitation of neuromusculoskeletal disorders and spinal pain There is insufficient evidence in the peer-reviewed medical literature to establish the efficacy or clinical value of spinal and paraspinal ultrasonography as a diagnostic tool in the management of back pain, radiculopathies or for monitoring of therapies. The use of ultrasound imaging to guide rehabilitation is under investigation. More research is needed to define the role of rehabilitative ultrasound imaging.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Cytological Examination of Breast Fluids for Cancer Screening	Sep. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale; replaced language indicating "*the HALO® Breast Pap Test* is unproven and not medically necessary for use in breast cancer screening of either low-risk or high-risk women" with "*breast ductal fluid aspiration and cytology* is unproven and not medically necessary for use in breast cancer screening of either low-risk or high-risk women" • Updated supporting information to reflect the most current clinical evidence, CMS information, and references	**Breast ductal lavage is unproven and not medically necessary for use in breast cancer screening of either low-risk or high-risk women**. There is inadequate clinical evidence that breast ductal lavage either allows for better clinical decision-making or reduces breast cancer mortality. Further studies are necessary to determine the efficacy of cytological examination of ductal fluid in detecting atypical cells to identify women at increased risk of breast cancer as well as comparing the results to established methods of detecting and diagnosing breast cancer. Ductal lavage is intended for use in high-risk women but no definite patient selection criteria for ductal lavage of the breast have been established. **Breast ductal fluid aspiration and cytology is unproven and not medically necessary for use in breast cancer screening of either low-risk or high-risk women**. There is inadequate clinical evidence that automated nipple aspiration either allows for better clinical decision-making or reduces breast cancer mortality. Further studies are necessary to determine the efficacy of cytological examination of ductal fluid in detecting atypical cells to identify women at increased risk of breast cancer as well as comparing the results to established methods of detecting and diagnosing breast cancer. **Fiberoptic ductoscopy, with or without ductal lavage, is unproven and not medically necessary for use in breast cancer diagnosis or screening or as an intraoperative tool to guide surgery**. There is insufficient clinical evidence demonstrating that fiberoptic

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Cytological Examination of Breast Fluids for Cancer Screening *(continued)*	Sep. 1, 2016		ductoscopy allows for better clinical decision-making, reduces breast cancer mortality or serves as a useful adjunct to or replacement of open surgical excision.
Neuropsychological Testing Under the Medical Benefit	Sep. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Added reference link to Optum Guideline titled *Psychological and Neuropsychological Testing* • Revised coverage rationale: ○ Modified list of proven/medically necessary conditions for evaluating patients when the result of testing will influence clinical decision making: ▪ Replaced "space-occupying brain lesion including brain abscess, brain tumors, and arteriovenous malformations within the brain" with "space-occupying brain lesion including*, but not limited to,* brain abscess, brain tumors, and arteriovenous malformations within the brain" ▪ Replaced "stroke *or more than one transient ischemic attack*" with "stroke" ○ Replaced language indicating "baseline neuropsychological	**Neuropsychological testing is proven and medically necessary for evaluating patients with the following conditions when the result of testing will influence clinical decision making**: • Attention-deficit/hyperactivity disorder (ADHD) when all of the following are present: ○ Specific neurocognitive behavioral deficits related to ADHD need to be evaluated and ○ Testing has been recommended by a physician and is related or secondary to a known or suspected organic-medical condition resulting from brain injury or disease process (e.g., concussion, intractable seizure disorder, cancer treatment effects, genetic disorders, inborn errors of metabolism) *The scope of these criteria is applicable only to neuropsychological testing that is covered by the medical benefit. These criteria do not apply to evaluate or determine educational interventions.* • Confirmed space-occupying brain lesion including but not limited to the following: ○ Brain abscess ○ Brain tumors ○ Arteriovenous malformations within the brain • Dementia or symptoms of dementia such as memory impairment or memory loss (including extrapyramidal disorders such as Parkinson's disease) that is associated with a new onset or progressive memory loss and a decline in at least one of the following cognitive domains (DSM-5): ○ Complex attention ○ Executive function ○ Learning and memory ○ Language ○ Perceptual-motor ○ Social cognition • Demyelinating disorders including multiple sclerosis • Intellectual disability or intellectual developmental disorder when all of the following are present:

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Neuropsychological Testing Under the Medical Benefit *(continued)*	Sep. 1, 2016	testing in asymptomatic persons to manage potential sport-related concussions is unproven and not medically necessary" with "baseline neuropsychological testing is unproven and not medically necessary in asymptomatic persons at risk for sport-related concussions" ○ Revised language pertaining to Mindstreams® Cognitive Health Assessment to indicate: ▪ Computerized cognitive testing such as Mindstreams® Cognitive Health Assessment and BrainCare™ is investigational, unproven, and not medically necessary for diagnosing dementia or mild cognitive impairment ▪ Available clinical trials have failed to document a beneficial effect of computerized cognitive testing on long-term clinical outcomes ▪ The evidence is insufficient to establish the validity of computerized cognitive testing compared with traditional tests for the assessment of dementia and cognitive	○ The intellectual disability or intellectual developmental disorder is associated with a known or suspected medical cause (e.g., traumatic brain injury, in utero toxin exposure, early seizure disorder, sickle cell disease, genetic disorders) and ○ The intellectual disability or intellectual developmental disorder meets all of the following criteria (DSM-5): ▪ Deficits in intellectual function, such as reasoning, problem solving, planning, abstract thinking, judgment, academic learning, and learning from experience, confirmed by both clinical assessment and individualized, standardized intelligence testing, ▪ Deficits in adaptive functioning that result in failure to meet developmental and sociocultural standards for personal independence and social responsibility. Without ongoing support, the adaptive deficits limit functioning in one or more activities of daily life, such as communication, social participation, and independent living across multiple environments, such as home, school, work and community, and ▪ Onset of intellectual and adaptive deficits during the developmental period *The scope of these criteria is applicable only to neuropsychological testing that is covered by the medical benefit. These criteria do not apply to evaluate or determine educational interventions.* • Encephalopathy including acquired immunodeficiency syndrome (AIDS) encephalopathy, human immunodeficiency virus (HIV) encephalopathy, hepatic encephalopathy, Lyme disease encephalopathy including neuroborreliosis, Wernicke's encephalopathy and systemic lupus erythematosus (SLE) encephalopathy. • Neurotoxin exposure with at least one of the following: ○ Demonstrated serum levels of neurotoxins ○ Individual with documented significant prenatal alcohol, drug, or toxin exposure • Seizure disorder including patients with epilepsy and patients being considered for epilepsy surgery • Stroke • Traumatic brain injury (TBI): TBI is defined as a bump, blow, or jolt to the head or a penetrating head injury that disrupts the normal function of the brain. (Centers for Disease Control and Prevention). See the following website for more information: http://www.cdc.gov/TraumaticBrainInjury/index.html. (Accessed April

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Neuropsychological Testing Under the Medical Benefit *(continued)*	Sep. 1, 2016	impairment ▪ No U.S. Food and Drug Administration (FDA) clearance was located in the FDA database for MindStreams Cognitive Health Assessment® or for BrainCare™ • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	2016) **Baseline neuropsychological testing is unproven and not medically necessary in asymptomatic persons at risk for sport-related concussions**. There is insufficient evidence to indicate that the use of baseline neuropsychological testing in athletes or other individuals alters risk from concussion. There is insufficient evidence that baseline tests influence physician decision-making or outcomes of treatment of concussion. **Computerized neuropsychological testing is unproven and not medically necessary when used alone for evaluating concussions**. Computerized neuropsychological testing should be used in conjunction with a standard non-computerized neuropsychological evaluation to evaluate concussions. The evidence is insufficient to establish the validity and reliability of computerized tests to evaluate concussions when used in isolation. Prospective controlled trials are needed to demonstrate the clinical utility of these tests to detect impairment following concussion when used alone. **Neuropsychological testing is unproven and not medically necessary for the following diagnoses alone without other proven conditions as noted above**: • Headaches including migraine headache • History of myocardial infarction • Intermittent explosive disorder There is insufficient clinical evidence to demonstrate that the use of neuropsychological testing for patients with myocardial infarction, migraine or other headaches or intermittent explosive disorder without associated cognitive disorders can be used effectively for clinical decision making to improve patient management of those conditions. **Computerized cognitive testing such as Mindstreams® Cognitive Health Assessment and BrainCare™ is investigational, unproven, and not medically necessary for diagnosing dementia or mild cognitive impairment**. Available clinical trials have failed to document a beneficial effect of computerized cognitive testing on long-term clinical outcomes. The evidence is insufficient to establish the validity of computerized cognitive testing

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Neuropsychological Testing Under the Medical Benefit *(continued)*	Sep. 1, 2016		compared with traditional tests for the assessment of dementia and cognitive impairment. No U.S. Food and Drug Administration (FDA) clearance was located in the FDA database for MindStreams Cognitive Health Assessment or for BrainCare.
Obstructive Sleep Apnea Treatment	Oct. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated benefit considerations; removed language indicating some benefit plan documents contain explicit exclusions or limitations of coverage and/or allow for the use of patient selection criteria in determining coverage • Revised coverage rationale for surgical treatment: ○ Added reference link to the Coverage Determination Guideline titled *Orthognathic (Jaw) Surgery* for additional information regarding medical necessity review for maxillomandibular advancement (MMA) surgery ○ Revised language pertaining to radiofrequency ablation of the soft palate and/or tongue base to indicate this procedure is unproven and not medically necessary for treating obstructive sleep apnea ▪ There is insufficient evidence to support the efficacy and long-term outcomes of radiofrequency ablation	**Nonsurgical Treatment** **Removable oral appliances are proven and medically necessary for treating obstructive sleep apnea (OSA) as documented by polysomnography**. Refer to the Medical Policy titled Attended Polysomnography for Evaluation of Sleep Disorders for further information. For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 20th edition, 2016, Oral Appliances (Mandibular Advancement Devices), A-0341 (ACG). **Removable oral appliances are unproven and not medically necessary for treating central sleep apnea**. This type of sleep apnea is caused by impaired neurological function, and these devices are designed to manage physical obstructions. **Nasal dilator devices are unproven and not medically necessary for treating obstructive sleep apnea (OSA)**. There is insufficient clinical evidence supporting the safety and efficacy of nasal dilators for treating OSA. Results from available studies indicate that therapeutic response is variable among the participants. Further research from larger, well-designed studies is needed to evaluate the effectiveness of the device compared with established treatments for OSA, to determine its long-term effectiveness and to determine which patients would benefit from this therapy. **Surgical Treatment** **The following surgical procedures are proven and medically necessary for treating obstructive sleep apnea as documented by polysomnography**. Refer to the Medical Policy titled Attended Polysomnography for Evaluation of Sleep Disorders for further information. Also see the *Definitions* section of the policy for information on the definitions and severity of OSA. • **Uvulopalatopharyngoplasty (UPPP)**: For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 20th edition, 2016, Uvulopalatopharyngoplasty (UPPP), A-0245 (ACG).

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Obstructive Sleep Apnea Treatment *(continued)*	Oct. 1, 2016	of the tongue or soft palate in the treatment of OSA ▪ Optimal patient selection criteria have not been defined ▪ Large controlled studies or comparative effectiveness trials with long-term follow-up comparing radiofrequency ablation to established procedures are necessary • Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references	• **Maxillomandibular Advancement Surgery (MMA)**: For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 20th edition, 2016, Maxillomandibular Osteotomy and Advancement, A-0248 (ACG). Also see the Coverage Determination Guideline titled Orthognathic (Jaw) Surgery. • **Multilevel Procedures Whether Done in a Single Surgery or Phased Multiple Surgeries**: There are a variety of procedure combinations, including mandibular osteotomy and genioglossal advancement with hyoid myotomy (GAHM). For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 20th edition, 2016, Mandibular Osteotomy, A-0247 (ACG). **The following surgical procedures are unproven and not medically necessary for treating obstructive sleep apnea**: • Laser-assisted uvulopalatoplasty (LAUP) • Palatal implants • Lingual suspension - also referred to as tongue stabilization, tongue stitch or tongue fixation • Transoral robotic surgery (TORS) • Implantable hypoglossal nerve stimulation • Radiofrequency ablation of the soft palate and/or tongue base There is insufficient evidence to conclude that laser-assisted uvulopalatoplasty (LAUP) results in improved apnea-hypopnea index (AHI) or secondary outcomes. Some studies saw a worsening of symptoms as well as increased complications. Results of studies provide preliminary but inconsistent evidence that palatal implants benefit patients with mild to moderate OSA. However, the magnitude of the benefits has been small; the largest randomized controlled trial (RCT) found that average OSA worsened in spite of treatment; and the available studies involved ≤ 1 year of patient monitoring after treatment. Additional studies are needed to determine the role of palatal implants in the management of OSA There is insufficient evidence to support the safety, efficacy and long-term outcomes of lingual suspension in the treatment of OSA. The published peer-reviewed medical literature includes a few small, uncontrolled studies with short-term follow-up. Large, controlled studies, with long-term follow-up, comparing lingual suspension to established procedures are necessary.

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Obstructive Sleep Apnea Treatment *(continued)*	Oct. 1, 2016		There is insufficient evidence to support the safety, efficacy and long-term outcomes of transoral robotic surgery (TORS) in the treatment of OSA. Large, controlled studies, with long-term follow-up, comparing TORS to established procedures are necessary. There is insufficient evidence to support the safety, efficacy and long-term outcomes of hypoglossal nerve stimulation in the treatment of OSA. The optimal patient selection criteria for the use of hypoglossal nerve stimulation have not been defined. Randomized controlled trials or comparative effectiveness trials with long-term follow-up, comparing hypoglossal nerve stimulation to established procedures are necessary to evaluate the effectiveness of this technology. There is insufficient evidence to support the efficacy and long-term outcomes of radiofrequency ablation of the tongue or soft palate in the treatment of OSA. Optimal patient selection criteria have not been defined. Large controlled studies or comparative effectiveness trials with long-term follow-up comparing radiofrequency ablation to established procedures are necessary. Follow-up polysomnography should be performed following surgery to evaluate response to treatment (Kushida et al., 2006; Ferguson et al., 2006). Refer to the Medical Policy titled Attended Polysomnography for Evaluation of Sleep Disorders for further information.
Omnibus Codes	Oct. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Revised coverage guidelines for: **Serum proteomic profiling, using mass spectrometry for guiding treatment decisions in patients with advanced non-small cell lung cancer (NSCLC) being considered for second-line therapy with an epidermal growth factor receptor (EGFR) inhibitor, such as erlotinib, and whose**	Refer to the policy for complete details on the coverage guidelines for Omnibus Codes.

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Omnibus Codes *(continued)*	Oct. 1, 2016	**EGFR mutation status is wild-type (no mutation detected) or unknown (CPT codes 81538 and 84999)** ○ Revised coverage rationale; added language to indicate the proven procedure is "medically necessary" **Pillcam Colon 2 (CPT code 0355T)** ○ Revised coverage rationale; added language to indicate the unproven procedure is "not medically necessary" **Use of drug eluting punctal plugs or implants into the lacrimal canaliculus (CPT code 0356T)** ○ Revised coverage rationale; added language to indicate the unproven procedure is "not medically necessary" **Bioelectrical impedance analysis whole body composition assessment (CPT code 0358T)** ○ Revised coverage rationale; added language to indicate the unproven procedure is "not medically necessary" **Chronic baroreceptor stimulation of the carotid sinus for treating hypertension, heart failure or other cardiovascular conditions (CPT codes 0266T, 0267T, 0268T, 0269T, 0270T, 0271T, 0272T, and 0273T)** ○ Updated coverage rationale;	

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Omnibus Codes *(continued)*	Oct. 1, 2016	removed language pertaining to clinical evidence/study findings indicating several large-scale randomized controlled clinical trials are ongoing to evaluate the long-term safety and efficacy of these devices **Implantable cardiac devices for percutaneous closure (occlusion) of the left atrial appendage (LAA) (CPT code 0281T)** ○ Revised coverage rationale; removed language indicating coverage may be available through participation in an eligible clinical trial, depending on the member specific benefit plan document **Leadless pacemakers for treating cardiac arrhythmias (CPT codes 0387T, 0388T, 0389T, 0390T, and 0391T)** ○ Revised coverage rationale to indicate leadless pacemakers are unproven and not medically necessary for treating cardiac arrhythmias due to insufficient clinical evidence of safety and/or efficacy in the published peer-reviewed medical literature **Multi-spectral digital skin lesion analysis (CPT codes 0400T and 0401T)** ○ Updated description for CPT	

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Omnibus Codes *(continued)*	Oct. 1, 2016	code 0400T ○ Updated coverage rationale; added language pertaining to clinical evidence/study findings to indicate too few studies are available to evaluate the consistency of patient-oriented outcomes of interest among different studies **Insertion of a temporary prostatic urethral stent (CPT code 53855)** ○ Updated coverage rationale; modified language pertaining to clinical evidence/study findings to indicate there is insufficient clinical evidence of safety and/or efficacy in the published peer-reviewed medical literature • Added coverage guidelines for the **use of the robotic lower body exoskeleton device for ambulation assistance (CPT code 97799 and HCPCS codes E1399 and L2999)** to indicate: ○ The use of the robotic lower body exoskeleton device is unproven and not medically necessary for ambulation assistance in all settings/ levels of care in patients with conditions which impair the ability to ambulate (e.g., spinal cord injury, stroke, Parkinson's disease, etc) due to insufficient clinical evidence of safety and/or	

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Omnibus Codes *(continued)*	Oct. 1, 2016	efficacy in published peer-reviewed medical literature • Removed coverage guidelines for: ○ Focused microwave thermal ablation for treating breast cancer (CPT code 0301T) ○ Implantable devices that detect cardiac ischemia (CPT codes 0302T, 0303T, 0304T, 0305T, 0306T, and 0307T) ○ Myocardial sympathetic innervation imaging (CPT codes 0331T and 0332T) ○ Transcatheter renal sympathetic denervation (unilateral or bilateral) for resistant hypertension (CPT codes 0338T and 0339T) ○ Optical coherence tomography (OCT) for the intraoperative assessment of lymph nodes or tumor margins in breast conserving surgery (CPT codes 0351T, 0352T, 0353T, and 0354T) ○ Subcutaneous implantable cardioverter-defibrillators (CPT codes 33270, 33271, 33272, 33273, 93260, 93261, and 93644) • Updated supporting information to reflect the most current clinical evidence and references	
Total Knee Replacement Surgery (Arthroplasty)	Sep. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale;	For information regarding medical necessity review, when applicable, see the following MCG™ Care Guidelines, 20th edition, 2016. • Total Knee Arthroplasty, S-700 (ISC) • Musculoskeletal Surgery or Procedure GRG: SG-MS (ISC GRG)

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Total Knee Replacement Surgery (Arthroplasty) *(continued)*	Sep. 1, 2016	added instruction to refer to the MCG™ Care Guidelines, 20th edition, 2016, *Musculoskeletal Surgery or Procedure GRG: SG-MS (ISC GRG)* for information regarding medical necessity review, when applicable	
Transcatheter Heart Valve Procedures	Sep. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale; replaced references to "U.S. Food and Drug Administration (FDA) labeled indications" with "U.S. Food and Drug Administration (FDA) labeled indications*, contraindications, warnings, and precautions*" • Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references	**Aortic Valve** **Transcatheter aortic heart valve replacement is proven and medically necessary, when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions, in patients who meet all of the following criteria**: • Severe calcific native aortic valve stenosis as indicated by ONE of the following: ○ Mean aortic valve gradient >40 mmHg; or ○ Peak aortic jet velocity >4.0 m/s; or ○ Aortic valve area of ≤ 0.8 cm2 • Patient is symptomatic (New York Heart Association [NYHA] class II or greater) and symptoms are due to aortic valve stenosis • Patient requires valve replacement surgery but is at high risk for serious surgical complications or death from open valve replacement surgery as determined by an interventional cardiologist and an experienced cardiothoracic surgeon. According to the FDA approval, high risk is defined as a Society of Thoracic Surgeons (STS) predicted operative risk score of >8% or an estimated >15% mortality risk for surgical aortic valve replacement (SAVR). For a complete list of indications, contraindications, warnings and precautions by device, see the *FDA* section of the policy. **Pulmonary Valve** **Transcatheter pulmonary heart valve replacement is proven and medically necessary, when used according to FDA labeled indications, contraindications, warnings and precautions, in patients with right ventricular outflow tract (RVOT) dysfunction who meet the following criteria**: • Existence of a full (circumferential) dysfunctional RVOT conduit that was

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Transcatheter Heart Valve Procedures *(continued)*	Sep. 1, 2016		equal to or greater than 16 mm in diameter when originally implanted, and • Dysfunctional RVOT conduit with one of the following clinical indications for intervention: o Moderate or greater pulmonary regurgitation, or o Pulmonary stenosis with a mean RVOT gradient ≥ 35 mmHg. **Mitral Valve** **Percutaneous transcatheter mitral valve leaflet repair is unproven and not medically necessary**. There is insufficient evidence in the clinical literature demonstrating the long-term efficacy of catheter-delivered mitral valve leaflet repair devices for treating mitral regurgitation. Further results from prospective, randomized controlled trials are needed to determine device durability and the ideal candidates for the procedure. See the *Benefit Considerations* section of the policy for coverage of unproven services when certain conditions are met. **Percutaneous transcatheter mitral valve annuloplasty via the coronary sinus is unproven, not medically necessary and investigational due to lack of FDA approval**. There is insufficient evidence in the clinical literature demonstrating the long-term efficacy of coronary sinus annuloplasty devices for treating mitral regurgitation. Further results from prospective, randomized controlled trials are needed to determine safety, efficacy, durability and the ideal candidates for the procedure. **Valve-in-Valve (ViV) Procedures** **Transcatheter heart valve replacement within a failed bioprosthesis (valve-in-valve procedure) is unproven and not medically necessary**. There is insufficient evidence in the clinical literature demonstrating the long-term efficacy of ViV procedures. Further results from prospective studies are needed to determine the ideal candidates for this procedure.

Drug and Biologics Policy Updates

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors	Aug. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated supporting information to reflect the most current clinical evidence, CMS information and references; no change to coverage rationale or lists of applicable codes	This policy provides information about the use of certain specialty pharmacy medications administered by the intravitreal route for ophthalmologic conditions. This policy refers to the following drug products, all of which are vascular endothelial growth factor (VEGF) inhibitors: • Eylea™ (aflibercept) • Avastin® (bevacizumab) • Macugen® (pegaptanib) • Lucentis® (ranibizumab) **Proven** **A. Eylea** is **proven and medically** necessary for the treatment of: 1. Neovascular age-related macular degeneration (AMD) 2. Diabetic macular edema (DME) 3. Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) 4. Diabetic retinopathy in patients with diabetic macular edema (DME) **B. Avastin** is **proven and medically** necessary for the treatment of: 1. Neovascular age-related macular degeneration (AMD) 2. Diabetic macular edema 3. Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) 4. Proliferative diabetic retinopathy 5. Neovascular glaucoma 6. Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome (OHS) **C. Macugen** is **proven and medically** necessary for the treatment of: 1. Neovascular age-related macular degeneration (AMD) 2. Diabetic macular edema **D. Lucentis** is **proven and medically** necessary for the treatment of: 1. Neovascular age-related macular degeneration (AMD) 2. Diabetic macular edema (DME) 3. Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)

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Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors *(continued)*	Aug. 1, 2016		4. Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome (OHS) 5. Diabetic retinopathy in patients with diabetic macular edema (DME) **Unproven** Aflibercept, bevacizumab, pegaptanib, and ranibizumab are **unproven** for the treatment of retinopathy of prematurity. Because VEGF is involved in a wide variety of physiologic processes, the ocular and systemic safety of anti-VEGF agents is of prime concern in neonates. **Additional Information** Bevacizumab is supplied in sterile vials containing a solution of 25 mg/mL. Doses utilized in ophthalmic conditions generally range from 6.2 mcg to 2.5 mg. Therefore, bevacizumab in vials is often divided into single-dose, prefilled syringes for intravitreal use by compounding pharmacies. Compounding pharmacies must comply with United States Pharmacopeia (USP) Chapter 797, which sets standards for the compounding, transportation, and storage of compounded sterile products (CSP). The Pharmacy Compounding Accreditation Board can verify that the pharmacy is adhering to these standards. The American Society of Retinal Specialists (ASRS) is committed to ensuring that retina specialists have access to compounded drugs (such as Avastin) that are prepared with high-quality material following good quality controls and sound engineering design by appropriately trained personnel. Please refer to their information page at https://www.asrs.org/advocacy-practice/access-to-safe-compounded-agents for resources pertaining to access of safe compounded agents. Please refer to the *US Food and Drug Administration (FDA)* section of this policy for information related to contamination of compounded bevacizumab. In an effort to guard against contamination during the compounding process, the United States Veterans Health Administration (USVHA) requires that only USVHA pharmacies may dispense bevacizumab for intravitreal administration to Veterans Administration beneficiaries. The medication must be dispensed directly to the VA ophthalmologist, who will then be responsible for preparing

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Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors *(continued)*	Aug. 1, 2016		and administering the bevacizumab dose for each patient. In addition to strict labeling and storage requirements, the ophthalmologist is required to prepare only one dose of medication from each vial; if both eyes are to be treated, a separate vial and syringe must be utilized.

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17-Alpha-Hydroxyprogest-erone Caproate (Makena™ and 17P)	Sep. 1, 2016	• Revised coverage rationale: ○ Updated proven/medically necessary criteria; added language to clarify administration of intramuscular injection of 17P for prevention of spontaneous preterm birth is to continue weekly until *week 37* (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first ○ Replaced language indicating "intramuscular injection of 17P is unproven and not medically necessary for prevention of spontaneous preterm birth *in women* with any of the listed criteria" with "intramuscular injection of 17P is unproven and not medically necessary for prevention of spontaneous preterm birth with any of the listed criteria" • Updated supporting information to reflect the most current clinical evidence and references	17-alpha-hydroxyprogesterone caproate, commonly called 17P, may also be referred to as 17-OHP, 17-OHPC, 17Pc, Makena™, 17-alpha hydroxyprogesterone, hydroxyprogesterone, hydroxy-progesterone, and hydroxy progesterone. Hereafter, it will be referred to as 17P. **Note**: Oral and intravaginal formulations of progesterone are not addressed in this policy. Intramuscular injection of 17P is **proven and medically necessary** for prevention of spontaneous preterm birth when **all** of the following criteria are met: A. Current singleton pregnancy **and** B. History of a prior spontaneous preterm birth of a singleton pregnancy **and** C. Treatment is initiated between 16 weeks, 0 days of gestation and 26 weeks, 6 days of gestation. **and** D. Administration is to continue weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first Intramuscular injection of 17P is **unproven and not medically** necessary for: 1. Prevention of spontaneous preterm birth with **any** of the following: a. Short cervix with or without cerclage and no prior preterm birth b. Current mutli-fetal pregnancy (twins or greater) c. Previous medically indicated preterm birth 2. Initiation of 17P after 26 weeks, 6 days of gestation Although there are ongoing clinical trials to broaden the indications for the

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
17-Alpha-Hydroxyprogest-erone Caproate (Makena™ and 17P) *(continued)*	Sep. 1, 2016		use of 17P, at this time uses as indicated above are considered unproven. ***Additional Information regarding compounded 17P** The active ingredient in the compounded 17P and Makena is hydroxyprogesterone caproate. Both have castor oil as an inactive ingredient. The compounded version can be made with an alternate oil base in the event of patient hypersensitivity to castor oil. Makena has the additional inactive ingredients of benzyl benzoate and benzyl alcohol (a preservative). Based on the active ingredient, compounded preservative-free 17P is considered clinically interchangeable with Makena. Compounding pharmacies must comply with United States Pharmacopeia (USP) Chapter 797, which sets standards for the compounding, transportation, and storage of compounded sterile products (CSP). The Pharmacy Compounding Accreditation Board will verify that the pharmacy is adhering to these standards. ***Note**: The FDA has stated that approved drug products provide a greater assurance of safety and effectiveness than do compounded products. Please refer to the U.S. Food and Drug Administration (FDA) section of this policy for additional information. **Centers for Medicare and Medicaid Services (CMS)** Medicare does not have a National Coverage Determination (NCD) for the identification or treatment of preterm labor; including the use of the drug 17-alpha-hydroxyprogesterone caproate (Makena™ and 17P). Local Coverage Determinations (LCDs) do not exist at this time. In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, Section 50 Drugs and Biologicals at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf. (Accessed March 24, 2016)

Coverage Determination Guideline (CDG) Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Breast Reconstruction Post Mastectomy	Sep. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated list of applicable HCPCS codes for breast reconstruction post mastectomy; added S2066, S2067, and S2068	**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

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Breast Reconstruction Post Mastectomy *(continued)*	Sep. 1, 2016		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 document for information regarding coverage from non-network providers.
			
			Breast reconstruction may be covered under certain circumstances for the surgical treatment of gender dysphoria. Please refer to the member specific benefit document for coverage.
			
			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 documents.
			• 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.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Breast Reconstruction Post Mastectomy *(continued)*	Sep. 1, 2016		○ 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. • 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.
Home Health Care	Sep. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated list of applicable HCPCS codes; revised description for G0159, G0160, G0161, G0162, G0163, G0164, S9212, S9338, S9363, and S9368 • Added list of applicable revenue codes for therapy by a home health care agency/facility (applies to the home health care visit limit when the bill type is either 032x or 034x): 0420, 0421, 0422, 0423, 0424, 0429, 0430, 0431, 0432, 0433, 0434, 0439, 0440, 0441, 0442, 0443, 0444, and 0449	**Indications for Coverage** The services being requested must meet all of the following: • Be ordered and directed by a treating practitioner or specialist (M.D., D.O., P.A. or N.P), and • The care must be delivered or supervised by a licensed professional in order to obtain a specified medical outcome; and • Services must be of Skilled Care in nature (refer to the Coverage Determination Guideline titled Skilled Care and Custodial Care Services and the *Definitions* section); and • Services must be intermittent and part time (typically provided for less than 4 hours per day; refer to the member specific benefit plan document for intermittent definitions, if provided); and • Services are provided in the home in lieu of Skilled Care in another setting (such as but not limited to a nursing facility, acute inpatient rehabilitation or a hospital) • Services must be clinically appropriate and not more costly than an alternative health services; and • A written treatment plan must be submitted with the request for specific services and supplies. Periodic review of the written treatment plan may be required for continued Skilled Care needs and progress toward goals; and

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Home Health Care *(continued)*	Sep. 1, 2016		• Services are not provided for the comfort and convenience of the member or the member's family; and • Services are not Custodial Care in nature. ***Medical Necessity Plans*** Use the criteria above where applicable. ***Additional Information*** • Medical supplies and medications that are used in conjunction with a home health care visit are covered as part of that visit. Some examples are, but not limited to, surgical dressing, catheters, syringes, irrigation devices. Reimbursement for home health care visits and supplies are contractually determined. • Eligible physical, occupational and speech therapy received in the home from a Home Health Agency is covered under the Home Health Care section of the COC. The Home Health Care section only applies to services that are rendered by a Home Health Agency. • Eligible physical, occupational and speech therapy received in the home from an independent physical, occupational or speech therapist (a therapist that is not affiliated with a Home Health Agency) is covered under the Rehabilitation Services-Outpatient Therapy section of the COC. **Coverage Limitations and Exclusions** • Home health care does not include custodial care, domiciliary care, private duty nursing, respite care, or rest cures and therefore these services are not covered (check the member specific benefit plan document). • Services of personal care attendants (these are not home health aides). • We will determine if benefits are available by reviewing both the skilled nature of the service and the need for Physician-directed medical management. A service will not be determined to be "skilled" simply because there is not an available caregiver. • Covered pharmaceuticals, drugs, and DME provided in connection with home health services may be subject to separate benefit categories. Please reference the Durable Medical Equipment and the Pharmaceutical Products benefit sections of the member specific benefit plan document. • Homemaker services such as home meal delivery services (e.g., Meals-on-Wheels) or transportation services (e.g., Dial-a-Ride) are excluded. • Private Duty Nursing (refer to the Coverage Determination Guideline

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Home Health Care *(continued)*	Sep. 1, 2016		titled Private Duty Nursing Services). • Services of an independent nurse hired directly by the family/patient are excluded. • Home health services beyond benefit limits, e.g., visits.
Skilled Care and Custodial Care Services	Aug. 1, 2016	• Reformatted and reorganized policy; transferred content to new template (no change to coverage rationale or lists of applicable codes)	**Indications for Coverage** • Skilled Care in the member's place of residence (see *Definitions* section of the policy). Skilled Care includes: ○ Skilled nursing ○ Skilled teaching ○ Skilled rehabilitation (physical therapy, occupational therapy and speech therapy) • For Skilled Care to be covered in the members place of residence, the following criteria must be met: ○ Be ordered and directed by a licensed practitioner or specialist *(M.D., D.O., P.A. or N.P).* ○ A plan of care must be established and periodically reviewed and updated by the treating practitioner or specialist. ○ The care must be delivered or supervised by a licensed nurse, technical or professional medical personnel in order to obtain a specified medical outcome. ○ It must not be Custodial Care (see *Definitions* section of the policy). ○ The care requires clinical training in order to be delivered safely and effectively. ○ The patient's condition must be documented to be such that they cannot receive the skilled care in a setting other than the member's place of residence. **Coverage Limitations and Exclusions** • Skilled Care does not include Custodial Care (see *Definitions* section of the policy), including but not limited to; domiciliary care, respite care, or rest cures. • Services provided by personal care attendants, family members or nonprofessional caregivers. • A service is not skilled care simply because there is not an available caregiver. • Homemaker services unrelated to the member's care or home meal

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Skilled Care and Custodial Care Services *(continued)*	Aug. 1, 2016		delivery services (e.g., Meals-on-Wheels) or transportation services (e.g., Dial-a-Ride). • Private Duty Nursing (check the member specific benefit plan document). • Home Health Services beyond benefit limits (e.g., visits). • Services provided as part of another benefit.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Cosmetic and Reconstructive Procedures	Sep. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale/criteria for a procedure to be considered reconstructive and medically necessary; added language to indicate: ○ Microtia repair is reconstructive; although no functional impairment may be documented for microtia, this has been deemed reconstructive surgery • Updated list of applicable procedure codes: ○ Removed CPT code 30120 (refer to the Coverage Determination Guideline titled *Rhinoplasty and Other Nasal Surgeries* for applicable coverage guidelines) ○ Removed HCPCS codes S2066, S2067, and S2068 (refer to the Coverage Determination Guideline titled *Breast Reconstruction Post Mastectomy* for applicable coverage	Some states require benefit coverage for services that UnitedHealthcare considers cosmetic procedures, such as repair of external congenital anomalies in the absence of a functional impairment. Please refer to the member's plan specific documents. **Indications for Coverage** ***Criteria for a Procedure to be Considered Reconstructive and Medically Necessary*** • There is documentation that the physical abnormality and/or physiological abnormality is causing a functional impairment (as defined in the Definitions section of the policy) that requires correction • The proposed treatment is of proven efficacy and is deemed likely to significantly improve or restore the patient's physiological function • Microtia repair (as defined in the Definitions section of the policy) is reconstructive; although no functional impairment may be documented for Microtia, this has been deemed reconstructive surgery **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 Procedures are excluded from coverage. Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures. The fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure. • Any procedure that does not meet the reconstructive criteria above in

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Cosmetic and Reconstructive Procedures *(continued)*	Sep. 1, 2016	guidelines) ○ Updated coding clarification language for flaps (skin and/or deep tissue) procedures (CPT codes 15570-15738); removed language indicating the regions listed refer to a donor site when a tube is formed for later transfer or when a "delay" of flap occurs prior to the transfer • Updated definitions: ○ Added definition of "microtia" ○ Removed definition of: ▪ Abdominoplasty ▪ Blepharoplasty ▪ Brow ptosis ▪ Breast reduction mammoplasty ▪ Cleft lip & palate ▪ Mastectomy ▪ Panniculectomy ▪ Panniculus ▪ Ptosis of eyelids ▪ Visual field	the *Indications for Coverage* section is excluded from coverage.
Pectus Deformity Repair	Sep. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale/indications for coverage for pectus excavatum to indicate surgical repair of pectus excavatum is considered reconstructive and medically necessary when the following criteria has been met:	**Indications for Coverage** **Surgical repair of pectus excavatum is considered reconstructive and medically necessary when the following criteria has been met**: ***Pectus Excavatum*** • Imaging studies confirm Haller index greater than 3.25; and • A functional impairment defined in physician current office notes, and ○ For restrictive lung capacity the total lung capacity is documented in the physician current office notes as <80% of the predicted value; or ○ There is cardiac compromise as demonstrated by decreased cardiac output on the echocardiogram; or

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Pectus Deformity Repair *(continued)*	Sep. 1, 2016	○ Imaging studies confirm Haller index greater than 3.25; and ○ A functional impairment defined in physician current office notes; and ▪ For restrictive lung capacity the total lung capacity is documented in the physician current office notes as <80% of the predicted value; or ▪ There is cardiac compromise as demonstrated by decreased cardiac output on the echocardiogram; or ▪ There is objective evidence of exercise intolerance as documented by cardiopulmonary exercise testing that is below the predicted values	○ There is objective evidence of exercise intolerance as documented by cardiopulmonary exercise testing that is below the predicted values. ***Pectus Carinatum*** It is extremely uncommon that pectus carinatum will cause a functional/physiological deficit. Pectus carinatum is not a congenital anomaly; it is a developmental condition of the cartilage that generally occurs during an adolescents growth spurt. (Goretsky, 2004) Requests for coverage of repair of pectus carinatum will be reviewed by a UHC Medical Director on a case by case basis. **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/ physical impairment. Please refer to the member specific benefit plan document. • Cosmetic Procedures are excluded from coverage. Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures. The fact that a Covered Person may suffer functional/psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure. • Any procedure that does not meet the reconstructive criteria above in the *Indications for Coverage* section.
Preventive Care Services	Oct. 1, 2016	• Removed all references to ICD-9 procedure and diagnosis codes (discontinued Oct. 1, 2015) • Revised list of applicable procedure and diagnosis codes for **Preventive Care Services**: ***Anemia, Iron Deficiency Anemia Screening*** ○ Removed benefit coverage guidelines due to September 2015 USPSTF 'I' rating ***Diabetes Screening***	Refer to the policy for complete details on the coverage guidelines for Preventive Care Services.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Oct. 1, 2016	○ Revised service description: ▪ Removed June 2008 USPSTF 'B' rating ▪ Added October 2015 USPSTF 'B' rating: - The USPSTF recommends screening for abnormal blood glucose as part of cardiovascular risk assessment in adults aged 40 to 70 years who are overweight or obese; clinicians should offer or refer patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthful diet and physical activity ○ Revised list of applicable ICD-10 diagnosis codes; expanded list of *Additional Diagnosis Codes* to include: ▪ **Overweight**: E66.3, Z68.25, Z68.26, Z68.27, Z68.28, and Z68.29 ▪ **Obesity**: E66.01, E66.09, E66.1, E66.8, E66.9, Z68.41, Z68.42, Z68.43, Z68.44, and Z68.45 ▪ **Body Mass Index 30.0-39.9**: Z68.30,	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Oct. 1, 2016	Z68.31, Z68.32, Z68.33, Z68.34, Z68.35, Z68.36, Z68.37, Z68.38, and Z68.39 ▪ **Body Mass Index 40.0 and Over**: Z68.41, Z68.42, Z68.43, Z68.44, and Z68.45 ○ Revised preventive benefit instructions; added age limit of 40-70 years (ends on 71st birthday) ***High Blood Pressure in Adults – Screening*** ○ Updated service title/heading; previously titled *Screening for High Blood Pressure* ○ Revised service description: ▪ Removed December 2007 USPSTF 'A' rating ▪ Added October 2015 USPSTF 'A' rating: - The USPSTF recommends screening for high blood pressure in adults aged 18 years or older - The USPSTF recommends obtaining measurements outside of the clinical setting for diagnostic confirmation before starting treatment ○ Added list of applicable codes for ambulatory blood	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Oct. 1, 2016	pressure measurement (outside of a clinical setting): ▪ CPT codes: 93784, 93786, 93788, or 93790 ▪ ICD-10 diagnosis code: R03.0 (abnormal blood-pressure reading without diagnosis of hypertension) ○ Updated preventive benefit instructions; added language to indicate coverage for ambulatory blood pressure measurement (outside of a clinical setting): ▪ Applies to patients age 18 years and older ▪ Is payable as preventive when billed with the listed diagnosis code	
Rhinoplasty and Other Nasal Surgeries	Sep. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale: ○ Added coverage guidelines/language to indicate: ▪ **Rhinoplasty – Primary (CPT codes 30410 and 30420)** is considered reconstructive and medically necessary when all of the following criteria are present: - Prolonged, persistent obstructed nasal breathing due to nasal bone and	**Indications for Coverage** Some states require benefit coverage for services that UnitedHealthcare considers cosmetic procedures, such as repair of external congenital anomalies in the absence of a functional impairment. Please refer to the member specific benefit plan document. ***Rhinoplasty-Primary (CPT Codes 30410, 30420)*** **Rhinoplasty-primary is considered reconstructive and medically necessary when all of the following criteria are present**: • Prolonged, persistent obstructed nasal breathing due to nasal bone and septal deviation that are the primary causes of an anatomic mechanical nasal airway obstruction, and • The nasal airway obstruction cannot be corrected by septoplasty alone as documented in the medical record, and • Photos clearly document the nasal bone/septal deviation as the primary cause of an anatomic mechanical nasal airway obstruction and are consistent with the clinical exam, and • The proposed procedure is designed to correct the anatomic mechanical

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Rhinoplasty and Other Nasal Surgeries *(continued)*	Sep. 1, 2016	septal deviation that are the primary causes of an anatomic mechanical nasal airway obstruction; and - The nasal airway obstruction cannot be corrected by septoplasty alone as documented in the medical record; and - Photos clearly document the nasal bone/septal deviation as the primary cause of an anatomic mechanical nasal airway obstruction and are consistent with the clinical exam; and - The proposed procedure is designed to correct the anatomic mechanical nasal airway obstruction and relieve the nasal airway obstruction by centralizing the nasal bony pyramid (30410) and also straightening the septum (30420); and - One of the following is present: • Nasal fracture	nasal airway obstruction and relieve the nasal airway obstruction by centralizing the nasal bony pyramid (30410) and also straightening the septum (30420), and • One of the following is present: ○ Nasal fracture with nasal bone displacement severe enough to cause nasal airway obstruction, or ○ Residual large cutaneous defect following resection of a malignancy or nasal trauma, and • Nasal airway obstruction is causing significant symptoms (e.g., chronic rhinosinusitis, difficulty breathing), and • Obstructive symptoms persist despite conservative management for 4 weeks or greater, which includes, where appropriate, nasal steroids or immunotherapy. ***Rhinoplasty-Tip (CPT Code 30400)*** **Rhinoplasty-tip is primarily cosmetic. However, it is considered reconstructive and medically necessary when all of the following criteria are present**: • Prolonged, persistent obstructed nasal breathing due to tip drop that is the primary cause of an anatomic mechanical nasal airway obstruction (this code is usually cosmetic), and • Photos clearly document tip drop as the primary cause of an anatomic mechanical nasal airway obstruction and are consistent with the clinical exam (acute columellar-labial angle), and • The proposed procedure is designed to correct the anatomic mechanical nasal airway obstruction and relieve the nasal airway obstruction by lifting the nasal tip, and • Nasal airway obstruction is causing significant symptoms (e.g., chronic rhinosinusitis, difficulty breathing), and • Obstructive symptoms persist despite conservative management for 4 weeks or greater, which includes, where appropriate, nasal steroids or immunotherapy. ***Rhinoplasty-Secondary (CPT Codes 30430, 30435, 30450)*** **Rhinoplasty-secondary is primarily cosmetic. However, it is considered reconstructive and medically necessary when all of the following criteria are present**: • Required as treatment of a complication/residual deformity from primary surgery performed to address a functional impairment when a

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Rhinoplasty and Other Nasal Surgeries *(continued)*	Sep. 1, 2016	with nasal bone displacement severe enough to cause nasal airway obstruction; or • Residual large cutaneous defect following resection of a malignancy or nasal trauma; and - Nasal airway obstruction is causing significant symptoms (e.g., chronic rhinosinusitis, difficulty breathing); and - Obstructive symptoms persist despite conservative management for 4 weeks or greater, which includes, where appropriate, nasal steroids or immunotherapy ▪ **Rhinoplasty – Tip (CPT code 30400)** is primarily cosmetic; however, it is considered reconstructive and medically necessary when all of the following criteria are present: - Prolonged, persistent	documented functional impairment persists due to the complication/deformity (these codes are usually cosmetic), and • Photos clearly document the secondary deformity/complication as the primary cause of an anatomic mechanical nasal airway obstruction and are consistent with the clinical exam, and • The proposed procedure is designed to correct the anatomic mechanical nasal airway obstruction and relieve the nasal airway obstruction by correcting the deformity or treating the complication (these codes are usually cosmetic), and • Nasal airway obstruction is causing significant symptoms (e.g., chronic rhinosinusitis, difficulty breathing), and • Obstructive symptoms persist despite conservative management for 4 weeks or greater, which includes, where appropriate, nasal steroids or immunotherapy. ***Rhinoplasty for Congenital Anomalies (CPT Codes 30460, 30462)*** **The following are considered reconstructive and medically necessary when the following are present**: • Rhinoplasty is considered reconstructive when performed for a nasal deformity associated with congenital craniofacial anomalies including, but not limited to Pierre Robin, Apert Syndrome, Fraser Syndrome, Binder Syndrome, Goldenhar Syndrome, Nasal dermoids, Tessier Nasal Cleft (most commonly #1) or associated with a cleft lip or cleft palate. ***Repair of Nasal Vestibular Stenosis or Alar Collapse (CPT Code 30465)*** **Repair of nasal vestibular stenosis or alar collapse is considered reconstructive and medically necessary when all of the following criteria are present**: • Prolonged, persistent obstructed nasal breathing due to internal and/or external nasal valve compromise (see *Definitions* section of the policy), and • Internal valve compromise due to collapse of the upper lateral cartilage and/or external nasal valve compromise due to collapse of the alar (lower lateral) cartilage resulting in an anatomic mechanical nasal airway obstruction that is a primary contributing factor for obstructed nasal breathing, and • Photos clearly document internal and/or external valve collapse as the

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Rhinoplasty and Other Nasal Surgeries *(continued)*	Sep. 1, 2016	considered reconstructive and medically necessary when all of the following criteria are present: - One of the following: • Prolonged, persistent obstructed nasal breathing due to rhinophyma; or • Chronic infection or bleeding unresponsive to medical management due to rhinophyma; and - Photos clearly document rhinophyma as the primary cause of an anatomic mechanical nasal airway obstruction or chronic infection and are consistent with the clinical exam; and - The proposed procedure is designed to correct the anatomic mechanical nasal airway obstruction and relieve the nasal airway obstruction by correcting the deformity or the	

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Rhinoplasty and Other Nasal Surgeries *(continued)*	Sep. 1, 2016	proposed procedure is designed to address the chronic infection o Updated coverage guidelines for; ▪ **Rhinoplasty for Congenital Anomalies (30460 and 30462)**: - Modified service specific content heading to include applicable CPT codes (30460 and 30462) ▪ **Repair of Nasal Vestibular Stenosis or Alar Collapse (30465)**: - Modified service specific content heading: • Retitled heading; previously titled "Rhinoplasty for Nasal Vestibular Stenosis or Alar Collapse" • Added applicable CPT code (30465) - Modified/expanded coverage criteria: • Added criterion requiring photos clearly documenting internal and/or external valve collapse as the primary cause of	

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Rhinoplasty and Other Nasal Surgeries *(continued)*	Sep. 1, 2016	Repair") ▪ Repair of Vestibular Stenosis (previously titled "Surgical Repair of Vestibular Stenosis") ○ Added list of applicable codes for Rhinophyma: 30120 ○ Removed list of Miscellaneous Codes: 30540 and 30545 • Updated definitions; added definition of: ○ Mechanical nasal airway obstruction ○ Prolonged, persistent nasal airway obstruction ○ Rhinitis medicamentosa (RM) • Updated supporting information to reflect the most current references	