UnitedHealthcare®

March 2017

medical policy update bulletin

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

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

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

Overview

This bulletin provides complete details on UnitedHealthcare Medical Policy, Medical Benefit Drug Policy, Coverage Determination Guideline (CDG), Utilization Review Guideline (URG), and/or Quality of Care Guideline (QOCG) updates. The appearance of a service or procedure in this bulletin indicates only that UnitedHealthcare has recently adopted a new policy and/or updated, revised, replaced or retired an existing policy; it does not imply that UnitedHealthcare provides coverage for the service or procedure. In the event of an inconsistency or conflict between the information provided in this bulletin and the posted policy, the provisions of the posted policy will prevail. Note that most benefit plan documents exclude from benefit coverage health services identified as investigational or unproven/not medically necessary. Physicians and other health care professionals may not seek or collect payment from a member for services not covered by the applicable benefit plan unless first obtaining the member's written consent, acknowledging that the service is not covered by the benefit plan and that they will be billed directly for the service.

The complete library of UnitedHealthcare Medical Policies, Medical Benefit Drug Policies, CDGs, URGs, and QOCGs is available at **UnitedHealthcareOnline.com** *> Tools & Resources > Policies, Protocols and Guides > Medical & Drug Policies and Coverage Determination Guidelines.*

Tips for using the Medical Policy Update Bulletin:

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

Policy Update Classifications

New

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

Updated

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

Revised

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

Replaced

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

Retired

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

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

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Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
UPDATED			
Collagen Crosslinks and Biochemical Markers of Bone Turnover	Mar. 1, 2017	• 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	**Serum or urine collagen crosslinks or biochemical markers are unproven and not medically necessary to assess risk of fracture, predict bone loss or assess response to antiresorptive therapy**. There is insufficient evidence in the clinical literature that current methods for measuring bone turnover markers are sufficiently sensitive to reliably determine individual treatment responses. In addition, there is insufficient evidence from controlled studies that bone turnover marker measurement improves adherence to treatment or improves health outcomes such as reducing fracture rates.
Cytological Examination of Breast Fluids for Cancer Screening	Apr. 1, 2017	• Updated supporting information; replaced reference to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017"	**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 ductoscopy allows for better clinical decision-making, reduces breast cancer mortality or serves as a useful adjunct to or replacement of open surgical excision.

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
UPDATED			
Manipulation Under Anesthesia	Mar. 1, 2017	• Updated lists of applicable CPT/HCPCS codes: ○ Modified table headings; removed descriptors classifying codes as "proven in certain circumstances" and "unproven" • Updated supporting information to reflect the most current clinical evidence and references	**Manipulation under anesthesia (MUA) is proven and medically necessary for**: • Elbow joint for arthrofibrosis following elbow surgery or fracture • Knee joint for arthrofibrosis following total knee arthroplasty, knee surgery, or fracture • Pelvis for acute traumatic fracture or dislocation • Shoulder joint for adhesive capsulitis (e.g., frozen shoulder) **Manipulation under anesthesia is unproven and not medically necessary for**: • Ankle • Finger* • Hip joint or adhesive capsulitis of the hip • Knee joint for any condition other than for arthrofibrosis following total knee arthroplasty, knee surgery, or fracture • Pelvis for diastasis or subluxation • Shoulder for any condition other than adhesive capsulitis (frozen shoulder) • Spine • Temporomandibular joint (TMJ) • Toe • Wrist Published studies which are available are of relatively small sample size, short-term outcomes and lack of randomization or a control group. * This policy does not apply to manipulation of the finger on the day following the injection of collagenase clostridium histolyticum (Xiaflex®) to treat Dupuytren's contracture. **Manipulation under anesthesia is unproven and not medically necessary for serial manipulations for any body part or multiple body joints for the management of acute or chronic pain conditions**. There is a lack of peer-reviewed published evidence supporting the need for multiple, repeat sessions of MUA for multiple body joints.

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
UPDATED			
Platelet Derived Growth Factors for Treatment of Wounds	Mar. 1, 2017	• Reformatted and reorganized policy; transferred content to new template • Updated lists of applicable CPT/HCPCS codes: ○ Revised description for CPT code 0232T ○ Modified table headings; removed descriptors classifying codes as "proven" and "unproven" • Updated supporting information to reflect the most current clinical evidence, FDA information, and references	**Recombinant-Human Platelet Derived Growth Factors** **When used according to U.S. Food and Drug Administration (FDA) approved indications, becaplermin (Regranex® Gel) is proven and medically necessary for the treatment of lower extremity diabetic neuropathic ulcers**. In June 2008, the U.S. Food and Drug Administration (FDA) announced the addition of a boxed warning to the labeling of becaplermin (Regranex Gel). Refer to the U.S. Food and Drug Administration section for more information. **Platelet Rich Plasma** **Autologous platelet rich plasma (e.g., Procuren®, AutoloGel®, or SafeBlood®) is unproven and not medically necessary for the treatment of wounds**. The better designed studies do not demonstrate that autologous platelet rich plasma such as Procuren, AutoloGel or SafeBlood improves health outcomes in patients with wounds. The remaining studies have design flaws that do not allow confidence in analyzing final study results. The clinical utility of autologous platelet rich plasma remains to be determined in larger well-designed controlled clinical trials comparing their use with standard wound care.
Thermal Capsulorrhaphy/ Thermal Shrinkage Therapy	Mar. 1, 2017	• 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 lists of applicable codes	**Thermal shrinkage therapy of joint capsules, ligaments, and tendons is unproven and not medically necessary**. Clinical evidence does not support the use of thermal capsulorrhaphy or thermal shrinkage for the treatment of joint instability or ligamentous laxity in any joint. Well-designed randomized trials are needed to compare thermal capsulorrhaphy/thermal shrinkage with surgical or other treatment options. Published data do not permit strong conclusions regarding the efficacy of thermal shrinkage and impact on improving health outcomes.

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Abnormal Uterine Bleeding and Uterine Fibroids	Apr. 1, 2017	• Revised coverage rationale; replaced reference to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017"	**Levonorgestrel-Releasing Intrauterine Device** **Levonorgestrel-releasing intrauterine devices (LNG-IUD) (e.g., Mirena®, Skyla® or Liletta®) are proven and medically necessary for treating menorrhagia**. Refer to the *U.S. Food and Drug Administration (FDA)* section of the policy for additional information.

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REVISED			
Abnormal Uterine Bleeding and Uterine Fibroids *(continued)*	Apr. 1, 2017		**Uterine Fibroids** **Uterine artery embolization (UAE) is proven and medically necessary for treating symptomatic uterine fibroids for women who do NOT wish to preserve their childbearing potential**. For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Uterine Artery Embolization, ACG: A-0287 (AC). **Uterine artery embolization (UAE) is unproven and not medically necessary for treating symptomatic uterine fibroids for women who wish to preserve their childbearing potential**. The effects of UAE on ovarian and uterine function and on fertility are relatively unknown. Further studies of safety and/or efficacy in published, peer-reviewed medical literature are necessary. **Magnetic resonance-guided focused ultrasound ablation (MRgFUS) is unproven and not medically necessary for treating uterine fibroids**. Further studies are needed to determine the long-term efficacy of this procedure and to evaluate the efficacy and safety of this procedure relative to other treatment options for uterine fibroids. See the *Benefit Considerations* section for potential coverage of unproven services. **Laparoscopic ultrasound-guided radiofrequency ablation (e.g., Acessa™) is unproven and not medically necessary for treating uterine fibroids**. Further studies are needed to determine the long-term efficacy of this procedure and to evaluate the efficacy and safety of this procedure relative to other treatment options for uterine fibroids. **Transcervical ultrasound-guided radiofrequency ablation is investigational, unproven and not medically necessary for treating uterine fibroids due to lack of FDA approval**. Further studies are needed to determine the long-term efficacy of this procedure and to evaluate the efficacy and safety of this procedure relative to other treatment options for uterine fibroids.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Attended Polysomnography for Evaluation of Sleep Disorders	Apr. 1, 2017	• Revised coverage rationale; replaced references to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017"	**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 Cortés, 2010) ○ Obesity hypoventilation syndrome ○ Documented ongoing epileptic seizures in the presence of symptoms of sleep disorder. Also, see Repeat Testing section. **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)

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REVISED			
Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Apr. 1, 2017		• 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 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, 21st edition, 2017, 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**

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Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Apr. 1, 2017		**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, 21st edition, 2017, 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**. **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.

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REVISED			
Breast Imaging for Screening and Diagnosing Cancer	Apr. 1, 2017	• Revised coverage rationale; removed language indicating digital tomosynthesis is unproven and not medically necessary for the screening and diagnosis of breast cancer *(refer to the Coverage Determination Guideline titled Preventive Care Services for applicable coverage guidelines for screening digital breast tomosynthesis)* • Updated list of applicable CPT codes: ○ Removed 77061, 77062, and 77063 ○ Revised description for 0159T and 76377 • Updated list of applicable HCPCS codes: ○ Removed G0279 • Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references	**Breast Imaging as an Adjunct to Mammography** **Digital mammography is proven and medically necessary for patients with dense breast tissue**. **Breast Magnetic Resonance Imaging (MRI)** **Breast magnetic resonance imaging (MRI) is proven and medically necessary for patients at high risk for breast cancer as defined as having any of the following**: • Personal history of atypical breast histologies • Family history or genetic predisposition for breast cancer • Prior therapeutic thoracic radiation therapy • Dense breast tissue with any one of the following risk factors: ○ Lifetime risk of breast cancer of ≥20%, according to risk assessment tools based on family history ○ Personal history of BRCA1 or BRCA 2 gene mutations ○ First-degree relative with a BRCA 1 or BRCA 2 gene mutation but not having had genetic testing themselves ○ Prior therapeutic thoracic radiation therapy between ages of 10-30 ○ Personal history of Li Fraumeni Syndrome, Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome or a first-degree relative with one of these syndromes **Breast magnetic resonance imaging (MRI) is unproven and not medically necessary for patients with dense breast tissue not accompanied by defined risk factors as described above**. **Magnetic Resonance Elastography of the Breast** **Magnetic resonance elastography (MRE) is unproven and not medically necessary for breast cancer screening or diagnosis**. There is insufficient evidence to conclude that MRE of the breast is effective for the screening or diagnosis of breast cancer. While data from small feasibility studies indicate that MRE may have some ability to discriminate between cancerous tissue and normal breast tissue or benign lesions based on tissue stiffness, there was overlap in values, and the diagnostic accuracy of MRE for detection of breast cancer remains to be determined. There are no definitive patient selection criteria for MRE for breast cancer detection. **Breast Specific Gamma Imaging (Scintimammography)**

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REVISED			
Breast Imaging for Screening and Diagnosing Cancer *(continued)*	Apr. 1, 2017		**Scintimammography is unproven and not medically necessary for breast cancer screening or diagnosis**. There is insufficient evidence that this diagnostic modality can differentiate benign from malignant breast lesions. Based on the evidence, the role of scintimammography remains unclear since this technology has not been shown to be accurate enough to screen for breast cancer or allow a confident decision to defer biopsy. **Electrical Impedance Scanning (EIS)** **Electrical impedance scanning (EIS) is unproven and not medically necessary for the detection of breast cancer**. There is insufficient evidence that EIS is effective in detecting malignant breast tissue. Evaluation of sensitivity and negative predictive value for EIS is inconsistent. Well-designed studies are needed to determine whether or not EIS is effective as an adjunct to mammography or provides a positive clinical benefit. **Computer-Aided Detection for MRI of the Breast** **Computer-aided detection (CAD) is unproven and not medically necessary as an aid for radiologists to interpret contrast-enhanced magnetic resonance imaging (MRI) of the breast**. Clinical evidence has not yet demonstrated that CAD improves patient outcomes or reduces breast cancer mortality when added to contrast-enhanced MRI. There is insufficient evidence to assess whether the use of CAD systems would maintain or increase the sensitivity, specificity, and recall rates of MRI of the breast. Prospective, well-designed and executed studies are needed to determine whether or not the use of CAD provides a positive clinical benefit. **Breast Ultrasound** **Breast ultrasound is unproven and not medically necessary for routine breast cancer screening including patients with dense breast tissue**. Clinical evidence has not yet demonstrated that routine use of ultrasonography as an adjunct to screening mammography reduces the mortality rate from breast cancer. **Breast ultrasound is proven and medically necessary as an aid for radiologists to localize breast lesions and in guiding placement of**

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REVISED			
Breast Imaging for Screening and Diagnosing Cancer *(continued)*	Apr. 1, 2017		**instruments for cyst aspiration and percutaneous breast biopsies**. **Computer-Aided Detection for Ultrasound** **Computer-aided detection (CAD) is unproven and not medically necessary as an aid for radiologists to detect breast cancer during ultrasound**. Clinical evidence has not yet demonstrated that CAD improves patient outcomes or reduces breast cancer mortality when added to ultrasonography. Future research should include better-designed studies, including prospective studies and randomized controlled trials evaluating this technology in large numbers of screening ultrasounds. **Computer-Aided Tactile Breast Imaging** **Computer-aided tactile breast imaging is unproven and not medically necessary**. Clinical evidence is insufficient to determine whether tactile breast imaging improves outcomes for the screening or diagnosis of breast cancer. Future research should include better-designed studies, including comparative, prospective and randomized controlled trials evaluating this technology. **Automated Breast Ultrasound** **Automated breast ultrasound is unproven and not medically necessary**. Clinical evidence is insufficient to determine whether automated breast ultrasound improves the detection rate of breast cancer compared to screening mammography. Future research should include better-designed studies, including prospective studies and randomized controlled trials evaluating this technology. Refer to the Evidence-Based Clinical Guidelines – Imaging for: • Magnetic resonance imaging (MRI) of the breast • 3D rendering of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modalities
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes	Apr. 1, 2017	• Revised coverage rationale; replaced references to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017"	**Insulin Delivery** **External insulin pumps that deliver insulin by continuous subcutaneous infusion are proven and medically necessary for the following**:

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REVISED			
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes *(continued)*	Apr. 1, 2017	*(refer to 21st edition for complete details on applicable updates to the MCG™ Care Guidelines)* • Updated supporting information to reflect the most current references	• Patients with type 1 diabetes ○ For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Insulin Infusion Pump ACG:A-0339 (AC). • Patients with type 2 diabetes who currently perform ≥4 insulin injections and ≥4 blood glucose measurements daily **Note**: Programmable disposable external insulin pumps are considered equivalent to standard insulin pumps. **Nonprogrammable transdermal insulin delivery systems are unproven and not medically necessary for treating patients with diabetes**. There is insufficient evidence in the clinical literature demonstrating the safety and efficacy of transdermal insulin delivery in the management of patients with diabetes. **Implantable insulin pumps are investigational, unproven and not medically necessary**. No implantable insulin pumps have received U.S. Food and Drug Administration (FDA) approval at this time. While some preliminary studies reported improved glycemic control and fewer episodes of hypoglycemia in carefully selected patients, complications such as catheter blockage and infection were observed. Larger, randomized controlled trials are needed to determine the long-term impact of implantable insulin pumps on diabetes management. **Insulin infuser ports are unproven and not medically necessary for insulin delivery in patients with diabetes**. There is insufficient evidence demonstrating that the use of insulin infuser ports results in improved glycemic control beyond what can be achieved by using standard insulin delivery methods. In addition, an increase in complications, such as infection at the port site, has been reported when using these devices. Further well-designed, large-scale randomized controlled trials are needed to establish the safety and efficacy of these devices. See the *Description of Services* section of the policy for further details on the various types of insulin delivery systems.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes *(continued)*	Apr. 1, 2017		**Continuous Glucose Monitoring** **Short-term (3-7 days) continuous glucose monitoring by a healthcare provider for diagnostic purposes is proven and medically necessary for patients with diabetes**. **Long-term continuous glucose monitoring for personal use at home is proven and medically necessary as a supplement to self-monitoring of blood glucose (SMBG) for patients with type 1 diabetes who have demonstrated adherence to a physician ordered diabetic treatment plan**. For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Continuous Glucose Monitoring ACG:A-0126 (AC). **Long-term continuous glucose monitoring for personal use at home is unproven and not medically necessary for patients with type 2 diabetes or gestational diabetes**. There is insufficient evidence that the use of long-term continuous glucose monitoring leads to improvement of glycemic control in patients with type 2 or gestational diabetes. **Continuous glucose monitoring using an implantable glucose sensor is investigational, unproven and not medically necessary due to lack of U.S. Food and Drug Administration (FDA) approval**. There is insufficient published clinical evidence to conclude that the use of continuous glucose monitoring using an implantable gluocose sensor leads to an improvement in glycemic control. The small sample sized studies lack adequate controls, randomization and blinding. **Remote Glucose Monitoring** **Remote glucose monitoring is unproven and not medically necessary for managing patients with diabetes**. There is insufficient evidence in the clinical literature to conclude that remote glucose monitoring demonstrates improvement in clinical outcomes.
Elbow Replacement Surgery (Arthroplasty)	Apr. 1, 2017	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale;	For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Elbow Arthroplasty, S-420 (ISC).

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Elbow Replacement Surgery (Arthroplasty)	Apr. 1, 2017	replaced reference to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017" • Updated supporting information to reflect the most current CMS information	
Electrical and Ultrasound Bone Growth Stimulators	Apr. 1, 2017	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale; replaced references to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017" *(refer to 21st edition for complete details on applicable updates to the MCG™ Care Guidelines)*	Two MCG™ Care Guidelines, 21st edition, 2017, are identified, one for electrical and electromagnetic bone growth stimulators, and one for ultrasonic bone growth stimulators. For information regarding medical necessity review of electrical and electromagnetic bone growth stimulators, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Bone Growth Stimulators, Electrical and Electromagnetic ACG: A-0565 (AC). For information regarding medical necessity review of ultrasonic bone growth stimulators, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Bone Growth Stimulators, Ultrasonic ACG: A-0414 (AC).
Genetic Testing	Apr. 1, 2017	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale; modified list of applicable MCG™ Care Guidelines: ○ Added new/additional references to applicable MCG™ Care Guidelines, 21st edition, 2017 ○ Replaced existing references to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017" *(refer to 21st edition for complete details on applicable updates to the MCG™ Care*	Refer to the policy for complete details on the coverage guidelines for Genetic Testing.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Genetic Testing *(continued)*	Apr. 1, 2017	*Guidelines)* • Updated supporting information to reflect the most current CMS information	
Glaucoma Surgical Treatments	Apr. 1, 2017	• Revised coverage rationale; added language to indicate the Xen Glaucoma Treatment System is unproven and is not medically necessary for treating refractory glaucoma when conventional medical or surgical treatments have failed, or in patients with primary open-angle glaucoma, pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy • Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references	**Glaucoma drainage devices, such as the ExPRESS™ mini glaucoma shunt, Molteno implant, Baerveldt tube shunt, Krupin Eye Valve, or the Ahmed glaucoma valve implant, are proven and medically necessary for treating refractory glaucoma when conventional medical or surgical treatments have failed or are inappropriate**. **The iStent® Trabecular Micro-Bypass Stent System is proven and medically necessary when used in combination with cataract surgery for treating mild to moderate open-angle glaucoma and a cataract in adults currently being treated with ocular hypotensive medication. The CyPass® Micro-Stent System is unproven and not medically necessary when used in combination with cataract surgery for treating mild-to-moderate primary open-angle glaucoma (POAG). The Xen Glaucoma Treatment System is unproven and is not medically necessary for treating refractory glaucoma when conventional medical or surgical treatments have failed, or in patients with primary open-angle glaucoma, pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy**. **Glaucoma drainage devices, such as Eyepass, DeepLight SOLX® Gold Shunt and other shunts that do not have FDA approval are investigational and unproven and not medically necessary for treating glaucoma**. Clinical evidence is limited to small studies; therefore, additional studies are needed to establish the safety and efficacy of these devices. **Canaloplasty is proven and medically necessary for treating primary open-angle glaucoma**. **Viscocanalostomy is unproven and not medically necessary for treating glaucoma**. Evidence from the majority of available randomized controlled trials indicates that viscocanalostomy is not as effective as trabeculectomy in reducing intraocular pressure (IOP).

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REVISED			
Hip Replacement Surgery (Arthroplasty)	Apr. 1, 2017	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale; replaced references to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017" *(refer to 21st edition for complete details on applicable updates to the MCG™ Care Guidelines)* • Updated list of applicable CPT codes; revised description for 27120, 27122, 27125, 27130, 27132, 27134, 27137 and 27138	For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st edition, 2017 Hip Arthroplasty, S-560 (ISC). For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Hip: Displaced Fracture of Femoral Neck, Hemiarthroplasty, S-600 (ISC).
Hysterectomy for Benign Conditions	Apr. 1, 2017	• Revised coverage rationale; replaced reference to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017" *(refer to 21st edition for complete details on applicable updates to the MCG™ Care Guidelines)*	For information regarding medical necessity review, when applicable, see the following MCG™ Care Guidelines, 21st edition, 2017: • Hysterectomy, Abdominal, ORG: S-650 (ISC) • Hysterectomy, Vaginal, ORG: S-660 (ISC) • Hysterectomy, Laparoscopic, ORG: S-665 (ISC)
Implanted Electrical Stimulator for Spinal Cord	Apr. 1, 2017	• Revised coverage rationale; replaced reference to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017" *(refer to 21st edition for complete details on applicable updates to the MCG™ Care Guidelines)*	For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Implanted Electrical Stimulator, Spinal Cord ACG: A-0243 (AC).
Obstructive Sleep Apnea Treatment	Apr. 1, 2017	• Revised coverage rationale; replaced references to "MCG™	**Nonsurgical Treatment** **Removable oral appliances are proven and medically necessary for**

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REVISED			
Obstructive Sleep Apnea Treatment *(continued)*	Apr. 1, 2017	Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017"	**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, 21st edition, 2017, 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 for information on the definitions and severity of OSA. • **Uvulopalatopharyngoplasty (UPPP)**: For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Uvulopalatopharyngoplasty (UPPP), A-0245 (ACG). • **Maxillomandibular Advancement Surgery (MMA)**: For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, 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

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Obstructive Sleep Apnea Treatment *(continued)*	Apr. 1, 2017		combinations, including mandibular osteotomy and genioglossal advancement with hyoid myotomy (GAHM). For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, 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. 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.

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Obstructive Sleep Apnea Treatment *(continued)*	Apr. 1, 2017		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.
Pneumatic Compression Devices	Apr. 1, 2017	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale; replaced reference to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017" *(refer to 21st edition for complete details on applicable updates to the MCG™ Care Guidelines)* • Updated list of applicable HCPCS codes: ○ Revised description for A4600 • Added reference link to the Coverage Determination Guideline titled *Durable Medical*	For information regarding medical necessity review of pneumatic compression devices, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Intermittent Pneumatic Compression with Extremity Pump ACG: ACG: A-0340 (AC).

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REVISED			
Pneumatic Compression Devices *(continued)*	Apr. 1, 2017	*Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements* for information regarding E0652	
Shoulder Replacement Surgery (Arthroplasty)	Apr. 1, 2017	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale; replaced references to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017" • Updated list of applicable CPT codes; added 23616	For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Shoulder Arthroplasty, S-634 (ISC). For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Shoulder Hemiarthroplasty, S-633 (ISC).
Surgical Treatment for Spine Pain	Apr. 1, 2017	• Revised coverage rationale and supporting information; replaced references to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017" *(refer to 21st edition for complete details on applicable updates to the MCG™ Care Guidelines)*	**Spinal fusion using extreme lateral interbody fusion (XLIF®) or direct lateral interbody fusion (DLIF) is proven**. For information regarding medical necessity review, when applicable, see the following MCG™ Care Guidelines, 21st edition, 2017: • Cervical Diskectomy or Microdiskectomy, Foraminotomy, Laminotomy, S-310 (ISC) • Lumbar Diskectomy, Foraminotomy, or Laminotomy S-810 (ISC) • Cervical Laminectomy S-340 (ISC) • Lumbar Laminectomy S-830 (ISC) • Cervical Fusion, Anterior S-320 (ISC) • Cervical Fusion, Posterior S-330 (ISC) • Lumbar Fusion S-820 (ISC) **The following spinal procedures are unproven**: • **Spinal fusion, when performed via the following methods** ○ Laparoscopic anterior lumbar interbody fusion (LALIF) ○ Transforaminal lumbar interbody fusion (TLIF) which utilizes only endoscopy visualization (such as a percutaneous incision with video visualization) ○ Axial lumbar interbody fusion (AxiaLIF ™) ○ Interlaminar lumbar instrumented fusion (ILIF) (e.g., Coflex-F®) This includes interbody cages, screws, and pedicle screw fixation devices with any of the above procedures.

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Surgical Treatment for Spine Pain *(continued)*	Apr. 1, 2017		Clinical evidence is limited primarily to retrospective studies and case series. Randomized, controlled trials comparing these procedures to standard procedures are needed to determine impact on health outcomes and long-term efficacy.
			• **Spinal decompression and interspinous process decompression systems**
			  ○ Interspinous process decompression (IPD) systems, for the treatment of spinal stenosis
			  ○ Minimally invasive lumbar decompression (MILD®)
			  ▪ Current clinical evidence is insufficient to permit conclusions about whether any beneficial effect from minimally invasive lumbar decompression provides a significant advantage over surgical decompression. In addition, the complication rates and reoperation rates for this procedure compared with those of decompression surgery is unknown.
			• **Spinal stabilization**
			  ○ Stabilization systems for the treatment of degenerative spondylolisthesis
			  ○ Total facet joint arthroplasty, including facetectomy, laminectomy, foraminotomy, vertebral column fixation
			  ▪ The current published evidence is insufficient to determine whether facet arthroplasty is as effective or as safe as spinal fusion, the current standard for surgical treatment of degenerative disc disease. In addition, no devices have received approval from the U.S. Food and Drug Administration for use outside the clinical trial setting.
			  ○ Percutaneous sacral augmentation (sacroplasty) with or without a balloon or bone cement for the treatment of back pain
			  ▪ The available clinical evidence shows that percutaneous sacroplasty, may alleviate the pain and functional impairment of sacral insufficiency fractures (SIF) in most patients with few and predominantly minor adverse effects, suggesting that this procedure may be relatively safe and efficacious for treatment of SIF. Despite these promising findings, the overall quality of the body of evidence is low given that the available studies were limited by methodological flaws (e.g., retrospective design, small sample size, subjective outcome measures, lack of a control group, and inadequate follow-up). Before reliable recommendations may be made, higher-quality studies are

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REVISED			
Surgical Treatment for Spine Pain *(continued)*	Apr. 1, 2017		required that entail large populations with sufficient statistical power. • **Stand-alone facet fusion without an accompanying decompressive procedure** ○ This includes procedures performed with or without bone grafting and/or the use of posterior intrafacet implants such as fixation systems, facet screw systems or anti-migration dowels. Clinical evidence is limited primarily to case series and nonrandomized studies. Randomized, controlled trials comparing facet fusion to standard procedures are needed to determine impact on health outcomes and long-term efficacy.
Temporo-mandibular Joint Disorders	Apr. 1, 2017	• Revised coverage rationale; replaced reference to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017" *(refer to 21st edition for complete details on applicable updates to the MCG™ Care Guidelines)*	**The following services are proven and medically necessary for treating disorders of the temporomandibular joint (TMJ)**: • Arthrocentesis • Arthroplasty [For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Temporomandibular Joint Arthroplasty, ACG: A-0523 (AC)] • Arthroscopy (with or without FDA approved bone anchor devices) • Arthrotomy/open joint surgery (with or without FDA approved bone anchor devices) • Injections of corticosteroids for rheumatoid arthritis-related TMJ disorders • Physical therapy • Stabilization and repositioning splint therapy (does not include low-load prolonged-duration stretch (LLPS) devices discussed below) **Partial or total joint replacement with an artificial prosthesis is proven and medically necessary for treating disorders of the Temporomandibular Joint (TMJ) when all other treatments have failed**. Not all services treat all TMJ disorders; specific treatments are based upon the specific diagnosis. **The following services are unproven and not medically necessary for treating disorders of the Temporomandibular Joint (TMJ)**: • Biofeedback • Craniosacral manipulation • Passive rehabilitation therapy

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REVISED			
Temporo-mandibular Joint Disorders *(continued)*	Apr. 1, 2017		• Low-load prolonged-duration stretch (LLPS) devices There are limited studies evaluating biofeedback for the treatment of musculoskeletal pain, including TMJ pain. One small uncontrolled study reported positive effects, while a larger randomized controlled study failed to demonstrate any treatment effect. Well-designed randomized, blinded and placebo-controlled outcome studies published on craniosacral manipulation for TMJ are not available. For additional information regarding manipulation under anesthesia for TMJ disorders, refer to the Medical Policy titled Manipulation Under Anesthesia. While there are some data from several randomized trials and case series studies that certain types of passive rehabilitation techniques may improve jaw mobility early in recovery in patients who have undergone TMJ surgery, or have lost jaw mobility due to TMJ derangement or to contracture following radiation therapy, these studies all included very small numbers of patients, and did not provide blinded assessment of outcomes, long-term follow-up, or information on optimal treatment protocols. Further prospective controlled clinical trials that directly compare LLPS devices to other treatment modalities are needed.
Total Knee Replacement Surgery (Arthroplasty)	Apr. 1, 2017	• Revised coverage rationale; replaced reference to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017" *(refer to 21st edition for complete details on applicable updates to the MCG™ Care Guidelines)* • Updated supporting information to reflect the most current CMS information	For information regarding medical necessity review, when applicable, see the following MCG™ Care Guidelines, 21st edition, 2017: • Total Knee Arthroplasty, S-700 (ISC) • Musculoskeletal Surgery or Procedure GRG: SG-MS (ISC GRG)
Wearable Cardioverter-Defibrillators	Apr. 1, 2017	• Reformatted and reorganized policy; transferred content to new template	For information regarding medical necessity review of wearable cardioverter-defibrillators, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Cardioverter-Defibrillator, Wearable. ACG: A-0566 (AC). Also see

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REVISED			
Wearable Cardioverter-Defibrillators *(continued)*	Apr. 1, 2017	• Revised coverage rationale; replaced references to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017" *(refer to 21st edition for complete details on applicable updates to the MCG™ Care Guidelines)* • Updated supporting information to reflect the most current FDA and CMS information	related MCG™ Care Guidelines, 21st edition, 2017, Electrophysiologic Study and Implantable Cardioverter-Defibrillator (ICD) Insertion, Transvenous. ORG: M-157 (ISC).

Policy Title	Effective Date	Summary of Changes
RETIRED		
Oscillatory Positive Expiratory Pressure Devices	Mar. 1, 2017	Policy retired; oscillatory positive expiratory pressure devices are now covered without need for clinical review

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Coverage Rationale
NEW		
Spinraza™ (Nusinersen)	Apr. 1, 2017	Spinraza™ (nusinersen) is **proven** and **medically necessary** for: 1. **The treatment of Spinal Muscular Atrophy (SMA) in patients who meet ALL of the following criteria**: a. **For initial therapy**, ALL of the following: (1) ONE of the following: (a) Diagnosis of spinal muscular atrophy type I, II, or III by a neurologist with expertise in the diagnosis of SMA; (b) Diagnosis of spinal muscular atrophy type I, II, or III by a physician in consultation with a neurologist with expertise in the diagnosis of SMA; **and** (2) Submission of medical records (e.g., chart notes, laboratory values) confirming BOTH of the following: (a) The mutation or deletion of genes in chromosome 5q resulting in ONE of the following: i. Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13); **or** ii. Compound heterozygous mutation (e.g., deletion of SMN1 exon 7[allele 1] and mutation of SMN1 [allele 2]); **and** (b) Patient has at least 2 copies of SMN2; **and** (3) Patient is not dependent on either of the following: (a) Invasive ventilation or tracheostomy (b) Non-invasive ventilation for at least 6 hours per day; **and** (4) Submission of medical records (e.g., chart notes, laboratory values) of the baseline exam of at least ONE of the following exams (based on patient age and motor ability) to establish baseline motor ability: (a) Hammersmith Infant Neurological Exam (HINE) (infant to early childhood) (b) Hammersmith Functional Motor Scale Expanded (HFMSE) (c) Upper Limb Module (ULM) Test (Non ambulatory) (d) Children's Hospital of Philadelphia Infant Test of Neuromucular Disorders (CHOP INTEND); **and** (5) ONE of the following: (a) Spinraza is prescribed by a neurologist with expertise in the treatment of SMA; (b) Spinraza is prescribed by a physician in consultation with a neurologist with expertise in the treatment of SMA; **and** (6) Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures; **and** (7) Spinraza dosing for SMA is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 12mg for each loading dose;

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NEW		
Spinraza™ (Nusinersen) *(continued)*	Apr. 1, 2017	**and** (8) Initial authorization will be for no more than 4 loading doses. b. **For continuation therapy**, ALL of the following: (1) ONE of the following (a) Diagnosis of spinal muscular atrophy type I, II, or III by a neurologist with expertise in the diagnosis of SMA; (b) Diagnosis of spinal muscular atrophy type I, II, or III by a physician in consultation with a neurologist with expertise in the diagnosis of SMA; **and** (2) Submission of medical records (e.g., chart notes, laboratory values) confirming BOTH of the following: (a) The mutation or deletion of genes in chromosome 5q resulting in ONE of the following: i. Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13); **or** ii. Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2]); **and** (b) Patient has at least 2 copies of SMN2; **and** (3) Patient is not dependent on either of the following: (a) Invasive ventilation or tracheostomy; (b) Non-invasive ventilation for at least 6 hours per day; **and** (4) Submission of medical records (e.g., chart notes, laboratory values) with the most recent results (< 1 month prior to request) documenting a positive clinical response **from pretreatment baseline status** to Spinraza therapy as demonstrated by at least ONE of the following exams: (a) HINE milestones: i. ONE of the following: (i) Improvement or maintenance of previous improvement of at least 2 point (or maximal score) increase in ability to kick; (ii) Improvement or maintenance of previous improvement of at least 1 point increase in any other HINE milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp; **and** ii. ONE of the following: (i) The patient exhibited improvement, or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement); (ii) Achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk);

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NEW		
Spinraza™ (Nusinersen) *(continued)*	Apr. 1, 2017	**or** (b) HFMSE: ONE of the following: i. Improvement or maintenance of previous improvement of at least a 3 point increase in score from pretreatment baseline; ii. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so; **or** (c) ULM: ONE of the following: i. Improvement or maintenance of previous improvement of at least a 2 point increase in score from pretreatment baseline; ii. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so; **or** (d) CHOP INTEND: ONE of the following: i. Improvement or maintenance of previous improvement of at least a 4 point increase in score from pretreatment baseline; ii. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so; **and** (5) ONE of the following: (a) Spinraza is prescribed by a neurologist with expertise in the treatment of SMA; (b) Spinraza is prescribed by a physician in consultation with a neurologist with expertise in the treatment of SMA. **and** (6) Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures; **and** (7) Spinraza dosing for SMA is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 12mg every 4 months, starting 4 months after the last loading dose; **and** (8) Reauthorization will be for no more than 3 maintenance doses (12 months). **Spinraza is not proven or medically necessary for spinal muscular atrophy without chromosome 5q mutations or deletions.**

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Exondys 51™ (Eteplirsen)	Apr. 1, 2017	• Policy" to "Medical Benefit Drug Policy" to clarify policy guidelines apply to drug coverage provided under the medical benefit • Revised coverage rationale/coverage criteria for the treatment of Duchenne muscular dystrophy (DMD): ***Initial Therapy*** ○ Replaced criterion requiring "diagnosis of Duchenne muscular dystrophy" with "diagnosis of Duchenne muscular dystrophy *by a neurologist with expertise in the diagnosis of DMD* ***or*** *by a physician in consultation with a neurologist with expertise in the diagnosis of DMD*" ○ Added criterion requiring: ▪ Submission of medical records (e.g., chart notes, laboratory values) confirming the patient has a 6-Minute Walk Time (6MWT) ≥ 300 meters while walking independently prior to beginning Exondys 51 therapy ▪ **One** of the following: - Exondys 51 is prescribed by a neurologist with expertise in the treatment of DMD - Exondys 51 is prescribed by a	**Exondys 51™ (eteplirsen) may be covered for the treatment of Duchenne muscular dystrophy (DMD) in patients who meet ALL of the following criteria:** • For initial therapy, ALLof the following: ○ ONE of the following: ▪ Diagnosis of Duchenne muscular dystrophy by a neurologist with expertise in the diagnosis of DMD • Diagnosis of Duchenne muscular dystrophy by a physician in consultation with a neurologist with expertise in the diagnosis of DMD **and** ○ Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation of the DMD gene is amenable to exon 51 skipping. **and** ○ Submission of medical records (e.g., chart notes, laboratory values) confirming that the patient has a 6-Minute Walk Time (6MWT) ≥ 300 meters while walking independently prior to beginning Exondys 51 therapy. **and** ○ ONE of the following: ▪ Exondys 51 is prescribed by a neurologist with expertise in the treatment of DMD ▪ Exondys 51 is prescribed by a physician in consultation with a neurologist with expertise in the treatment of DMD **and** ○ Exondys 51 dosing for DMD is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 30 mg/kg infused once weekly **and** ○ Initial authorization will be for no more than 4 weeks • For continuation therapy, ALL of the following: ○ ONE of the following: ▪ Exondys 51 is prescribed by a neurologist with expertise in the treatment of DMD ▪ Exondys 51 is prescribed by a physician in consultation with a neurologist with expertise in the treatment of DMD **and** ○ Submission of medical records (e.g., chart notes) confirming that the

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REVISED			
Exondys 51™ (Eteplirsen) *(continued)*	Apr. 1, 2017	physician in consultation with a neurologist with expertise in the treatment of DMD ***Continuation Therapy*** ○ Added criterion requiring: ▪ **One** of the following: - Exondys 51 is prescribed by a neurologist with expertise in the treatment of DMD - Exondys 51 is prescribed by a physician in consultation with a neurologist with expertise in the treatment of DMD ▪ Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory **without** needing an assistive device (e.g., cane, walker, wheelchair, etc.) • Updated supporting information to reflect the most current references	patient is ambulatory without needing an assistive device (e.g., cane, walker, wheelchair, etc.) **and** ○ Exondys 51 dosing for DMD is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 30 mg/kg infused once weekly **and** ○ Reauthorization will be for no more than 6 months **Exondys 51 will not be covered for other forms of muscular dystrophy**.
Infliximab (Remicade® and Inflectra™)	Apr. 1, 2017	• Changed policy type classification from "Drug Policy" to "Medical Benefit Drug Policy" • Revised coverage rationale; added preferred product information to indicate: **Medical Necessity Plans**	This policy refers to the following infliximab products: • Remicade® (infliximab) • Inflectra™ (infliximab-dyyb) **A. Preferred Product** ***Medical Necessity Plans*** Remicade® (infliximab) is the preferred infliximab product. Coverage will be

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Infliximab (Remicade® and Inflectra™) *(continued)*	Apr. 1, 2017	○ Remicade® (infliximab) is the preferred infliximab product; coverage will be provided for Remicade® contingent on the diagnosis-specific coverage criteria listed in the policy ○ Coverage for Inflectra™ (infliximab-dyyb) will be provided contingent on the preferred product coverage criteria and the diagnosis-specific coverage criteria listed in the policy ▪ In order to continue coverage, members already on Inflectra™ will be required to change therapy to Remicade® unless they meet the preferred product coverage criteria ***Preferred Product Coverage Criteria*** ○ Treatment with Inflectra™ (infliximab-dyyb) or other infliximab biosimilar is medically necessary for the indications listed in the policy when the following criteria are met: ▪ **Both** of the following: 1. **One** of the following: - **Both** of the following: a. History of a trial of at least 14 weeks of Remicade	provided for Remicade® contingent on the coverage criteria in section B. Coverage for Inflectra™ (infliximab-dyyb) will be provided contingent on the criteria in this section and the coverage criteria in section B. In order to continue coverage, members already on Inflectra™ will be required to change therapy to Remicade® unless they meet the criteria in this section. ***Preferred Product Criteria*** **Treatment with Inflectra™ (infliximab-dyyb) or other infliximab biosimilar is medically necessary for the indications specified in this policy when the following criteria are met**: 1. **Both** of the following: a. **One** of the following: (1) **Both** of the following: (a) History of a trial of at least 14 weeks of Remicade resulting in minimal clinical response to therapy and residual disease activity; and (b) Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Inflectra or other infliximab biosimilar product, than experienced with Remicade. **or** (2) **Both** of the following: (a) History of intolerance or adverse event to Remicade; and (b) Physician attests that, in their clinical opinion, the same intolerance or adverse event would not be expected to occur with Inflectra or other infliximab biosimilar product **and** b. **Both** of the following (1) Patient has NOT had a loss of a favorable response after established maintenance therapy with Remicade or other infliximab biosimilar product; and (2) Patient has NOT developed neutralizing antibodies to any infliximab biosimilar product that has lead to an attenuation of efficacy of therapy. ***Non-Medical Necessity Plans*** Any infliximab product is to be approved contingent on the coverage criteria in section B.

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Infliximab (Remicade® and Inflectra™) *(continued)*	Apr. 1, 2017	resulting in minimal clinical response to therapy and residual disease activity b. Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Inflectra or other infliximab biosimilar product, than experienced with Remicade **OR** - **Both** of the following: a. History of intolerance or adverse event to Remicade b. Physician attests that, in their clinical	**B. Diagnosis-Specific Criteria** "Infliximab" will be used to refer to all infliximab products. **Infliximab is proven and medically necessary for the treatment of**: 1. Ankylosing spondylitis when the following criterion is met: a. Diagnosis of ankylosing spondylitis (AS). 2. Crohn's disease when the following criterion is met: a. ONE of the following: (1) Diagnosis of fistulizing Crohn's disease (Crohn's Disease Activity Index (CDAI) ≥ 220 and ≤ 400); **or** (2) BOTH of the following: (a) Diagnosis of moderately to severely active Crohn's disease; **and** (b) History of failure, contraindication, or intolerance to at least ONE conventional therapy (e.g., corticosteroids, 6-mercaptopurine, azathioprine, methotrexate, etc.). 3. Noninfectious uveitis when BOTH of the following criteria are met: a. Diagnosis of refractory noninfectious uveitis that is causing or threatening vision loss (e.g., noninfectious uveitis associated with Behçet's or Reiter's syndromes); **and** b. History of failure, contraindication, or intolerance to ALL of the following: (1) Topical corticosteroids (2) Systemic corticosteroids (3) Immunosuppressive drugs (e.g., azathioprine, cyclosporine, or methotrexate). 4. **Plaque psoriasis** when BOTH of the following criteria are met: a. Diagnosis of chronic severe plaque psoriasis (i.e., extensive and/or disabling); **and** b. Patient is a candidate for systemic therapy. 5. Psoriatic arthritis when the following criterion is met: a. Diagnosis of psoriatic arthritis (PsA). 6. Rheumatoid arthritis when BOTH of the following criteria are met:

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Infliximab (Remicade® and Inflectra™) *(continued)*	Apr. 1, 2017	opinion, the same intolerance or adverse event would not be expected to occur with Inflectra or other infliximab biosimilar product. **AND** 2. **Both** of the following: a. Patient has **not** had a loss of a favorable response after established maintenance therapy with Remicade or other infliximab biosimilar product b. Patient has **not** developed neutralizing antibodies to any infliximab biosimilar product that has led to an attenuation of efficacy of therapy **Non- Medical Necessity Plans**	a. Diagnosis of moderately to severely active rheumatoid arthritis (RA); **and** b. ONE of the following: (1) Patient is receiving concurrent therapy with methotrexate. (2) History of contraindication or intolerance to methotrexate. 7. Sarcoidosis when ALL of the following criteria are met: a. Diagnosis of sarcoidosis; **and** b. History of failure, contraindication, or intolerance to corticosteroids (e.g., prednisone, methylprednisolone); **and** c. History of failure, contraindication, or intolerance to ONE immunosuppressant (e.g., methotrexate, cyclophosphamide, azathioprine). 8. Ulcerative colitis when BOTH of the following criteria are met: a. Diagnosis of moderately to severely active ulcerative colitis (UC); **and** b. History of failure, contraindication, or intolerance to at least ONE conventional therapy (e.g., 6-mercaptopurine, aminosalicylate, azathioprine, corticosteroids). There may be other conditions that qualify as serious, rare diseases for which the use of infliximab may be appropriate. Please refer to the *Benefit Considerations* section of the policy for additional information. **Infliximab is unproven and not medically necessary for the treatment of**: 1. Still's disease 2. Sjogren's syndrome 3. Graft-vs-host disease 4. Myelodysplastic syndromes 5. Undifferentiated spondyloarthropathy 6. Reiter's syndrome 7. Hidradenitis suppurativa 8. Wegener's granulomatosis 9. Juvenile idiopathic arthritis (juvenile rheumatoid arthritis)

Medical Benefit Drug Policy Updates

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Infliximab (Remicade® and Inflectra™) *(continued)*	Apr. 1, 2017	○ Any infliximab product is to be approved contingent on the diagnosis-specific coverage criteria listed in the policy • Updated supporting information to reflect the most current references	Infliximab is unproven for the treatment of the above conditions because statistically robust randomized controlled trials are needed to address the issue of whether infliximab has sufficient superiority in clinical efficacy compared to other available treatments to justify the inherent clinical risk in the use of a monoclonal antibody anti-tumor necrosis factor agent.

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Blepharoplasty, Blepharoptosis and Brow Ptosis Repair	Apr. 1, 2017	• Updated supporting information; replaced reference to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017"	Refer to the policy for complete details on the coverage guidelines for Blepharoplasty, Blepharoptosis and Brow Ptosis Repair.
Breast Reduction Surgery	Apr. 1, 2017	• Updated supporting information; replaced reference to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017"	**California Mandate for Medically Necessary Surgery** The State of California requires that all breast reduction surgeries be reviewed for medical necessity. Benefits will be provided if the breast reduction meets the *Criteria for a Coverage Determination as Reconstructive* identified below. **Indications for Coverage** Breast reduction surgery following mastectomy to achieve symmetry is covered as part of the Women's Health and Cancer Rights Act (WHCRA). Please refer to the Coverage Determination Guideline titled Breast Reconstruction Post Mastectomy. Breast reconstruction may be covered under certain circumstances for the surgical treatment of gender dysphoria. Please refer to the member specific benefit plan document for coverage. **All plans cover breast reduction surgeries that qualify under the Women's Health and Cancer Rights Act of 1998**. If a surgery does not qualify under the Women's Health and Cancer Rights Act of 1998, certain plans may allow breast reduction surgery which we determine to treat a physiologic functional impairment. However, certain plans exclude breast reduction surgery even if it treats a physiologic functional impairment. Refer to the member specific benefit plan document to determine coverage. ***For Plans that Cover Breast Reduction Surgery that Treat a Physiologic Functional Impairment (Including California Reviews for Medical Necessity)*** **Criteria for a Coverage Determination as Reconstructive** Breast reduction surgery is considered reconstructive and medically necessary when the following criteria are met and a physiologic functional impairment is identified: • Macromastia is the primary etiology of the member's functional

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Breast Reduction Surgery *(continued)*	Apr. 1, 2017		impairment or impairments (as defined in the *Definitions* section). The following are examples of functional impairments that must be attributable to macromastia to be considered (not an all-inclusive list): ○ Severe skin excoriation/intertrigo unresponsive to medical management ○ Severe restriction of physical activities that meets the definition of functional impairment below ○ Signs and symptoms of nerve compression that are unresponsive to medical management (e.g., ulnar paresthesias) ○ Acquired kyphosis that is attributed to macromastia ○ Chronic breast pain due to weight of the breasts ○ Upper back, neck, or shoulder pain ○ Shoulder grooving from bra straps ○ Headache; and • The amount of tissue to be removed plots above the 22nd percentile; or • If the amount of tissue to be removed plots between the 5th and 22nd percentiles, the procedure may be either reconstructive or cosmetic; the determination is based on the review of the information provided; and • The proposed procedure is likely to result in significant improvement of the functional impairment. **The Following Documentation Should be Available for Review** Reduction Mammoplasty documentation should include the evaluation and management note for the date of service and the note for the day the decision to perform surgery was made. The member's medical record must contain, and be available for review on request, the following information: • Height and weight • Body surface area (BSA) • Photographs that document macromastia. **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

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Breast Reduction Surgery *(continued)*	Apr. 1, 2017		Covered Person may suffer psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure. • Any procedure that does not meet the reconstructive criteria above in the *Indications for Coverage* section above (e.g., psychological or social reasons, breast size asymmetry unless post mastectomy, exercise). • Breast reduction surgery is cosmetic when done to improve appearance without improving a functional/physiologic impairment. • The use of liposuction as the sole procedure for breast reduction surgery is considered cosmetic. **Appendix** This Schnur chart may be used to assess whether the amount of tissue that will be removed is reasonable for the body habitus, and whether the procedure is cosmetic or reconstructive in nature. • If the amount plots above the 22nd percentile and the member has a functional impairment, the procedure is reconstructive. • If the amount plots below the 5th percentile, the procedure is cosmetic. • If the amount plots between the 5th and 22nd percentiles, the procedure may be either reconstructive or cosmetic based on review of information. To calculate body surface area (BSA), see: • http://www.cornellpediatrics.org/ser_div/critical/calc/bsacalc.htm; or • BSA = (W 0.425 x H 0.725) x 0.007184 (weight is in kilograms and height is in centimeters).
Panniculectomy and Body Contouring Procedures	Apr. 1, 2017	• Updated supporting information; replaced reference to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017"	**Indications for Coverage** ***Panniculectomy*** **Panniculectomy is considered reconstructive and medically necessary when ALL of the following criteria have been met**: • Panniculus hangs at or below symphysis pubis; • The panniculus is the primary cause of skin conditions when present, such a cellulitis requiring systemic antibiotics or transdermal skin ulcerations that require medical treatment; • There is presence of a functional impairment due to the panniculus; • The surgery is expected to restore or improve the functional impairment; • The panniculus is interfering with activities of daily living.

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Panniculectomy and Body Contouring Procedures *(continued)*	Apr. 1, 2017		**Note**: • After significant weight loss not following bariatric surgery, in addition to the criteria listed above, there must be documentation that a stable weight has been maintained for six months. • After significant weight loss following bariatric surgery, in addition to meeting the criteria listed above there must be documentation that a stable weight has been maintained for six months. This often occurs 12-18 months after surgery. **Panniculectomy is not considered reconstructive, and is not a covered service, in the following situations (not an all-inclusive list)**: • When performed to relieve neck or back pain as there is no evidence that reduction of redundant skin and tissue results in less spinal stress or improved posture/alignment. • When performed in conjunction with abdominal or gynecologic surgery including but not limited to hernia repair, obesity surgery, C-section and hysterectomy unless the member meets the criteria for panniculectomy as stated above in this document. • Performed post childbirth in order to return to pre-pregnancy shape. • Performed for intertrigo, a superficial inflammatory response or any other condition that does not meet the criteria above in this document. Documentation may be requested as part of the review, including but not limited to photographs and physician office notes. ***Abdominoplasty*** **Abdominoplasty is not considered reconstructive, and is not a covered service**. ***Lipectomy*** **Lipectomy is not considered reconstructive, and is not a covered service in the following situation (not an all-inclusive list)**: • Performed on any site including buttocks, arms, legs, neck, abdomen and medial thigh. ***Suction-Assisted Lipectomy of the Trunk*** **Suction-assisted lipectomy of the trunk (CPT code 15877) is not considered reconstructive (unless part of an approved procedure), and is not a covered service**.

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Panniculectomy and Body Contouring Procedures *(continued)*	Apr. 1, 2017		For post-mastectomy patients, refer to the Coverage Determination Guideline titled Breast Reconstruction Post Mastectomy. **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 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 the *Indications for Coverage* section.
Rhinoplasty and Other Nasal Surgeries	Apr. 1, 2017	• Updated coverage rationale; removed duplicative language pertaining to use of noted criteria for medical necessity plans • Updated supporting information to reflect the most current references ○ Replaced reference to "MCG™ Care Guidelines, 19th edition, 2015" with "MCG™ Care Guidelines, 21st edition, 2017	**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 nasal airway obstruction and relieve the nasal airway obstruction by centralizing the nasal bony pyramid (30410) and also straightening the septum (30420), and

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Rhinoplasty and Other Nasal Surgeries *(continued)*	Apr. 1, 2017		• 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 documented functional impairment persists due to the complication/deformity (these codes are usually cosmetic), and
			• Photos clearly document the secondary deformity/complication as the

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Rhinoplasty and Other Nasal Surgeries *(continued)*	Apr. 1, 2017		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 primary cause of an anatomic mechanical nasal airway obstruction and are consistent with the clinical exam, and • Other causes have been eliminated as the primary cause of nasal obstruction (e.g., sinusitis, allergic rhinitis, vasomotor rhinitis, nasal

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Rhinoplasty and Other Nasal Surgeries *(continued)*	Apr. 1, 2017		polyposis, adenoid hypertrophy, nasopharyngeal masses, nasal septal deviation, turbinate hypertrophy and choanal atresia). ***Septal Dermatoplasty (CPT Code 30620)*** **Septal dermatoplasty is considered reconstructive when**: • There is a documented functional impairment (e.g., obstruction, pain or bleeding) due to diseased nasal mucosa, and • The functional impairment will be eliminated by a skin graft. ***Lysis Intranasal Synechia (CPT Code 30560)*** **Lysis intranasal synechia is considered reconstructive when**: • There is a documented functional impairment (e.g., obstruction, pain or bleeding) due to intranasal synechia (adhesions/scar bands), and • The functional impairment will be eliminated by lysis of the synechia. ***Rhinophyma (CPT Code 30120)*** **Rhinophyma is 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 proposed procedure is designed to address the chronic infection. ***California Only*** This is the mandated language for Reconstructive Procedures: • Reconstructive procedures to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease. Reconstructive procedures include surgery or other procedures which are associated with an Injury, Sickness or Congenital Anomaly. The primary result of the procedure is

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Rhinoplasty and Other Nasal Surgeries *(continued)*	Apr. 1, 2017		not a changed or improved physical appearance for cosmetic purposes only, but rather to improve function and/or create a normal appearance, to the extent possible. ***Documentation Requirements*** Rhinoplasty or other nasal surgery documentation should include the evaluation and management note for the date of service and the note for the day the decision to perform surgery was made. The member's medical record must contain, and be available for review on request, the following information: • Physician office notes • Radiologic imaging if done • Photographs that document the nasal deformity **Coverage Limitations and Exclusions** Cosmetic Procedures are excluded from coverage, including but not limited to: • 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 • Rhinoplasty, unless rhinoplasty criteria above are met • Any procedure that does not meet the reconstructive criteria • Rhinoplasty procedures performed to improve appearance (check member specific benefit plan document)
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
REVISED			
Orthognathic (Jaw) Surgery	Apr. 1, 2017	• Revised coverage rationale: ○ Removed duplicative language pertaining to use of noted criteria for medical necessity plans ○ Replaced references to "MCG™ Care Guidelines,	**Indications for Coverage** Orthognathic (jaw) surgery is a standard exclusion from coverage in most fully-insured plans. The following list represents the covered *exceptions* to the orthognathic (jaw) surgery exclusion. **The following are eligible for coverage as reconstructive and medically necessary**:

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Orthognathic (Jaw) Surgery *(continued)*	Apr. 1, 2017	20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017"	• Acute traumatic injury and post-surgical sequela (see post-surgical sequela in *Definitions* section of the policy)
			• Cancerous or non-cancerous tumors and cysts, cancer and post-surgical sequela (see cancer sequela and post-surgical sequela in *Definitions* section of the policy)
			
			The following are eligible for coverage when the criteria are met (refer to Criteria section below):
			• Obstructive sleep apnea (also see Medical Policy titled Obstructive Sleep Apnea Treatment)
			• Cleft lip/palate (for cleft lip/palate related jaw surgery)
			• Congenital anomalies that meet the criteria for reconstructive. Depending on a patient-specific clinical review, examples include: Pierre Robin Syndrome, Hemifacial Microsomia, and Treacher Collins Syndrome.
			
			Criteria
			All orthognathic (jaw) surgeries are subject to some level of review. For the above covered exceptions that require review, the following criteria should be applied.
			
			Orthognathic (jaw) surgery is a reconstructive procedure and medically necessary and is considered covered when both the skeletal deformity AND the functional impairment criteria below are met:
			• The presence of any of the following facial skeletal deformities associated with masticatory malocclusion:
			  ○ *Anteroposterior Discrepancies*
			  ▪ Maxillary/Mandibular incisor relationship: overjet of 5mm or more, or a 0 to a negative value (norm 2mm)
			  ▪ Maxillary/Mandibular anteroposterior molar relationship discrepancy of 4mm or more (norm 0 to 1mm)
			  ▪ These values represent two or more standard deviation from published norms
			  ○ *Vertical Discrepancies*
			  Presence of a vertical facial skeletal deformity which is two or more standard deviations from published norms for accepted skeletal landmarks:
			  ▪ Open bite:
			  - No vertical overlap of anterior teeth

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Orthognathic (Jaw) Surgery *(continued)*	Apr. 1, 2017		- Unilateral or bilateral posterior open bite greater than 2mm ▪ Deep overbite with impingement or irritation of buccal or lingual soft tissues of the opposing arch ▪ Supraeruption of a dentoalveolar segment due to lack of occlusion ○ *Transverse Discrepancies* ▪ Presence of a transverse skeletal discrepancy which is two or more standard deviations from published norms ▪ Total bilateral maxillary palatal cusp to mandibular fossa discrepancy of 4mm or greater, or a unilateral discrepancy of 3mm or greater, given normal axial inclination of the posterior teeth ○ *Asymmetries* ▪ Anteroposterior, transverse or lateral asymmetries greater than 3mm with concomitant occlusal asymmetry • In addition to meeting the skeletal deformity requirement above, the patient must also have one or more of the following functional impairments: ○ Masticatory (chewing) and swallowing dysfunction due to skeletal malocclusion (e.g., inability to incise/and or chew solid foods, choking on incompletely masticated solid foods, damage to soft tissue during mastication, malnutrition) ○ Documentation of speech deficits to support existence of speech impairment due to skeletal malocclusion ○ Moderate to severe obstructive sleep apnea, as measured by polysomnography (AASM Obstructive Sleep Apnea; and Practice Parameters for the Surgical Modifications of the Upper Airway for Obstructive Sleep Apnea in Adults), is defined as: ▪ Moderate for AHI or RDI ≥ 15 and ≤ 30 ▪ Severe for AHI or RDI > 30/hr; AND oropharyngeal narrowing secondary to maxillomandibular deficiency is the primary cause of moderate to severe obstructive sleep apnea [see MCG™ Care Guidelines, 21st edition, 2017, Maxillomandibular Osteotomy and Advancement A-0248 (ACG)] **For Obstructive Sleep Apnea** For medical necessity plans, in addition to the criteria above, please also refer to the following: • Maxillomandibular advancement surgery (MMA):

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Orthognathic (Jaw) Surgery *(continued)*	Apr. 1, 2017		○ For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Maxillomandibular Osteotomy and Advancement, A-0248 (ACG). • Multilevel procedures whether done in a single surgery or phased multiple surgeries: ○ There are a variety of procedure combinations, including mandibular osteotomy and genioglossal advancement with hyoid myotomy (GAHM). For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Mandibular Osteotomy, A-0247 (ACG). ***California Only*** This is the mandated language for Reconstructive Procedures: • Reconstructive procedures to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease. Reconstructive procedures include surgery or other procedures which are associated with an Injury, Sickness or Congenital Anomaly. The primary result of the procedure is not a changed or improved physical appearance for cosmetic purposes only, but rather to improve function and/or create a normal appearance, to the extent possible. **Coverage Limitations and Exclusions** Except where state mandated, the following are not covered: • Cosmetic and non-reconstructive jaw surgery and jaw alignment procedures (orthognathic surgery) that do not meet the criteria in the *Indications for Coverage* section above are excluded from coverage. • Surgery for torus mandibularis and torus palatinus for fabrication of dentures is not covered. • Pre and post-surgical orthodontic treatment. ***Additional Information*** Some states may require orthognathic (jaw) surgery for cleft lip and cleft palate, or 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.

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Preventive Care Services	Apr. 1, 2017	• Revised list of applicable procedure and diagnosis codes for **Preventive Care Services**: *HIV – Human Immunodeficiency Virus – Screening for Adolescents and Adults* ○ Updated list of applicable CPT codes; added 87391 and 87806 (HIV antigen detection) *Screening Mammography* ○ Updated list of applicable CPT codes; added 77063 (screening digital breast tomosynthesis, bilateral) ○ Revised preventive benefit instructions; removed language indicating this benefit does not apply to digital breast tomosynthesis (3-D mammography) *Primary Care Interventions to Promote Breastfeeding* ○ Updated service description: ▪ Removed October 2008 USPSTF 'B' rating ▪ Added October 2016 USPSTF 'B' rating indicating USPSTF recommends providing interventions during pregnancy and after birth to support breastfeeding	Refer to the policy for complete details on the coverage guidelines for Preventive Care Services.
Speech Language Pathology Services	Apr. 1, 2017	• Revised coverage rationale: ○ Replaced reference to "MCG™ Care Guidelines, 20th edition, 2016" with	**Indications for Coverage** ***Information Pertaining to Medical Necessity Review (When Applicable)***

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Speech Language Pathology Services *(continued)*	Apr. 1, 2017	"MCG™ Care Guidelines, 21st edition, 2017" *(refer to 21st edition for complete details on applicable updates to the MCG™ Care Guidelines)* ○ Updated benefit interpretation guidelines for treatment of injuries affecting speech; added "polyps" to list of examples of vocal cord injuries • Updated list of applicable HCPCS codes; revised description for V5362 and V5363	See the following MCG™ Care Guidelines, 21st edition, 2017: • Acquired Apraxia of Speech Rehabilitation ACG: A-0555 (AC) • Dysarthria Rehabilitation ACG: A-0556 (AC) • Voice Disorders Rehabilitation ACG: A-0559 (AC) • Developmental Speech Disorders Rehabilitation ACG: A-0560 (AC) • Developmental Language Disorders Rehabilitation ACG: A-0561 (AC) ***Benefit Interpretation*** • Speech therapy (speech–language pathology services) for the treatment of disorders of speech, language, voice, communication and auditory processing are covered when the disorder results from injury, stroke, cancer, congenital anomaly, or autism spectrum disorders. • Services of a speech-language pathologist or other licensed healthcare professional (within the scope of his/her licensure) may be covered when: ○ There is a need for the supervision of a licensed therapist for speech–language therapy, swallowing or feeding rehabilitative or restorative therapy services. ○ The services are part of a treatment plan with documented goals for functional improvement of the patient's condition, e.g., speech, articulation, swallowing or communication with or without alternative methods. ○ The teaching of patient and or caregiver is required to strengthen muscles, improve feeding techniques or improve speech–language skills to progress toward the documented treatment plan goals. Once patient and/or caregiver are trained the services are no longer skilled, therefore custodial, and not a covered health service. Refer to the Coverage Determination Guideline titled Skilled Care and Custodial Care Services. ○ Mandated benefits (federal and state) for speech therapy. Examples may include developmental delay, autism, cleft palate and/or lip, aphasia. **Note**: State mandates always take precedence over plan language. • Treatment of congenital anomaly which includes but are not limited to the following: ○ Downs syndrome ○ Cleft palate ○ Tongue tie • Speech therapy for autism spectrum disorders is covered when the

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Speech Language Pathology Services *(continued)*	Apr. 1, 2017		member has a speech therapy benefit.
			• Treatment of injury affecting speech:
			  ○ Otitis media
			  ▪ This is an illness but if the illness caused damage resulting in hearing loss, this may also be injury.
			  ▪ Once the fluid is gone there must be hearing loss documented by testing (such as audiogram or notes of such testing) to result in injury and coverage of speech therapy.
			  ○ Vocal cord injuries (e.g., edema, nodules, polyps)
			  ○ Stroke/CVA
			  ○ Trauma
			  ○ Cerebral palsy
			  ○ Static encephalopathy
			• Rehabilitation services for feeding and or swallowing rehabilitative or restorative therapy services
			  ○ Swallowing disorders (dysphagia)
			  ○ Feeding disorders including problems with gathering food and sucking, chewing, or swallowing food. For example, a child who cannot pick up food and get it to his/her mouth or cannot completely close his/her lips to keep food from falling out of his/her mouth may have a feeding disorder.
			  ○ Auditory (Aural) rehabilitation which includes speech–language therapy, e.g., when a auditory implant or cochlear implant is a covered healthcare service
			• Outpatient rehabilitation can occur in the following settings:
			  ○ Physician's office
			  ○ Therapist's office
			  ○ Member's place of residence
			  ○ Separate part of a clinic or hospital where speech therapy is performed
			
			Additional Information
			• Eligible speech therapy received in the home from a Home Health Agency is covered under Home Health Care. The Home Health Care section only applies to services that are rendered by a Home Health Agency.
			• Eligible speech therapy received in the home from an independent speech therapist (a speech therapist that is not affiliated with a Home Health Agency) is covered under Rehabilitation Services-Outpatient Therapy.

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Speech Language Pathology Services *(continued)*	Apr. 1, 2017		• Swallowing and feeding rehabilitation therapy may be done with speech rehabilitation services; when performed together both should be billed and only the speech therapy will count toward the speech therapy benefit limit, if applicable. • Swallowing therapy (92526) when billed alone will count toward the speech therapy benefit limit, if applicable. • Cochlear implant monitoring (remapping and reprogramming of implant) and rehabilitation following the cochlear implant surgery is usually billed as aural rehabilitation. This is not covered as a speech therapy benefit. The member specific benefit plan document must be referenced for any applicable limits that may apply to aural rehabilitation. **Coverage Limitations and Exclusions** • Devices and computers to assist in communication and speech (refer to the Coverage Determination Guideline titled Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements). • Speech therapy if the provider is school based (check benefit language and state mandates). • Idiopathic developmental delay (no illness to explain the cause of developmental delay in speech–language). • Sign language (does not require the services of a licensed or certified healthcare professional). • Speech therapy beyond the benefit maximum (visits limits). • A child being bilingual is not considered a developmental speech or developmental delay and speech therapy is usually not a covered health service, except when other criteria for speech therapy are met (see the *Definitions* section of the policy for Speech Delay – Bilingualism). • Home Speech Therapy for the convenience of a provider or member.

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Utilization Management Guiding Principles
NEW		
Office Based Program	Apr. 1, 2017	**Introduction** In an effort to minimize out-of-pocket costs for United HealthCare members and to improve cost efficiencies for the overall health care system, we are implementing prior authorization guidelines that aim to encourage more cost-effective sites of service for certain outpatient surgical procedures, when medically appropriate. These prior authorization requirements apply to UnitedHealthcare commercial plans that require services to be medically necessary, including being cost-effective. Refer to the member specific benefit document to determine if medical necessity applies. Specific procedure codes for services can be found on the Prior Authorization List. See the *References* section of the guideline for more information. **Coverage Rationale** With the exception of the qualifying conditions below, certain elective procedures should be performed in an Office setting. The following will be taken into account to determine whether the elective procedure is being performed in a cost effective setting; • Members benefit plan • Geographic availability of an in network provider • Office capability (i.e., appropriate equipment) • Significant member comorbidities (see list of examples of *Qualifying Conditions*) **Certain Qualifying Conditions** Some patients may require more complex care due to certain medical factors or functional limitations and it may be appropriate to have the procedure in an outpatient hospital setting or ambulatory surgery center. (Not an all-inclusive list) • Patient unable to cooperate with procedure due to mental status, severe anxiety, or extreme pain sensitivity. • Failed office based procedure attempt due to body habitus, abnormal anatomy, or technical difficulties. • Bleeding disorder that would cause a significant risk of morbidity. • Allergy to local anesthetic. **Potential Documentation Requirements** • Physician office notes **Elective Procedures List** Prior authorization is required for the listed procedures if not performed in an office setting (see *Applicable Codes* table).

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Utilization Management Guiding Principles
UPDATED			
Immune Globulin Site of Care Review Guidelines for Medical Necessity of Hospital Outpatient Facility Infusion	Apr. 1, 2017	• Updated supporting information; replaced reference to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017"	**Introduction** This guideline addresses the criteria for consideration of allowing hospital outpatient facility infusion service for immune globulin (IVIG and SCIG) therapy. This includes hospital based services with the following CMS/AMA Place of Service codes: • 22 On Campus-Outpatient Hospital; and • 19 Off Campus-Outpatient Hospital. **Criteria and Clinical Indications for Hospital Outpatient Site of Care Selection** ***Criteria*** When requested, hospital outpatient site of care may be approved when: • **Any** of the questions to the Clinical Indications below can be answered 'yes'; and • The provider has submitted the appropriate supporting documentation. **Clinical Indications** See the above criteria for the following questions. **Note**: If more than one of the criteria addressed in the questions below are met, then the greatest of the applicable approval time periods will be allowed. • Is this the patient's initial infusion of immune globulin or re-initiation after more than 6 months off of immune globulin? • Is the patient changing immune globulin products? • Has the patient previously experienced a severe adverse event to immune globulin (examples might include, but are not limited to anaphylaxis, seizure, thromboembolism, myocardial infarction, and renal failure, other – provide reaction)? • Is the patient clinically unstable? • Is the patient continually experiencing moderate or severe adverse events not able to be mitigated by use of acetaminophen, steroids, diphenhydramine, fluids or other pre-medications on therapy? • Has the patient had an adverse event not able to be mitigated by use of acetaminophen, steroids, diphenhydramine, fluids or other pre-medications to immune globulin therapy documented for which the physician is uncomfortable administering immune globulin in a home or ambulatory setting? • Is the patient physically or cognitively disabled to the point where receiving treatment at home or in a physician office would present a risk

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Utilization Management Guiding Principles
UPDATED			
Immune Globulin Site of Care Review Guidelines for Medical Necessity of Hospital Outpatient Facility Infusion *(continued)*	Apr. 1, 2017		to their health? • Does the patient have immunoglobulin A (IgA) deficiency with anti-IgA antibodies? **Benefit Considerations** This guideline applies to: • Members with 2011 COC or Summary Plan Document with benefits available for healthcare services if medically necessary • UnitedHealthcare Commercial plans This guideline does not apply to Medicare or Medicaid plans. **Supporting Information and Clinical Evidence** • Clinical use of immune globulin use is proven according to the UnitedHealthcare Drug Policy titled Immune Globulin (IVIG and SCIG). • With respect to the site of care there are several options for administering immune globulin and should be based on patient clinical characteristics ○ Hospital inpatient physician/nurse supervised infusion ○ Hospital outpatient physician/nurse supervised infusion ○ Physician office based physician/nurse supervised infusion ○ Home based infusion with nurse supervision ○ Home based infusion without nurse supervision • Immune globulin infusion is widely used throughout the various sites of care. According to a 2008 survey by the Immune Deficiency Foundation of 1,030 patients being treated with immune globulin, two out of five (42%) IVIG users reported that they usually received their infusion at home. Of those, 7% were able to self-infuse, while the other 35% had a nurse perform the infusion. Twenty-six percent of IVIG users usually got their infusion at a hospital outpatient department (21%), or at a hospital clinic (5%). Most of the remainder said that they usually got their infusion in a doctor's private office (9%) or an infusion suite (16%). • Home infusion as a place of service is well established and accepted by physicians. A 2010 home infusion provider survey by the National Home Infusion Association reported providing 1.24 million therapies to approximately 829,000 patients, including 129,071 infusion therapies of specialty medications, which includes immune globulin.

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Utilization Management Guiding Principles
UPDATED			
Inpatient Pediatric Feeding Programs	Mar. 1, 2017	• Reformatted and reorganized policy; transferred content to new template • Updated supporting information to reflect the most current references; no change to utilization management guiding principles	**Introduction** This clinical guideline addresses inpatient, multi-disciplinary, pediatric feeding disorders programs for infants and young children under age 3 who meet certain qualifications. Refer to the *Protocol* section below. **Inpatient pediatric feeding programs are not covered for members who have any of the following**: • Are age 3 and older • Are without a history of corrective surgery for a physical defect that caused earlier feeding problems • Have a primary diagnosis of failure to thrive • Are currently using parenteral nutrition • Have developmental, age-related behavioral issues (e.g., temper tantrums) as the primary cause of food refusal • Refuse certain food groups but not others **Protocol for Initiation of Multi-Disciplinary Intensive Pediatric Feeding Program** Benefits for an inpatient, multi-disciplinary, pediatric feeding disorders program are available to infants and children under three years of age who meet ALL of the following requirements: • Have had corrective surgery for a physical defect that prevented normal enteral nutrition but who refuse to eat following corrective surgery. The following are examples of qualifying conditions (this list is not all inclusive): o Gastroesophageal Reflux Disease o Gastrointestinal Motility Disorders o Cleft Palate o Tracheo-Esophageal Fistula o Gastrostomy Tube Dependence o Nasogastric Feeding Tube Dependence; and • Have failed outpatient treatment by a multidisciplinary team; and • Are medically unstable as manifested by one or more of the following: o Hypothermia o Hypotension o Bradycardia or Persistent Tachycardia o Dehydration Confirmed On Clinical and Laboratory Grounds

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Utilization Management Guiding Principles
UPDATED			
Inpatient Pediatric Feeding Programs *(continued)*	Mar. 1, 2017		○ Electrolyte Abnormalities ○ Congestive Heart Failure. Who should be part of a multi-disciplinary, intensive, pediatric feeding program? A multi-disciplinary, intensive, pediatric feeding program must be led by a Physician (MD or DO), along with the following: • Developmental Pediatrician (as a consultant only when needed) • Family members and/or care givers of the patient • Occupational Therapist • Physical Therapist • Speech Therapist • Social Worker **Discharge and Follow-up** Follow-up and outpatient therapy as ordered by the treating physician. **Medical Necessity Plans** Use the criteria above where applicable.
Propranolol Treatment for Infantile Hemangiomas: Inpatient Protocol	Mar. 1, 2017	• Reformatted and reorganized policy; transferred content to new template • Updated supporting information to reflect the most current references; no change to utilization management guiding principles	**Introduction** This clinical guideline addresses the use of oral propranolol for the treatment of infantile hemangiomas (IH) and the need for up to a two day inpatient stay to monitor certain patients for heart rate, blood pressure and glycemic control. However, the mechanism of action of propranolol on IH is yet to be clearly defined. Some of the proposed hypotheses include vasoconstriction, decreased renin production, inhibition of angiogenesis, and stimulation of apoptosis. • Oral propranolol is proven for the treatment of infantile hemangiomas (IH). • The physicians and facility providing care must follow a written protocol. • A two day inpatient length of stay in a licensed acute care hospital is medically necessary for the treatment of patients 2 months or younger: ○ Medical management is highly individualized and treatment with oral propranolol is considered in the presence of ulceration, impairment, of a vital function, (ocular compromise or airway obstruction), or risk of permanent disfigurement. ○ Newborns (up 2 months or age) may be admitted to an inpatient setting for 48 hours with oral propranolol.

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Utilization Management Guiding Principles
UPDATED			
Propranolol Treatment for Infantile Hemangiomas: Inpatient Protocol *(continued)*	Mar. 1, 2017		○ Children over 2 months of age with medical problems that require closer monitoring when initiating propranolol (e.g., SGA, prematurity requiring apnea monitoring, cardiac disease) are treated as inpatients for the same 2 day protocol unless the medical issues require longer monitoring. In that event, comorbidities requiring a longer stay must be identified, with an anticipated length of inpatient stay. ○ Any requests for an extension of the inpatient stay beyond two days must be clinically reviewed.
Policy Title	**Effective Date**	**Summary of Changes**	**Utilization Management Guiding Principles**
REVISED			
Chemotherapy Observation or Inpatient Hospitalization	Apr. 1, 2017	• Reformatted and reorganized policy; transferred content to new template • Revised utilization management guiding principles; replaced references to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017" *(refer to 21st edition for complete details on applicable updates to the MCG™ Care Guidelines)* • Updated supporting information to reflect the most current references	**Introduction** Most cancer chemotherapies can be administered safely and effectively in a physician office or through home healthcare services. However, because of the risk of certain toxicities or patient co-morbidities, some cancer chemotherapy may be administered either in a facility observation unit or an inpatient unit. **Observation or Overnight Stay** **TACE (Transcatheter Arterial Chemoembolization)**: This procedure is one form of treatment for primary or secondary liver neoplasms. Various chemotherapy drugs are administered through a catheter into the feeding artery of a tumor in the liver, the drugs can including Adriamycin, Cisplatinum, etc. This procedure is performed by an interventional radiologist usually at a hospital radiology suite and requested by a radiologist or a radiology department. Please refer to MCG™ Care Guidelines, 21st edition, 2017, Chemotherapy: Observation Care OCG: OC-008 (ISC) for generic observation criteria. The following drugs may require an observation unit stay: • Methotrexate > 500 mg/m2. Requires hydration, urinary alkalinization and folate rescue. May be used with other drugs. • Campath® (alemtuzumab). The drug has a 40% hypersensitivity reaction rate. ○ Nursing care must be immediately available to manage potential hypersensitivity reaction ○ May be administered in a physician office if professional staff and

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Utilization Management Guiding Principles
REVISED			
Chemotherapy Observation or Inpatient Hospitalization *(continued)*	Apr. 1, 2017		equipment are available to manage hypersensitivity reaction • Cisplatin (high-dose) > 75 mg/m2 • Other complex multiple-drug or multiple-day regimens such as ESHAP or EPOCH, Einhorn regimen The following are clinical conditions or complications of cancer chemotherapy which, when present, may require an observation stay: • Known hypersensitivity reactions from previous infusion o Nursing care must be immediately available o May be administered in a physician office if professional staff and equipment are available • Congestive heart failure or chronic renal failure requiring high volume fluid infusions. o Assess for performance status • Intra-arterial hepatic infusion o Sites other than the liver require case-by-case review • Comorbidities that of themselves require an observation or overnight stay o Review on a case by case basis • Cancer chemotherapy administered during a hospitalization for an unrelated problem • Other conditions require case-by-case review Please refer to MCG™ Care Guidelines, 21st edition, 2017, Chemotherapy: ORG: M-87 (ISC) and MCG™ Care Guidelines, 21st edition, 2017, Neutropenia after Chemotherapy ORG: P-300 (ISC) for generic inpatient admission criteria for administration of chemotherapy. The following drugs may require an observation stay or inpatient hospital stay: • Interleukin 2. Infusions o Requires cardiac monitoring and clinical assessment. • Ifosphamide 5 day infusions (usually given consecutive days) o Comorbidities that of themselves require an inpatient stay ▪ Review on a case by case basis - Complex chemotherapy programs requiring more than 6 hours of continuous observation and drug administration - Prevention of a significant adverse event that occurred during a prior outpatient administration • The following are clinical conditions which require an inpatient hospital stay:

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Utilization Management Guiding Principles
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Chemotherapy Observation or Inpatient Hospitalization *(continued)*	Apr. 1, 2017		○ Acute leukemia induction therapy or consolidation therapy. ○ iIntra-arterial infusion of chemotherapy. Medical director should review for any site other than liver. Some infusion protocols are more than one day. ○ Prophylaxis of tumor lysis syndrome. Must have diagnosis of lymphoma (high grade with large masses). ○ Must have lab evaluations every 6 hours for potassium, calcium and renal function. ○ Conditions other than these with potential for complications requiring inpatient hospital treatment require case-by-case review. • Please refer to MCG™ Care Guidelines, 21st edition, 2017, Chemotherapy: ORG: M-2087 (HC) and MCG™ Care Guidelines, 21st edition, 2017, Neutropenia after Chemotherapy ORG: P-2300 (HC) for criteria for admission to home health services for all the above drugs or therapeutic agents. • Please refer to MCG™ Care Guidelines, 21st edition, 2017, Infusion Pump: ACG: A-0618(AC) for use of infusion pump for delivery of chemotherapy and therapeutic agents. **Additional Review Points** • A written protocol will be expected to be followed by the provider administering the chemotherapy drug. • Any requests for an extension of the inpatient stay beyond the recommended day(s) must be clinically reviewed.
Specialty Medication Administration – Site of Care Review Guidelines	Apr. 1, 2017	• Revised coverage rationale and supporting information; replaced references to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017"	**Introduction** This guideline addresses the criteria for consideration of allowing hospital outpatient facility specialty medication infusion services. This includes claim submission for hospital based services with the following CMS/AMA Place of Service codes: • 22 On Campus-Outpatient Hospital, and • 19 Off Campus-Outpatient Hospital Alternative sites of care, such as non-hospital outpatient infusion, physician office, ambulatory infusion or home infusion services are well accepted places of service for medication infusion therapy. If a patient does not meet criteria for outpatient hospital facility infusion, alternative sites of care may be used.

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Utilization Management Guiding Principles
REVISED			
Specialty Medication Administration – Site of Care Review Guidelines *(continued)*	Apr. 1, 2017		This policy applies to these specialty medications that require healthcare provider administration: • Abatacept (Orencia®) • Eculizumab (Soliris®) • Eteplirsen (Exondys 51™) • Golimumab (Simponi® Aria™) • Infliximab (Remicade® lyophilized concentrate for intravenous use) • Infliximab-dyyb (Inflectra™) • Tocilizumab (Actemra® injection for intravenous use) • Vedolizumab (Entyvio®) **Review Criteria for Site of Care Selection** **Outpatient hospital facility-based intravenous medication infusion is medically necessary for persons who meet any of the following criteria**: • Medically unstable based upon submitted clinical history; or • Initial medication infusion of or re-initiation after more than 6 months following discontinuation of therapy; or • Previous experience of a severe adverse event following infusion. Examples include but are not limited to anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure; or • Continuing experience of adverse events that cannot be mitigated by pre-medications; or • Physically and/or cognitively impaired AND no home caregiver available. ***Additional Information*** Medical necessity criteria for administration of intravenous infusion therapy at home are addressed in MCG™ Care Guidelines, 21st edition, 2017, Home Infusion Therapy, CMT: CMT-0009(SR). **Benefit Considerations** This guideline applies to members with 2011 COC or Summary Plan Document with benefits available for health care services if medically necessary and have been approved for the requested medication clinical use. This guideline applies to UnitedHealthcare Commercial plans. This guideline does not apply to Medicare or Medicaid plans.

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Utilization Management Guiding Principles
REVISED			
Specialty Medication Administration – Site of Care Review Guidelines *(continued)*	Apr. 1, 2017		**Supporting Information and Clinical Evidence Background** Home infusion as a place of service is well established and accepted by physicians. A 2010 home infusion provider survey by the National Home Infusion Association reported providing 1.24 million therapies to approximately 829,000 patients, including 129,071 infusion therapies of specialty medications. **Clinical Evidence** MCG™ Care Guidelines, 21st edition, 2017, Home Infusion Therapy, CMT: CMT-0009(SR) addresses criteria for home infusion therapy. Clinical patient characteristics for home suitability include: clinical stability, no need for close observation or daily nurse care, and reliable venous access. Additional criteria for home environment, infusion plan and patient ability to participate in care are summarized. **Professional Societies** The American Academy of Allergy Asthma and Immunology has published guidelines for the suitability of patients to receive treatment in various care setting including clinical characteristics of patients needing a high level of care in the hospital outpatient facility which includes patient characteristics: previous serious infusion reaction such as anaphylaxis, seizure, myocardial infarction, or renal failure, immune globulin therapy naïve, continual experience of moderate or serious infusion related adverse reactions, physical or cognitive impairment. The Hunter Syndrome European Expert Council: European recommendations for the diagnosis and multidisciplinary management of a rare disease published an article reviewing the collective experiences with agalsidase beta home infusion therapy and outlines how safe, patient-centered homecare can be organized in enzyme replacement therapy for patients with Fabry disease. Criteria include that "Patients must have received ERT in hospital for 3-6 months; if patients have previously had IRRs, they must be under control with premedication, and they must not have had an IRR in the 2-8 weeks before homecare is approved and premedication must be given. If a patient has significant respiratory disease (%FVC, 40% or less; or evidence of serious obstructive airway disease), homecare may not be suitable." The Agency for Healthcare Research and Quality (AHRQ) publication on Enzyme Replacement Therapy states, "Home infusion of ERT was initially

Utilization Review Guideline (URG) Updates

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Specialty Medication Administration – Site of Care Review Guidelines *(continued)*	Apr. 1, 2017		studied in patients with type I Gaucher disease. It has been reported as an option for patients with Fabry disease, MPS I, and MPS II, and MPS VI. However, patients with infantile Pompe disease may not be able to transfer to home care because of an increased risk for serious adverse events during an infusion. In general, the outcomes measured in these studies and the follow-up durations were similar to those reported by disease in the clinical studies summarized under Guiding Question 3. Safety was the main focus of most home infusion studies, as the patients had already been receiving ERT in a more controlled setting." **Medication or Condition Specific Studies** In a trial evaluating patients with paroxysmal nocturnal hemoglobinuria, after initial 2-5 doses of eculizumab (Soliris), 79 patients received continued infusion with every 14 days in the home setting for the duration of the study – 1-98 months, mean duration of 39 months. The survival of patients treated with eculizumab was not different from age- and sex-matched normal controls (P = .46) but was significantly better than 30 similar patients managed before eculizumab (P = .030). Three patients on eculizumab, all over 50 years old, died of causes unrelated to PNH. Twenty-one patients (27%) had a thrombosis before starting eculizumab (5.6 events per 100 patient-years) compared with 2 thromboses on eculizumab (0.8 events per 100 patient-years; P < .001). Twenty-one patients with no previous thrombosis discontinued warfarin on eculizumab with no thrombotic sequelae. Forty of 61 (66%) patients on eculizumab for more than 12 months achieved transfusion independence. The 12-month mean transfusion requirement reduced from 19.3 units before eculizumab to 5.0 units in the most recent 12 months on eculizumab (P < .001). Eculizumab dramatically alters the natural course of PNH, reducing symptoms and disease complications as well as improving survival to a similar level to that of the general population. Infliximab has been shown to be safely infused in the community setting. A chart review of 3161 patients who received a combined 20,976 infusions in community clinics was conducted to evaluate safety across all types of patients. Infliximab infusions are safe in the community setting. Severe ADRs were rare. A total of 524 (2.5% of all infusions) acute ADRs in 353 patients (11.2%) were recorded. Most reactions (ie, ADRs) were mild (n=263 [50.2%, 1.3% of all infusions]) or moderate (n=233 [44.5%, 1.1% of all infusions]). Twenty-eight reactions (5.3%, 0.1% of all infusions) were

Utilization Review Guideline (URG) Updates

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Specialty Medication Administration – Site of Care Review Guidelines *(continued)*	Apr. 1, 2017		severe. Emergency medical services were called to transport patients to hospital for seven of the severe reactions, of which none required admission. As per pre-established medical directives adrenaline was administered three times. The authrors concluded that infliximab infusions are safe in the community setting. Severe ADRs were rare. None required active physician intervention; nurses were able to treat all reactions by following standardized medical directives.7 Ten children were enrolled in the home infusion program if they were compliant with hospital-based infliximab infusions and other medications, had no adverse events during hospital-based infliximab infusions, were in remission and had access to experienced pediatric homecare nursing. The children received 59 home infusions with a dose range of 7.5 to 10 mg/kg/dose. Home infusions ranged from 2 to 5 hours. Since infusions could be performed any day of the week, school absenteeism was decreased. The average patient satisfaction rating for home infusions was 9 on a scale from 1 to 10 (10 = most satisfied). Three patients experienced difficulty with IV access requiring multiple attempts, but all were able to receive their infusions. One infusion was stopped because of arm pain above the IV site. This patient had his next infusion in the hospital before returning to the home infusion program. No severe adverse events (palpitations, blood pressure instability, hyperemia, respiratory symptoms) occurred during home infusions. In the carefully selected patients, infliximab infusions administered at home were safe and are cost-effective. Patients and families preferred home infusions, since time missed from school and work was reduced.

Quality of Care Guideline (QOCG) Updates

Policy Title	Effective Date	Summary of Changes	Guiding Principles
REVISED			
Hospital Readmissions	Apr. 1, 2017	• Revised guiding principles and supporting information; replaced references to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017"	**Readmission Review Overview** ***UnitedHealthcare Commercial (Employer & Individual Plan Readmissions)*** Admissions to an acute, general, short-term hospital occurring within 30 days of the date of discharge from the same acute, general, short-term hospital or hospital system for the same, similar, or related diagnosis may be subject to readmission review. UnitedHealthcare and its affiliates may conduct readmission reviews to determine if there was an admission that was considered clinically related with a reasonable expectation that it could have been prevented by one of more of the following: • Optimal provision of quality care during the initial hospitalization • Optimal discharge planning • Optimal post-discharge follow-up • Improved coordination between inpatient and outpatient health care teams Excluded from readmission review are: • Transfers from out of network to in-network facilities • Transfers of patients to receive care not available at the first facility • Readmissions that are planned for repetitive treatments such as cancer chemotherapy, transfusions for chronic anemia, other similar repetitive treatments or for scheduled elective surgery • Skilled Nursing and Rehabilitation facilities (SNF and Rehab) • Admits associated with malignancies , burns , and cystic fibrosis • Admissions with a discharge status of left against medical advice • Obstetrical readmissions • Readmissions > = 30 days from the initial admission ***Documentation for Determination*** Upon request from the Health Plan, the facility and/or facilities agree to forward all medical records and supporting documentation of the first and subsequent admissions to UnitedHealthcare or one of its affiliates. This can occur either concurrently during the inpatient stay, prepayment or post-payment review of the claim. ***Review Process***

Quality of Care Guideline (QOCG) Updates

Policy Title	Effective Date	Summary of Changes	Guiding Principles
REVISED			
Hospital Readmissions *(continued)*	Apr. 1, 2017		• Review of the facility contract to determine if readmission review is applicable. • At the request of UHC, the hospital must submit medical records pertaining to the readmission as well as the index/anchor admission to first identify whether the case is a potentially preventable readmission. Initial review should determine whether the readmission was **clinically related** to the index/anchor admission. A readmission is considered to be clinically related to the initial admission if it belongs to one of five different categories: ○ A medical readmission for a continuation or recurrence of the reason for the initial admission or closely related condition (e.g., readmission for diabetes following an initial admission for diabetes) ○ A medical readmission for an acute decompensation of a chronic problem that was not related to the initial admission but was plausibly related to care either during or immediately after the initial admission (e.g., a readmission for previously diagnosed diabetes in a patient whose initial admission was for an acute myocardial infarction) ○ A medical readmission for an acute medical complication plausibly related to care during the initial admission (e.g., a patient with a hernia repair discharged with a urinary catheter readmitted for treatment of a urinary tract infection) ○ An unplanned readmission for surgical procedure to address a continuation or a recurrence of the problem causing the initial admission (e.g., a patient readmitted for an appendectomy following an initial admit for abdominal pain and fever) ○ An unplanned readmission for a surgical procedure to address a complication resulting from care during the initial admission (e.g., a readmission for drainage of a post-operative wound abscess following an initial admission for a bowel resection) Once the initial review has determined to be **clinically related**, further evaluation would determine whether the readmission was **potentially preventable**. The review shall focus on the following: • Whether the patient meets inpatient or alternative setting criteria using the appropriate MCG™ Care Guidelines, 21st edition, 2017. • Whether discharge plans were followed according to generally accepted medical standards (*Generally Accepted Standards of Medical Practice, 2011 Certificate of Coverage).* These are standards that are based on

Quality of Care Guideline (QOCG) Updates

Policy Title	Effective Date	Summary of Changes	Guiding Principles
REVISED			
Hospital Readmissions *(continued)*	Apr. 1, 2017		credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying primarily on controlled clinical trials, or, if not available, observational studies from more than one institution that suggest a causal relationship between the service or treatment and health outcomes. If no credible scientific evidence is available, then standards that are based on physician specialty society recommendations or professional standards of care may be considered. • Documentation in the hospital record that an appointment was made within the first week or within an appropriate time frame after discharge from the initial admission. • Whether appropriate telephone numbers have been given to the patient for calls to the hospital or primary care provider for related discharge questions. • Whether a health care advocate/provider did an in-home safety assessment and appropriate follow up as needed. • Whether written discharge instructions were provided and explained to the patient/caregiver prior to discharge (Project Boost). • Documentation that all required prescriptions were given to the patient and the patient was educated in the appropriate use of the medication. • Whether documentation supports that durable medical equipment has been arranged for the patient and the patient has been appropriately educated on its use. • Whether documentation supports that all salient financial and social needs of the patient have been addressed.