UnitedHealthcare®

May 2016

medical policy update bulletin

Medical Policy, Drug Policy & Coverage Determination Guideline Updates

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

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

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

Overview

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

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

Tips for using the Medical Policy Update Bulletin:

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

Policy Update Classifications

New

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

Updated

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

Revised

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

Replaced

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

Retired

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

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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Gait Analysis	May 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated supporting information to reflect the most current clinical evidence, CMS information, and references; no change to coverage rationale or list of applicable codes	**Gait analysis is unproven and not medically necessary for surgical or clinical decision making.** The available clinical evidence does not establish that gait analysis benefits health outcomes. The evidence is too limited to draw definitive conclusions regarding the role of gait analysis in the continuum of care. Evidence that includes clinical outcome results from randomized controlled trials is needed.

Gene Expression Tests	May 1, 2016	• Reformatted and reorganized policy; transferred content to new template
		• Updated supporting information to reflect the most current clinical evidence, CMS information, and references; no change to coverage rationale or lists of applicable codes
			Oncology Indications
			Thyroid Cancer
			Multi-panel gene expression tests (e.g., Afirma®) are proven and medically necessary for assessing thyroid nodules that are not clearly benign or malignant based on fine-needle aspiration biopsy results alone.
			
			Gene expression tests are unproven and not medically necessary for the following indications:
			• ***Cancer of Unknown Primary***
			  ○ Identifying tissue of origin in difficult to diagnose cancers (e.g., ResponseDX Tissue of Origin® or CancerTYPE ID®)
			• ***Colon Cancer***
			  ○ Predicting the likelihood of colon cancer recurrence (e.g., Oncotype DX® Colon Cancer Assay)
			• ***Multiple Myeloma***
			  ○ Guiding therapy in patients with multiple myeloma (e.g., MyPRS®)
			• ***Prostate Cancer***
			  ○ Predicting tumor aggressiveness and guiding disease management in patients with newly diagnosed prostate cancer (e.g., Oncotype DX® Prostate Cancer Assay and Prolaris®)
			  ○ Predicting risk of recurrence and metastasis and guiding disease management following radical prostatectomy (e.g., Decipher® Prostate Cancer Classifier)
			• ***Uveal Melanoma***
			  ○ Predicting metastatic risk of uveal melanoma (e.g., DecisionDx-UM)
			
			There is insufficient evidence in the clinical literature demonstrating that

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Gene Expression Tests *(continued)*	May 1, 2016		these tests have a role in clinical decision-making or have a beneficial effect on health outcomes. Further studies are needed to determine the clinical utility of these tests. **Non-Oncology Indications** ***Coronary Artery Disease*** **Gene expression tests are unproven and not medically necessary for predicting the likelihood of obstructive coronary artery disease (e.g., Corus® CAD).** There is insufficient evidence in the clinical literature demonstrating that this test has a role in clinical decision-making or has a beneficial effect on health outcomes. Further studies are needed to determine the clinical utility of this test.
Hepatitis Screening	May 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Reformatted list of applicable ICD-9 diagnosis codes (discontinued 10/01/15); removed descriptor classifying codes as "proven" • Updated supporting information to reflect the most current description of services, CMS information, and references	**Hepatitis screening for "at risk" persons for acute and chronic infections is proven and medically necessary for the following indications:** • Persons with a history of sexually transmitted infections (STI) • Men who have sexual relations with men • Persons with multiple sexual partners • Persons who have experienced Intercourse with trauma • Human Immunodeficiency Virus (HIV) infected persons • Persons who have history of using injection and non injection illicit drugs • Persons born in regions or who have traveled to countries with high or intermediate prevalence of hepatitis A virus (HAV) or hepatitis B virus (HBV) infection • All pregnant women including those with a sexually transmitted infection (STI) • Persons who have received blood transfusion or organ transplantation before July 1992 • Recipient of clotting factor concentrates made before 1987 • Hemodialysis patients • Patients prior to initiating TNF blocker immunosuppressive therapy • Patients needing immunosuppressive or cytotoxic therapy • Patients with signs and symptoms of liver disease/elevated liver enzymes (abnormal ALT/AST) • Patients with positive test for anti hepatitis C virus (HCV) • Patients with clotting factor disorders • Patients with history of working with non human primates susceptible to

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Hepatitis Screening *(continue)*	May 1, 2016		HAV infection • Infants born to HBV or HCV positive mothers (do not test before 18 months of age) • US born infants whose parents were born in regions with high rates of Hepatitis B • Sexual partners of infected persons • Household, needle sharing or secondary contacts of HbsAg positive persons • Health care and public safety workers at risk for occupational exposure to blood or blood contaminated body fluids • Residents and staff of facilities for developmentally disabled persons • Persons with known exposure to HCV (health care workers after needle sticks involving HCV positive blood or recipients of blood or organs from a donor who later tested HCV positive) • Donors of blood, plasma, organs, tissue or semen **Hepatitis screening is proven and medically necessary for one-time screening for HCV infection for adults born between 1945-1965, whether or not risk factors have been identified.**
In Utero Fetal Surgery	May 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Reformatted lists of applicable CPT and HCPCS codes; removed descriptor classifying codes as "proven" or "unproven" • Updated supporting information to reflect the most current clinical evidence and references	**Intrauterine fetal surgery is proven and medically necessary for the following indications:** • Congenital cystic adenomatoid malformation (CCAM) and extralobar pulmonary sequestration (EPS): fetal lobectomy or thoracoamniotic shunt placement for CCAM and thoracoamniotic shunt placement for EPS • Sacrococcygeal teratoma (SCT): SCT resection • Urinary tract obstruction (UTO): urinary decompression via vesicoamniotic shunt placement • Twin-twin transfusion syndrome: fetoscopic laser surgery • Twin reversed arterial perfusion (TRAP): ablation or occlusion of anastomotic vessels (e.g., laser coagulation or radiofrequency ablation) • Myelomeningocele (MMC) repair **Intrauterine fetal surgery is unproven and not medically necessary for the following indications:** • Congenital diaphragmatic hernia (CDH) There is insufficient evidence that in utero correction of CDH improves health outcomes for fetuses with CDH compared with standard postnatal surgery. Consistent improvements in survival following in utero fetal

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In Utero Fetal Surgery *(continued)*	May 1, 2016		surgery have not been observed. • Congenital heart disease (CHD) There is insufficient evidence that in utero fetal surgery for complex heart disease improves health outcomes or survival.
Manipulative Therapy	May 1, 2016	• Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references; no change to coverage rationale or lists of applicable codes	**Manipulative therapy is proven and medically necessary for treatment of musculoskeletal disorders, except as noted below.** **Manipulative therapy is unproven and not medically necessary for treatment of:** • Non-musculoskeletal disorders (e.g., asthma, otitis media, infantile colic, etc) • Prevention/maintenance/custodial care • Internal organ disorders (e.g., gallbladder, spleen, intestinal, kidney, or lung disorders) • Temporomandibular Joint (TMJ) Disorder • Scoliosis correction • Craniosacral therapy (cranial manipulation/Upledger technique) • Manipulative services that utilize nonstandard techniques such as applied kinesiology technique, NUCCA, network and neural organizational technique The role of manipulation for the above has not been established in scientific literature. A beneficial impact on health outcomes, e.g., improved physical function, durable pain relief, has not been established. **Manipulative therapy is unproven and not medically necessary when ANY of the following apply:** 1. The patient's condition has returned to the pre-symptom state. 2. Little or no improvement is demonstrated within 30 days of the initial visit despite modification of the treatment plan. 3. Concurrent manipulative therapy, for the same or similar condition, provided by another health professional whether or not the healthcare professional is in the same professional discipline. This policy does not address manipulation under anesthesia; refer to the policy titled Manipulation Under Anesthesia.

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Occipital Neuralgia and Headache Treatment	May 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated supporting information to reflect the most current clinical evidence, CMS information, and references; no change to coverage rationale or lists of applicable codes	**Injection of local anesthetics and/or steroids, used as occipital nerve blocks, is proven and medically necessary for treating pain due to malignancy involving the head and neck.** **Injection of local anesthetics and/or steroids, used as occipital nerve blocks, is unproven and not medically necessary for diagnosing and treating occipital neuralgia or headaches including migraine and cervicogenic headaches.** There is insufficient evidence that greater occipital nerve blocks can be used as a specific diagnostic test for occipital neuralgia or headaches. The efficacy of local injection therapies for occipital neuralgia or cervicogenic headache and other headaches has not been established in well-designed clinical trials. See the Drug Policy titled Botulinum Toxin A and B for information regarding the use of botulinum toxin for treatment of headaches. **Surgery including but not limited to the following is unproven and not medically necessary for treating occipital neuralgia or cervicogenic headache:** • Occipital neurectomy • Partial posterior intradural C1-C3 rhizotomy • Rhizotomy of C1-C3 spinal dorsal roots • Surgical decompression of second cervical nerve root and ganglion • Surgical decompression of the greater occipital nerve The available evidence is insufficient to conclude that surgery is an effective treatment for occipital neuralgia or cervicogenic headaches. The long-term efficacy of surgical procedures for occipital neuralgia or cervicogenic headaches has not been established in well-designed clinical trials. **Occipital neurectomy or surgical nerve decompression is unproven and not medically necessary for treating headaches.** The available evidence is insufficient to conclude that occipital neurectomy or nerve decompression including decompression of the supraorbital, supratrochlear, zygomaticotemporal, or greater occipital nerves is an effective treatment for headaches. The long-term efficacy of these procedures for headaches has not been established in well-designed clinical trials.

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Occipital Neuralgia and Headache Treatment *(continued)*	May 1, 2016		**Radiofrequency ablation (thermal or pulsed) or denervation is unproven and not medically necessary for treating of occipital neuralgia or headaches including migraine, cluster and cervicogenic headache.** The available evidence from published studies is not sufficient to conclude that radiofrequency ablation or denervation is an effective treatment for occipital neuralgia or headaches. Well-designed studies are needed to evaluate the potential advantages of radiofrequency ablation for these conditions and to identify which patients would benefit from this procedure. **Neurostimulation or electrical stimulation is unproven and not medically necessary for treating of occipital neuralgia or headaches including migraine, cluster and cervicogenic headache.** The available studies were limited and had significant methodological flaws, making it difficult to draw conclusions regarding the efficacy of electrical stimulation for the treatment of headache or occipital neuralgia. There are no well-designed randomized controlled studies in the medical literature comparing neurostimulation to established treatment options or a sham procedure. Studies on larger populations with longer follow-up are needed to establish the benefits of neurostimulation and electrical stimulation for treating these conditions.
Prolotherapy for Musculoskeletal Indications	May 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references; no change to coverage rationale or lists of applicable codes	**Prolotherapy is unproven and not medically necessary.** The available studies are limited to those that include short to medium term follow-up with no significant functional improvement compared to placebo. Additional studies are needed to further define treatment parameters and to determine whether a clinically significant improvement is achieved.
Total Artificial Disc Replacement for the Spine	Jun. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated coverage rationale; added language to clarify lumbar artificial total disc replacement is	**Cervical artificial total disc replacement of FDA-approved prosthesis for degenerative cervical disc disease with symptomatic intractable radiculopathy and/or myelopathy is proven and medically necessary in a skeletally mature individual when at least one of the following criteria is met:** • herniated disc

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Total Artificial Disc Replacement for the Spine *(continued)*	Jun. 1, 2016	*not medically necessary* for treating single or multiple level degenerative disc disease in skeletally mature patients • Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references	• osteophyte formation **And** both of the following: • documented patient history of neck and/or arm pain and/or a functional/neurological deficit associated with the cervical level to be treated • failed at least six weeks of non-operative treatment prior to implantation (only applicable for elective surgery; emergent surgery**, or** does not require prior non-operative treatment) **Cervical artificial disc replacement is proven and medically necessary for treating symptoms of degenerative disc disease at one level even if they have radiological evidence of degenerative disc disease at multiple levels.** Radiologic evidence of degenerative disc disease is common in persons who are middle aged and older and does not necessarily correlate with clinical symptoms. **Cervical artificial total disc replacement is proven and medically necessary for treating symptomatic contiguous two level degenerative disc disease in skeletally mature patients when used according to U.S. Food and Drug Administration (FDA) labeled indications.** **Note**: not all cervical artificial discs have FDA labeling for contiguous two level degenerative disc disease. Only cervical artificial discs FDA labeled for contiguous two level disease are proven and medically necessary for this indication. Refer to the *FDA* section of the policy. **Cervical artificial disc replacement at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent) performed at the same surgical setting is unproven and not medically necessary.** This is commonly referred to as a hybrid surgery. There is insufficient published clinical evidence in peer-reviewed medical literature demonstrating the safety and efficacy of combination cervical spine surgery at multiple adjacent or non-adjacent levels. **Lumbar artificial total disc replacement is unproven and not medically necessary for treating single or multiple level degenerative**

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Total Artificial Disc Replacement for the Spine *(continued)*	Jun. 1, 2016		**disc disease in skeletally mature patients.** The long-term clinical outcome of lumbar disc replacement is unclear. The evidence from uncontrolled long-term studies suggests that potential degeneration of adjacent discs and facets and wear of the polyethylene part of the disc may occur and that, in some cases, revision surgery may be needed.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ablative Treatment for Spinal Pain	Jun. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale: ○ Updated coverage criteria for thermal radiofrequency ablation of facet joint nerves; replaced criterion requiring: ▪ "Temperature of 60 degrees celsius or more" with "operative notes documenting temperature of 60 degrees Celsius or more" ▪ "Duration of ablation 40 - 90 seconds" with "operative notes documenting duration of ablation at least 40 seconds" ○ Updated/clarified list of proven/medically necessary indications for a ***repeat*** thermal radiofrequency ablation ***of the same facet joint***; replaced "There has been a 50% or greater documented reduction in	**Thermal radiofrequency ablation of facet joint nerves is proven and medically necessary for chronic cervical, thoracic and lumbar pain when confirmed by:** • Positive response to medial branch block injection at the side and level of the proposed ablation • Confirmation of needle placement by fluoroscopic guided imaging • Operative notes document: ○ temperature 60 degrees celsius or more ○ duration of ablation at least 40 seconds **A repeat thermal radiofrequency ablation of the same facet joint is proven and medically necessary when:** • Performed at a frequency of six months or longer (maximum of 2 times over a 12 month period); **and** • There has been a 50% or greater documented reduction in pain for 10 to 12 weeks following the previous ablation **Thermal radiofrequency ablation of facet joint nerves is unproven and not medically necessary:** • When there has been no positive response to medial branch block injection; **or** • When performed more frequently than every six months For additional information regarding frequency guidelines, refer to the *American Society of Interventional Pain Physicians* section of the policy Documentation requirements for the aforementioned procedures must include: • Temperature of administration of procedure

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Ablative Treatment for Spinal Pain *(continued)*	Jun. 1, 2016	pain for 10 to 12 weeks" with "there has been a 50% or greater documented reduction in pain for 10 to 12 weeks *following the previous ablation"* ○ Updated/clarified list of unproven/not medically necessary indications for thermal radiofrequency ablation ***of facet joint nerves****;* replaced "there has been no significant improvement after medial branch block injection" with "there has been no positive response to medial branch block injection" ○ Removed language indicating ablation procedures performed more frequently than every 6 months increase the risk of adverse events without improving the clinical outcome ○ Replaced language indicating "thermal radiofrequency ablation is unproven and not medically necessary for *the treatment of all other causes of spinal pain*" with "thermal radiofrequency ablation is unproven and not medically necessary for *treating all other pain indications*" • Updated supporting information to reflect the most current clinical evidence and references	• Duration of ablation • Specific identification of side and level of medial branch blocks • Specific cervical, thoracic and/or lumbar ablated by side and level • Percentage of pain relief with prior ablation if applicable • Duration of improvement from previous ablation if applicable **Thermal radiofrequency ablation is unproven and not medically necessary for treating ALL other pain indications including but not limited to:** • Diabetic neuropathy • Sacroiliac pain • Complex regional pain syndrome or regional pain disorders and syndromes in the absence of spinal pain • Definitive clinical and/or imaging findings identifying a condition requiring surgical treatment • Identified specific causes of spinal pain (e.g., disc herniation) requiring definitive treatment Studies of radiofrequency ablation for other conditions were limited, uncontrolled, and insufficient to support conclusions regarding efficacy or duration of effect. Additional well-designed, longer-term randomized controlled trials are required to evaluate the safety and efficacy of radiofrequency ablation and to compare this technique with other medical or surgical therapies for pain. **The following ablation procedures are unproven and not medically necessary for treating spinal pain:** • Pulsed radiofrequency therapy of the facet nerves of the cervical, thoracic, or lumbar region, sacral nerve root or dorsal root ganglion • Endoscopic radiofrequency ablation (rhizotomy) • Cryoablation (cryodenervation, cryoneurolysis, cryosurgery, or cryoanesthesia) • Chemical ablation (including but not limited to alcohol, phenol or sodium morrhuate • Laser ablation (including pulsed, continuous, or low level) There is insufficient evidence to establish the efficacy of the ablation therapies bulleted immediately above to reduce or relieve spinal pain. Studies are limited by small sample size, retrospective and case series

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ablative Treatment for Spinal Pain *(continued)*	Jun. 1, 2016		studies. The clinical value needs to be examined in well-designed, randomized controlled trials with large sample size and long term follow-up.
Computerized Dynamic Posturography	Jun. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale to indicate computerized dynamic posturography (CDP) testing, also called balance board testing or equilibrium platform testing (EPT), is unproven and not medically necessary for evaluating ***any condition including but not limited to*** balance disorders ○ Overall, there is weak evidence in the peer-reviewed literature regarding the efficacy of CDP for evaluating vestibular ***and other*** disorders ○ There is a lack of well-designed, randomized controlled trials (RCTs) with blinded assessments to demonstrate the diagnostic utility of CDP compared with standard tests ○ Furthermore, there is insufficient evidence demonstrating consistent and beneficial effects of CDP testing on patient-relevant outcomes ○ Therefore, CDP is considered unproven and not medically necessary	**Computerized dynamic posturography (CDP) testing, also called balance board testing or equilibrium platform testing (EPT), is unproven and not medically necessary for evaluating any condition including but not limited to balance disorders.** Overall, there is weak evidence in the peer-reviewed literature regarding the efficacy of CDP for evaluating vestibular and other disorders. There is a lack of well-designed, randomized controlled trials (RCTs) with blinded assessments to demonstrate the diagnostic utility of CDP compared with standard tests. Furthermore, there is insufficient evidence demonstrating consistent and beneficial effects of CDP testing on patient-relevant outcomes. Therefore, CDP is considered unproven and not medically necessary.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Computerized Dynamic Posturography (continued)	Jun. 1, 2016	• Removed coding clarification notation reiterating computerized dynamic posturography is unproven and not medically necessary for all diagnosis codes • Updated supporting information to reflect the most current clinical evidence, CMS information, and references	
Glaucoma Surgical Treatments	Jun. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale; replaced language indicating "glaucoma drainage devices, such as the ExPRESS™ mini glaucoma shunt, Molteno implant, Baerveldt tube shunt, Krupin Eye Valve, or the Ahmed glaucoma valve implant, are proven and medically necessary for treatment of refractory glaucoma when *there is intolerance, contraindication, or failure of topical or oral medication, when used according to U.S. Food and Drug Administration (FDA) labeled indications*" with "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*	**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.** **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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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Glaucoma Surgical Treatments *(continued)*	Jun. 1, 2016	*medical or surgical treatments have failed or are inappropriate*" • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	

Drug and Biologics Policy Updates

UPDATED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Actemra® (Tocilizumab) Injection for Intravenous Infusion	May 1, 2016	• Added reference link to related Coverage Determination Guideline titled *Specialty Medication Administration: Site of Care Review Guidelines* • Updated coverage rationale; added instruction to refer to the *Oncology Medication Clinical Coverage Policy* for updated information based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®) for oncology indications • Updated supporting information to reflect the most current clinical evidence and references	Please refer to the Oncology Medication Clinical Coverage Policy for updated information based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®) for oncology indications. This policy refers to Actemra (tocilizumab) injection for intravenous infusion. Actemra is **proven and medically necessary** for the treatment of: 1. **Polyarticular juvenile idiopathic arthritis** when **all** of the following criteria are met: a. Diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) **AND** b. Actemra is initiated and titrated according to US Food and Drug Administration labeled dosing for polyarticular juvenile idiopathic arthritis up to a maximum of (or equivalent dose and interval schedule): (1) 10mg/kg every 4 weeks for patients weighing < 30kg (2) 8mg/kg every 4 weeks for patients weighing ≥ 30kg **AND** c. Patient is **not** receiving Actemra in combination with either of the following: (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] 2. **Rheumatoid arthritis** when **all** of the following criteria are met: a. Diagnosis of moderately to severely active rheumatoid arthritis (RA) **AND** b. History of failure, contraindication, or intolerance to at least **one** non-biologic disease modifying anti-rheumatic drugs (DMARDs) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, minocycline, etc.] **AND** c. Actemra is initiated and titrated according to US Food and Drug Administration labeled dosing for rheumatoid arthritis up to a maximum of 800mg every 4 weeks (or equivalent dose and interval schedule) **AND** d. Patient is **not** receiving Actemra in combination with either of the

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Actemra® (Tocilizumab) Injection for Intravenous Infusion *(continued)*	May 1, 2016		following: (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] 3. **Systemic juvenile idiopathic arthritis** when **all** of the following criteria are met: a. Diagnosis of systemic juvenile idiopathic arthritis (SJIA) **AND** b Actemra is initiated and titrated according to US Food and Drug Administration labeled dosing for systemic juvenile idiopathic arthritis up to a maximum of (or equivalent dose and interval schedule): (1) 12mg/kg every 2 weeks for patients weighing < 30kg (2) 8mg/kg every 2 weeks for patients weighing ≥ 30kg **AND** c. Patient is **not** receiving Actemra in combination with either of the following: (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] **Centers for Medicare and Medicaid Services (CMS):** Medicare does not have a National Coverage Determination (NCD) for Actemra® (tocilizumab). Local Coverage Determinations (LCDs) do not exist at this time. In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, Section 50 Drugs and Biologicals at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf. (Accessed February 3, 2016)
Entyvio® (Vedolizumab)	May 1, 2016	• Added reference link to related Coverage Determination Guideline titled *Specialty Medication Administration: Site of Care Review Guidelines*	Entyvio (vedolizumab) is **proven and medically necessary** for the treatment of: 1. **Crohn's disease** when **all** of the following criteria are met: a. Diagnosis of moderately to severely active Crohn's disease (CD) **AND**

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Entyvio® (Vedolizumab) *(continued)*	May 1, 2016	• Updated supporting information to reflect the most current clinical evidence, CMS information, and references	b. **One** of the following: (1) History of failure, contraindication, or intolerance to at least **one** of the following conventional therapies: (a) Tumor necrosis factor (TNF) blocker [e.g., Humira (adalimumab), Cimzia (certolizumab)] (b) Immunomodulator (e.g., azathioprine, 6-mercaptopurine) (c) Corticosteroid (2) Corticosteroid dependent (e.g., unable to successfully taper corticosteroids without a return of the symptoms of CD) **AND** c. Entyvio is initiated and titrated according to US Food and Drug Administration labeled dosing for Crohn's disease up to a maximum of 300mg every 8 weeks (or equivalent dose and interval schedule) **AND** d. Patient is **not** receiving Entyvio in combination with either of the following: (1) Tumor necrosis factor (TNF) blocker [e.g., Humira (adalimumab), Cimzia (certolizumab)] (2) Tysabri (natalizumab) 2. **Ulcerative colitis** when **all** of the following criteria are met: a. Diagnosis of moderately to severely active ulcerative colitis (UC) **AND** b. **One** of the following: (1) History of failure, contraindication, or intolerance to at least **one** of the following conventional therapies: (a) Tumor necrosis factor (TNF) blocker [e.g., Humira (adalimumab), Simponi (golimumab)] (b) Immunomodulator (e.g., azathioprine, 6-mercaptopurine) (c) Corticosteroid (2) Corticosteroid dependent (e.g., unable to successfully taper corticosteroids without a return of the symptoms of UC) **AND** c. Entyvio is initiated and titrated according to US Food and Drug Administration labeled dosing for ulcerative colitis up to a maximum of 300mg every 8 weeks (or equivalent dose and interval schedule) **AND** d. Patient is **not** receiving Entyvio in combination with either of the following:

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Entyvio® (Vedolizumab) *(continued)*	May 1, 2016		(1) Tumor necrosis factor (TNF) blocker [e.g., Humira (adalimumab), Simponi (golimumab)] (2) Tysabri (natalizumab) **Centers for Medicare and Medicaid Services (CMS):** Medicare does not have a National Coverage Determination (NCD) for Entyvio™ (vedolizumab). Local Coverage Determinations (LCDs) do not exist at this time. Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf. (Accessed February 5, 2016)
Orencia® (Abatacept) Injection for Intravenous Infusion	May 1, 2016	• Added reference link to related Coverage Determination Guideline titled *Specialty Medication Administration: Site of Care Review Guidelines* • Updated supporting information to reflect the most current clinical evidence, CMS information, and references	This policy refers to Orencia (abatacept) injection for intravenous infusion. Orencia is **proven and medically necessary** for the treatment of: 1. **Polyarticular juvenile idiopathic arthritis** when **all** of the following criteria are met: a. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) **AND** b. Orencia is initiated and titrated according to US Food and Drug Administration labeled dosing for polyarticular juvenile idiopathic arthritis up to a maximum of (or equivalent dose and interval schedule): (1) 10mg/kg every 4 weeks for patients weighing <75kg (2) 1,000mg every 4 weeks for patients weighing ≥75kg **AND** c. Patient is **not** receiving Orencia in combination with either of the following: (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] 2. **Rheumatoid arthritis** when **all** of the following criteria are met: a. Diagnosis of moderately to severely active rheumatoid arthritis (RA)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Orencia® (Abatacept) Injection for Intravenous Infusion *(continued)*	May 1. 2016		**AND** b. Orencia is initiated and titrated according to US Food and Drug Administration labeled dosing for rheumatoid arthritis up to a maximum of (or equivalent dose and interval schedule): (1) 500mg every 4 weeks for patients weighing <60kg (2) 750mg every 4 weeks for patients weighing 60kg to 100kg (3) 1,000mg every 4 weeks for patients weighing >100kg **AND** c. Patient is **not** receiving Orencia in combination with either of the following: (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] Orencia is **unproven and not medically necessary** for the treatment of: 1. Multiple sclerosis 2. Systemic lupus erythematosus 3. Graft versus host disease (GVHD) 4. Psoriatic arthropathy 5. Uveitis associated with Behçet's disease **Centers for Medicare and Medicaid Services (CMS):** Medicare does not have a National Coverage Determination (NCD) that addresses Orencia® (abatacept). Local Coverage Determinations (LCDs) exists; refer to the LCDs for Abatacept and Drugs and Biologicals (Non-chemotherapy). Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf. (Accessed February 2, 2016)
Simponi® Aria™ (Golimumab) Injection for Intravenous Infusion	May 1, 2016	• Added reference link to related Coverage Determination Guideline titled *Specialty Medication Administration: Site of Care Review Guidelines*	This policy refers to Simponi Aria (golimumab) injection for intravenous infusion. Simponi Aria is **proven and medically necessary** for the treatment of: 1. **Rheumatoid arthritis** when **all** of the following criteria are met.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Simponi® Aria™ (Golimumab) Injection for Intravenous Infusion *(continued)*	May 1, 2016	• Updated supporting information to reflect the most current clinical evidence and references	a. Diagnosis of moderately to severely active rheumatoid arthritis **AND** b. **One** of the following: (1) Patient is receiving concurrent therapy with methotrexate (2) History of contraindication or intolerance to methotrexate. **AND** c. Simponi Aria is initiated and titrated according to US Food and Drug Administration labeled dosing for rheumatoid arthritis up to a maximum of 2mg/kg every 8 weeks (or equivalent dose and interval schedule) **AND** d. Patient is **not** receiving Simponi Aria in combination with either of the following: (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)] (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] **Centers for Medicare and Medicaid Services (CMS):** Medicare does not have a National Coverage Determination (NCD) for SIMPONI® ARIA™ (golimumab). Local Coverage Determinations (LCDs) do not exist at this time. In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, Section 50 Drugs and Biologicals at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf (Accessed February 3, 2016)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Stelara® (Ustekinumab) Injection for Intravenous Infusion	Jun. 1, 2016	• Added reference link to related Coverage Determination Guideline titled *Specialty Medication Administration: Site of Care Review Guidelines* • Revised coverage criteria for	This policy refers to Stelara (ustekinumab) injection for intravenous infusion. Stelara is **proven and medically necessary** for the treatment of: 1. **Plaque psoriasis** when **all** of the following criteria are met: a. Diagnosis of moderate to severe plaque psoriasis. **AND** b. **One** of the following:

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Stelara® (Ustekinumab) Injection for Intravenous Infusion *(continued)*	Jun. 1, 2016	treatment of plaque psoriasis and psoriatic arthritis; added language to indicate Stelara is not proven/medically necessary for use in combination with phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] • Updated supporting information to reflect the most current clinical evidence and references	(1) Patient is a candidate for phototherapy (2) Patient is a candidate for systemic therapy. **AND** c. Stelara is initiated and titrated according to US Food and Drug Administration labeled dosing for plaque psoriasis up to a maximum of (or equivalent dose and interval schedule): (1) 45mg every 12 weeks for patients weighing ≤100kg (2) 90mg every 12 weeks for patients weighing >100kg **AND** d. Patient is not receiving Stelara in combination with either of the following: (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] 2. **Psoriatic arthritis** when **all** of the following criteria are met: a. Diagnosis of psoriatic arthritis. **AND** b. Stelara is initiated and titrated according to US Food and Drug Administration labeled dosing for psoriatic arthritis up to a maximum of 90mg every 12 weeks (or equivalent dose and interval schedule) **AND** c. Patient is not receiving Stelara in combination with either of the following: (1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] (2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] Stelara is **unproven and not medically necessary** for the treatment of: 1. Crohn's disease 2. Multiple sclerosis The findings of available studies are limited by short duration and/or relatively small patient population. Larger and longer term phase III studies are needed to further characterize Stelara efficacy and safety for treatment of Crohn's disease.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Stelara® (Ustekinumab) Injection for Intravenous Infusion *(continued)*	Jun. 1, 2016		In available studies, Stelara does not demonstrate efficacy in the treatment of multiple sclerosis. **Centers for Medicare and Medicaid Services (CMS):** Medicare does not have a National Coverage Determination (NCD) for STELARA® (ustekinumab). Local Coverage Determinations (LCDs) do not exist at this time. Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf. (Accessed February 5, 2016)

Coverage Determination Guideline (CDG) Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ambulance Services	May 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Routine review; no change to coverage rationale or lists of applicable codes	**Indications for Coverage** **Emergency Ambulance (Ground, Water, or Air)** Coverage includes Emergency ambulance transportation (including wait time and treatment at the scene) by a licensed ambulance service from the location of the sudden illness or injury, to the nearest hospital where Emergency health services can be performed. Check member specific benefit document for prior authorization and notification requirements. The following Emergency ambulance services are covered: 1. Ground ambulance or air ambulance transportation requiring basic life support or advanced life support. 2. Treatment at the scene (paramedic services) without ambulance transportation. 3. Wait time associated with covered ambulance transportation. 4. To a hospital that provides a required higher level of care that was not available at the original hospital. **Air Ambulance** As a general guideline, when it would take a ground ambulance 30-60 minutes or more to transport a member whose medical condition at the time of pick-up required immediate and rapid transport due to the nature and/or severity of the member's illness/injury, air transportation may be appropriate. Air ambulance transportation should meet the following criteria: 1. The patient's destination is an acute care hospital, **and** 2. The patient's condition is such that the ground ambulance (basic or advanced life support) would endanger the member's life or health, **or** 3. Inaccessibility to ground ambulance transport or extended length of time required to transport the patient via ground ambulance transportation could endanger the member, **or** 4. Weather or traffic conditions make ground ambulance transportation impractical, impossible, or overly time consuming. *Refer to #4 (Medicare Benefit Policy Manual) in the References section of the policy.* Additional Information:

Coverage Determination Guideline (CDG) Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ambulance Services *(continued)*	May 1, 2016		For covered Emergency ambulance, supplies that are needed for advanced life support or basic life support to stabilize a patient's medical condition are covered under the ambulance benefit. **Non-Emergency Ambulance (Ground or Air) Between Facilities** Coverage includes non-Emergency ambulance transportation by a licensed ambulance service (either ground or air ambulance), between health care facilities when the ambulance transportation is any of the following: 1. From a non-network hospital to a network hospital 2. To a hospital that provides a required higher level of care that was not available at the original hospital 3. To a more cost-effective acute care facility 4. From an acute facility to a sub-acute setting. **Cost Effective Alternatives (UHIC 2007 COC and 2009 Amendment)** If an alternate method of ambulance transportation is clinically appropriate and more cost effective, we reserve the right to adjust the amount of eligible expenses. As we determine to be appropriate, the coverage determination is based on the member's medical condition, and geographic location. **Medically Necessary (UHIC 2011 COC)** Non-emergency ambulance transportation is medically necessary when the patient's condition requires treatment at another facility and when another mode of transportation would endanger the patient's medical condition. If another mode of transportation could be used safely and effectively, then ambulance transportation is not medically necessary. **Benefit Level for Non-Emergency Ambulance** The applicable benefit for eligible non-Emergency ambulance transportation depends on the patient pick-up location (origin) as follows: 1. *If the patient is inpatient and is transported from a hospital to another hospital or inpatient facility*, coverage levels for these ambulance services may vary. Please refer to the member's specific plan document to determine benefits. The following are UHIC examples for inpatient ambulance transfer: a. UHIC 2001 COC: The *Hospital Inpatient Stay* section of the COC b. UHIC 2007 and 2011 COC: the *Ambulance Services* section of the COC 2. *If the patient is in a sub-acute setting and is transported to an outpatient*

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Ambulance Services *(continued)*	May 1, 2016		*facility and back* (outpatient hospital, outpatient facility, or physician's office), these ambulance services are covered under the benefits that apply to that sub-acute setting. For example, if the patient is at a Skilled Nursing Facility, the ambulance transport to an outpatient facility (dialysis facility, or radiation whether or not it is attached to a hospital) and back is covered under the Skilled Nursing Facility/Inpatient Rehabilitation Facility Services section of the COC. **Member Pre-Service Notification Requirements for Non-Emergency Ambulance** • If UHIC initiates the non-Emergency ambulance transportation, member notification is not required. • If UHIC does **not** initiate the non-Emergency ambulance transportation certain plans may require the member or the provider to call in for notification. Please see the member-specific plan documents for details on the notification requirements. Additional Information: Provider notification requirements are not addressed by this document. Ambulance transportation that is done for convenience of the patient is not covered. Please see the *Coverage Limitations and Exclusions* section of the policy for more information on non-covered ambulance transportation. **Benefit Level for Non-Network Ambulance (Emergency)** If the ambulance transportation is covered, non-network Emergency ambulance (ground, water, or air), is covered at the network level of deductible and coinsurance. Additional Information: • For UHIC Choice, Choice+, and Options PPO plans: Non-network Emergency ambulance is covered at a negotiated rate, or, at billed charges if a negotiated rate is not reached. • For UHIC Non-Differential PPO plans: The benefits for network and non-network are the same level but these plans do not require billed charges to be paid on non-network ambulance. • For UHIC Plans without a Network (eg, Managed Indemnity): These plans do not have network benefit levels. These plans do not require billed charges to be paid on ambulance services.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ambulance Services *(continued)*	May 1, 2016		**Coverage Limitations and Exclusions** The following services are not eligible for coverage: 1. Ambulance services from providers that are not properly licensed to be performing the ambulance services rendered. 2. Air ambulance that does not meet the covered indications in the Air Ambulance criteria listed above. 3. Non-ambulance transportation. Non-ambulance transportation is not covered even if rendered in an Emergency situation. Examples include but are not limited to commercial or private airline or helicopter, a police car ride to a hospital, medi-van transportation, wheel-chair van, taxi ride, bus ride, etc. 4. Ambulance transportation when other mode of transportation is appropriate. Except as indicated under the *Indications for Coverage* section of this policy, ambulance services when transportation by other means would not endanger the member's health, are not covered. 5. Ambulance transportation to a home, residential, domiciliary or custodial facility is not covered. 6. Ambulance transportation that violates the notification criteria listed in the *Indications for Coverage* section above. 7. Ambulance transportation for patient convenience or other miscellaneous reasons for patient and/or family. Examples include but are not limited to: a. Patient wants to be at a certain hospital or facility for personal/preference reasons; b. Patient is in foreign country, or out of state, wants to come home to for a surgical procedure or treatment (this includes those recently discharged from inpatient care); c. Patient is going to a routine service and is medically able to use another mode of transportation but can't find it; d. Patient is deceased (i.e., transportation to the coroner's office or mortuary) 8. Ambulance transportation deemed not appropriate. Examples include but are not limited to: a. Hospital to home b. Home to physician's office c. Home (e.g., residence, nursing home, domiciliary or custodial facility) to a hospital for a scheduled service Additional Information:

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ambulance Services *(continued)*	May 1, 2016		If the patient is at a Skilled Nursing Facility/Inpatient Rehabilitation Facility and has met the annual day/visit limit on Skilled Nursing Facility/Inpatient Rehabilitation Facility Services, ambulance transports (during the non-covered days) are not eligible.
Gender Dysphoria (Gender Identity Disorder) Treatment	May 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated benefit considerations; added language to clarify: • The member specific benefit plan document must be referenced to determine whether there is a basis for coverage of gender dysphoria and whether this Coverage Determination Guideline applies; this Coverage Determination Guideline is to be used only in conjunction with specific benefit plan documents and is not designed as a UnitedHealthcare Medical Policy	**Indications for Coverage** **Non-Surgical Treatment of Gender Dysphoria** Plans may cover non-surgical treatment for gender dysphoria. If there is a difference between a member specific benefit document and the information below, the member specific benefit document should be used for making benefit determinations. For plans that cover non-surgical treatment of gender dysphoria, please note the following Covered Services, and Limitations and Exclusions, sections below. ***Covered Services (for Plans That Cover Non-Surgical Treatment of Gender Dysphoria)*** If a plan covers non-surgical treatment for gender dysphoria, the following non-surgical treatments are covered: 1. **Psychotherapy** for gender dysphoria and associated co-morbid psychiatric diagnoses. **Note**: If mental health services are not covered on the UHC plan (for example when mental health services are carved out of the plan design) the UHC plan will not cover psychotherapy for gender dysphoria. 2. **Continuous Hormone Replacement Therapy** – hormones of the desired gender. Hormones injected by a medical provider (for example hormones injected during an office visit) are covered by the medical plan. Benefits for these injections vary depending on the plan design. Oral and self-injected hormones from a pharmacy are not covered under the medical plan. Refer to the Outpatient Prescription Drug Rider, or SPD for self-funded plans, for specific prescription drug product coverage and exclusion terms. **Eligibility Qualifications for Continuous Hormone Replacement Therapy** – The covered person must meet **all** of the following eligibility qualifications for hormone replacement: • Persistent, well-documented gender dysphoria (see definition of Gender Identity Disorder below); **and** • Capacity to make a fully informed decision and to consent for

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gender Dysphoria (Gender Identity Disorder) Treatment *(continued)*	May 1, 2016		treatment; **and** • Age of majority in a given country. **Note**: WPATH guidelines address age of majority in a given country. For the purposes of this guideline, the age of majority is age 18. However, this refers to chronological age not biological age. Where approval or denial of benefits is based solely on the age of the individual a case-by-case medical director review is necessary; **and** • If significant medical or mental health concerns are present, they must be reasonably well-controlled. 3. **Laboratory testing** to monitor the safety of continuous hormone therapy. **Coverage Limitations and Exclusions** Certain non-surgical treatments are not covered. Examples that apply to this exclusion include, but are not limited to: 1. Treatment received outside of the United States. 2. Non-surgical treatments that are not listed in the Covered Services section above. 3. Reproduction services including, but not limited to: sperm preservation in advance of hormone treatment or gender dysphoria surgery, cryopreservation of fertilized embyros, oocyte preservation, surrogate parenting, donor eggs, donor sperm and host uterus. (See the Reproduction exclusion in the member specific benefit document.) 4. Drugs* for hair loss or growth. 5. Drugs* for sexual performance for patients that have undergone genital reconstruction. 6. Drugs* for cosmetic purposes. 7. Hormone therapy except as described in the Covered Services section above. 8. Pubertal suppression therapy is considered unsafe in managing children and adolescents with gender identity dysphoria and is, therefore, not covered. See the policy titled Lupron Depot / Lupron Depot-Ped (leuprolide acetate) for Non-Oncology Use 9. Voice therapy. 10. Services that exceed the maximum dollar limit on the plan. 11. Transportation, meals, lodging or similar expenses. * The drugs exclusions listed above apply to drugs administered by a provider in a medical setting (including, but not limited to: office, outpatient,

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Gender Dysphoria (Gender Identity Disorder) Treatment *(continued)*	May 1, 2016		or inpatient facility). For drugs obtained at a pharmacy, check with the pharmacy plan administrator for information on covered and excluded drugs. **Note the following:** 1. Certain plans may have a different list of exclusions. Check the member specific benefit document before making a determination. 2. Additional exclusions are listed in the surgical treatment section below. **Surgical Treatment for Gender Dysphoria** Most plans exclude coverage for surgical treatment for gender dysphoria. However, certain self-funded plans may include a benefit that covers surgical treatment for gender dysphoria. Please refer to the member specific benefit document to verify coverage. If there is a difference between an member specific benefit document and the information below, the member specific benefit document should be used for making benefit determinations. For plans that **cover** surgical treatment for gender dysphoria, please note the following: ***Covered Surgical Treatment for Gender Dysphoria*** If a plan covers surgical treatment for gender dysphoria, the following are **covered** when the Eligibility Qualifications for Surgery below are met: 1. **Genital Surgery** (by various techniques which must be appropriate to each patient), including: complete hysterectomy; orchiectomy; penectomy; vaginoplasty; vaginectomy; clitoroplasty; labiaplasty; salpingo-oophorectomy; metoidioplasty; scrotoplasty; urethroplasty; placement of testicular prosthesis; phalloplasty 2. **Surgery to change specified secondary sex characteristics, specifically**: • Thyroid chondroplasty (removal or reduction of the Adam's Apple); and • Bilateral mastectomy; and • Augmentation mammoplasty (including breast prosthesis if necessary) if the Physician prescribing hormones and the surgeon have documented that breast enlargement after undergoing hormone treatment for 18 months is not sufficient for comfort in the social role. 3. **Related Services**: In addition to the surgeon fees, the benefit applies to the services related to the surgery, including but not limited to:

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Gender Dysphoria (Gender Identity Disorder) Treatment *(continued)*	May 1, 2016		anesthesia, laboratory testing, pathology, radiologic procedures, hospital and facility fees, and/or surgical center fees. ***Eligibility Qualifications for Surgery*** The following criteria apply to genital surgery, and to surgery to change specified secondary sex characteristics listed above. It is our expectation that surgery be performed by a qualified provider at a facility with a history of treating individuals with gender identity disorder. If a plan covers surgical treatment for gender dysphoria, the Covered Person must meet **all** of the following eligibility qualifications prior to surgery: 1. Persistent, well-documented gender dysphoria (see definition of Gender Identity Disorder below); **and** 2. Capacity to make a fully informed decision and to consent for treatment; **and** 3. Age of majority in a given country. Note: WPATH* guidelines address age of majority in a given country. For the purposes of this guideline, the age of majority is age 18. However, this refers to chronological age, not biological age. Where approval or denial of benefits is based solely on the age of the individual a case-by-case medical director review is necessary; **and** 4. If significant medical or mental health concerns are present, these must be reasonably well-controlled; **and** 5. The covered person must complete 12 months of successful continuous full time real life experience in the desired gender; **and** 6. The covered person may be required to complete continuous hormone therapy (for those without contraindications). In consultation with the patient's physician, this should be determined on a case-by-case basis through the Notification process; **and** 7. The treatment plan must conform to identifiable external sources including the World Professional Association for Transgender Health Association (WPATH) standards, and/or evidence-based professional society guidance. ***Clarifications for Breast/Chest Surgery*** In addition to the Eligibility Qualifications for Surgery listed above, please note the following: 1. **A biologic female** patient that is only requesting a **bilateral mastectomy**:

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Gender Dysphoria (Gender Identity Disorder) Treatment *(continued)*	May 1, 2016		• Does not need to complete hormone therapy in order to qualify for the mastectomy. • Although not a requirement for coverage, UnitedHealthcare recommends that the patient complete at least **3 months of psychotherapy** before having the mastectomy. 2. **A biologic male** patient that is only requesting a **breast augmentation**: • If able to take female hormones, the patient should take the female hormones for at least **12 – 24 months*** before being considered for bilateral breast augmentation since the patient may achieve adequate breast development without surgery. • Although not a requirement for coverage, UnitedHealthcare recommends that the patient complete at least **3 months of psychotherapy** before having the breast augmentation. *12 months is listed by WPATH v7, whereas, 2 years is listed by, *Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline (2009)* Note the following: 1. Certain plans may have a different list of Covered Services for Treatment of Gender Identity Disorder and may not cover all services listed above. Check the member specific benefit document to determine. 2. Benefits are limited to one sex transformation reassignment per lifetime which may include several staged procedures. 3. Check the member specific benefit document for any applicable prior authorization or notification requirements, or limits and maximum dollar amounts to this coverage. 4. Sterilization surgery is not required in order to receive the covered services under this benefit. ***Excluded Services for Surgical Treatment of Gender Dysphoria*** The following are **not covered** even if the plan includes coverage for surgical treatment for gender dysphoria: 1. Treatment received outside of the United States. 2. Reversal of genital surgery or reversal of surgery to revise secondary sex characteristics. 3. Voice modification surgery. 4. Facial feminization surgery, including but not limited to: facial bone

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gender Dysphoria (Gender Identity Disorder) Treatment *(continued)*	May 1, 2016		reduction, face "lift", facial hair removal, and certain facial plastic reconstruction. 5. Suction-assisted lipoplasty of the waist. 6. Rhinoplasty (except if rhinoplasty criteria are met; see the CDG titled Rhinoplasty and Other Nasal Surgeries) 7. Blepharoplasty (except if blepharoplasty criteria are met; see the CDG titled Blepharoplasty, Blepharoptosis, and Brow Ptosis Repair) 8. Abdominoplasty (except if abdominoplasty criteria are met; see the CDG titled Panniculectomy and Body Contouring Procedures) 9. Breast reduction (except if breast reduction criteria are met; see the CDG titled Breast Reduction Surgery 10. For plans that do not cover surgical treatment of gender dysphoria, surgical treatments for gender dysphoria are not covered even if considered to be medically necessary by the prescribing physician or other health practitioner. 11. For plans that cover surgical treatment of gender dysphoria, coverage does not apply to members that do not meet the criteria listed in the Eligibility Qualifications for Surgery section above. Note the following: 1. Certain plans may have a different list of exclusions. Check the member specific benefit plan document before making a determination. 2. Additional exclusions are listed in the non-surgical treatment section above.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Blepharoplasty, Blepharoptosis and Brow Ptosis Repair	Jun. 1, 2016	• Reformatted policy; transferred content to new template • Revised coverage rationale: ○ Updated coverage criteria for treatment of **ectropion (eyelid turned outward) or punctal eversion** (CPT codes 67914 through 67917); removed criterion requiring trial and failure of conservative treatments	**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. **Criteria for a Coverage Determination that Surgery is Reconstructive and Medically Necessary** The following must be available when requested by UnitedHealthcare: • Best corrected visual acuity in both eyes, all patients (except pediatrics). • Eye exam (chief complaint, HPI)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)*	Jun. 1, 2016	○ Added language to indicate **repair of floppy eyelid syndrome (FES)** (CPT codes 67961 and 67966) is considered reconstructive and medically necessary when all of the following are present when documented and confirmed by history and examination: ▪ Subjective symptoms must include eyelids spontaneously "flipping over" when they sleep due to rubbing on the pillow **and** one of the following: - Eye pain or discomfort; or - Excess tearing; or - Eye irritation, ocular redness and discharge ▪ Physical examination that documents the following: - Eyelash Ptosis; and - Significant upper eyelid laxity; and - Presence of Giant Papillary Conjunctivitis **or** - Corneal findings such as: • Superficial Punctate Erosions (SPK);	• Color photograph(s) (eye level, frontal with patient looking straight ahead, light reflex visible and centered) • Peripheral or superior visual fields automated, reliable (see Definitions), un-taped/taped are preferable. Note the following: ○ In situations where computerized visual field testing is not available we will accept manual visual field testing. ○ In situations where visual field testing is not possible, see section below: "When Patient is Not Capable of Visual Field Testing". **Note**: The visual fields and color photograph(s) must be consistent. **If multiple procedures are requested, the following criteria must be met**: 1. All criteria for each individual procedure must be met; and 2. Visual field testing shows visual impairment which can't be addressed by one procedure alone; and 3. Color photograph findings are consistent with visual field findings. **A. Upper eyelid blepharoplasty (CPT 15822 and 15823) is considered reconstructive and medically necessary when the following criteria are present:** 1. Ptosis has been ruled out as the primary cause of visual field obstruction; **and** 2. The color photograph must show: i. The extra skin, but **not** the lid margin, taped up to show it reverses the visual field obstruction; **and/or** ii. Lateral hooding present; **and** 3. The patient must have a Functional/Physical Impairment complaint directly related to an abnormality of the eyelid(s); **and** 4. Excess skin (dermatochalasis/blepharochalasis) touches the lashes; **and** 5. Automated peripheral or superior visual field testing, with the eyelids taped and un-taped, showing improvement of 30% or more in number of points seen. • (In situations where computerized visual field testing is not available we will accept manual visual field testing. • In situations where visual field testing is not possible, see section below, "When Patient is Not Capable of Visual Field Testing". **Note**: Extended blepharoplasty may be indicated for blepharospasm

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Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)*	Jun. 1, 2016	or • Corneal abrasion (Note: Documentation of a history of corneal abrasion or recurrent erosion syndrome is considered sufficient); or • Microbial Keratitis ▪ Color photos that clearly document floppy eyelid syndrome; the photographs must clearly demonstrate **both** of the following: - Lids must be everted in the photos and - Conjunctival surface (underbelly) of the lids must clearly demonstrate Giant Papillary Conjunctivitis ▪ Documentation that conservative treatment has been tried and failed; examples may include: - Ocular lubricants both drops (daytime) and ointments (bedtime); or - Short trial of antihistamines; or - Topical steroid	(eyelids are forced shut) when the following two criteria are met: 1. Debilitating symptoms (e.g., pain); **and** 2. Conservative treatment has been tried and failed, or is contraindicated (e.g., Botox®) **B. Upper eyelid blepharoptosis repair (CPT 67901– 67909) is considered reconstructive and medically necessary when the following criteria are present:** 1. The patient must have a Functional/Physical Impairment complaint directly related to the position of the eyelid(s); **and** 2. Other causes of ptosis are ruled out (e.g., recent botox injections, myasthenia gravis when applicable); **and** 3. Eyelid droop (upper eyelid ptosis) and an MRD-1 of 2.0 mm or less; **and** 4. The MRD is documented in color photographs with patient looking straight ahead and light reflex centered on the pupil; **and** 5. Automated peripheral or superior visual field testing, with the eyelids taped and un-taped, showing improvement of 30% or more improvement in the number of points seen. • In situations where computerized visual field testing is not available we will accept manual visual field testing. • In situations where visual field testing is not possible, see section below, "When Patient is Not Capable of Visual Field Testing". **Note**: For children under age 10 years, ptosis repair is covered to prevent amblyopia. Visual field testing is not required, but, a color photograph is required. **C. Brow ptosis (CPT 67900) is considered reconstructive and medically necessary when the following criteria are present:** 1. Other causes have been eliminated as the primary cause for the visual field obstruction (e.g., Botox® treatments within the past six (6) months); **and** 2. Patient must have a functional complaint related to brow ptosis. Brow ptosis must be documented in two color photographs. One showing the eyebrow below the bony superior orbital rim, and a second photograph with the brow taped up that eliminates the visual field defect; **and** • Automated peripheral and superior visual field testing, with differential taping (eyebrow and eyebrow + eyelid) showing 30%

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Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)*	Jun. 1, 2016	drops; or - Eye Shield and/or Taping the lids at bedtime ▪ Other causes of the eye findings have been ruled out; examples may include: - Allergic Conjunctivitis - Atopic Keratoconjunctivitis - Blepharitis - Contact Lens (CL) Complication - Dermatochalasis - Ectropion - GPC (Giant Papillary Conjunctivitis) that is not related to FES - Ptosis of the lid(s) - Superior Limbic Keratoconjunctivitis (SLK) • Updated definitions; added definition of: ○ Giant papillary conjunctivitis ○ Floppy eyelid syndrome (FES) • Updated list of applicable CPT codes; added 67961 and 67966 (floppy eyelid syndrome)	or more improvement in total number of points seen with the eyebrow taped up. In situations where computerized visual field testing is not available we will accept manual visual field testing. • In situations where visual field testing is not possible, see section below, "When Patient is Not Capable of Visual Field Testing". **D. Eyelid surgery with an anophthalmic socket (has no eyeball) is considered reconstructive and medically necessary when both of the following criteria are present:** 1. Patient has an anophthalmic condition; **and** 2. Patient is experiencing difficulties fitting or wearing an ocular prosthesis. **E. Lower eyelid blepharoplasty (CPT 15820 and 15821) is usually cosmetic, however, is considered reconstructive and medically necessary only when all of the following criteria are present:** 1. There is documented facial nerve damage; **and** 2. Color photograph documents the pathology; **and** 3. Patient is unable to close the eye due to the lower lid dysfunction; **and** 4. Functional impairment including **both** of the following: • Documented uncontrolled tearing or irritation; **and** • Conservative treatments tried and failed. **F. Ectropion (eyelid turned outward) (CPT 67914 through 67917) or punctal eversion is considered reconstructive and medically necessary when all of the following criteria are present:** 1. Color photograph documents the pathology; **and** 2. Corneal or conjunctival injury with **both** of the following criteria: • Subjective symptoms include either: a. Pain or discomfort; **or** b. Excess tearing; **and** • Any one of the following: a. Exposure keratitis; **and/or** b. Keratoconjunctivitis; **and/or** c. Corneal ulcer **G. Entropion (eyelid turned inward) (CPT 67921-67924) is considered reconstructive and medically necessary when all of the following criteria are present:**

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Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)*	Jun. 1, 2016		1. Color photograph must document the following: • Lid turned inward; **and** • At least one of the following: a. Trichiasis; **or** b. Irritation of cornea or conjunctiva; **and** 2. Conservative treatments have been tried and failed; **and** 3. Subjective symptoms including either of the following: • Excessive tearing; **or** • Pain or discomfort **H. Lid Retraction Surgery (CPT 67911) Lid retraction surgery is considered reconstructive and medically necessary when all of the following criteria are present:** 1. Other causes have been eliminated as the reason for the lid retraction such as use of dilating eye drops, glaucoma medications; **and** 2. Color photograph documents the pathology; **and** 3. There is functional impairment (such as 'dry eyes', pain/discomfort, tearing, blurred vision); **and** 4. Tried and failed conservative treatments; **and** 5. In cases of thyroid eye disease two or more Hertel measurements at least 6 months apart with the same base measurements are unchanged. **I. Canthoplasty/Canthopexy (CPT 21280, 21282, 67950, 67961, 67966) is considered reconstructive and medically necessary when all of the following criteria are present:** 1. Functional impairment; **and** 2. Conservative treatments have been tried and failed; **and** 3. Color photograph documents the pathology; **and** 4. Simple repair of ectropion or entropion will not correct condition; **and** 5. At least one of the following patient complaints is present: • Epiphora (excess tearing) not resolved by conservative measures; **or** • Corneal dryness unresponsive to lubricants; **or** • Corneal ulcer **J. Repair of floppy eyelid syndrome (FES) (CPT 67961 and 67966) is considered reconstructive and medically necessary when all of**

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)*	Jun. 1, 2016		**the following are present when documented and confirmed by history and examination:** 1. Subjective symptoms must include eyelids spontaneously "flipping over" when they sleep due to rubbing on the pillow, AND one of the following: • Eye pain or discomfort; or • Excess tearing; or • Eye irritation, ocular redness and discharge 2. Physical Examination that documents the following: • Eyelash Ptosis; and • Significant upper eyelid laxity; and • Presence of Giant Papillary Conjunctivitis **OR** • Corneal findings such as: a) Superficial Punctate Erosions (SPK); or b) Corneal abrasion*; or c) Microbial Keratitis ***Note**: Documentation of a history of corneal abrasion or recurrent erosion syndrome is considered sufficient for the corneal findings requirement above. 3. Color photos that clearly document floppy eyelid syndrome. The photographs must clearly demonstrate **both** of the following: • Lids must be everted in the photos and • Conjunctival surface (underbelly) of the lids must clearly demonstrate Giant Papillary Conjunctivitis 4. Documentation that conservative treatment has been tried and failed, examples may include: • Ocular lubricants both drops (daytime) and ointments (bedtime); or • Short trial of antihistamines; or • Topical steroid drops; or • Eye Shield and/or Taping the lids at bedtime 5. Other causes of the eye findings have been ruled out, examples may include: • Allergic Conjunctivitis • Atopic Keratoconjunctivitis • Blepharitis • Contact Lens (CL) Complication

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)*	Jun. 1, 2016		• Dermatochalasis • Ectropion • GPC (Giant Papillary Conjunctivitis) that is not related to FES • Ptosis of the lid(s) • Superior Limbic Keratoconjunctivitis (SLK) **When Patient Is Not Capable of Visual Field Testing** Visual field testing is not required when the patient is not capable of performing a visual field test. The following are some examples: • If the patient is a child 12 years old or under • If the patient has intellectual disabilities (previously known as mental retardation) or some other severe neurologic disease **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: A. 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. B. Any procedure that does not meet the reconstructive criteria above in the *Indications for Coverage* section of the policy.

Utilization Review Guideline (URG) Updates

UPDATED

Policy Title	Effective Date	Summary of Changes	Utilization Management Guiding Principles
Inpatient Pediatric Feeding Programs	May 1, 2016	• Updated supporting information to reflect the most current references; no change to utilization management guidelines	**Essential Health Benefits for Individual and Small Group** For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the member specific benefit plan document to determine benefit coverage. **Introduction** This clinical guideline addresses inpatient, multi-disciplinary, pediatric feeding disorders programs for infants and young children under age 3 who meet certain qualifications (see 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:** 1. 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):

Utilization Review Guideline (URG) Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Utilization Management Guiding Principles**
Inpatient Pediatric Feeding Programs *(continued)*	May 1, 2016		a. gastroesophageal reflux disease b. gastrointestinal motility disorders c. cleft palate d. tracheo-esophageal fistula e. gastrostomy tube dependence f. nasogastric feeding tube dependence **AND** 2. Have failed outpatient treatment by a multidisciplinary team **AND** 3. Are medically unstable as manifested by one or more of the following: a. hypothermia b. hypotension c. bradycardia or persistent tachycardia d. dehydration confirmed on clinical and laboratory grounds e. electrolyte abnormalities f. 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: 1. Occupational Therapist 2. Physical Therapist 3. Speech Therapist 4. Social Worker 5. Developmental Pediatrician (as a consultant only when needed) 6. Family members and/or care givers of the patient **Discharge and Follow-up** Follow-up and outpatient therapy as ordered by the treating physician. **Medical Necessity Plans** Use the criteria above where applicable.