UnitedHealthcare®

May 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 inclusion of a health service (e.g., test, drug, device 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 health service. 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, Medical Benefit Drug Policy & Coverage Determination Guideline Updates

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## Medical Benefit Drug Policy Updates

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## Coverage Determination Guideline (CDG) Updates

**UPDATED**



**REVISED**



## Utilization Review Guideline (URG) Updates

**REVISED**

## Medical Policy Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
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| **UPDATED** | | | |
| Computerized Dynamic Posturography | May 1, 2017 | • Updated supporting information to reflect the most current clinical evidence, FDA information, and references; no change to coverage rationale or list of applicable codes | **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**.<br>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. |
| Gait Analysis | May 1, 2017 | • Updated supporting information to reflect the most current clinical evidence 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**.<br>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, 2017 | • Updated list of applicable CPT codes; added 0005U | **Oncology Indications**<br>***Thyroid Cancer***<br>**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**.<br><br>**Gene expression tests are unproven and not medically necessary for the following indications**:<br>• ***Cancer of Unknown Primary***<br>  ○ Identifying tissue of origin in difficult to diagnose cancers (e.g., ResponseDX Tissue of Origin® or CancerTYPE ID®)<br>• ***Colon Cancer***<br>  ○ Predicting the likelihood of colon cancer recurrence (e.g., Oncotype DX® Colon Cancer Assay)<br>• ***Multiple Myeloma***<br>  ○ Guiding therapy in patients with multiple myeloma (e.g., MyPRS®)<br>• ***Prostate Cancer***<br>  ○ Predicting tumor aggressiveness and guiding disease management in patients with newly diagnosed prostate cancer (e.g., Oncotype DX® |

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| **UPDATED** | | | |
| Gene Expression Tests *(continued)* | May 1, 2017 | | Prostate Cancer Assay and Prolaris®)<br>○ Predicting risk of recurrence and metastasis and guiding disease management following radical prostatectomy (e.g., Decipher® Prostate Cancer Classifier)<br>• ***Uveal Melanoma***<br>○ Predicting metastatic risk of uveal melanoma (e.g., DecisionDx-UM)<br><br>There is insufficient evidence in the clinical literature demonstrating that 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.<br><br>**Non-Oncology Indications**<br>***Coronary Artery Disease***<br>**Gene expression tests are unproven and not medically necessary for predicting the likelihood of obstructive coronary artery disease (e.g., Corus® CAD)**.<br>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, 2017 | • Updated list of applicable ICD-10 diagnosis codes; removed crosswalk mapping to ICD-9 code 714.30 for M08.811, M08.812, M08.819, M08.821, M08.822, M08.829, M08.831, M08.832, M08.839, M08.841, M08.842, M08.849, M08.851, M08.852, M08.859, M08.861, M08.862, M08.869, M08.871, M08.872, M08.879, M08.88, M08.89, M08.90, M08.911, M08.912, M08.919, M08.921, M08.922, M08.929, M08.931, M08.932, M08.939, M08.941, M08.942, M08.949, M08.951, M08.952, M08.959, M08.961, | **Hepatitis screening for "at-risk" persons for acute and chronic infections is proven and medically necessary for the following indications**:<br>• Persons with a history of sexually transmitted infections (STI)<br>• Men who have sexual relations with men<br>• Persons with multiple sexual partners<br>• Persons who have experienced Intercourse with trauma<br>• Human Immunodeficiency Virus (HIV) infected persons<br>• Persons who have history of using injection and non-injection illicit drugs<br>• 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<br>• All pregnant women including those with a sexually transmitted infection (STI)<br>• Persons who have received blood transfusion or organ transplantation before July 1992<br>• Recipient of clotting factor concentrates made before 1987 |

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| **UPDATED** | | | |
| Hepatitis Screening *(continued)* | May 1, 2017 | M08.962, M08.969, M08.971, M08.972, M08.979, M08.98, and M08.99<br>• Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references | • Hemodialysis patients<br>• Patients prior to initiating TNF blocker immunosuppressive therapy<br>• Patients needing immunosuppressive or cytotoxic therapy<br>• Patients with signs and symptoms of liver disease/elevated liver enzymes (abnormal ALT/AST)<br>• Patients with positive test for anti-hepatitis C virus (HCV)<br>• Patients with clotting factor disorders<br>• Patients with history of working with non-human primates susceptible to HAV infection<br>• Infants born to HBV or HCV positive mothers (do not test before 18 months of age)<br>• US born infants whose parents were born in regions with high rates of Hepatitis B<br>• Sexual partners of infected persons<br>• Household, needle sharing or secondary contacts of HbsAg positive persons<br>• Health care and public safety workers at risk for occupational exposure to blood or blood contaminated body fluids<br>• Residents and staff of facilities for developmentally disabled persons<br>• 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)<br>• Donors of blood, plasma, organs, tissue or semen<br><br>**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**. |
| Intrauterine Fetal Surgery | May 1, 2017 | • Changed policy title; previously titled *In Utero Fetal Surgery*<br>• Replaced references to "in utero fetal surgery" with "intrauterine fetal surgery"<br>• Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or lists of applicable codes | **Intrauterine fetal surgery is proven and medically necessary for the following indications**:<br>• Congenital cystic adenomatoid malformation (CCAM) and extralobar pulmonary sequestration (EPS): Fetal lobectomy or thoracoamniotic shunt placement for CCAM and thoracoamniotic shunt placement for EPS<br>• Sacrococcygeal teratoma (SCT): SCT resection<br>• Urinary tract obstruction (UTO): Urinary decompression via vesicoamniotic shunt placement<br>• Twin-twin transfusion syndrome: Fetoscopic laser surgery<br>• Twin reversed arterial perfusion (TRAP): Ablation or occlusion of anastomotic vessels (e.g., laser coagulation or radiofrequency ablation) |

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| **UPDATED** | | | |
| Intrauterine Fetal Surgery *(continued)* | May 1, 2017 | | • Myelomeningocele (MMC) repair<br><br>**Intrauterine fetal surgery is unproven and not medically necessary for the following indications**:<br>• Congenital diaphragmatic hernia (CDH)<br>  ○ 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 surgery have not been observed.<br>• Congenital heart disease (CHD)<br>  ○ There is insufficient evidence that in utero fetal surgery for complex heart disease improves health outcomes or survival. |
| Manipulative Therapy | May 1, 2017 | • Reformatted and reorganized policy; transferred content to new template<br>• Updated/reformatted coverage rationale:<br>  ○ Added language to clarify craniosacral therapy (cranial manipulation/Upledger technique) or manipulative services that utilize nonstandard techniques including but not limited to applied kinesiology, NUCCA, and neural organizational technique are unproven and not medically necessary *for any indication*<br>  ○ Replaced reference to "network and neural organizational technique" with "neural organizational technique"<br>• Updated supporting information to reflect the most current description of services, clinical evidence, and references | **Manipulative therapy is proven and medically necessary for treating musculoskeletal disorders, except as noted below**.<br><br>**Manipulative therapy is unproven and not medically necessary for treating**:<br>• Non-musculoskeletal disorders (e.g., asthma, otitis media, infantile colic, etc.)<br>• Prevention/maintenance/custodial care<br>• Internal organ disorders (e.g., gallbladder, spleen, intestinal, kidney, or lung disorders)<br>• Temporomandibular joint (TMJ) disorder<br>• Scoliosis correction<br><br>**Craniosacral therapy (cranial manipulation/Upledger technique) or manipulative services that utilize nonstandard techniques including but not limited to applied kinesiology, NUCCA, and neural organizational technique are unproven and not medically necessary for any indication**.<br>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.<br><br>**Manipulative therapy is unproven and not medically necessary when ANY of the following apply:**<br>• The patient's condition has returned to the pre-symptom state.<br>• Little or no improvement is demonstrated within 30 days of the initial |

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| **UPDATED** | | | |
| Manipulative Therapy *(continued)* | May 1, 2017 | | visit despite modification of the treatment plan.<br>• 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.<br><br>This policy does not address manipulation under anesthesia; refer to the policy titled Manipulation Under Anesthesia. |
| Occipital Neuralgia and Headache Treatment | May 1, 2017 | • Updated list of applicable CPT codes; revised description for 64553<br>• Updated list of applicable HCPCS codes; revised description for L8680<br>• Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references | **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**.<br><br>**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**.<br>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.<br><br>See the Medical Benefit Drug Policy titled Botulinum Toxins A and B for information regarding the use of botulinum toxin for treatment of headaches.<br><br>**Surgery including but not limited to the following is unproven and not medically necessary for treating occipital neuralgia or cervicogenic headache**:<br>• Occipital neurectomy<br>• Partial posterior intradural C1-C3 rhizotomy<br>• Rhizotomy of C1-C3 spinal dorsal roots<br>• Surgical decompression of second cervical nerve root and ganglion<br>• Surgical decompression of the greater occipital nerve<br><br>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.<br><br>**Occipital neurectomy or surgical nerve decompression is unproven** |

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| Occipital Neuralgia and Headache Treatment *(continued)* | May 1, 2017 | | **and not medically necessary for treating headaches**.<br>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.<br><br>**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**.<br>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.<br><br>**Neurostimulation or electrical stimulation is unproven and not medically necessary for treating of occipital neuralgia or headaches including migraine, cluster and cervicogenic headache**.<br>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, 2017 | • Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references; no change to coverage rationale or lists of applicable codes | **Prolotherapy is unproven and not medically necessary**.<br>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. |

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| Total Artificial Disc Replacement for the Spine | May 1, 2017 | • Updated list of related policies; added reference link to Medicare Advantage Coverage Summary titled *Artificial Disc Replacement, Cervical and Lumbar*<br>• 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 | **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**:<br>• Herniated disc<br>• Osteophyte formation<br>**AND both of the following**:<br>• Documented patient history of neck and/or arm pain and/or a functional/neurological deficit associated with the cervical level to be treated<br>• 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)<br><br>**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**.<br>Radiologic evidence of degenerative disc disease is common in persons who are middle aged and older and does not necessarily correlate with clinical symptoms.<br><br>**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**.<br>**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.<br><br>**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**.<br>This is commonly referred to as a hybrid surgery. There is insufficient published clinical evidence in peer-reviewed medical literature demonstrating |

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| Total Artificial Disc Replacement for the Spine *(continued)* | May 1, 2017 | | the safety and efficacy of combination cervical spine surgery at multiple adjacent or non-adjacent levels.<br><br>**Lumbar artificial total disc replacement is unproven and not medically necessary for treating single or multiple level degenerative disc disease in skeletally mature patients**.<br>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. |
| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| **REVISED** | | | |
| Bariatric Surgery | Jun. 1, 2017 | • Updated list of related policies; added reference link to policy titled *Obstructive Sleep Apnea Treatment*<br>• Revised coverage rationale:<br>○ Updated list of required co-morbidities for Class II obesity in adults; replaced "cardiopulmonary problems *[e.g.,* documented obstructive sleep apnea (OSA) confirmed on polysomnography with an AHI or RDI of ≥ 30 *(as defined by AASM Task Force Sleep1999;22:667-89)]*" with "cardiopulmonary problems *as a result of another disease process, including but not limited to* documented obstructive sleep apnea (OSA) confirmed on polysomnography with an AHI or RDI of ≥30" | **The following bariatric surgical procedures are proven in adults for treating extreme obesity**:<br>• Gastric bypass (Roux-en-Y; gastrojejunal anastomosis)<br>• Adjustable gastric banding (laparoscopic adjustable silicone gastric banding) – Refer to the *U.S. Food and Drug Administration* section of the policy<br>• Gastric sleeve procedure (also known as laparoscopic vertical gastrectomy or laparoscopic sleeve gastrectomy)<br>• Vertical banded gastroplasty (gastric banding; gastric stapling)<br>• Biliopancreatic bypass (Scopinaro procedure)<br>• Biliopancreatic diversion with duodenal switch<br><br>**Bariatric surgery using one of the procedures identified above (primary, secondary or revisions) for treating weight loss is medically necessary when ALL of the following criteria are met:**<br>• Class III obesity (extreme obesity) [body mass index (BMI) > 40 kg/m$^2$)]; or<br>• Class II obesity (BMI 35-39.9 kg/m$^2$) in the presence of one or more of the following co-morbidities:<br>○ Type 2 diabetes; or<br>○ Cardiovascular disease [e.g., stroke, myocardial infarction, poorly controlled hypertension (systolic blood pressure greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite pharmacotherapy)]; or |

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| **REVISED** | | | |
| Bariatric Surgery *(continued)* | Jun. 1, 2017 | ○ Updated medical necessity criteria for bariatric surgical procedures in adolescents:<br>▪ Replaced criterion requiring "Class III obesity (extreme obesity) [body mass index (BMI) > 40 kg/m2)]" with "Class III obesity (extreme obesity) [body mass index (BMI) > 40 kg/m2)] *with mild obstructive sleep apnea*"<br>▪ Removed criterion requiring "cardiopulmonary problems [e.g., documented obstructive sleep apnea (OSA) confirmed on polysomnography with an AHI or RDI of >= 30 (as defined by AASM Task Force Sleep1999;22:667-89)]"<br>▪ Added criterion requiring "BMI 35-39.9 kg/$m^2$ with moderate to severe obstructive sleep apnea"<br>○ Replaced language indicating "bariatric surgery *for treating* gynecological abnormalities, osteoarthritis, gallstones, urinary stress incontinence, gastroesophageal reflux (including for Barrett's esophagus or gastroparesis) or other obesity- associated | ○ History of coronary artery disease with a surgical intervention such as cardiopulmonary bypass or percutaneous transluminal coronary angioplasty; or<br>○ Cardiopulmonary problems as a result of another disease process, including but not limited to documented obstructive sleep apnea (OSA) confirmed on polysomnography with an AHI or RDI of ≥30; or<br>○ History of cardiomyopathy;<br>AND<br>• The individual must also meet the following criteria:<br>○ Documentation of a motivated attempt of weight loss through a structured diet program, prior to bariatric surgery, which includes physician or other health care provider notes and/or diet or weight loss logs from a structured weight loss program for a minimum of 6 months; and<br>○ Psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges that may contribute to a poor postoperative outcome.<br><br>**The bariatric surgical procedures identified above are medically necessary in adolescents for treating extreme obesity and who have**:<br>• Achieved greater than 95% of estimated adult height based on documented individual growth pattern; and<br>• A minimum Tanner stage of 4; and<br>• Meet the following medical necessity criteria:<br>○ Class III obesity (extreme obesity) [body mass index (BMI) > 40 kg/$m^2$)] with mild obstructive sleep apnea; or<br>○ Class II obesity (BMI 35-39.9 kg/$m^2$) in the presence of one or more of the following co-morbidities:<br>▪ Type 2 diabetes; or<br>▪ Cardiovascular disease [e.g., stroke, myocardial infarction, poorly controlled hypertension (systolic blood pressure greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite pharmacotherapy)]; or<br>▪ History of coronary artery disease with a surgical intervention such as cardiopulmonary bypass or percutaneous transluminal coronary angioplasty; or<br>▪ BMI 35-39.9 kg/$m^2$with moderate to severe obstructive sleep apnea; or<br>▪ History of cardiomyopathy; |

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| **REVISED** | | | |
| Bariatric Surgery *(continued)* | Jun. 1, 2017 | diseases that generally do not lead to life threatening consequences is unproven and not medically necessary" with "Bariatric surgery *as the primary treatment* for gynecological abnormalities, osteoarthritis, gallstones, urinary stress incontinence, gastroesophageal reflux (including for Barrett's esophagus or gastroparesis) or other obesity- associated diseases that generally do not lead to life threatening consequences is unproven and not medically necessary"<br>○ Modified language pertaining to clinical evidence/study findings to indicate:<br>▪ There is insufficient published clinical evidence to support bariatric surgery for the definitive treatment of gynecological abnormalities, osteoarthritis, gallstones, urinary stress incontinence or as treatment for gastroesophageal reflux and other obesity-associated diseases<br>▪ Bariatric surgery will frequently ameliorate symptoms of these co-morbidities; however, the primary purpose of | AND<br>○ The individual must also meet the following criteria:<br>▪ Documentation of a motivated attempt of weight loss through a structured diet program, prior to bariatric surgery, which includes physician or other health care provider notes and/or diet or weight loss logs from a structured weight loss program for a minimum of 6 months; and<br>▪ Psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges that may contribute to a poor postoperative outcome.<br><br>**Note**: See additional information in the *Description of Services* section of the policy for growth and BMI charts.<br><br>**Bariatric surgical procedures in a person who has not attained an adult level of physical development and maturation are unproven and not medically necessary**.<br>Potential safety issues must be addressed in studies with sufficient sample size and adequate follow-up times necessary to demonstrate the impact of the surgery on physical, sexual and reproductive maturation and the long term improvement of co-morbidities in this age group.<br><br>**Bariatric surgery as the primary treatment for gynecological abnormalities, osteoarthritis, gallstones, urinary stress incontinence, gastroesophageal reflux (including for Barrett's esophagus or gastroparesis) or other obesity-associated diseases that generally do not lead to life threatening consequences is unproven and not medically necessary**.<br>There is insufficient published clinical evidence to support bariatric surgery for the definitive treatment of gynecological abnormalities, osteoarthritis, gallstones, urinary stress incontinence or as treatment for gastroesophageal reflux and other obesity-associated diseases. Bariatric surgery will frequently ameliorate symptoms of these co-morbidities; however, the primary purpose of bariatric surgery in obese persons is to achieve weight loss.<br><br>**Robotic-assisted gastric bypass surgery is proven as equivalent but not superior to other types of minimally invasive bariatric surgery**.<br><br>**Surgical adjustment or alteration of a prior bariatric procedure is** |

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| Bariatric Surgery *(continued)* | Jun. 1, 2017 | bariatric surgery in obese persons is to achieve weight loss<br>• Updated definitions:<br>○ Modified definition of "extreme obesity"<br>○ Added definition of "obstructive sleep apnea (OSA)"<br>• Updated supporting information to reflect the most current clinical evidence and references | **proven and medically necessary for complications of the original surgery, such as stricture, obstruction, pouch dilatation, erosion, or band slippage when the complication causes abdominal pain, inability to eat or drink or causes vomiting of prescribed meals**.<br><br>**The following procedures are unproven and not medically necessary for treating obesity**:<br>• Transoral endoscopic surgery<br>• Mini-gastric bypass (MGB) or laparoscopic mini-gastric bypass (LMGBP)<br>• Gastric electrical stimulation with an implantable gastric stimulator (IGS)<br>• VBLOC® vagal blocking therapy<br>• Intragastric balloon<br>• Laparoscopic greater curvature plication, also known as total gastric vertical plication<br>• Stomach aspiration therapy (AspireAssist®)<br>• Bariatric artery embolization (BAE)<br><br>Further studies are needed to determine the safety and efficacy of these procedures as a treatment option for obesity.<br><br>**Gastrointestinal liners (EndoBarrier®) are investigational, unproven and not medically necessary for treating obesity**.<br>Gastrointestinal liners have not received FDA approval. Their long-term efficacy has not been demonstrated. |
| Cochlear Implants | Jun. 1, 2017 | • Reformatted and reorganized policy; transferred content to new template<br>• Updated benefit considerations; replaced language indicating:<br>○ "If benefits exist for a cochlear implant, the external components (i.e., speech processor, microphone, and transmitter coil) are considered durable medical equipment (DME), and the implantable components are considered | **When used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions, bilateral or unilateral cochlear implantation is proven and medically necessary for treating patients who meet ALL of the following criteria**:<br>• Diagnosis of bilateral prelingual or postlingual moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids; and<br>• Ability to follow or participate in a program of aural rehabilitation; and<br>• Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system; and<br>• No contraindications to surgery. |

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|---|---|---|---|
| **REVISED** | | | |
| Cochlear Implants *(continued)* | Jun. 1, 2017 | under the medical-surgical benefit*(s)*" with "if benefits exist for a cochlear implant, the external components (i.e., speech processor, microphone, and transmitter coil) are considered *under the* durable medical equipment (DME) *benefit*, and the implantable components are considered under the medical-surgical benefit"<br>○ "The member specific benefit plan document must be referenced to determine *the* DME benefits for repair or replacement of external components" with "the member specific benefit plan document must be referenced to determine *if there are* DME benefits for repair or replacement of external components"<br>○ "Frequency modulated (FM) systems do not prevent, diagnose or treat a sickness or injury, and are not integral to the cochlear implant itself" with "frequency modulated (FM) systems do not prevent, diagnose or treat a sickness or injury, and are not integral to *the function of* the cochlear implant itself"<br>• Revised coverage rationale:<br>○ Replaced reference to "U.S. | Refer to the *U.S. Food and Drug Administration (FDA)* section of the policy for indications for each cochlear implant device. Specific criteria vary with the device.<br><br>**Cochlear hybrid implants are unproven and not medically necessary for treating hearing loss**.<br>There is insufficient high quality evidence in the published clinical literature demonstrating the safety and efficacy of cochlear hybrid implants in the management of patients with severe hearing loss. Published evidence has shown that there is a potential risk of low frequency hearing loss as a result of cochlear hybrid implant surgery. Studies are needed to verify that benefits are likely to outweigh the risks of cochlear hybrid implantation and to determine which group of patients would benefit most from this device. |

## Medical Policy Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **REVISED** | | | |
| Cochlear Implants *(continued)* | Jun. 1, 2017 | Food and Drug Administration (FDA) labeled indications" with "U.S. Food and Drug Administration (FDA) labeled indications, *contraindications, warnings, and precautions*"<br>○ Modified language pertaining to clinical evidence/study findings to indicate there is insufficient *high quality* evidence in the *published* clinical literature demonstrating the safety and efficacy of cochlear hybrid implants in the management of patients with severe hearing loss<br>• Added definition of "degree of hearing loss"<br>• Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references | |
| Genetic Testing | May 1, 2017 | • Revised coverage rationale for clinical utility of genetic tests that are not medically necessary:<br>• Updated reference to applicable MCG™ Care Guideline for **Coronary Artery Disease (9p21 Allele)**; replaced "MCG™ Care Guidelines, 21st edition, 2017, Clopidogrel Pharmacogenetics – CYP2C19 Gene ACG: A-0631 (AC)" with "MCG™ Care Guidelines, 21st | Refer to the policy for complete details on the coverage guidelines for Genetic Testing. |

## Medical Policy Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **REVISED** | | | |
| Genetic Testing *(continued)* | May 1, 2017 | edition, 2017, Coronary Artery Disease – 9p21 Allele ACG: A-0657 (AC)" | |
| Omnibus Codes | Jun. 1, 2017 | • Revised coverage rationale for **instrument-based ocular screening using photoscreening for vision screening (CPT codes 99174 and 99177)**; updated list of proven/medically necessary indications:<br>○ Replaced "as a mass screening instrument for children 1-*2* years of age (ends on *3rd* birthday)" with "as a mass screening instrument for children 1-*3* years of age (ends on *4th* birthday)"<br>○ Replaced "children *3* years of age and older who are developmentally delayed and are unable or unwilling to cooperate with routine visual acuity screening" with "children *4* years of age and older who are developmentally delayed and are unable or unwilling to cooperate with routine visual acuity screening"<br>• Updated supporting information to reflect the most current clinical evidence and references | Refer to the policy for complete details on the coverage guidelines for Omnibus Codes. |

## Medical Policy Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **REVISED** | | | |
| Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins | Jul. 1, 2017 | • Updated list of related policies; added reference link to policy titled *Embolization of the Ovarian and Iliac Veins for Pelvic Congestion Syndrome*<br>• Revised coverage rationale; added language to indicate endovascular embolization of varicose veins using cyanoacrylate-based adhesive is unproven and not medically necessary for treating venous reflux<br>• Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references | **Varicose Vein Ablative and Stripping Procedures**<br>**Radiofrequency ablation, endovenous laser ablation, stripping, ligation and excision of the great saphenous vein and small saphenous veins are considered reconstructive and medically necessary when ALL of the following criteria are present**:<br>• Junctional Reflux (see *Definitions* section of the policy):<br>  ○ Ablative therapy for the great or small saphenous veins will be considered reconstructive and therefore medically necessary only if junctional reflux is demonstrated in these veins; or<br>  ○ Ablative therapy for accessory veins will be considered reconstructive and medically necessary only if anatomically related persistent junctional reflux is demonstrated after the great or small saphenous veins have been removed or ablated.<br>• Member must have one of the following functional impairments:<br>  ○ Skin ulceration; or<br>  ○ Documented episode(s) of frank bleeding of the varicose vein due to erosion of/or trauma to the skin; or<br>  ○ Documented superficial thrombophlebitis or documented venous stasis dermatitis; or<br>  ○ Moderate to severe pain causing functional/physical impairment.<br>• Venous Size:<br>  ○ The great saphenous vein must be 5.5 mm or greater when measured at the proximal thigh immediately below the saphenofemoral junction via duplex ultrasonography.<br>  ○ The small saphenous vein or accessory veins must measure 5 mm or greater in diameter immediately below the appropriate junction.<br>• Duration of reflux, in the standing or reverse Trendelenburg position that meets the following parameters:<br>  ○ Greater than or equal to 500 milliseconds (ms) for the great saphenous, small saphenous or principle tributaries.<br>  ○ Perforating veins > 350 ms.<br>  ○ Some duplex ultrasound readings will describe this as moderate to severe reflux which will be acceptable.<br><br>**Ablation of perforator veins is considered reconstructive and medically necessary when the following criteria are present**:<br>• Evidence of perforator venous insufficiency measured by recent duplex ultrasonography report (see criteria above); and<br>• Perforator vein size is 3.5 mm or greater; and |

## Medical Policy Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **REVISED** | | | |
| Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins *(continued)* | Jul. 1, 2017 | | • Perforating vein lies beneath a healed or active venous stasis ulcer.<br><br>**Endovenous mechanochemical ablation (MOCA) of varicose veins using a percutaneous infusion catheter is unproven and not medically necessary for treating venous reflux**.<br>There is insufficient evidence in the clinical literature supporting the safety and efficacy of MOCA for treating varicose veins. Further results from large, well-designed studies are needed to support the clinical utility of this approach.<br><br>**Ligation Procedures**<br>**Ligation of the great saphenous vein at the saphenofemoral junction, as a stand-alone procedure, is unproven and not medically necessary for treating venous reflux**.<br>Ligation performed without stripping or ablation is associated with high long-term recurrence rates due to neovascularization.<br><br>**Ligation of the small saphenous vein at the saphenopopliteal junction, as a stand-alone procedure, is unproven and not medically necessary for treating venous reflux**.<br>Ligation performed without stripping or ablation is associated with high long-term recurrence rates due to neovascularization.<br><br>**Ligation at the saphenofemoral junction, as a stand-alone procedure, is proven and medically necessary, when used to prevent the propagation of an active clot to the deep venous system in patients with ascending superficial thrombophlebitis who fail or are intolerant of anticoagulation therapy**.<br><br>**Ligation at the saphenofemoral junction, as an adjunct to radiofrequency ablation or endovenous laser ablation of the main saphenous veins, is unproven and not medically necessary for treating venous reflux**.<br>Published clinical evidence has not demonstrated that the addition of saphenofemoral ligation to endovenous ablation procedures provides an additive benefit in resolving venous reflux or preventing varicose vein recurrence. Endovenous ablation is a clinically effective therapy for treating venous reflux. Adding ligation to the procedure adds clinical risk without adding clinical benefit. |

## Medical Policy Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **REVISED** | | | |
| Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins *(continued)* | Jul. 1, 2017 | | **Endovascular embolization of varicose veins using cyanoacrylate-based adhesive is unproven and not medically necessary for treating venous reflux.**<br>There is insufficient evidence in the published clinical literature supporting the safety and efficacy of endovascular embolization using cyanoacrylate-based adhesive for treating varicose veins. Further long-term results from large, well-designed studies are needed to support the clinical utility of this approach. |

## Medical Benefit Drug Policy Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **UPDATED** | | | |
| Actemra® (Tocilizumab) Injection for Intravenous Infusion | May 1, 2017 | • Reformatted and reorganized policy; transferred content to new template<br>○ Changed policy type classification from "Drug Policy" to "Medical Benefit Drug Policy" to clarify policy guidelines apply to drug coverage provided under the medical benefit<br>• Removed list of applicable ICD-9 codes (discontinued Oct. 1, 2015)<br>• Updated supporting information to reflect the most current background information, clinical evidence, FDA information, and references<br>○ Replaced reference to "Milliman Care Guidelines®, Ambulatory Care, 19th edition" with "MCG™ Care Guidelines, Ambulatory Care, 21st edition" | 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.<br><br>This policy refers to Actemra (tocilizumab) injection for intravenous infusion.<br><br>**Actemra is proven and medically necessary for the treatment of**:<br>1. **Polyarticular juvenile idiopathic arthritis** when **all** of the following criteria are met:<br>a. Diagnosis of polyarticular juvenile idiopathic arthritis (PJIA)<br>**AND**<br>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):<br>(1) 10mg/kg every 4 weeks for patients weighing < 30kg<br>(2) 8mg/kg every 4 weeks for patients weighing ≥ 30kg<br>**AND**<br>c. Patient is **not** receiving Actemra in combination with either of the following:<br>(1) Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]<br>(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]<br><br>2. **Rheumatoid arthritis** when **all** of the following criteria are met:<br>a. Diagnosis of moderately to severely active rheumatoid arthritis (RA)<br>**AND**<br>b. History of failure, contraindication, or intolerance to at least **one** non-biologic DMARD [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, minocycline, etc.]<br>**AND**<br>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)<br>**AND**<br>d. Patient is **not** receiving Actemra in combination with either of the |

## Medical Benefit Drug Policy Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **UPDATED** | | | |
| Actemra® (Tocilizumab) Injection for Intravenous Infusion *(continued)* | May 1, 2017 | | following:<br>(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]<br>(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]<br><br>3. **Systemic juvenile idiopathic arthritis** when **all** of the following criteria are met:<br>a. Diagnosis of systemic juvenile idiopathic arthritis (SJIA)<br>**AND**<br>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):<br>(1) 12mg/kg every 2 weeks for patients weighing < 30kg<br>(2) 8mg/kg every 2 weeks for patients weighing ≥ 30kg<br>**AND**<br>c. Patient is **not** receiving Actemra in combination with either of the following:<br>(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]<br>(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] |
| Orencia® (Abatacept) Injection for Intravenous Infusion | May 1, 2017 | • Reformatted and reorganized policy; transferred content to new template<br>○ Changed policy type classification from "Drug Policy" to "Medical Benefit Drug Policy" to clarify policy guidelines apply to drug coverage provided under the medical benefit<br>• Removed list of applicable ICD-9 codes (discontinued Oct. 1, 2015)<br>• Updated supporting information to reflect the most current clinical evidence, FDA information, and references<br>○ Replaced reference to | This policy refers to Orencia (abatacept) injection for intravenous infusion.<br><br>**Orencia is proven and medically necessary for the treatment of**:<br>1. **Polyarticular juvenile idiopathic arthritis** when **all** of the following criteria are met:<br>a. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA)<br>**AND**<br>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):<br>(1) 10mg/kg every 4 weeks for patients weighing <75kg<br>(2) 1,000mg every 4 weeks for patients weighing ≥75kg<br>**AND**<br>c. Patient is **not** receiving Orencia in combination with either of the following:<br>(1) Biologic disease-modifying antirheumatic drug (DMARD) [e.g., |

## Medical Benefit Drug Policy Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **UPDATED** | | | |
| Orencia® (Abatacept) Injection for Intravenous Infusion *(continued)* | May 1, 2017 | "MCG®, Ambulatory Care, 19th edition" with "MCG™ Care Guidelines, Ambulatory Care, 21st edition" | Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]<br>(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]<br><br>2. **Rheumatoid arthritis** when **all** of the following criteria are met:<br>a. Diagnosis of moderately to severely active rheumatoid arthritis (RA) **AND**<br>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):<br>(1) 500mg every 4 weeks for patients weighing <60kg<br>(2) 750mg every 4 weeks for patients weighing 60kg to 100kg<br>(3) 1,000mg every 4 weeks for patients weighing >100kg **AND**<br>c. Patient is **not** receiving Orencia in combination with either of the following:<br>(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]<br>(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]<br><br>**Orencia is unproven and not medically necessary for the treatment of**:<br>1. Multiple sclerosis<br>2. Systemic lupus erythematosus<br>3. Graft versus host disease (GVHD)<br>4. Psoriatic arthropathy<br>5. Uveitis associated with Behçet's disease |
| Simponi Aria® (Golimumab) Injection for Intravenous Infusion | Jun. 1, 2017 | • Reformatted and reorganized policy; transferred content to new template<br>○ Changed policy type classification from "Drug Policy" to "Medical Benefit Drug Policy" to clarify policy guidelines apply to drug coverage provided under the medical benefit<br>• Updated coverage rationale; | **Simponi Aria is proven and medically necessary for the treatment of:**<br>1. **Rheumatoid arthritis** when **all** of the following criteria are met.<br>a. Diagnosis of moderately to severely active rheumatoid arthritis (RA) **AND**<br>b. **One** of the following:<br>(1) Patient is receiving concurrent therapy with methotrexate<br>(2) History of contraindication or intolerance to methotrexate **AND**<br>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 |

## Medical Benefit Drug Policy Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **UPDATED** | | | |
| Simponi Aria® (Golimumab) Injection for Intravenous Infusion *(continued)* | Jun. 1, 2017 | added language to clarify:<br>○ This policy refers *only* to Simponi Aria (golimumab) injectin *for intravenous infusion for the treatment of rheumatoid arthritis*"<br>○ Simponi for self-administered subcutaneous injection is obtained under the pharmacy benefit and is indicated in the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis<br>• Removed list of applicable ICD-9 codes (discontinued Oct. 1, 2015)<br>• Updated supporting information to reflect the most current clinical evidence, FDA information, and references<br>○ Replaced reference to "MCG®, Ambulatory Care, 19th edition" with "MCG™ Care Guidelines, Ambulatory Care, 21st edition" | schedule)<br>**AND**<br>d. Patient is **not** receiving Simponi Aria in combination with either of the following:<br>(1) Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]<br>(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] |
| Stelara® (Ustekinumab) | Jun. 1, 2017 | • Updated policy template/header; changed policy type classification from "Drug Policy" to "Medical Benefit Drug Policy" to clarify policy guidelines apply to drug coverage provided under the medical benefit<br>• Updated list of applicable codes; added maximum dosage requirements<br>• Updated supporting information | This policy refers to Stelara (ustekinumab) injection.<br><br>**Stelara is proven and medically necessary for the treatment of:**<br>1. **Crohn's disease** when **all** of the following criteria are met:<br>a. Diagnosis of moderately to severely active Crohn's disease<br>**AND**<br>b. **One** of the following:<br>(1) History of failure, contraindication, or intolerance to at least **one** tumor necrosis factor (TNF) blocker [e.g., Remicade/Inflectra (infliximab), Humira (adalimumab), Cimzia (certolizumab)]<br>**OR** |

## Medical Benefit Drug Policy Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **UPDATED** | | | |
| Stelara® (Ustekinumab) *(continued)* | Jun. 1, 2017 | to reflect the most current clinical evidence and references | (2) **Both** of the following:<br>(a) History of failure, contraindication, or intolerance to at least **one** immunomodulator or corticosteroid (e.g., corticosteroids, 6-mercaptopurine, azathioprine, methotrexate, etc.)<br>(b) Patient has never failed a TNF blocker [e.g., Remicade/Inflectra (infliximab), Humira (adalimumab), Cimzia (certolizumab)]<br>**AND**<br>c. **One** of the following:<br>(1) **Initial Therapy:**<br>(a) Stelara is to be administered as an intravenous induction dose<br>**AND**<br>(b) Stelara induction dosing is accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's disease:<br>i. 260mg for patients weighing ≤55kg<br>ii. 390mg for patients weighing >55kg to ≤85kg<br>iii. 520mg for patients weighing >85kg<br>**AND**<br>(c) Patient is not receiving Stelara in combination with **any** of the following:<br>i. Biologic DMARD [e.g., Remicade/Inflectra (infliximab), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]<br>ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]<br>iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]<br>**AND**<br>(d) Authorization will be for one induction dose.<br>**OR**<br>(2) **Continuation Therapy:**<br>(a) Patient is unable to self-administer subcutaneous doses<br>**AND**<br>(b) Stelara is to be subcutaneously administered 8 weeks after the initial intravenous dose.<br>**AND**<br>(c) Stelara continuation dosing is in accordance with the United |

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **UPDATED** | | | |
| Stelara® (Ustekinumab) *(continued)* | Jun. 1, 2017 | | States Food and Drug Administration approved labeled dosing for Crohn's disease:<br>i. 90mg every 8 weeks subcutaneously<br>**AND**<br>(d) Patient is not receiving Stelara in combination with **any** of the following:<br>i. Biologic DMARD [e.g., Remicade/Inflectra (infliximab), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]<br>ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]<br>iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]<br><br>2. **Plaque psoriasis** when **all** of the following criteria are met:<br>a. Diagnosis of moderate to severe plaque psoriasis.<br>**AND**<br>b. **One** of the following:<br>(1) Patient is a candidate for phototherapy<br>(2) Patient is a candidate for systemic therapy.<br>**AND**<br>c. Patient is unable to self-administer subcutaneous doses<br>**AND**<br>d. 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):<br>(1) 45mg every 12 weeks for patients weighing ≤100kg subcutaneously<br>(2) 90mg every 12 weeks for patients weighing >100kg subcutaneously<br>**AND**<br>e. Patient is not receiving Stelara in combination with **any** of the following:<br>(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]<br>(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]<br>(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]<br><br>3. **Psoriatic arthritis** when **all** of the following criteria are met:<br>a. Diagnosis of psoriatic arthritis. |

## Medical Benefit Drug Policy Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **UPDATED** | | | |
| Stelara® (Ustekinumab) *(continued)* | Jun. 1, 2017 | | **AND**<br>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 subcutaneously (or equivalent dose and interval schedule)<br>**AND**<br>c. Patient is unable to self-administer subcutaneous doses<br>**AND**<br>d. Patient is not receiving Stelara in combination with **any** of the following:<br>(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]<br>(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]<br>(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]<br><br>**Stelara is unproven and not medically necessary for the treatment of:**<br>1. Multiple sclerosis<br><br>In available studies, Stelara does not demonstrate efficacy in the treatment of multiple sclerosis. |
| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| **REVISED** | | | |
| Entyvio® (Vedolizumab) | Jul. 1, 2017 | • Reformatted and reorganized policy; transferred content to new template<br>○ Changed policy type classification from "Drug Policy" to "Medical Benefit Drug Policy" to clarify policy guidelines apply to drug coverage provided under the medical benefit<br>• Revised coverage rationale; added language to indicate:<br>○ Initial authorization will be for no more than 14 weeks<br>○ For continuation therapy, the | **Entyvio (vedolizumab) is proven and medically necessary for the treatment of**:<br>1. **Crohn's disease** when **all** of the following criteria are met:<br>a. For **initial therapy, all** of the following:<br>(1) Diagnosis of moderately to severely active Crohn's disease (CD)<br>**AND**<br>(2) **One** of the following:<br>(a) History of failure, contraindication, or intolerance to at least **one** of the following conventional therapies:<br>i. Tumor necrosis factor (TNF) blocker [e.g., Humira (adalimumab), Cimzia (certolizumab)]<br>ii. Immunomodulator (e.g., azathioprine, 6-mercaptopurine)<br>iii. Corticosteroid<br>(b) Corticosteroid dependent (e.g., unable to successfully taper |

## Medical Benefit Drug Policy Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **REVISED** | | | |
| Entyvio® (Vedolizumab) *(continued)* | Jul. 1, 2017 | following criteria must be met:<br>▪ Documentation of positive clinical response to Entyvio; and<br>▪ Dosing for Crohn's disease or ulcerative colitis is in accordance with the FDA labeled dosing up to a maximum of 300mg every 8 weeks (or equivalent dose and interval schedule)<br>▪ Reauthorization will be for no more than 12 months<br>• Updated list of applicable codes; added maximum dosage requirements<br>• Updated supporting information to reflect the most current references | corticosteroids without a return of the symptoms of CD)<br>**AND**<br>(3) Entyvio is initiated and titrated according to US Food and Drug Administration (FDA) labeled dosing for Crohn's disease up to a maximum of 300mg every 8 weeks (or equivalent dose and interval schedule)<br>**AND**<br>(4) Patient is **not** receiving Entyvio in combination with either of the following:<br>(a) Tumor necrosis factor (TNF) blocker [e.g., Humira (adalimumab), Cimzia (certolizumab)]<br>(b) Tysabri (natalizumab)<br>**AND**<br>(5) Initial authorization will be for no more than 14 weeks<br>b. For **continuation therapy, all** of the following:<br>(1) Documentation of positive clinical response to Entyvio<br>**AND**<br>(2) Entyvio dosing for Crohn's disease is in accordance with the FDA labeled dosing up to a maximum of 300mg every 8 weeks (or equivalent dose and interval schedule)<br>**AND**<br>(3) Reauthorization will be for no more than 12 months<br><br>2. **Ulcerative colitis** when **all** of the following criteria are met:<br>a. For **initial therapy, all** of the following:<br>(1) Diagnosis of moderately to severely active ulcerative colitis (UC)<br>**AND**<br>(2) **One** of the following:<br>(a) History of failure, contraindication, or intolerance to at least **one** of the following conventional therapies:<br>i. Tumor necrosis factor (TNF) blocker [e.g., Humira (adalimumab), Simponi (golimumab)]<br>ii. Immunomodulator (e.g., azathioprine, 6-mercaptopurine)<br>iii. Corticosteroid<br>(b) Corticosteroid dependent (e.g., unable to successfully taper corticosteroids without a return of the symptoms of UC)<br>**AND**<br>(3) Entyvio is initiated and titrated according to US Food and Drug |

## Medical Benefit Drug Policy Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **REVISED** | | | |
| Entyvio® (Vedolizumab) *(continued)* | Jul. 1, 2017 | | Administration labeled dosing for ulcerative colitis up to a maximum of 300mg every 8 weeks (or equivalent dose and interval schedule)<br>**AND**<br>(4) Patient is **not** receiving Entyvio in combination with either of the following:<br>(a) Tumor necrosis factor (TNF) blocker [e.g., Humira (adalimumab), Simponi (golimumab)]<br>(b) Tysabri (natalizumab)<br>**AND**<br>(5) Initial authorization will be for no more than 14 weeks<br>b. For **continuation therapy, all** of the following:<br>(1) Documentation of positive clinical response to Entyvio<br>**AND**<br>(2) Entyvio dosing for ulcerative colitis is in accordance with the FDA labeled dosing up to a maximum of 300mg every 8 weeks (or equivalent dose and interval schedule)<br>**AND**<br>(3) Reauthorization will be for no more than 12 months |
| Lemtrada (Alemtuzumab) | Jun. 1, 2017 | • Reformatted and reorganized policy; transferred content to new template<br>○ Changed policy type classification from "Drug Policy" to "Medical Benefit Drug Policy" to clarify policy guidelines apply to drug coverage provided under the medical benefit<br>• Revised coverage rationale:<br>○ Updated list of drugs (options) for which history of failure, contraindication, or intolerance must be demonstrated when treatment-naïve to alemtuzumab; added:<br>▪ natalizumab (Tysabri®) | **Lemtrada (alemtuzumab) is proven and medically necessary for treatment of relapsing-remitting multiple sclerosis when all of the following criteria are met:**<br>1. Diagnosis of relapsing-remitting multiple sclerosis (RRMS)<br>**AND**<br>2. **One** of the following:<br>a. **Treatment-naïve to alemtuzumab:**<br>(1) Patient has history of failure following a trial for at least 4 weeks **or** history of intolerance or contraindication to **two** of the following:<br>• Interferon β-1a (Avonex® or Rebif®)<br>• Interferon β-1b (Betaseron® or Extavia®)<br>• Glatiramer acetate (Copaxone®)<br>• Dimethyl fumarate (Tecfidera®)<br>• Teriflunomide (Aubagio®)<br>• Fingolimod (Gilenya®)<br>• Peginterferon beta-1a (Plegridy™)<br>• Natalizumab (Tysabri®)<br>• Daclizumab (Zinbryta™) |

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|---|---|---|---|
| **REVISED** | | | |
| Lemtrada (Alemtuzumab) *(continued)* | Jun. 1, 2017 | ▪ daclizumab (Zinbryta™)<br>▪ ocrelizumab (Ocrevus®)<br>○ Replaced criterion requiring "patient is not receiving alemtuzumab in combination with another disease modifying agent (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, *or* teriflunomide) " with "patient is not receiving alemtuzumab in combination with another disease modifying agent *for multiple sclerosis* (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, teriflunomide, *etc.*)"<br>• Updated supporting information to reflect the most current background information, clinical evidence, CMS information, and references | • Ocrelizumab (Ocrevus®)<br>**AND**<br>(2) Patient has not been previously treated with alemtuzumab<br>**AND**<br>(3) Patient is **not** receiving alemtuzumab in combination with another disease modifying agent for multiple sclerosis (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, teriflunomide, etc.)<br>**AND**<br>(4) Initial dosing is administered: 12 mg intravenously daily for 5 consecutive days<br>**AND**<br>(5) Regimen is administered only once within 12 months<br>**OR**<br>b. **Treatment-experienced with alemtuzumab:**<br>(1) Patient has previously received treatment with alemtuzumab<br>**AND**<br>(2) Patient is **not** receiving alemtuzumab in combination with another disease modifying agent for multiple sclerosis (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, teriflunomide, etc.)<br>**AND**<br>(3) Retreatment dosing is administered: 12 mg intravenously daily for 3 consecutive days<br>**AND**<br>(4) Regimen is administered only once within 12 months.<br><br>Coverage of Lemtrada is limited to up to two treatment courses (5 day initial and 3 day end course). Requests for additional doses/courses beyond two courses will not be approved.<br><br>**Alemtuzumab is unproven for the treatment of**:<br>1. Rheumatoid arthritis<br>2. Autoimmune neutropenia<br>3. Autoimmune hemolytic anemia<br>4. Pure red cell aplasia<br>5. Immune thrombocytopenic purpura<br>6. Evans syndrome<br>7. Autoimmune pancytopenia |

# Medical Benefit Drug Policy Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **REVISED** | | | |
| Oncology Medication Clinical Coverage Policy | Jun. 1, 2017 | • Reformatted and reorganized policy; transferred content to new template<br>  ○ Changed policy type classification from "Drug Policy" to "Medical Benefit Drug Policy" to clarify policy guidelines apply to drug coverage provided under the medical benefit<br>• Revised coverage rationale:<br>  ○ Replaced language indicating "this policy provides parameters for coverage of injectable oncology medications (J9000 - J9999) and select *other medications used* for oncology conditions [including, but not limited to octreotide acetate (J2353 and J2354) and leuprolide acetate (J1950)] covered under the medical benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®)" with "this policy provides parameters for coverage of injectable oncology medications (J9000 - J9999) and select *ancillary and supportive care medications* for oncology conditions [including, but not limited to octreotide acetate (J2353 and J2354), leuprolide acetate (J1950), *leucovorin* | **Description**<br>This policy provides parameters for coverage of injectable oncology medications (J9000 - J9999) and select ancillary and supportive care medications for oncology conditions [including, but not limited to octreotide acetate (J2353 and J2354), leuprolide acetate (J1950), leucovorin (J0640) and levoleucovorin (J0641)] covered under the medical benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®). The Compendium lists the appropriate drugs and biologics for specific cancers using US Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category.<br><br>**Coverage Rationale**<br>UnitedHealthcare recognizes indications and uses of injectable oncology medications listed in the NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as **proven and medically necessary**, and Categories of Evidence and Consensus of 3 as **unproven and not medically necessary**. (However, see *Benefit Considerations* section of the policy.)<br><br>UnitedHealthcare will cover all chemotherapy agents for individuals under the age of 19 years for oncology indications. The majority of pediatric patients receive treatments on national pediatric protocols that are quite similar in concept to the NCCN patient care guidelines.<br><br>Select ancillary and supportive care medications for oncology conditions have therapeutically equivalent products available. When a therapeutically equivalent alternative is available, as determined by the United Healthcare Pharmacy and Therapeutics (P&T) Committee, certain medications may be excluded and/or not medically necessary. For purposes of the United Healthcare P&T Committee review, therapeutic equivalence refers to medications that can be expected to produce essentially the same therapeutic outcome and adverse events.<br><br>Below are ancillary and supportive care medications for oncology conditions with therapeutically equivalent alternatives as determined by the United Healthcare P&T Committee:<br>• Leucovorin (Preferred) |

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|---|---|---|---|
| **REVISED** | | | |
| Oncology Medication Clinical Coverage Policy *(continued)* | Jun. 1, 2017 | *(J0640), and levoleucovorin (J0641)*] covered under the medical benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®)"<br>○ Added language to indicate:<br>▪ Select ancillary and supportive care medications for oncology conditions have therapeutically equivalent products available<br>▪ When a therapeutically equivalent alternative is available, as determined by the UnitedHealthcare Pharmacy and Therapeutics (P&T) Committee, certain medications may be excluded and/or not medically necessary<br>▪ For purposes of the UnitedHealthcare P&T Committee review, therapeutic equivalence refers to medications that can be expected to produce essentially the same therapeutic outcome and adverse events<br>▪ Leucovorin (preferred) and Levoleucovorin (non-preferred) are | • Levoleucovorin (Non-Preferred)<br><br>***Additional Information***<br>The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) are a comprehensive set of guidelines documenting sequential management decisions and interventions and interventions that apply to malignancies which affect about 97% of all patients with cancer. They also address supportive care issues. The guidelines are developed and updated by 67 individual panels, composed of more than 1000 clinicians and oncology researchers from the 26 NCCN member institutions and their affiliates.<br><br>***NCCN Categories of Evidence and Consensus***<br>**Category 1**<br>The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the panel has reached uniform consensus that the recommendation is indicated. In this context, uniform means near unanimous positive support with some possible neutral positions.<br><br>**Category 2A**<br>The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate. Lower level evidence is interpreted broadly, and runs the gamut from phase II to large cohort studies to case series to individual practitioner experience. Importantly, in many instances, the retrospective studies are derived from clinical experience of treating large numbers of patients at a member institution, so panel members have first-hand knowledge of the data. Inevitably, some recommendations must address clinical situations for which limited or no data exist. In these instances the congruence of experience-based opinions provides an informed if not confirmed direction for optimizing patient care. These recommendations carry the implicit recognition that they may be superseded as higher level evidence becomes available or as outcomes-based information becomes more prevalent.<br><br>**Category 2B**<br>The recommendation is based on lower level evidence, and there is nonuniform consensus that the recommendation should be made. In these |

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| Oncology Medication Clinical Coverage Policy *(continued)* | Jun. 1, 2017 | ancillary and supportive care medications for oncology conditions with therapeutically equivalent alternatives as determined by the UnitedHealthcare P&T Committee | instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This nonuniform consensus does not represent a major disagreement, rather it recognizes that given imperfect information, institutions may adopt different approaches. A Category 2B designation should signal to the user that more than one approach can be inferred from the existing data.<br><br>**Category 3**<br>The recommendation has engendered a major disagreement among the panel members. Several circumstances can cause major disagreements. For example, if substantial data exist about two interventions but they have never been directly compared in a randomized trial, adherents to one set of data may not accept the interpretation of the other side's results. Another situation resulting in a Category 3 designation is when experts disagree about how trial data can be generalized. A Category 3 designation alerts users to a major interpretation issue in the data and directs them to the manuscript for an explanation of the controversy. |
| Spinraza™ (Nusinersen) | May 1, 2017 | • Revised coverage rationale; modified coverage criteria for treatment of spinal muscular atrophy (SMA):<br>○ Replaced criterion requiring "patient is not dependent on non-invasive ventilation *for at least 6 hours per day*" with "patient is not dependent on *use of* non-invasive ventilation *beyond use for naps and nighttime sleep*" | **Spinraza™ (nusinersen) is proven and medically necessary for**:<br>1. **The treatment of Spinal Muscular Atrophy (SMA) in patients who meet ALL of the following criteria**:<br>a. For **initial therapy**, **all** of the following:<br>(1) ONE of the following:<br>(a) Diagnosis of spinal muscular atrophy type I, II, or III by a neurologist with expertise in the diagnosis of SMA<br>(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;<br>**AND**<br>(2) Submission of medical records (e.g., chart notes, laboratory values) confirming BOTH of the following:<br>(a) The mutation or deletion of genes in chromosome 5q resulting in ONE of the following:<br>i. Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13);<br>**OR**<br>ii. Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2]);<br>**AND** |

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|---|---|---|---|
| **REVISED** | | | |
| Spinraza™ (Nusinersen) *(continued)* | May 1, 2017 | | (b) Patient has at least 2 copies of SMN2;<br>**AND**<br>(3) Patient is not dependent on either of the following:<br>(a) Invasive ventilation or tracheostomy<br>(b) Non-invasive ventilation for at least 6 hours per day;<br>**AND**<br>(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:<br>(a) Hammersmith Infant Neurological Exam (HINE)(infant to early childhood)<br>(b) Hammersmith Functional Motor Scale Expanded (HFMSE)<br>(c) Upper Limb Module (ULM) Test (Non ambulatory)<br>(d) Children's Hospital of Philadelphia Infant Test of Neuromucular Disorders (CHOP INTEND);<br>**AND**<br>(5) ONE of the following:<br>(a) Spinraza is prescribed by a neurologist with expertise in the treatment of SMA<br>(b) Spinraza is prescribed by a physician in consultation with a neurologist with expertise in the treatment of SMA;<br>**AND**<br>(6) Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures;<br>**AND**<br>(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;<br>**AND**<br>(8) Initial authorization will be for no more than 4 loading doses.<br>b. For **continuation therapy**, **all** of the following:<br>(1) ONE of the following:<br>(a) Diagnosis of spinal muscular atrophy type I, II, or III by a neurologist with expertise in the diagnosis of SMA<br>(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; |

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| **REVISED** | | | |
| Spinraza™ (Nusinersen) *(continued)* | May 1, 2017 | | **AND**<br>(2) Submission of medical records (e.g., chart notes, laboratory values) confirming BOTH of the following:<br>(a) The mutation or deletion of genes in chromosome 5q resulting in ONE of the following:<br>i. Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13);<br>**OR**<br>ii. Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2]);<br>**AND**<br>(b) Patient has at least 2 copies of SMN2;<br>**AND**<br>(3) Patient is not dependent on either of the following:<br>(a) Invasive ventilation or tracheostomy<br>(b) Non-invasive ventilation for at least 6 hours per day;<br>**AND**<br>(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:<br>(a) HINE milestones:<br>i. ONE of the following:<br>(i) Improvement or maintenance of previous improvement of at least 2 point (or maximal score) increase in ability to kick<br>(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;<br>**AND**<br>ii. ONE of the following:<br>(i) The patient exhibited improvement or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement)<br>(ii) Achieved and maintained any new motor milestones when they would otherwise be unexpected to do so |

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **REVISED** | | | |
| Spinraza™ (Nusinersen) *(continued)* | May 1, 2017 | | (e.g., sit unassisted, stand, walk);<br>**OR**<br>(b) HFMSE: ONE of the following:<br>i. Improvement or maintenance of previous improvement of at least a 3 point increase in score from pretreatment baseline<br>ii. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so;<br>**OR**<br>(c) ULM: ONE of the following:<br>i. Improvement or maintenance of previous improvement of at least a 2 point increase in score from pretreatment baseline<br>ii. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so;<br>**OR**<br>(d) CHOP INTEND: ONE of the following:<br>i. Improvement or maintenance of previous improvement of at least a 4 point increase in score from pretreatment baseline<br>ii. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so;<br>**AND**<br>(5) ONE of the following:<br>(a) Spinraza is prescribed by a neurologist with expertise in the treatment of SMA<br>(b) Spinraza is prescribed by a physician in consultation with a neurologist with expertise in the treatment of SMA;<br>**AND**<br>(6) Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures;<br>**AND**<br>(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 |

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| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **REVISED** | | | |
| Spinraza™ (Nusinersen) *(continued)* | May 1, 2017 | | loading dose;<br>**AND**<br>(8) Reauthorization will be for no more than 3 maintenance doses (12 months).<br><br>**Spinraza is not proven or medically necessary for spinal muscular atrophy without chromosome 5q mutations or deletions**. |

## Coverage Determination Guideline (CDG) Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **UPDATED** | | | |
| Ambulance Services | May 1, 2017 | • Updated list of related policies; added reference link to Medicare Advantage Coverage Summary titled *Ambulance Services* (no change to coverage rationale or lists of applicable codes) | **Indications for Coverage**<br>***Emergency Ambulance (Ground, Water, or Air)***<br>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.<br><br>Check the member specific benefit plan document for prior authorization and notification requirements.<br><br>The following Emergency ambulance services are covered:<br>• Ground ambulance or air ambulance transportation requiring basic life support or advanced life support.<br>• Treatment at the scene (paramedic services) without ambulance transportation.<br>• Wait time associated with covered ambulance transportation.<br>• To a hospital that provides a required higher level of care that was not available at the original hospital.<br><br>***Air Ambulance***<br>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.<br><br>Air ambulance transportation should meet the following criteria:<br>• The patient's destination is an acute care hospital, and<br>• The patient's condition is such that the ground ambulance (basic or advanced life support) would endanger the member's life or health, or<br>• Inaccessibility to ground ambulance transport or extended length of time required to transport the patient via ground ambulance transportation could endanger the member, or<br>• Weather or traffic conditions make ground ambulance transportation impractical, impossible, or overly time consuming.<br><br>Refer to Medicare Benefit Policy Manual in the *References* section. |

## Coverage Determination Guideline (CDG) Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **UPDATED** | | | |
| Ambulance Services *(continued)* | May 1, 2017 | | **Additional Information**<br>• 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.<br><br>***Non-Emergency Ambulance (Ground or Air) Between Facilities***<br>Coverage includes non-emergency ambulance transportation by a licensed ambulance service (either ground or air ambulance, as we determine appropriate) between facilities when the transport is any of the following:<br>• From a non-Network Hospital to the closest Network Hospital.<br>• To the closest Network Hospital or facility that provides Covered Health Services that were not available at the original Hospital or facility.<br>• From a short-term acute care facility to the closest Network long-term acute care facility (LTAC), Network Inpatient Rehabilitation Facility, or other Network sub-acute facility.<br><br>***Cost Effective Alternatives (UHIC 2007 COC and 2009 Amendment)***<br>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.<br><br>***Medically Necessary (UHIC 2011 COC)***<br>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.<br><br>***Benefit Level for Non-Emergency Ambulance***<br>The applicable benefit for eligible non-Emergency ambulance transportation depends on the patient pick-up location (origin) as follows:<br>• 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 specific benefit plan document to determine benefits. The following are UHIC examples for inpatient ambulance transfer:<br>○ UHIC 2001 COC: The Hospital Inpatient Stay section of the COC |

## Coverage Determination Guideline (CDG) Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **UPDATED** | | | |
| Ambulance Services *(continued)* | May 1, 2017 | | ○ UHIC 2007 and 2011 COC: The Ambulance Services section of the COC<br>• If the patient is in a sub-acute setting and is transported to an outpatient 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.<br><br>***Member Pre-Service Notification Requirements for Non-Emergency Ambulance***<br>• If UHIC initiates the non-Emergency ambulance transportation, member notification is not required.<br>• 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 benefit plan document for details on the notification requirements.<br><br>**Additional Information**<br>• Provider notification requirements are not addressed by this document.<br>• Ambulance transportation that is done for convenience of the patient is not covered. Please see the Coverage Limitations and Exclusions section below for more information on non-covered ambulance transportation.<br><br>***Benefit Level for Non-Network Ambulance (Emergency)***<br>If the ambulance transportation is covered, non-network Emergency ambulance (ground, water, or air) is covered at the network level of deductible and coinsurance.<br><br>**Additional Information**<br>• 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.<br>• 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. |

## Coverage Determination Guideline (CDG) Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **UPDATED** | | | |
| Ambulance Services *(continued)* | May 1, 2017 | | • For UHIC Plans Without a Network (e.g., Managed Indemnity): These plans do not have network benefit levels. These plans do not require billed charges to be paid on ambulance services.<br><br>**Coverage Limitations and Exclusions**<br>The following services are not eligible for coverage:<br>• Ambulance services from providers that are not properly licensed to be performing the ambulance services rendered.<br>• Air ambulance that does not meet the covered indications in the Air Ambulance criteria listed above.<br>• 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.<br>• Ambulance transportation when other mode of transportation is appropriate. Except as indicated under the Indications for Coverage section of the policy, ambulance services when transportation by other means would not endanger the member's health are not covered.<br>• Ambulance transportation to a home, residential, domiciliary or custodial facility is not covered.<br>• Ambulance transportation that violates the notification criteria listed in the Indications for Coverage section above.<br>• Ambulance transportation for patient convenience or other miscellaneous reasons for patient and/or family.<br>• Examples include but are not limited to:<br>  ○ Patient wants to be at a certain hospital or facility for personal/preference reasons;<br>  ○ 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);<br>  ○ Patient is going to a routine service and is medically able to use another mode of transportation but can't find it;<br>  ○ Patient is deceased (i.e., transportation to the coroner's office or mortuary)<br>• Ambulance transportation deemed not appropriate. Examples include but are not limited to:<br>  ○ Hospital to home<br>  ○ Home to physician's office |

## Coverage Determination Guideline (CDG) Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **UPDATED** | | | |
| Ambulance Services *(continued)* | May 1, 2017 | | ○ Home (e.g., residence, nursing home, domiciliary or custodial facility) to a hospital for a scheduled service<br><br>***Additional Information***<br>• 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. |
| Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/ Replacements | May 1, 2017 | • Added coding guidelines to indicate:<br>○ UnitedHealthcare has adopted the requirements and intent of the National Correct Coding Initiative<br>○ The Centers for Medicare & Medicaid Services (CMS) has contracted with Noridian to manage Pricing, Data and Coding (PDAC) for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)<br>○ This notice is to confirm UnitedHealthcare has established the PDAC as its definitive source for correct coding and coding clarification | Refer to the policy for complete details on the coverage guidelines for Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/ Replacements. |
| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| **REVISED** | | | |
| Blepharoplasty, Blepharoptosis and Brow Ptosis Repair | Jun. 1, 2017 | • Revised coverage rationale:<br>○ Replaced references to "color photographs" with "*clear* color photographs"<br>○ Updated coverage criteria for **upper eyelid** | **Indications for Coverage**<br>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. |

## Coverage Determination Guideline (CDG) Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **REVISED** | | | |
| Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)* | Jun. 1, 2017 | **blepharoplasty**; replaced language indicating:<br>▪ "The color photograph must show the extra skin, but not the lid margin, *taped up* to show it reverses the visual field obstruction, and/*or* lateral hooding *present*" with "*clear* color photographs must show *that the extra skin is the primary cause of visual field obstruction*; the extra skin, but not the lid margin, is *elevated* to show it reverses the visual field obstruction, and lateral hooding *(if present) resolves*"<br>▪ "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* [is required]" with "automated peripheral or superior visual field testing, with the *eyelid skin* taped and un-taped, showing improvement of 30% or more [is required]"<br>○ Updated coverage criteria for **upper eyelid blepharoptosis repair**; replaced language indicating | ***Criteria for a Coverage Determination that Surgery is Reconstructive and Medically Necessary***<br>The following must be available when requested by UnitedHealthcare:<br>• Best corrected visual acuity in both eyes, all patients (except pediatrics)<br>• Eye exam (chief complaint, HPI)<br>• Clear color photographs (eye level, frontal with patient looking straight ahead, light reflex visible and centered)<br>• Peripheral or superior visual fields automated, reliable (refer to the *Definitions* section of the policy), un-taped/taped are preferable. Note the following:<br>○ In situations where computerized visual field testing is not available, we will accept manual visual field testing.<br>○ In situations where visual field testing is not possible, see section below: "When Patient is Not Capable of Visual Field Testing."<br><br>**Note**: The visual fields and color photographs must be consistent.<br><br>If multiple procedures are requested, the following criteria must be met:<br>• All criteria for each individual procedure must be met; and<br>• Visual field testing shows visual impairment which can't be addressed by one procedure alone; and<br>• Color photograph findings are consistent with visual field findings.<br><br>**Upper eyelid blepharoplasty (CPT 15822 and 15823) is considered reconstructive and medically necessary when the following criteria are present**:<br>• Ptosis has been ruled out as the primary cause of visual field obstruction; and<br>• Clear color photographs must show that the extra skin is the primary cause of visual field obstruction. The extra skin, but not the lid margin, is elevated to show it reverses the visual field obstruction; and lateral hooding (if present) resolves; and<br>• The patient must have a Functional/Physical Impairment complaint directly related to an abnormality of the eyelid(s); and<br>• Excess skin (dermatochalasis/blepharochalasis) touches the lashes; and<br>• Automated peripheral or superior visual field testing, with the eyelid skin taped and un-taped, showing improvement of 30% or more.<br>○ In situations where computerized visual field testing is not available, we will accept manual visual field testing. |

## Coverage Determination Guideline (CDG) Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **REVISED** | | | |
| Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)* | Jun. 1, 2017 | "upper eyelid blepharoptosis repair is considered reconstructive and medically necessary when other causes of ptosis are ruled out" with "upper eyelid blepharoptosis repair is considered reconstructive and medically necessary when other *treatable* causes of ptosis are ruled out"<br>○ Updated coverage criteria for **brow ptosis**:<br>▪ Replaced language indicating "a second photograph [is required] with the brow *taped up* that eliminates the visual field defect" with "a second photograph [is required] with the brow *elevated* that eliminates the visual field defect"<br>▪ Revised list of examples of brow lift procedures to include supra-ciliary, mid-forehead, coronal, or pretrichial direct brow lift vs. browpexy or internal brow lift<br>○ Updated coverage criteria for **entropion (eyelid turned inward)**; removed criterion requiring "conservative treatments have been tried and failed"<br>○ Updated coverage criteria for **canthoplasty/canthopex**:<br>▪ Removed criterion | ○ In situations where visual field testing is not possible, see section below: "When Patient is Not Capable of Visual Field Testing."<br><br>**Note**: Extended blepharoplasty may be indicated for blepharospasm (eyelids are forced shut) when the following two criteria are met:<br>• Debilitating symptoms (e.g., pain); and<br>• Conservative treatment has been tried and failed, or is contraindicated (e.g., Botox®).<br><br>**Upper eyelid blepharoptosis repair (CPT 67901–67909) is considered reconstructive and medically necessary when the following criteria are present**:<br>• The patient must have a Functional/Physical Impairment complaint directly related to the position of the eyelid(s); and<br>• Other treatable causes of ptosis are ruled out (e.g., recent Botox® injections, myasthenia gravis when applicable); and<br>• Eyelid droop (upper eyelid ptosis) and an MRD-1 of 2.0 mm or less; and<br>• The MRD is documented in clear color photographs with patient looking straight ahead and light reflex centered on the pupil; and<br>• 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.<br>○ In situations where computerized visual field testing is not available, we will accept manual visual field testing.<br>○ In situations where visual field testing is not possible, see section below: "When Patient is Not Capable of Visual Field Testing."<br>**Note**: For children under age 10 years, ptosis repair is covered to prevent amblyopia. Visual field testing is not required, but color photographs are required.<br><br>**Brow ptosis (CPT 67900) is considered reconstructive and medically necessary when the following criteria are present**:<br>• 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<br>• Patient must have a functional complaint related to brow ptosis. Brow ptosis must be documented in two color photographs. One showing the eyebrow below the bony superior orbital rim, and a second photograph with the brow elevated that eliminates the visual field defect; and |

## Coverage Determination Guideline (CDG) Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **REVISED** | | | |
| Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)* | Jun. 1, 2017 | requiring "conservative treatments have been tried and failed"<br>▪ Replaced criterion requiring "*simple* repair of ectropion or entropion will not correct condition" with "repair of ectropion or entropion will not correct condition"<br>○ Updated coverage criteria for **repair of floppy eyelid syndrome (FES)**; replaced criterion requiring "color photos that clearly document floppy eyelid syndrome*; the photographs must clearly* demonstrate both of the [listed criteria]" with "*clear* color photographs that clearly document floppy eyelid syndrome *and* demonstrate both of the [listed criteria]" | ○ Automated peripheral and superior visual field testing, with differential taping (eyebrow and eyebrow + eyelid) showing 30% or more improvement in total number of points seen with the eyebrow taped up. In situations where computerized visual field testing is not available, we will accept manual visual field testing.<br>○ In situations where visual field testing is not possible, see section below: "When Patient is Not Capable of Visual Field Testing."<br>• Documentation indicating the specific brow lift procedure (e.g., supra-ciliary, mid forehead or coronal, pretrichial, direct brow lift vs browpexy, internal brow lift).<br><br>**Note:** For Browpexy/internal brow lift, see Coverage Limitations and Exclusions.<br><br>**Eyelid surgery with an anophthalmic socket (has no eyeball) is considered reconstructive and medically necessary when both of the following criteria are present**:<br>• Patient has an anophthalmic condition; and<br>• Patient is experiencing difficulties fitting or wearing an ocular prosthesis.<br><br>**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**:<br>• There is documented facial nerve damage; and<br>• Clear color photographs document the pathology; and<br>• Patient is unable to close the eye due to the lower lid dysfunction; and<br>• Functional impairment including both of the following:<br>○ Documented uncontrolled tearing or irritation; and<br>○ Conservative treatments tried and failed.<br><br>**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**:<br>• Clear color photographs document the pathology; and<br>• Corneal or conjunctival injury with both of the following criteria:<br>○ Subjective symptoms include either:<br>▪ Pain or discomfort; or<br>▪ Excess tearing; and<br>○ Any one of the following: |

## Coverage Determination Guideline (CDG) Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **REVISED** | | | |
| Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)* | Jun. 1, 2017 | | ▪ Exposure keratitis; and/or<br>▪ Keratoconjunctivitis; and/or<br>▪ Corneal ulcer<br><br>**Entropion (eyelid turned inward) (CPT 67921–67924) is considered reconstructive and medically necessary when all of the following criteria are present**:<br>• Clear color photographs must document the following:<br>o Lid turned inward; and<br>o At least one of the following:<br>▪ Trichiasis; or<br>▪ Irritation of cornea or conjunctiva; and<br>o Subjective symptoms including either of the following:<br>▪ Excessive tearing; or<br>▪ Pain or discomfort<br><br>**Lid retraction surgery (CPT 67911) is considered reconstructive and medically necessary when all of the following criteria are present**:<br>• Other causes have been eliminated as the reason for the lid retraction such as use of dilating eye drops, glaucoma medications; and<br>• Clear color photographs document the pathology; and<br>• There is functional impairment (such as 'dry eyes', pain/discomfort, tearing, blurred vision); and<br>• Tried and failed conservative treatments; and<br>• In cases of thyroid eye disease two or more Hertel measurements at least 6 months apart with the same base measurements are unchanged.<br><br>**Canthoplasty/canthopexy (CPT 21280, 21282, 67950, 67961, 67966) is considered reconstructive and medically necessary when all of the following criteria are present**:<br>• Functional impairment; and<br>• Clear color photographs document the pathology; and<br>• Repair of ectropion or entropion will not correct condition; and<br>• At least one of the following patient complaints is present:<br>o Epiphora (excess tearing) not resolved by conservative measures; or<br>o Corneal dryness unresponsive to lubricants; or<br>o Corneal ulcer.<br><br>**Repair of floppy eyelid syndrome (FES) (CPT 67961 and 67966) is** |

## Coverage Determination Guideline (CDG) Updates

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| **REVISED** | | | |
| Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)* | Jun. 1, 2017 | | **considered reconstructive and medically necessary when all of the following are present when documented and confirmed by history and examination**:<br>• Subjective symptoms must include eyelids spontaneously "flipping over" when they sleep due to rubbing on the pillow, AND one of the following:<br>o Eye pain or discomfort; or<br>o Excess tearing; or<br>o Eye irritation, ocular redness and discharge<br>• Physical Examination that documents the following:<br>o Eyelash Ptosis; and<br>o Significant upper eyelid laxity; and<br>o Presence of Giant Papillary Conjunctivitis;<br>or<br>o Corneal findings such as:<br>▪ Superficial Punctate Erosions (SPK); or<br>▪ Corneal abrasion (documentation of a history of corneal abrasion or recurrent erosion syndrome is considered sufficient); or<br>▪ Microbial Keratitis<br>• Clear color photographs that clearly document floppy eyelid syndrome and demonstrate both of the following:<br>o Lids must be everted in the photographs; and<br>o Conjunctival surface (underbelly) of the lids must clearly demonstrate Giant Papillary Conjunctivitis<br>• Documentation that conservative treatment has been tried and failed, examples may include:<br>o Ocular lubricants both drops (daytime) and ointments (bedtime); or<br>o Short trial of antihistamines; or<br>o Topical steroid drops; or<br>o Eye Shield and/or Taping the lids at bedtime<br>• Other causes of the eye findings have been ruled out, examples may include:<br>o Allergic conjunctivitis<br>o Atopic keratoconjunctivitis<br>o Blepharitis<br>o Contact lens (CL) complication<br>o Dermatochalasis<br>o Ectropion<br>o GPC (giant papillary conjunctivitis) that is not related to FES<br>o Ptosis of the lid(s) |

## Coverage Determination Guideline (CDG) Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| **REVISED** | | | |
| Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)* | Jun. 1, 2017 | | ○ Superior limbic keratoconjunctivitis (SLK)<br><br>***When Patient Is Not Capable of Visual Field Testing***<br>Visual field testing is not required when the patient is not capable of performing a visual field test. The following are some examples:<br>• If the patient is a child 12 years old or under<br>• If the patient has intellectual disabilities (previously known as mental retardation) or some other severe neurologic disease<br><br>**Coverage Limitations and Exclusions**<br>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.<br><br>Cosmetic Procedures are excluded from coverage:<br>• 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.<br>• Any procedure that does not meet the reconstructive criteria above in the Indications for Coverage section of the policy.<br>• Browpexy/internal brow lift is not designed to improve function. It is considered a cosmetic procedure and is not a covered service. |
| Preventive Care Services | Jun. 1, 2017 | • Revised list of applicable procedure and diagnosis codes for **Preventive Care Services**: *Cholesterol Screening (Lipid Disorders Screening)*<br>○ Updated service description:<br>▪ Added November 2016 USPSTF 'B' rating for statin use for the primary prevention of | Refer to the policy for complete details on the coverage guidelines for Preventive Care Services. |

## Coverage Determination Guideline (CDG) Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
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| **REVISED** | | | |
| Preventive Care Services *(continued)* | Jun. 1, 2017 | cardiovascular disease in adults:<br>- USPSTF recommends that adults without a history of cardiovascular disease (CVD) (i.e., symptomatic coronary artery disease or ischemic stroke) use a low- to moderate-dose statin for the prevention of CVD events and mortality when all of the following criteria are met:<br>• they are aged 40 to 75 years;<br>• they have 1 or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking); and<br>• they have a calculated 10-year risk of a cardiovascular event of 10% or greater<br>- Identification of dyslipidemia and calculation of 10-year CVD event risk requires universal lipids screening in adults aged 40 to 75 | |

## Coverage Determination Guideline (CDG) Updates

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
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| **REVISED** | | | |
| Preventive Care Services *(continued)* | Jun. 1, 2017 | years<br>▪ Added notation to refer to the pharmacy plan administrator for statin medications benefits<br>▪ Added notation to indicate preventive coverage for the June 2008 USPSTF ratings expires Nov. 30, 2017<br>○ Updated preventive benefit instructions:<br>▪ Added language to indicate:<br>- Cholesterol screening is preventive for patients 40–75 years old (ends on 76th birthday) when billed with one of the [listed] required cholesterol screening diagnosis codes<br>- Blood draw for cholesterol screening is payable for patients 40–75 years old when billed with one of the listed cholesterol screening procedure codes **and** one of the [listed] required cholesterol screening diagnosis codes<br>▪ Replaced language indicating:<br>- "Cholesterol | |

## Coverage Determination Guideline (CDG) Updates

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| **REVISED** | | | |
| Preventive Care Services *(continued)* | Jun. 1, 2017 | screening is preventive for patients 35 years old and older when billed with one of the [listed] required cholesterol screening diagnosis codes" with "cholesterol screening is preventive for patients 35-*39* years old *and 76 years old* and older when billed with one of the [listed] required cholesterol screening diagnosis codes"<br>- "Blood draw for cholesterol screening is payable for patients 35 years old and older when billed with one of the listed cholesterol screening procedure codes **and** with one of the [listed] required cholesterol screening diagnosis codes" with "blood draw for cholesterol screening is payable for patients 35-*39* years old *and 76 years old* and older when billed with one of the listed cholesterol screening procedure codes | |

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| **REVISED** | | | |
| Preventive Care Services *(continued)* | Jun. 1, 2017 | **and** with one of the [listed] required cholesterol screening diagnosis codes"<br>*Colorectal Cancer Screening*<br>○ Updated list of applicable procedure codes for fecal occult blood testing (FOBT), sigmoidoscopy, or colonoscopy; modified Code Group 4 (Anesthesia):<br>▪ Added CPT codes 99152, 99153, 99156, and 99157<br>▪ Added HCPCS code G0500<br>*Latent Tuberculosis Infection: Screening, Adults* (new to policy)<br>○ Added September 2016 USPSTF 'B' rating:<br>▪ USPSTF recommends screening for latent tuberculosis infection (LTBI) in populations at increased risk<br>▪ This recommendation applies to asymptomatic adults 18 years and older at increased risk for tuberculosis<br>○ Added list of applicable procedure codes:<br>▪ Screening: CPT codes 86480, 86481, 86580, and 99211<br>▪ Blood draw: CPT codes 36415 and 36416<br>○ Added list of applicable ICD-10 diagnosis codes: R76.11, | |

## Coverage Determination Guideline (CDG) Updates

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| Preventive Care Services *(continued)* | Jun. 1, 2017 | R76.12, Z00.00, Z00.01, Z11.1, and Z20.1<br>▪ Added notation for patients 18–20 years old (ends on 21st birthday) to indicate, in addition to the listed diagnosis codes, the preventive benefit also applies to the ICD-10 diagnosis codes listed under the *Bright Futures: Tuberculosis TB Testing* section of the policy<br>○ Added preventive benefit instructions to indicate:<br>▪ For screening:<br>- Ages 18 years and up<br>- CPT codes 86480, 86481, and 86580 are payable as preventive with any of the diagnosis codes listed for this service<br>- CPT code 99211 is only payable as preventive with diagnosis code R76.11 or R76.12<br>▪ For blood draw:<br>- Ages 18 years and up<br>- Payable as preventive when billed with CPT codes 86480 or 86481 **and** one of the | |

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| **REVISED** | | | |
| Preventive Care Services *(continued)* | Jun. 1, 2017 | diagnosis codes listed for this service<br>*Tuberculosis - TB Testing (Bright Futures)*<br>○ Changed service title/heading; previously titled *TB Testing (Bright Futures)*<br>○ Added instruction to refer to the *Latent Tuberculosis Infection: Screening, Adults* section of the policy for patients 18 years and older<br>○ Updated list of applicable procedure codes; added language to clarify CPT code 99211 is for follow-up visit to check skin results<br>○ Updated list of applicable ICD-10 diagnosis codes; added Z20.1<br>○ Added language pertaining to patients 18 years and older to indicate, in addition to the codes listed for this service, the preventive benefit also applies to all codes listed under the *Latent Tuberculosis Infection: Screening, Adults* section of the policy | |

# Utilization Review Guideline (URG) Updates

| Policy Title | Effective Date | Summary of Changes | Utilization Management Guiding Principles |
|---|---|---|---|
| **REVISED** | | | |
| Site of Service Guidelines for Certain Outpatient Surgical Procedures | Jul. 1, 2017 | • Revised introduction; removed language indicating specific procedure codes for services requiring prior authorization can be found on the *Prior Authorization List*<br>• Revised *Elective Procedures List*:<br>○ Reformatted and relocated list of service type categories requiring prior authorization in the outpatient hospital setting:<br>▪ Removed "cardiovascular procedures" from list of applicable services<br>▪ Added list of applicable CPT codes and corresponding descriptions (see *Applicable Codes* section of the policy for complete details)<br>○ Replaced language indicating "prior authorization may be required for the [listed] procedures *to be* performed in an outpatient hospital setting *(not an all-inclusive list)*" with "prior authorization *is* required for the [listed] procedures *if* performed in an outpatient hospital setting (see list of *Applicable Codes*)"<br>• Added list of applicable CPT codes for services requiring prior authorization in the outpatient hospital setting:<br>○ Abdominal Paracentesis: | **Introduction**<br>In an effort to minimize out-of-pocket costs for UnitedHealthCare 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.<br>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 plan document to determine if medical necessity applies.<br>**Coverage Rationale**<br>With the exception of the qualifying conditions below, certain elective procedures should be performed in an Ambulatory Surgical Center (ASC).<br>The following will be taken into account to determine whether the elective procedure is being performed in a cost effective setting:<br>• Member's benefit plan<br>• Geographic availability of an in network provider<br>• Ambulatory surgical care (ASC) capability<br>• Physician privileging<br>• Significant member comorbidities (see list of examples of qualifying conditions below)<br>• American Society of Anesthesiologist (ASA) physical status (PS), classification system<br>***Potential Documentation Requirements***<br>• Physician office notes<br>• Physician privileging<br>• ASA score<br>***Certain Qualifying Conditions***<br>Some patients may require more complex care due to factors such as age or medical conditions. Also, some ASCs may have specific guidelines that prohibit members who are above a certain weight or have certain health conditions from receiving care in those facilities.<br>Patients with severe systemic disease and some functional limitation (ASA PS classification III or higher) may be appropriate to have the procedure in an |

## Utilization Review Guideline (URG) Updates

| Policy Title | Effective Date | Summary of Changes | Utilization Management Guiding Principles |
|---|---|---|---|
| **REVISED** | | | |
| Site of Service Guidelines for Certain Outpatient Surgical Procedures *(continued)* | Jul. 1, 2017 | 49083<br>○ Carpal Tunnel Surgery: 64721<br>○ Cataract Surgery: 66821, 66982, and 66984<br>○ Cosmetic & Reconstructive: 13101, 13132, 14040, 14060, 14301, 21552, and 21931<br>○ ENT Procedures: 21320, 30140, 30520, 69436, and 69631<br>○ Gynecologic Procedures: 57522, 58353, 58558, 58563, and 58565<br>○ Hernia: 49505, 49585, 49587, 49650, 49651, 49652, 49653, 49654, and 49655<br>○ Liver Biopsy: 47000<br>○ Miscellaneous: 20680<br>○ Ophthalmologic: 65426, 65730, 65855, 66170, 66761, 67028, 67036, 67040, 67228, 67311, and 67312<br>○ Tonsillectomy & Adenectomy: 42820, 42821, 42825, 42826, and 42830<br>○ Upper & Lower Gastrointestinal Endoscopy: 43235, 43239, 43249, 45378, 45380, 45384, and 45385<br>○ Urology: 50590, 52000, 52005, 52204, 52224, 52234, 52235, 52260, 52281, 52310, 52332, 52351, 52352, 52353, | outpatient hospital setting (not an all-inclusive list):<br>• Morbid obesity (>BMI.40)<br>• Diabetes (brittle diabetes*)<br>• Resistant hypertension (poorly controlled**)<br>• Chronic obstructive pulmonary disease (COPD) (FEV1 < 50%)<br>• Advance liver disease (MELD Score > 8***)<br>• Alcohol dependence (at risk for withdrawal syndrome)<br>• End stage renal disease (hyperkalemia (above reference range **** peritoneal or hemodialysis)<br>• Uncompensated chronic heart failure (CHF) (NYHA class III or IV*****)<br>• History of myocardial infarction (MI) (recent event (< 3 mo))<br>• History of cerebrovascular accident (CVA) or transient ischemic attack (TIA) (recent event (< 3 mo))<br>• Coronary artery disease (CAD/peripheral vascular disease (PVD) (ongoing cardiac ischemia requiring medical management recently placed drug eluting stent (within 1 year))<br>• Sleep apnea (moderate to severe obstructive sleep apnea (OSA)******)<br>• Implanted pacemaker<br>• Personal history or family history of complication of anesthesia such as malignant hyperthermia<br>• Pregnancy<br>• Bleeding disorder requiring replacement factor or blood products or special infusion products to correct a coagulation defect (DDAVP is not blood product and is OK)<br>• Prolonged surgery (>3 hrs)<br>• Anticipated need for transfusion<br>• Recent history of drug abuse (especially cocaine)<br>• Patients with drug eluting stents (DES) placed within one year or bare metal stents (BMS) or plain angioplasty within 90 days unless acetylsalicylic acid (ASA) and antiplatelet drugs will be continued by agreement of surgeon, cardiologist and anesthesia<br>• Ongoing evidence of myocardial ischemia<br>• Poorly controlled asthma (FEV1 < 80% despite medical management)<br>• Significant valvular heart disease<br>• Cardiac arrhythmia (symptomatic arrhythmia despite medication)<br>**Footnotes**<br>* (1) predominant hyperglycemia with recurrent ketoacidosis, (2) predominant hypoglycemia, and (3) |

## Utilization Review Guideline (URG) Updates

<table>
<tr><th>Policy Title</th><th>Effective Date</th><th>Summary of Changes</th><th>Utilization Management Guiding Principles</th></tr>
<tr><td colspan="4">REVISED</td></tr>
<tr><td>Site of Service Guidelines for Certain Outpatient Surgical Procedures (continued)</td><td>Jul. 1, 2017</td><td>52356, 54161, 55040, 55700, and 57288</td><td>
<table>
<tr><td></td><td>mixed hyper- and hypoglycemia</td></tr>
<tr><td>**</td><td>3 or more drugs to control blood pressure</td></tr>
<tr><td>***</td><td>http://reference.medscape.com/calculator/meld-score-end-stage-liver-disease<br>Surgery in the Patient with Liver Disease, Friedman, L S. Trans Am Clin Climatol Assoc. 2010; 121: 192–205.</td></tr>
<tr><td>****</td><td>https://www.kidney.org/sites/default/files/02-10-6785_HBE_Hyperkalemia_Bulletin.pdf</td></tr>
<tr><td>*****</td><td>http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/Classes-of-Heart-Failure_UCM_306328_Article.jsp</td></tr>
<tr><td>******</td><td>OSA:<br>Moderate for AHI or RDI ≥ 15 and ≤ 30<br>Severe for AHI or RDI > 30/hr (Epstein, 2009)</td></tr>
</table>
Elective Procedures List<br>Prior authorization is required for the [listed] procedures if performed in an outpatient hospital setting (see Applicable Codes section of the policy).
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