UnitedHealthcare®

April 2016

# medical policy update **bulletin**

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

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

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

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

# Overview

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

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

### Tips for using the Medical Policy Update Bulletin:

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

### Policy Update Classifications

**New**

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

**Updated**

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

**Revised**

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

**Replaced**

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

**Retired**

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

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

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**REVISED**



## Drug and Biologics Policy Updates

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## Coverage Determination Guideline (CDG) Updates

**REVISED**



## Utilization Review Guideline (URG) Updates

**UPDATED**



**REVISED**

# Medical Policy Updates

**NEW**

| Policy Title | Effective Date | Coverage Rationale |
|---|---|---|
| Functional Endoscopic Sinus Surgery (FESS) | May 1, 2016 | ***Notice of Revision:*** *The coverage rationale for this service has been modified. Revisions to the original policy update announcement are outlined in red below. Please take note of the amended guidelines to be applied beginning May 1, 2016.*<br><br>~~**Please Note:** Medical necessity reviews will also include site of service (SOS), per the member's benefit plan. Please refer to the Site of Service Utilization Review Guideline for additional information on SOS reviews for these services.~~<br><br>**Functional endoscopic sinus surgery (FESS) is medically necessary for one or more of the following:**<br>• Patients with chronic rhinosinusitis (defined as rhinosinusitis lasting longer than 12 weeks) with both of the following:<br>  ○ Chronic rhinosinusitis is confirmed on computed tomography (CT) scan by one or more of the following:<br>  ▪ mucosal thickening<br>  ▪ bony remodeling<br>  ▪ bony thickening or<br>  ▪ obstruction of the ostiomeatal complex<br>  ▪ opacified sinus<br>  ○ Symptoms persist despite medical therapy with one or more of the following:<br>  ▪ Nasal lavage<br>  ▪ Antibiotic therapy, if bacterial infection is suspected<br>  ▪ Intranasal corticosteroids<br>• Mucocele documented on CT scan<br>• Complications of sinusitis such as abscess<br>• Tumor documented on CT scan (such as polyposis or malignancy)<br>• Recurrent acute rhinosinusitis (RARS)<br><br>**Drug eluting stents or drug eluting implants are unproven and not medically necessary for maintaining sinus ostial patency after sinus surgery.**<br>The evidence is insufficient to determine whether drug eluting sinus stents or drug eluting implants improve outcomes when used postoperatively following endoscopic sinus surgery. Further randomized clinical trials are needed that compare the devices to postoperative care without the device to determine whether they can improve postoperative outcomes for patients undergoing endoscopic sinus surgery. |

**UPDATED**

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| Chelation Therapy for Non-Overload Conditions | Apr. 1, 2016 | • Reformatted policy; transferred content to new template<br>• Reformatted list of applicable | **Chelation for heavy metal toxicity and overload conditions (e.g., iron, copper, lead, aluminum) is proven and medically necessary and not addressed in this policy.** |

## Medical Policy Updates

| UPDATED | | | |
|---|---|---|---|
| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Chelation Therapy for Non-Overload Conditions *(continued)* | Apr. 1, 2016 | HCPCS codes; removed descriptor classifying codes as "unproven"<br>• Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references | **Chelation therapy is unproven and not medically necessary for the treatment of "mercury toxicity" from dental amalgam fillings**. Randomized controlled trials do not identify a causal association between amalgam fillings and various systemic symptoms and disorders attributed to mercury.<br><br>**Chelation therapy is unproven and not medically necessary for the treatment of chronic, progressive diseases (not involving heavy metal toxicity or overload conditions) and other disorders including but not limited to:**<br>• Alzheimer's disease<br>• apoplectic coma<br>• autism spectrum disorder<br>• cancer<br>• cardiovascular disease<br>• chronic fatigue syndrome<br>• chronic renal insufficiency<br>• defective hearing<br>• diabetes<br>• diabetic ulcer<br>• cholelithiasis<br>• gout<br>• erectile dysfunction<br>• multiple sclerosis<br>• osteoarthritis<br>• osteoporosis<br>• Parkinson's disease<br>• Raynaud's disease<br>• renal calculus<br>• rheumatoid arthritis<br>• schizophrenia<br>• scleroderma<br>• snake venom poisoning<br>• varicose veins<br>• vision disorders (glaucoma, cataracts, etc.)<br><br>Much of the evidence supporting chelation treatment for other chronic progressive disease is based on testimonials and single-case studies. Thus, there still is no scientific evidence that demonstrates any benefit from this form of therapy. |

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| UPDATED | | | |
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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Chromosome Microarray Testing | May 1, 2016 | • Updated definition of "intellectual disability"<br>• Updated list of applicable ICD-10 diagnosis codes:<br>  ○ Arranged codes in alphanumeric order<br>  ○ Added Q93.3<br>• Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references | **Comparative genomic hybridization microarray testing or single nucleotide polymorphism (SNP) chromosomal microarray analysis is proven and medically necessary to evaluate an embryo/fetus in the following cases**:<br>• Women undergoing invasive prenatal testing (i.e. amniocentesis, chorionic villus sampling or fetal tissue sampling)<br>• Intrauterine fetal demise or stillbirth<br><br>**Comparative genomic hybridization microarray testing or single nucleotide polymorphism (SNP) chromosomal microarray analysis is proven and medically necessary in the evaluation of patients with one or more of the following**:<br>• Multiple anomalies not specific to a well-delineated genetic syndrome and cannot be identified by a clinical evaluation alone<br>• Non-syndromic developmental delay/intellectual disability<br>• Autism spectrum disorders<br><br>**Comparative genomic hybridization microarray testing and single nucleotide polymorphism (SNP) chromosomal microarray analysis are unproven and not medically necessary for all other patient populations and conditions including but not limited to the following**:<br>• Preimplantation genetic diagnosis or screening in embryos<br>• Diagnosis, management, and prognosis of cancer<br><br>There is insufficient evidence in the clinical literature demonstrating that comparative genomic hybridization (CGH) microarray testing or single nucleotide polymorphism (SNP) chromosomal microarray analysis has a role in clinical decision-making or has a beneficial effect on health outcomes for other conditions such as preimplantation genetic diagnosis or screening in embryos or aiding diagnosis or tumor classification or determining the most appropriate treatment and establishing an accurate prognosis for cancer. Further studies are needed to determine the analytic validity, clinical validity and clinical utility of this test for indications other than those listed above as proven.<br><br>**Genetic Counseling**<br>Genetic counseling is strongly recommended prior to this test in order to inform persons being tested about the advantages and limitations of the test as applied to a unique person. |

# Medical Policy Updates

| UPDATED | | | |
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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Cochlear Implants | Apr. 1, 2016 | • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references; no change to coverage rationale or list of applicable codes | **When used according to U.S. Food and Drug Administration (FDA) labeled indications, bilateral or unilateral cochlear implantation is proven and medically necessary for 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;<br>• Ability to follow or participate in a program of aural rehabilitation;<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;<br>• No contraindications to surgery<br><br>See the *U.S. Food and Drug Administration (FDA)* section of the policy for FDA indications for each cochlear implant device. Specific criteria vary with the device.<br><br>**Cochlear hybrid implants are unproven and not medically necessary for hearing loss.**<br>There is insufficient evidence in the 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. |
| Cognitive Rehabilitation | Apr. 1, 2016 | • Reformatted policy; transferred content to new template<br>• Updated coverage rationale; clarified language pertaining to "minimally conscious/vegetative state"<br>• Added definition of:<br>  ○ Coma<br>  ○ Minimally conscious state<br>  ○ Persistent vegetative state<br>• Updated supporting information to reflect the most current | **Cognitive rehabilitation is proven and medically necessary** for the treatment of traumatic brain injury (TBI) and brain injury due to stroke, aneurysm, anoxia, encephalitis, brain tumors, and brain toxins when the patient can actively participate in the program (e.g., is not comatose or a vegetative or minimally conscious state which precludes such active engagement).<br><br>The treatment regimen usually includes one of the following modalities:<br>• Specific interventions for functional communication deficits, including pragmatic conversational skills, or<br>• Compensatory memory strategy training |

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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Cognitive Rehabilitation (continued) | Apr. 1, 2016 | clinical evidence, FDA and CMS information, and references | **Cognitive rehabilitation is unproven and not medically necessary** for the treatment of cerebral palsy, Down syndrome, Alzheimer's disease, attention deficit hyperactivity disorder, developmental disorders such as autism, schizophrenia and Parkinson's disease. Evidence in the published, peer-reviewed, medical literature to support the use of cognitive rehabilitation for these conditions is limited and conflicting. Available studies also contain design flaws including small study samples, lack of comparison groups and lack of long-term follow-up.<br><br>**Coma stimulation is unproven and not medically necessary** for the treatment of comatose patients or patients in a vegetative or minimally conscious state who have sustained a brain injury due to limited evidence with overall poor quality in methodology and design, and diversity in reporting outcome measures. |
| Collagen Crosslinks and Biochemical Markers of Bone Turnover | Apr. 1, 2016 | • Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or list of applicable codes | **Serum or urine collagen crosslinks or biochemical markers are unproven and not medically necessary to assess risk of fracture, predict bone loss or assess response to antiresorptive therapy.**<br>There is insufficient evidence in the clinical literature that current methods for measuring bone turnover markers are sufficiently sensitive to reliably determine individual treatment responses. In addition, there is insufficient evidence from controlled studies that bone turnover marker measurement improves adherence to treatment or improves health outcomes such as reducing fracture rates. |
| Hearing Aids and Devices Including Wearable, Bone-Anchored and Semi-Implantable | Apr. 1, 2016 | • Updated supporting information to reflect the most current description of services and references; no change to coverage rationale or lists of applicable codes | **Wearable Hearing Aids (Including Non-Implantable Bone Conduction Hearing Aids Utilizing a Headband)**<br>**Hearing aids required for the correction of a hearing impairment (a reduction in the ability to perceive sound which may range from slight to complete deafness) are proven and medically necessary.**<br><br>**Bilateral or unilateral bone-anchored hearing aids utilizing a headband (without osseointegration) are proven and medically necessary for hearing loss in a patient who is not a candidate for an air-conduction hearing aid and when used according to U.S. Food and Drug Administration (FDA) approved indications.**<br><br>**Semi-Implantable Electromagnetic Hearing Aids (SEHA)**<br>**A semi-implantable electromagnetic hearing aid is proven and** |

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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Hearing Aids and Devices Including Wearable, Bone-Anchored and Semi-Implantable *(continued)* | Apr. 1, 2016 | | **medically necessary for sensorineural hearing loss in a patient who is not a candidate for an air-conduction hearing aid and when used according to FDA approved indications.**<br><br>**Bone Anchored Hearing Aids**<br>**Implantable Bone-Anchored Hearing Aid (BAHA) for Sensorineural Hearing Loss:**<br>**A unilateral implantable bone-anchored hearing aid is proven and medically necessary for sensorineural hearing loss in one ear in a patient who is not a candidate for an air-conduction hearing aid and when used according to FDA approved indications.**<br><br>**Unilateral or bilateral implantable bone-anchored hearing aids are proven and medically necessary for sensorineural hearing loss in both ears when both of the following criteria are present:**<br>• The poorer ear is not a candidate for an air-conduction hearing aid due to a speech reception threshold of 70 dB or more OR a word discrimination score of less than 60%; and<br>• The better hearing ear has a speech reception threshold of 35 dB or less and a speech discrimination score of 60% or more.<br><br>**Implantable Bone-Anchored Hearing Aid (BAHA) for Conductive or Mixed Hearing Loss:**<br>**A unilateral implantable bone-anchored hearing aid is proven and medically necessary for conductive or mixed hearing loss in one or both ears in a patient who is not a candidate for an air-conduction hearing aid and when used according to FDA approved indications.**<br><br>**Bilateral implantable bone-anchored hearing aids are proven and medically necessary for conductive or mixed hearing loss in both ears in a patient who is not a candidate for an air-conduction hearing aid and when used according to FDA approved indications.**<br><br>**Totally Implanted Hearing Systems**<br>**Totally implanted hearing systems are unproven and not medically necessary for hearing loss.**<br>There is inadequate evidence demonstrating the efficacy of totally implanted hearing systems for treating hearing loss or deafness. Well-designed studies with larger patient populations and longer follow-up are required to |

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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Hearing Aids and Devices Including Wearable, Bone-Anchored and Semi-Implantable *(continued)* | Apr. 1, 2016 | | demonstrate the safety and benefits of these devices.<br><br>**Partially Implantable Bone Conduction Hearing Aid With Magnetic Coupling**<br>**Partially implantable magnetic bone conduction hearing devices are unproven and not medically necessary for hearing loss.**<br>There is limited evidence to support the use of partially implantable magnetic bone conduction hearing devices to treat hearing loss. The evidence assessing the effectiveness of this device is limited to preliminary uncontrolled studies with small populations. Additional studies with larger populations and long-term follow-up are needed to evaluate improvement of hearing with this device.<br><br>**Intraoral Bone Conduction Hearing Aids**<br>**An intraoral bone conduction hearing aid is unproven and not medically necessary for treating hearing loss.**<br>There is insufficient evidence to support the use of an intraoral bone conduction hearing aid to treat hearing loss. The quality of the studies was low due to small study populations, short follow-up, and lack of randomization and appropriate control groups. Future studies with larger populations of patients wearing the device for longer periods are needed to evaluate hearing benefits and device safety. |
| Intermittent Intravenous Insulin Therapy | Apr. 1, 2016 | • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references; no change to coverage rationale or list of applicable codes | **Intermittent intravenous insulin therapy (IIIT) is unproven and not medically necessary for reducing symptoms, improving glycemic control or preventing diabetic sequelae in patients with insulin dependent diabetes.**<br>There is insufficient evidence in the clinical literature demonstrating the clinical utility of IIIT. The limited number of published studies lack adequate controls, randomization and blinding. Further studies, with larger sample sizes, are necessary to determine the health benefit of IIIT.<br><br>**Insulin potentiation therapy is unproven and not medically necessary for the treatment of cancer, infectious diseases, arthritis and other conditions.**<br>There is inadequate evidence in the peer-reviewed, published clinical literature demonstrating that this therapy is safe and/or effective. |

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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Thermography | Apr. 1, 2016 | • Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or list of applicable codes | **Thermography (including digital infrared thermal imaging, temperature gradient studies, and magnetic resonance (MR) thermography) is unproven and not medically necessary.**<br><br>There is insufficient evidence to conclude that thermography has a beneficial impact on health outcomes. The available evidence is limited and weak, and standards for image evaluation and cut-off values that would allow clinical recommendations based on this technology have not been established. |

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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Implanted Electrical Stimulator for Spinal Cord | Apr. 1, 2016 | • Revised coverage rationale:<br>  ○ Replaced reference to "MCG™ Care Guidelines, 19th edition, 2015" with "MCG™ Care Guidelines, 20th edition, 2016" (effective Apr. 1, 2016); refer to 20th edition for complete details on applicable updates to the MCG™ Care Guidelines<br>• Updated list of applicable CPT/HCPCS codes to reflect quarterly code edits (effective Apr. 1, 2016); revised description for C1820<br>• Updated supporting information to reflect the most current CMS information | For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 20th edition, 2016, Implanted Electrical Stimulator, Spinal Cord ACG: A-0243 (AC). |
| Omnibus Codes | May 1, 2016 | • Revised coverage rationale for skin substitutes/ wound care management:<br>  ○ Added language to indicate PuraPly™ and PuraPly™ Antimicrobial (HCPCS code | Refer to the policy for complete details on the coverage guidelines for Omnibus Codes. |

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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Omnibus Codes *(continued)* | May 1, 2016 | C9349) are unproven/not medically necessary<br>○ Updated supporting information to reflect the most current clinical evidence and references | |

# Drug and Biologics Policy Updates

| REVISED | | | |
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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Maximum Dosage | May 1, 2016 | • Revised coverage rationale; added language to indicate:<br>○ This policy creates an upper dose limit based on the clinical evidence and the 95th percentile for adult body weight (119 kg) and body surface area (2.45 meters$^2$) in the U.S. (Fryar, 2012); in some cases, the maximum allowed units and/or vials may exceed the upper level limit as defined within this policy due to an individual patient body weight > 119 kg or body surface area > 2.45 meters$^2$ | This policy provides information about the maximum dosage per administration for certain medications administered by a medical professional.<br><br>**Drug Products:**<br>• bevacizumab (Avastin®)<br>• infliximab (Remicade®)<br>• pegfilgrastim (Neulasta®)<br>• rituximab (Rituxan®)<br>• trastuzumab (Herceptin®)<br>• zoledronic acid (zoledronic acid, Reclast® and Zometa®)<br><br>Most medications have a maximum dosage based upon body surface area or patient weight or a set maximal dosage independent of patient body size, and are proven when used according to labeled indications or when otherwise supported by published clinical evidence. The medications included in this policy when given beyond maximum dosages based upon body surface area or patient weight or a set maximal dosage independent of patient body size are not supported by package labeling or published clinical evidence and are unproven.<br><br>This policy creates an upper dose limit based on the clinical evidence and the 95th percentile for adult body weight (119 kg) and body surface area (2.45 meters$^2$) in the U.S. (Fryar, 2012). In some cases, the maximum allowed units and/or vials may exceed the upper level limit as defined within this policy due to an individual patient body weight > 119 kg or body surface area > 2.45 meters$^2$.<br><br>Refer to the policy for complete details on Maximum Dosage guidelines. |
| Off-Label/Unproven Specialty Drug Treatment | May 1, 2016 | • Revised coverage rationale; added new/additional medical necessity criterion to indicate **one** of the following must be met:<br>○ The requested drug is considered "unproven" per UnitedHealthcare drug | **Description**<br>This policy provides parameters for coverage of off-label and unproven indications of FDA-approved medications for **one** of the following:*<br>• Injectable specialty drug with a corresponding UnitedHealthcare policy that does not address the requested indication<br>• Injectable specialty drug with a corresponding UnitedHealthcare policy that lists the drug as unproven for the requested indication<br>• Injectable specialty drug without a UnitedHealthcare drug policy |

## Drug and Biologics Policy Updates

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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Off-Label/Unproven Specialty Drug Treatment *(continued)* | May 1, 2016 | policy, where applicable<br>○ The indication for the requested drug is not addressed by a UnitedHealthcare drug policy, where applicable<br>○ A UnitedHealthcare drug policy does not exist for the requested drug | * *http://www.uhcspecialtyrx.com/*<br><br>This policy does **not** address 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™. Please refer to the UnitedHealthcare drug policy titled *Oncology Medication Clinical Coverage* for more information.<br><br>This policy does **not** address coverage of vaccines. Please refer to UnitedHealthcare's *Vaccines* Drug Policy and *Preventative Care Services* Coverage Determination Guideline for additional information on vaccines covered as preventive services.<br><br>**Coverage Rationale**<br>A specialty drug may be determined medically necessary for the requested off-label or unproven indication when **all** of the criteria are met:<br><br>1. The drug is approved by the U.S. Food and Drug Administration<br>**AND**<br>2. **One** of the following:<br>a. The requested drug is considered 'unproven' per UnitedHealthcare drug policy, where applicable<br>b. The indication for the requested drug is not addressed by a UnitedHealthcare drug policy, where applicable<br>c. A UnitedHealthcare drug policy does not exist for the requested drug.<br>**AND**<br>3. The drug is prescribed by a licensed health care professional<br>**AND**<br>4. The requested drug is intended to treat a chronic and seriously debilitating condition<br>**AND**<br>5. Documented history of failure, contraindication, or intolerance to standard, conventional therapies to treat or manage the disease or condition, where available<br>**AND**<br>6. Diagnosis is *clinically supported* as a use by at least **one** of the following:<br>a. **One** of the following compendia: |

## Drug and Biologics Policy Updates

| REVISED | | | |
|---|---|---|---|
| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Off-Label/Unproven Specialty Drug Treatment *(continued)* | May 1, 2016 | | 1. The American Hospital Formulary Service Drug Information (AHFS-DI) under the Therapeutic Uses section<br>2. The Elsevier Gold Standard's Clinical Pharmacology under the Indications section<br>3. DRUGDEX System by Micromedex® has a Strength of Recommendation rating of Class I, Class IIa, or Class IIb under the Therapeutic Uses section<br>**OR**<br>b. MCG™ Ambulatory Care Guideline<br>**OR**<br>c. **Two (2)** articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is validated and uncontested contradictory evidence presented in a major peer-reviewed medical journal.<br><br>*[Examples of accepted journals include, but are not limited to, Journal of American Medical Association, New England Journal of Medicine, and Lancet. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials.]* |

## Coverage Determination Guideline (CDG) Updates

| REVISED | | | |
|---|---|---|---|
| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Blepharoplasty, Blepharoptosis and Brow Ptosis Repair | Jun. 1, 2016 | • Reformatted policy; transferred content to new template<br>• Revised coverage rationale:<br>○ Updated coverage criteria for treatment of **ectropion (eyelid turned outward) or punctal eversion** (CPT codes 67914 through 67917); removed criterion requiring trial and failure of conservative treatments<br>○ Added language to indicate **repair of floppy eyelid syndrome (FES)** (CPT codes 67961 and 67966) is considered reconstructive and medically necessary when all of the following are present when documented and confirmed by history and examination:<br>▪ Subjective symptoms must include eyelids spontaneously "flipping over" when they sleep due to rubbing on the pillow **and** one of the following:<br>- Eye pain or discomfort; or<br>- Excess tearing; or<br>- Eye irritation, ocular redness and discharge<br>▪ Physical examination that documents the following:<br>- Eyelash Ptosis; and | Refer to the policy for complete details on the coverage guidelines for Blepharoplasty, Blepharoptosis and Brow Ptosis Repair. |

## Coverage Determination Guideline (CDG) Updates

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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)* | Jun. 1, 2016 | - Significant upper eyelid laxity; and<br>- Presence of Giant Papillary Conjunctivitis<br>**or**<br>- Corneal findings such as:<br>• Superficial Punctate Erosions (SPK); or<br>• Corneal abrasion (Note: Documentation of a history of corneal abrasion or recurrent erosion syndrome is considered sufficient); or<br>• Microbial Keratitis<br>▪ Color photos that clearly document floppy eyelid syndrome; the photographs must clearly demonstrate **both** of the following:<br>- Lids must be everted in the photos and<br>- Conjunctival surface (underbelly) of the lids must clearly demonstrate Giant Papillary Conjunctivitis<br>▪ Documentation that | |

## Coverage Determination Guideline (CDG) Updates

| REVISED | | | |
|---|---|---|---|
| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)* | Jun. 1, 2016 | conservative treatment has been tried and failed; examples may include:<br>- Ocular lubricants both drops (daytime) and ointments (bedtime); or<br>- Short trial of antihistamines; or<br>- Topical steroid drops; or<br>- Eye Shield and/or Taping the lids at bedtime<br>▪ Other causes of the eye findings have been ruled out; examples may include:<br>- Allergic Conjunctivitis<br>- Atopic Keratoconjunctivitis<br>- Blepharitis<br>- Contact Lens (CL) Complication<br>- Dermatochalasis<br>- Ectropion<br>- GPC (Giant Papillary Conjunctivitis) that is not related to FES<br>- Ptosis of the lid(s)<br>- Superior Limbic Keratoconjunctivitis (SLK)<br>• Updated definitions; added definition of:<br>○ Giant papillary conjunctivitis | |

## Coverage Determination Guideline (CDG) Updates

| REVISED | | | |
|---|---|---|---|
| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)* | Jun. 1, 2016 | ○ Floppy eyelid syndrome (FES)<br>• Updated list of applicable CPT codes; added 67961 and 67966 (floppy eyelid syndrome) | |
| Preventive Care Services | Apr. 1, 2016 | ***Notice of Revision**: The following summary of changes has been modified. Revisions to the original policy update announcement are outlined in red below. Please take note of the additional updates to be implemented on Apr. 1, 2016.*<br>• Revised list of applicable procedure and diagnosis codes: **Preventive Care Services**<br>○ Modified table headings; replaced column/content descriptor titled "Claims Edit Criteria" with "Preventive Benefit Instructions"<br>○ Revised service description for ***Screening for Depression in Adults***:<br>▪ Removed December 2009 USPSTF 'B' rating<br>▪ Added January 2016 USPSTF 'B' rating:<br>- The USPSTF recommends screening for depression in the general adult population, including pregnant and postpartum women<br>- The USPSTF | Refer to the policy for complete details on the coverage guidelines for Preventive Care Services. |

## Coverage Determination Guideline (CDG) Updates

| REVISED | | | |
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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Preventive Care Services *(continued)* | Apr. 1, 2016 | recommends screening should be implemented with adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up<br>**Preventive Immunizations**<br>○ Updated list of applicable CPT codes for ***Measles, Mumps, Rubella (MMR)***; added 90707 (code removed from previous policy version in error)<br>**Expanded Women's Preventive Health**<br>○ Modified table headings; replaced column/content descriptor titled "Claims Edit Criteria" with "Preventive Benefit Instructions"<br>○ Revised coverage guidelines for ***Contraceptive Methods (Including Sterilizations)***:<br>▪ Updated lists of applicable codes*; a*dded Code Group 5:<br>- CPT codes 99211 and 99212 (IUD follow-up visit)<br>- ICD-10 diagnosis code Z30.431<br>▪ Updated preventive benefit instructions; added language to indicate a *Code Group 5* | |

## Coverage Determination Guideline (CDG) Updates

| REVISED | | | |
|---|---|---|---|
| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Preventive Care Services *(continued)* | Apr. 1, 2016 | CPT code is considered preventive when billed with a listed *Code Group 5* diagnosis code | |

## Utilization Review Guideline (URG) Updates

**UPDATED**

| Policy Title | Effective Date | Summary of Changes | Utilization Management Guiding Principles |
|---|---|---|---|
| Propranolol Treatment for Infantile Hemangiomas: Inpatient Protocol | Apr. 1, 2016 | • Routine review; no content changes | **Essential Health Benefits for Individual and Small Group**<br>For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the member specific benefit document to determine benefit coverage.<br><br>**Introduction**<br>This clinical guideline addresses the use of oral propranolol for the treatment of infantile hemangiomas (IH) and the need for up to a two day inpatient stay to monitor certain patients for heart rate, blood pressure and glycemic control. However, the mechanism of action of propranolol on IH is yet to be clearly defined. Some of the proposed hypotheses include vasoconstriction, decreased renin production, inhibition of angiogenesis, and stimulation of apoptosis.<br><br>1. Oral propranolol is proven for the treatment of infantile hemangiomas (IH).<br>2. The physicians and facility providing care must follow a written protocol.<br>3. A two day inpatient length of stay in a licensed acute care hospital is medically necessary for the treatment of patients 2 months or younger:<br>a. Medical management is highly individualized and treatment with oral propranolol is considered in the presence of ulceration, impairment, of a vital function, (ocular compromise or airway obstruction), or risk of permanent disfigurement<br>b. Newborns (up 2 months or age) may be admitted to an inpatient setting for 48 hours with oral propranolol<br>c. Children over 2 months of age with medical problems that require closer monitoring when initiating propranolol (e.g. SGA, prematurity requiring apnea monitoring, cardiac disease) are treated as inpatients for the same 2 day protocol unless the medical issues require longer monitoring. In that event, comorbidities requiring a |

# Utilization Review Guideline (URG) Updates

**UPDATED**

| Policy Title | Effective Date | Summary of Changes | Utilization Management Guiding Principles |
|---|---|---|---|
| Propranolol Treatment for Infantile Hemangiomas: Inpatient Protocol *(continued)* | Apr. 1, 2016 | | longer stay must be identified, with an anticipated length of inpatient stay.<br>d. Any requests for an extension of the inpatient stay beyond two days must be clinically reviewed. |

**REVISED**

| Policy Title | Effective Date | Summary of Changes | Utilization Management Guiding Principles |
|---|---|---|---|
| Site of Service Guidelines for Certain Outpatient Surgical Procedures | May 1, 2016 | • Reformatted policy; transferred content to new template<br>• Added reference link to related policy titled *Obstructive Sleep Apnea Treatment*<br>• Revised utilization management guiding principles:<br>○ Updated introduction language pertaining to prior authorization requirements to indicate specific procedure codes for services can be found on the Prior Authorization List (see the *References* section of the policy for details)<br>○ Updated list of elective procedures that may require preauthorization when performed in the outpatient hospital setting;<br>▪ Added "gynecologic procedures"<br>▪ Added notation to indicate the list is not all inclusive<br>▪ Removed language indicating prior authorization is not | **Introduction**<br>In an effort to minimize out-of-pocket costs for United HealthCare members and to improve cost efficiencies for the overall health care system, we are implementing prior authorization guidelines that aim to encourage more cost-effective sites of service for certain outpatient surgical procedures, when medically appropriate.<br><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 document to determine if medical necessity applies.<br><br>Specific procedure codes for services can be found on the Prior Authorization List (see *References* section of the policy).<br><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><br>The following will be taken into account to determine whether the elective procedure is being performed in a cost effective setting;<br>1. Members benefit plan<br>2. Geographic availability of an in network provider<br>3. Ambulatory surgical care (ASC) capability<br>4. Physician privileging<br>5. Significant member comorbidities (see list of examples of *Qualifying Conditions* below)<br>6. American Society of Anesthesiologist (ASA) physical status (PS), classification system |

## Utilization Review Guideline (URG) Updates

**REVISED**

| Policy Title | Effective Date | Summary of Changes | Utilization Management Guiding Principles |
|---|---|---|---|
| Site of Service Guidelines for Certain Outpatient Surgical Procedures *(continued)* | May 1, 2016 | required if the procedure is performed at a participating network ambulatory surgery center<br>○ Updated list of qualifying conditions for services to be performed in an outpatient hospital setting; modified language pertaining to sleep apnea [moderate to severe obstructive sleep apnea (OSA)]:<br>▪ Removed listings specific to OSA for surgery (duplicative to OSA)<br>▪ Revised footnote defining OSA to specify:<br>- Moderate for AHI or RDI ≥ 15 and ≤ 30<br>- Severe for AHI or RDI > 30/hr (Epstein, 2009)<br>• Removed list of applicable CPT codes | **Potential Documentation Requirements**<br>• Physician office notes<br>• Physician privileging<br>• ASA Score<br><br>**Elective Procedures List**<br>Prior authorization may be required for the following procedures to be performed in an outpatient hospital setting (Not an all-inclusive list):<br>• Abdominal Paracentesis<br>• Carpal Tunnel Surgery<br>• Cataract Surgery<br>• Gynecologic Procedures<br>• Hernia Repair<br>• Liver Biopsy<br>• Tonsillectomy & Adenectomy<br>• Upper & Lower Gastrointestinal Endoscopy<br>• Urologic Procedures<br><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><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 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) |

## Utilization Review Guideline (URG) Updates

| REVISED | | | |
|---|---|---|---|
| **Policy Title** | **Effective Date** | **Summary of Changes** | **Utilization Management Guiding Principles** |
| Site of Service Guidelines for Certain Outpatient Surgical Procedures *(continued)* | May 1, 2016 | | • 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 hours)<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 bear 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) |