UnitedHealthcare®

June 2015

medical policy update bulletin

Medical Policy, Drug Policy & Coverage Determination Guideline Updates

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

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

Overview

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

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NEW		
Policy Title	**Effective Date**	**Coverage Rationale**
Embolization of the Ovarian and Iliac Veins for Pelvic Congestion Syndrome	Sep. 1, 2015	**Embolization of the ovarian or internal iliac veins is considered unproven and not medically necessary as a treatment for pelvic congestion syndrome.** The body of evidence in the peer-reviewed medical literature regarding embolization of the ovarian or internal iliac veins for the treatment of pelvic congestion syndrome is insufficient and poor quality. Additional well-designed randomized controlled trials are necessary to establish the relative safety and efficacy of the embolization procedure as a treatment of pelvic congestion syndrome.
Genetic Testing	Jul. 1, 2015	**The following genetic tests are medically necessary when criteria are met:** • **Arrhythmogenic right ventricular cardiomyopathy (ARVC genes).** For information regarding medical necessity review, see MCG™ Care Guidelines, 19th edition, 2015, Arrhythmogenic Right Ventricular Cardiomyopathy - ARVC Genes ACG: A-0627 (AC). • **Ashkenazi Jewish genetic panel**. For information regarding medical necessity review see MCG™ Care Guidelines, 19th edition, 2015, Ashkenazi Jewish Genetic Panel ACG: A-0592 (AC) • **Catecholaminergic polymorphic ventricular tachycardia (RYR2 and CASQ2 Genes)**. For information regarding medical necessity review, see MCG™ Care Guidelines, 19th edition, 2015, Catecholaminergic Polymorphic Ventricular Tachycardia - RYR2 and CASQ2 Genes ACG: A-0636 (AC) • **Dilated cardiomyopathy (ANKRD1, DMD, GATAD1, LDB3, LMNA, MYBPC3, MYH7, RBM20, SCN5A, TNNI3, TNNT2, and TTN Genes).** For information regarding medical necessity review, see MCG™ Care Guidelines, 19th edition, 2015, Dilated Cardiomyopathy - ANKRD1, DMD, GATAD1, LDB3, LMNA, MYBPC3, MYH7, RBM20, SCN5A, TNNI3, TNNT2, and TTN Genes ACG: A-0648 (AC) • **Hypertrophic cardiomyopathy (Sarcomere Genes)**. For information regarding medical necessity review, see MCG™ Care Guidelines, 19th edition, 2015, Hypertrophic Cardiomyopathy - Sarcomere Genes ACG: A-0633 (AC) • **Long QT Syndromes (ANK2, ANKB, CACNA1C, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, SCN4B, and SCN5A Genes).** For information regarding medical necessity review, see MCG™ Care Guidelines, 19th edition, 2015, Long QT Syndromes - ANK2, ANKB, CACNA1C, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, SCN4B, and SCN5A Genes ACG: A-0607 (AC) • **Lynch Syndrome (EPCAM, MLH1, MSH2, MSH6, and PMS2 Genes).** For information regarding medical necessity review, see MCG™ Care Guidelines, 19th edition, 2015, Lynch Syndrome - EPCAM, MLH1, MSH2, MSH6, and PMS2 Genes ACG: A-0533 (AC) **The clinical utility of the following genetic tests have not been established and therefore these tests are not medically necessary:** • **5-Fluorouracil pharmacogenetics (DPYD, MTHFR, and TYMS Genes)**. See MCG™ Care Guidelines, 19th edition, 2015, 5-Fluorouracil Pharmacogenetics - DPYD, MTHFR, and TYMS Genes ACG: A-0665 (AC) • **Amyotrophic Lateral Sclerosis (C9ORF72 and SOD1 Genes)**.See MCG™ Care Guidelines, 19th edition, 2015, Amyotrophic Lateral Sclerosis (ALS) - C9ORF72 and SOD1 Genes ACG: A-0591 (AC) • **Clopidogrel pharmacogenetics (CYP2C19 Gene)**. See MCG™ Care Guidelines, 19th edition, 2015, Clopidogrel Pharmacogenetics - CYP2C19 Gene ACG: A-0631 (AC) • **Coronary artery disease (9p21 Allele).** See MCG™ Care Guidelines, 19th edition, 2015,Coronary Artery

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Policy Title	**Effective Date**	**Coverage Rationale**
Genetic Testing *(continued)*	Jul. 1, 2015	Disease - 9p21 Allele ACG: A-0657 (AC) • **Coronary artery disease (KIF6 Gene)**. See MCG™ Care Guidelines, 19th edition, 2015, Coronary Artery Disease - KIF6 Gene ACG: A-0656 (AC) • **Coronary artery disease genetic panel.** See MCG™ Care Guidelines, 19th edition, 2015, Coronary Artery Disease Genetic Panel ACG: A-0658 (AC) • **Genome-wide association studies**. See MCG™ Care Guidelines, 19th edition, 2015, Genome-Wide Association Studies ACG: A-0531 (AC) • **Hyperhomocysteinemia (MTHFR Gene)**. See MCG™ Care Guidelines, 19th edition, 2015, Hyperhomocysteinemia - MTHFR Gene ACG: A-0629 (AC) • **Inflammatory bowel disease (TPMT Gene)** See MCG™ Care Guidelines, 19th edition, 2015, Inflammatory Bowel Disease - TPMT Gene ACG: A-0628 (AC) • **Irinotecan pharmacogenetics (UGT1A1 Gene)**. See MCG™ Care Guidelines, 19th edition, 2015, Irinotecan Pharmacogenetics - UGT1A1 Gene ACG: A-0624 (AC) • **Malignant melanoma, familial (BAP1, CDK4, and CDKN2A Genes).** See MCG™ Care Guidelines, 19th edition, 2015, Malignant Melanoma, Familial - BAP1, CDK4, and CDKN2A Genes ACG: A-0601 (AC) • **MicroRNA detection**. See MCG™ Care Guidelines, 19th edition, 2015, MicroRNA Detection ACG: A-0705 (AC) • **Parkinson disease (ATP13A2, GBA, LRRK2, MAPT, PARK2, PARK7, PINK1, and SNCA Genes)**. See MCG™ Care Guidelines, 19th edition, 2015, Parkinson Disease - ATP13A2, GBA, LRRK2, MAPT, PARK2, PARK7, PINK1, and SNCA Genes ACG: A-0671 (AC) • **Prostate cancer genetic profiles (BRCA1, BRCA2, HOXB13, MMR, PCA3, PTEN, and TMPRSS2-ETS Fusion Genes).** See MCG™ Care Guidelines, 19th edition, 2015, Prostate Cancer - Genetic Profiles, BRCA1, BRCA2, HOXB13, MMR, PCA3, PTEN, and TMPRSS2-ETS Fusion Genes ACG: A-0612 (AC) • **Proteomics ovarian cancer biomarker panels (OVA1, ROMA).** See MCG™ Care Guidelines, 19th edition, 2015, Proteomics - Ovarian Cancer Biomarker Panels (OVA1, ROMA) ACG: A-0709 (AC) • **Psychotropic medication pharmacogenetics (AmpliChip Panel; CYP450 Polymorphisms; BDNF, DRD, HTR, SLC6A4, and TPH1 Genes)**. See MCG™ Care Guidelines, 19th edition, 2015, Psychotropic Medication Pharmacogenetics (AmpliChip Panel, CYP450 Polymorphisms) - BDNF, DRD, HTR, SLC6A4, and TPH1 Genes ACG: A-0692 (AC) • **Septin 9 (SEPT9) DNA methylation testing**. See MCG™ Care Guidelines, 19th edition, 2015, Septin 9 (SEPT9) DNA Methylation Testing ACG: A-0706 (AC) • **Tamoxifen pharmacogenetics (CYP2D6 Gene)**. See MCG™ Care Guidelines, 19th edition, 2015,Tamoxifen Pharmacogenetics - CYP2D6 Gene ACG: A-0647 (AC) • **Telomere analysis**. See MCG™ Care Guidelines, 19th edition, 2015, Telomere Analysis ACG: A-0672 (AC) • **Topographic genotyping (PathFinderTG)**. See MCG™ Care Guidelines, 19th edition, 2015, Topographic Genotyping – PathFinderTG ACG: A-0632 (AC) • **Warfarin pharmacogenetics (CYP2C9, VKORC1, and CYP4F2 Genes).** See MCG™ Care Guidelines, 19th edition, 2015, Warfarin Pharmacogenetics - CYP2C9, VKORC1, and CYP4F2 Genes ACG: A-0587 (AC) • **Whole genome or exome sequencing**. See MCG™ Care Guidelines, 19th edition, 2015, Whole Genome/Exome Sequencing ACG: A-0710 (AC)

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Policy Title	Effective Date	Coverage Rationale
Intraoperative Hyperthermic Intraperitoneal Chemotherapy (HIPEC)	Jul. 1, 2015	***Note**: This medical policy does not apply to normothermic (no hyperthermia is used) postoperative intraperitoneal chemotherapy, delivered via an indwelling port or catheter, used to treat ovarian cancer.* **When performed in conjunction with cytoreductive surgery (CRS), intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) is proven and medically necessary for treating the following conditions:** • Peritoneal mesothelioma • Pseudomyxoma peritonei (PMP) resulting from a mucus-producing tumor **Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) is unproven and not medically necessary for all other indications including, but not limited to, peritoneal carcinomatosis resulting from the following cancers:** • Colorectal • Gastric • Ovarian Clinical evidence demonstrating the safety and efficacy of intraoperative HIPEC to treat conditions other than those listed above as proven is insufficient at this time. Further prospective studies comparing this treatment option to standard treatment protocols are needed to determine impact on survival and to identify patient selection criteria and effective chemotherapy regimens. However, depending on the enrollee-specific benefit document, coverage may be available through participation in an eligible clinical trial.

UPDATED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Athletic Pubalgia Surgery	Jun. 1, 2015	• Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or list of applicable codes	**Surgical repair for treating athletic pubalgia is unproven and not medically necessary.** Several studies have shown that groin pain and function are improved after surgical repair for athletic pubalgia. However, most of these studies were uncontrolled, used small sample sizes and did not provide comparisons of the surgical methods used to treat athletic pubalgia. Large prospective randomized studies of individuals with athletic pubalgia with more detailed patient outcome measurements are needed to determine optimal treatment.
Breast Imaging for Screening and Diagnosing Cancer	Jun. 1, 2015	• Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references; no	**Breast Imaging as an Adjunct to Mammography** **Digital mammography is proven and medically necessary for patients with dense breast tissue.** **Breast Magnetic Resonance Imaging (MRI)**

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**

Breast Imaging for Screening and Diagnosing Cancer *(continued)*	Jun. 1, 2015	change to coverage rationale or lists of applicable codes	**Breast magnetic resonance imaging (MRI) is proven and medically necessary for patients at high risk for breast cancer as defined as having any of the following:**
			• **Personal history of atypical breast histologies**
			• **Family history or genetic predisposition for breast cancer**
			• **Prior therapeutic thoracic radiation therapy**
			• **Dense breast tissue with any one of the following risk factors:**
			  ○ Lifetime risk of breast cancer of ≥20%, according to risk assessment tools based on family history
			  ○ Personal history of BRCA1 or BRCA 2 gene mutations
			  ○ First-degree relative with a BRCA 1 or BRCA 2 gene mutation but not having had genetic testing themselves
			  ○ Prior therapeutic thoracic radiation therapy between ages of 10-30
			  ○ Personal history of Li Fraumeni Syndrome, Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome or a first-degree relative with one of these syndromes.
			
			Breast magnetic resonance imaging (MRI) is unproven and not medically necessary for patients with dense breast tissue not accompanied by defined risk factors as described above.
			
			Digital Breast Tomosynthesis (3-D Mammography)
			Digital tomosynthesis is unproven and not medically necessary for the screening and diagnosis of breast cancer.
			There is insufficient evidence to conclude that digital tomosynthesis of the breast is effective for the screening or diagnosis of breast cancer. Clinical evidence has not yet demonstrated that digital breast tomosynthesis used as an adjunct to standard mammography reduces the mortality rate from breast cancer.
			
			Magnetic Resonance Elastography of the Breast
			Magnetic resonance elastography (MRE) is unproven and not medically necessary for breast cancer screening or diagnosis.
			There is insufficient evidence to conclude that MRE of the breast is effective for the screening or diagnosis of breast cancer. While data from small feasibility studies indicate that MRE may have some ability to discriminate between cancerous tissue and normal breast tissue or benign lesions based on tissue stiffness, there was overlap in values, and the diagnostic accuracy of MRE for detection of breast cancer remains to be determined. There are

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Breast Imaging for Screening and Diagnosing Cancer *(continued)*	Jun. 1, 2015		no definitive patient selection criteria for MRE for breast cancer detection. **Breast Specific Gamma Imaging (Scintimammography)** **Scintimammography is unproven and not medically necessary for breast cancer screening or diagnosis.** There is insufficient evidence that this diagnostic modality can differentiate benign from malignant breast lesions. Based on the evidence, the role of scintimammography remains unclear since this technology has not been shown to be accurate enough to screen for breast cancer or allow a confident decision to defer biopsy **Electrical Impedance Scanning (EIS)** **Electrical impedance scanning (EIS) is unproven and not medically necessary for the detection of breast cancer.** There is insufficient evidence that EIS is effective in detecting malignant breast tissue. Evaluation of sensitivity and negative predictive value for EIS is inconsistent. Well-designed studies are needed to determine whether or not EIS is effective as an adjunct to mammography or provides a positive clinical benefit. **Computer Aided Detection for MRI of the Breast** **Computer aided detection (CAD) is unproven and not medically necessary as an aid for radiologists to interpret contrast-enhanced magnetic resonance imaging (MRI) of the breast.** Clinical evidence has not yet demonstrated that CAD improves patient outcomes or reduces breast cancer mortality when added to contrast-enhanced MRI. There is insufficient evidence to assess whether the use of CAD systems would maintain or increase the sensitivity, specificity, and recall rates of MRI of the breast. Prospective, well-designed and executed studies are needed to determine whether or not the use of CAD provides a positive clinical benefit. **Breast Ultrasound** **Breast ultrasound is unproven and not medically necessary for routine breast cancer screening including patients with dense breast tissue.** Clinical evidence has not yet demonstrated that routine use of ultrasonography as an adjunct to screening mammography reduces the mortality rate from breast cancer.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Breast Imaging for Screening and Diagnosing Cancer *(continued)*	Jun. 1, 2015		**Breast ultrasound is proven and medically necessary as an aid for radiologists to localize breast lesions and in guiding placement of instruments for cyst aspiration and percutaneous breast biopsies.** **Computer Aided Detection for Ultrasound** **Computer-aided detection (CAD) is unproven and not medically necessary as an aid for radiologists to detect breast cancer during ultrasound.** Clinical evidence has not yet demonstrated that CAD improves patient outcomes or reduces breast cancer mortality when added to ultrasonography. Future research should include better-designed studies, including prospective studies and randomized controlled trials evaluating this technology in large numbers of screening ultrasounds. **Automated Breast Ultrasound:** **Automated breast ultrasound is unproven and not medically necessary.** Clinical evidence is insufficient to determine whether automated breast ultrasound improves the detection rate of breast cancer compared to screening mammography. Future research should include better-designed studies, including prospective studies and randomized controlled trials evaluating this technology. **Refer to the Evidence-Based Clinical Guidelines – Imaging for:** • Magnetic resonance imaging (MRI) of the breast • 3D rendering of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modalities
Corneal Hysteresis and Intraocular Pressure Measurement	Jul. 1, 2015	• Updated list of applicable CPT codes; added 66999 • Updated supporting information to reflect the most current clinical evidence, CMS information, and references; no change to coverage rationale	**Measurement of corneal hysteresis is unproven and not medically necessary for the diagnosis and management of corneal disorders and glaucoma.** There is insufficient evidence to evaluate corneal hysteresis measurement for the purpose of assessing corneal viscoelasticity. Studies do not demonstrate that the measurement of corneal hysteresis impacts health outcomes such as improving vision or increasing the detection of ocular disorders. Further investigation that demonstrates the clinical usefulness of this procedure is necessary before it can be considered proven.

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Corneal Hysteresis and Intraocular Pressure Measurement *(continued)*	Jul. 1, 2015		**Measurement of ocular blood flow by intraocular pressure sampling using an ocular blood flow tonometer is unproven and not medically necessary for the diagnosis and management of glaucoma and other ocular disorders.** There is insufficient evidence to evaluate ocular blood flow measurement. Studies do not demonstrate that the measurement of ocular blood flow improves health outcomes such as improving vision or increasing the detection of glaucoma and other ocular disorders. Further clinical trials demonstrating the clinical usefulness of this procedure are necessary before it can be considered proven. **Monitoring of intraocular pressure during vitrectomy is unproven and not medically necessary.** There is insufficient evidence to indicate that intraocular pressure improves health outcomes such as visual acuity recovery in patients who undergo vitrectomy. Additional clinical trials are required to determine if monitoring of intraocular pressure during vitrectomy accurately measures intraocular pressure and if it improves visual acuity recovery after vitrectomy. **Continuous monitoring of intraocular pressure for 24 hours or longer in patients with glaucoma is unproven and not medically necessary.** There is insufficient evidence to conclude that continuous monitoring of intraocular pressure improves health outcomes in patients with glaucoma. Further studies are needed to evaluate the long-term safety and tolerability of continuous monitoring of intraocular pressure before it can be implemented in clinical practice.
Extracorporeal Shock Wave Therapy	Jun. 1, 2015	• Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references; no change to coverage rationale or list of applicable codes	**Extracorporeal shock wave therapy (ESWT), whether low energy, high energy or radial wave, is unproven and not medically necessary for the treatment of:** • Achilles tendonitis • Calcaneal spur • Calcific tendonitis of the shoulder (rotator cuff) • Chronic plantar fasciitis (including plantar fibromatosis and plantar nerve lesion) • Delayed or nonunion of fractures • Hammer toe • Lateral epicondylitis (tennis and golfers elbow) • Tenosynovitis of the foot or ankle

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Extracorporeal Shock Wave Therapy *(continued)*	Jun. 1, 2015		• Tibialis tendinitis • Wounds including ulcers The available evidence regarding the efficacy of ESWT is conflicting. There is insufficient evidence regarding the durability of the treatment effects of ESWT. Patient selection criteria have not been adequately defined and optimal treatment parameters have not been established. Finally, in some studies, ESWT is no more effective than sham treatment in relieving pain. This policy does not address extracorporeal shock wave lithotripsy (ESWL).
Fetal Aneuploidy Testing Using Cell-Free Fetal Nucleic Acids in Maternal Blood	Jul. 1, 2015	• Updated list of applicable CPT codes to reflect quarterly code edits (effective 07/01/2015); added 0009M	**DNA-based noninvasive prenatal tests of fetal aneuploidy are proven and medically necessary as screening tools for trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome) or trisomy 13 (Patau syndrome) in ANY ONE of the following circumstances:** • Maternal age of 35 years or older at delivery • Fetal ultrasound findings indicating an increased risk of aneuploidy • History of a prior pregnancy with a trisomy • Positive first- or second-trimester screening test results for aneuploidy • Parental balanced Robertsonian translocation with an increased risk of fetal trisomy 13 or trisomy 21. **DNA-based noninvasive prenatal tests of fetal aneuploidy are unproven and not medically necessary for pregnant women who do not meet the above criteria or women with multiple gestations.** Further studies are needed to evaluate the use of these tests in low-risk populations or women with multiple gestations. **Genetic Counseling** 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.
Gastrointestinal Motility Disorders, Diagnosis and Treatment	Jun. 1, 2015	• Updated supporting information to reflect the most current CMS information; no change to coverage rationale or list of applicable codes	**Gastric Electrical Stimulation Therapy** **Gastric electrical stimulation therapy is proven and medically necessary for refractory diabetic gastroparesis that has failed other therapies, the treatment of chronic, intractable (drug-refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology when used according to U.S. Food and Drug**

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Gastrointestinal Motility Disorders, Diagnosis and Treatment *(continued)*	Jun. 1, 2015		**Administration (FDA) labeled indications.** See the U.S. Food and Drug Administration (FDA) section for information regarding FDA labeling and Humanitarian Device Exemption (HDE) for gastric electrical stimulation. **Manometry and Rectal Sensation, Tone, and Compliance Test** **The following tests are proven for evaluating anorectal function:** • **Rectal sensation, tone, and compliance test** • **Anorectal manometry** **Colonic manometry is unproven and not medically necessary for evaluating colon motility.** There is insufficient clinical evidence of efficacy in the published peer-reviewed medical literature for the use of colon motility testing or colonic manometry. Patient selection criteria and the role of colonic manometry in the management of motility abnormalities such as refractory constipation must be better defined in statistically robust, well-designed clinical trials. **Defecography** **Defecography is proven and medically necessary for the evaluation of intractable constipation, and for patients with constipation who have one or more of the following conditions that are suspected to be the cause of impaired defecation:** • Pelvic floor dyssynergia (inappropriate contraction of the puborectalis muscle) or • Enterocele (e.g. after hysterectomy) or • Anterior rectocele **Defecography is unproven and not medically necessary for the routine evaluation of constipation for conditions other than those listed above.** Direct visualization is the preferred method of evaluating intractable constipation in the absence of the stated indications above. **MRI defecography is unproven and not medically necessary for the evaluation of constipation and anorectal or pelvic floor disorders.** There is insufficient clinical evidence of efficacy in the published peer-reviewed medical literature for the use of MRI defecography. The utility of this advanced imaging technology in the evaluation and management of refractory constipation must be better defined in statistically robust, well-designed clinical trials.

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Gastrointestinal Motility Disorders, Diagnosis and Treatment *(continued)*	Jun. 1, 2015		**Electrogastrography and Electroenterography** **Cutaneous, mucous, or serosal electrogastrography or electroenterography is unproven and not medically necessary for diagnosing intestinal or gastric disorders including gastroparesis.** There is insufficient evidence to conclude that electrogastrography or electroenterography can accurately diagnose gastroparesis and other gastric or intestinal disorders. There are no data to conclude that electrogastrography or electroenterography is beneficial for health outcomes in patients with gastric or intestinal disorders.
Macular Degeneration Treatment Procedures	Jul. 1, 2015	• Added benefit considerations language for *Essential Health Benefits for Individual and Small Group* plans to indicate: ○ 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	**Implantable Miniature Telescope (IMT)** **The Implantable Miniature Telescope is proven and medically necessary when used according to U.S. Food and Drug Administration (FDA) labeled indications for the treatment of patients with end-stage, age-related macular degeneration.** See the FDA section of this policy for a complete list of FDA indications and contraindications for IMT. **Conjunctival Incision with Placement of a Pharmacologic Agent** **Conjunctival incision with posterior extrascleral placement of a pharmacologic agent is unproven and not medically necessary to treat ocular disorders including age-related macular degeneration.** Conjunctival incision with posterior extrascleral placement of a pharmacologic agent has not been demonstrated to be as effective as standard therapy for ocular disorders including macular degeneration. Further studies with larger sample sizes are needed to demonstrate the efficacy of this treatment. **Epiretinal Radiation Therapy** **Epiretinal radiation therapy is unproven and not medically necessary for the treatment of ocular disorders including age-related macular degeneration.** The evidence does not support the use of epiretinal radiation therapy. Controlled trials with larger patient populations are needed to demonstrate the effectiveness of this procedure. **Laser Photocoagulation** **Laser photocoagulation is unproven and not medically necessary for**

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Macular Degeneration Treatment Procedures *(continued)*	Jul. 1, 2015	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 enrollee specific benefit document to determine benefit coverage • 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	**the treatment of macular drusen.** Results of available studies lead to the conclusion that current prophylactic laser treatment does not benefit patients who have macular drusen.
Magnetoencephalography and Magnetic Source Imaging for Specific Neurological Applications	Jun. 1, 2015	• Routine review; no change to coverage rationale or lists of applicable codes	**Magnetoencephalography and magnetic source imaging (MEG/MSI) are proven and medically necessary for the following:** • **Presurgical evaluation in patients with intractable focal epilepsy** • **Presurgical evaluation of brain tumors and vascular malformations** • **Presurgical planning for refractory epilepsy when other methods do not localize a seizure focus.** **Magnetoencephalography and magnetic source imaging (MEG/MSI) are unproven and not medically necessary for the evaluation of brain function in patients with trauma, stroke, learning disorders, or other neurologic disorders and psychiatric conditions such as schizophrenia.** There is insufficient evidence to conclude that the use of MEG/MSI improves health outcomes such as improved diagnostic accuracy and treatment planning for patients with trauma, stroke, learning disorders, or other neurologic disorders and psychiatric conditions. Further clinical trials

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Magnetoenceph-alography and Magnetic Source Imaging for Specific Neurological Applications *(continued)*	Jun. 1, 2015		demonstrating the clinical usefulness of this procedure are necessary before it can be considered proven to have a benefit on health outcomes for these conditions.
Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD)	Jul. 1, 2015	• Updated list of applicable CPT codes to reflect quarterly code edits (effective 07/01/2015): ○ Added 0392T and 0393T	**Endoscopic therapies are unproven and not medically necessary for the treatment of gastroesophageal reflux disease (GERD).** Endoscopic therapies include: 1. Radiofrequency energy • Stretta System 2. Endoscopic plication or suturing • Bard EndoCinch Endoscopic Suturing System • Endoscopic Suturing Device (ESD) • Surgical Endoscopic Plication System (EPS) • EsophyX™ System with SerosaFuse™ Fastener (transoral incisionless fundoplication procedure) 3. Injection or implantation techniques • Gatekeeper Reflux Repair System • Plexiglas (polymethylmethacrylate [PMMA]) procedure • Durasphere® The safety and efficacy of endoscopic therapies for the treatment of GERD have not been established in the published medical literature. Current studies are generally of small to moderate size, lack adequate control or comparison groups, and provide only short-term follow-up. Well-designed clinical trials with long-term follow up are required to establish that endoscopic therapies benefit health outcomes in patients with GERD by eliminating symptoms, preventing recurrence of symptoms or progression of disease, healing esophagitis, and reducing or eliminating the need for pharmacologic therapy. **The LINX™ Reflux Management System is unproven and not**

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) *(continued)*	Jul. 1, 2015		**medically necessary for the treatment of GERD.** The safety and efficacy of this system has not been established in the peer-reviewed medical literature. Available studies are hampered by a number of limitations, including small study size, lack of statistical power, lack of controls or comparators, and lack of long-term follow-up. See the Medical Policy titled Bariatric Surgery for information regarding transoral endoscopic surgery (such as transoral gastroplasty [TOGA®], StomaphyX, and Restorative Obesity Surgery, Endoluminal [ROSE] procedure) for the treatment of obesity.
Obstructive Sleep Apnea Treatment	Jul. 1, 2015	• Updated list of applicable HCPCS codes to reflect quarterly code edits (effective 07/01/2015); removed S8262	**Nonsurgical Treatment** **Removable oral appliances are proven and medically necessary for treating obstructive sleep apnea (OSA) as documented by polysomnography.** Refer to the Medical Policy titled Attended Polysomnography for Evaluation of Sleep Disorders for further information. For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 19th edition, 2015, Oral Appliances (Mandibular Advancement Devices), A-0341 (ACG). **Removable oral appliances are unproven and not medically necessary for treating central sleep apnea.** This type of sleep apnea is caused by impaired neurological function, and these devices are designed to manage physical obstructions. **Nasal dilator devices are unproven and not medically necessary for treating obstructive sleep apnea (OSA).** There is insufficient clinical evidence supporting the safety and efficacy of nasal dilators for treating OSA. Results from available studies indicate that therapeutic response is variable among the participants. Further research from larger, well-designed studies is needed to evaluate the effectiveness of the device compared with established treatments for OSA, to determine its long-term effectiveness and to determine which patients would benefit from this therapy. **Surgical Treatment** **The following surgical procedures are proven and medically necessary for treating obstructive sleep apnea as documented by polysomnography.** Refer to the medical policy titled Attended

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Obstructive Sleep Apnea Treatment *(continued)*	Jul. 1, 2015		Polysomnography for Evaluation of Sleep Disorders for further information. Also see the *Definitions* section of the policy for information on the definitions and severity of OSA. • **Uvulopalatopharyngoplasty (UPPP)** For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 19th edition, 2015, Uvulopalatopharyngoplasty (UPPP), A-0245 (ACG). • **Maxillomandibular advancement surgery (MMA)** For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 19th edition, 2015, Maxillomandibular Osteotomy and Advancement, A-0248 (ACG). • **Multilevel procedures whether done in a single surgery or phased multiple surgeries.** There are a variety of procedure combinations, including mandibular osteotomy and genioglossal advancement with hyoid myotomy (GAHM). For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 19th edition, 2015, Mandibular Osteotomy, A-0247 (ACG). **Radiofrequency ablation of the soft palate and/or tongue base is proven and medically necessary for treating** mild to moderate obstructive sleep apnea **as documented by polysomnography.** Refer to the medical policy titled Attended Polysomnography for Evaluation of Sleep Disorders for further information. In addition to the criteria listed above, radiofrequency ablation of the soft palate and/or tongue base is medically necessary for patients who fail to improve with or cannot tolerate an adequate trial of continuous positive airway pressure (CPAP) or another device, including bi-level positive airway pressure (BiPAP), auto-titrating positive airway pressure (APAP) and/or oral appliances. **The following surgical procedures are unproven and not medically necessary for treating obstructive sleep apnea:** • Laser-assisted uvulopalatoplasty (LAUP) • Palatal implants • Lingual suspension - also referred to as tongue stabilization, tongue stitch or tongue fixation • Transoral robotic surgery (TORS) • Implantable hypoglossal nerve stimulation

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Obstructive Sleep Apnea Treatment *(continued)*	Jul. 1, 2015		There is insufficient evidence to conclude that laser-assisted uvulopalatoplasty (LAUP) results in improved apnea-hypopnea index (AHI) or secondary outcomes. Some studies saw a worsening of symptoms as well as increased complications. Results of studies provide preliminary but inconsistent evidence that palatal implants benefit patients with mild to moderate OSA. However, the magnitude of the benefits has been small; the largest randomized controlled trial (RCT) found that average OSA worsened in spite of treatment; and the available studies involved ≤ 1 year of patient monitoring after treatment. Additional studies are needed to determine the role of palatal implants in the management of OSA There is insufficient evidence to support the safety, efficacy and long-term outcomes of lingual suspension in the treatment of OSA. The published peer-reviewed medical literature includes a few small, uncontrolled studies with short-term follow-up. Large, controlled studies, with long-term follow-up, comparing lingual suspension to established procedures are necessary. There is insufficient evidence to support the safety, efficacy and long-term outcomes of transoral robotic surgery (TORS) in the treatment of OSA. Large, controlled studies, with long-term follow-up, comparing TORS to established procedures are necessary. There is insufficient evidence to support the safety, efficacy and long-term outcomes of hypoglossal nerve stimulation in the treatment of OSA. The optimal patient selection criteria for the use of hypoglossal nerve stimulation have not been defined. Randomized controlled trials or comparative effectiveness trials with long-term follow-up, comparing hypoglossal nerve stimulation to established procedures are necessary to evaluate the effectiveness of this technology. Follow-up polysomnography should be performed following surgery to evaluate response to treatment (Kushida et al., 2006; Ferguson et al., 2006). Refer to the medical policy titled Attended Polysomnography for Evaluation of Sleep Disorders for further information.
Preterm Labor: Identification and Treatment	Jun. 1, 2015	• Updated supporting information to reflect the most current clinical evidence and references;	**Tocolytic Therapy** **The use of tocolytic therapy beyond 7 days is unproven and not medically necessary for preventing spontaneous preterm birth by**

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Preterm Labor: Identification and Treatment *(continued)*	Jun. 1, 2015	no change to coverage rationale or list of applicable codes	**prolonging pregnancy.** See note below regarding terbutaline. Available studies fail to demonstrate any benefit of maintenance tocolysis in terms of gestational age at birth, pregnancy prolongation or birth weight. **Subcutaneous terbutaline pump maintenance therapy is unproven and not medically necessary for delaying or preventing spontaneous preterm birth by prolonging pregnancy.** Terbutaline pump maintenance therapy has not been shown to decrease the risk of preterm birth by prolonging pregnancy. **Note:** On February 17, 2011, the U.S. Food and Drug Administration (FDA) notified healthcare professionals that treatment of preterm labor with terbutaline administered by injection or by continuous infusion pump should not be used beyond 48 to 72 hours in a hospital setting. In particular, injectable terbutaline should not be used in the outpatient or home setting. In addition, oral terbutaline should not be used for prevention or any treatment of preterm labor because it has not been shown to be effective and has similar safety concerns. Death and serious maternal heart problems have been reported after prolonged administration of oral or injectable terbutaline to pregnant women. Additional information available at: http://www.fda.gov/Drugs/DrugSafety/ucm243539.htm. Accessed March 20, 2015. **Home Uterine Activity Monitoring** **Home uterine activity monitoring (HUAM) is unproven and not medically necessary for preventing spontaneous preterm birth.** There is insufficient clinical evidence that home uterine activity monitoring, as an independent variable, reduces the frequency of preterm births. Available studies fail to demonstrate that the use of HUAM reduces the rate of preterm delivery and neonatal complications or improves pregnancy outcomes.
Sodium Hyaluronate	Jul. 1, 2015	• Updated list of applicable ICD-10 diagnosis codes (preview draft effective 10/01/15); added 3E0U36Z, 3E0U37Z, 3E0U3SF, 3E0U3BZ, 3E0U3KZ, 3E0U3NZ and 3E0U3TZ • Updated supporting information	**Treatment with intra-articular injections of sodium hyaluronate is proven and medically necessary for pain due to osteoarthritis of the knee when administered according to U.S. Food and Drug Administration (FDA) labeled indications.** FDA Labeling*: Euflexxa | 3 injections

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Sodium Hyaluronate *(continued)*	Jul. 1, 2015	to reflect the most current clinical evidence, FDA information, and references; no change to coverage rationale	

Gel One	1 injection
Hyalgan	5 injections
Monovisc	1 injection
Orthovisc	3 to 4 injections
Supartz	3 to 5 injections
Synvisc	3 injections
Synvisc One	1 injection

*Hyaluronic acid preparations for the treatment of pain due to osteoarthritis of the knee are deemed therapeutically equivalent. The UnitedHealth Group National Pharmacy and Therapeutics Committee has defined as therapeutically equivalent, products that can be expected to produce essentially the same therapeutic outcome and toxicity.

Note: *There is no evidence that use of one intra-articular hyaluronan product is superior to another.*

Repeated courses of intra-articular hyaluronan injections may be considered under the following conditions:

- Significant pain relief was achieved with the prior course of injections; **and**
- Pain has recurred; **and**
- At least 6 months have passed since the prior course of treatment

Intra-articular injections of sodium hyaluronate are proven and medically necessary for temporomandibular joint (TMJ) disc displacement and osteoarthritis.

Treatment with sodium hyaluronate preparations is unproven and not medically necessary for any other indication not listed above as proven including but not limited to:

- Pain due to osteoarthritis in any joint other than the knee or TMJ
- Any other form of arthritis (including rheumatoid arthritis)
- Patello-femoral syndrome
- Chondromalacia of the knee
- Following total or partial knee joint replacement

Increase in viscoelasticity of synovial fluid after sodium hyaluronate injection

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Sodium Hyaluronate *(continued)*	Jul. 1, 2015		has not been demonstrated in patients with rheumatoid arthritis, and it has not been determined whether sodium hyaluronate is protective in joints affected by rheumatoid arthritis. Further studies are needed to determine the safety and durability of such treatment for patello-femoral syndrome and chondromalacia of the knee and whether it significantly delays the need for more invasive treatment, e.g. surgery, joint replacement or arthroplasty. There are no clinical studies evaluating the use of sodium hyaluronate in persons following total or partial knee joint replacement surgery. **Treatment with hyaluronic acid gel preparations to improve the skin's contour and/or reduce depressions due to acne, scars, injury or wrinkles is considered cosmetic.** The use of sodium hyaluronate preparations to improve the skin's contour and/or reduce depressions in the skin due to acne, scars, injury or wrinkles improves physical appearance but does not remove or improve a functional impairment of the skin.
Temporo-mandibular Joint Disorders	Jul. 1, 2015	• Updated list of applicable HCPCS codes to reflect quarterly code edits (effective 07/01/2015); removed S8262	**The following services are proven and medically necessary for treating disorders of the temporomandibular joint (TMJ):** • Arthrocentesis • Arthroplasty [For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines®, 19th edition, 2015, Temporomandibular Joint Arthroplasty, ACG: A-0523 (AC)] • Arthroscopy (with or without FDA approved bone anchor devices) • Arthrotomy/open joint surgery (with or without FDA approved bone anchor devices) • Injections of corticosteroids for rheumatoid arthritis-related TMJ disorders • Physical therapy • Stabilization and repositioning splint therapy *(Does not include low-load prolonged-duration stretch (LLPS) devices discussed below)* **Partial or total joint replacement with an artificial prosthesis is proven and medically necessary for treating disorders of the temporomandibular joint (TMJ) when all other treatments have failed.** Not all services treat all TMJ disorders; specific treatments are based upon the specific diagnosis.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Temporo-mandibular Joint Disorders *(continued)*	Jul. 1, 2015		**The following services are unproven and not medically necessary for treating disorders of the temporomandibular joint (TMJ):** • Biofeedback • Craniosacral manipulation • Passive rehabilitation therapy • Low-load prolonged-duration stretch (LLPS) devices There are limited studies evaluating biofeedback for the treatment of musculoskeletal pain, including TMJ pain. One small uncontrolled study reported positive effects, while a larger randomized controlled study failed to demonstrate any treatment effect. Well-designed randomized, blinded and placebo-controlled outcome studies published on craniosacral manipulation for TMJ are not available. For additional information regarding manipulation under anesthesia for TMJ disorders, see the Medical Policy titled Manipulation Under Anesthesia. While there are some data from several randomized trials and case series studies that certain types of passive rehabilitation techniques may improve jaw mobility early in recovery in patients who have undergone TMJ surgery, or have lost jaw mobility due to TMJ derangement or to contracture following radiation therapy, these studies all included very small numbers of patients, and did not provide blinded assessment of outcomes, long-term follow-up, or information on optimal treatment protocols. Further prospective controlled clinical trials that directly compare LLPS devices to other treatment modalities are needed.
Transpupillary Thermotherapy	Jul. 1, 2015	• Added benefit considerations language for *Essential Health Benefits for Individual and Small Group* plans to indicate: ○ 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	**Transpupillary thermotherapy is proven and medically necessary for the treatment of retinoblastoma and choroidal melanomas.** **Transpupillary thermotherapy is unproven and not medically necessary for the treatment choroidal neovascularization or macular degeneration.** Results of studies evaluating the use of transpupillary thermotherapy for the prevention or control of choroidal neovascularization lesions in patients with age-related macular degeneration (AMD) do not provide sufficient evidence to conclude that transpupillary thermotherapy improves loss of vision due to AMD.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Transpupillary Thermotherapy *(continued)*	Jul. 1, 2015	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 enrollee specific benefit document to determine benefit coverage • Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or list of applicable codes	

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REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**

Omnibus Codes	Jun. 1, 2015	***Notice of Revision**: The following summary of changes has been modified. Revisions to the policy update announcement previously appearing in the Policy Update Bulletin are outlined in red below. Please take note of the additional updates to be implemented on **June 1, 2015.***
		
		• Revised coverage guidelines for cardiac devices for percutaneous closure (occlusion) of the left atrial appendage (LAA):
		  ○ Changed coverage status for CPT code 0281T from "investigational, unproven and not medically necessary due to lack of U.S. Food and Drug Administration (FDA) approval and insufficient clinical evidence of safety and/or efficacy in the published peer-reviewed medical literature" to "unproven and not medically necessary due to insufficient clinical evidence of safety and/or efficacy in the published peer-reviewed medical literature"
		• Revised coverage guidelines for VeriStrat® serum test:
		  ○ Changed coverage status for CPT code 84999 [Unlisted chemistry procedure (when used to report VeriStrat)] from "unproven" to "proven in certain circumstances"
			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)*	Jun. 1, 2015	○ Revised coverage rationale to indicate the VeriStrat serum-based biomarker test (serum proteomic profiling, using mass spectrometry) is proven for guiding treatment decisions in patients with advanced non-small cell lung cancer (NSCLC) being considered for second-line therapy with an epidermal growth factor receptor (EGFR) inhibitor, such as erlotinib, and whose EGFR mutation status is wild-type (no mutation detected) or unknown ○ Updated supporting information to reflect the most current clinical evidence and references	

RETIRED/REPLACED		
Policy Title	**Effective Date**	**Summary of Changes**
Radiofrequency Therapy and Tibial Nerve Stimulation for Urinary Disorders	Jun. 1, 2015	Policy retired; radiofrequency therapy and tibial nerve stimulation for the treatment of urinary disorders is now covered without need for clinical review

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Entyvio (Vedolizumab)	Jun. 1, 2015	• Updated coverage rationale: ○ Modified coverage criteria for treatment of ulcerative colitis (UC); corrected list of examples of tumor necrosis factor (TNF) blocker*: ▪ Added Simponi (golimumab)] ▪ Removed Cimzia (certolizumab) ○ Modified coverage criteria for treatment of active Crohn's disease (CD); corrected list of examples of tumor necrosis factor (TNF)*: ▪ Added Cimzia (certolizumab) ▪ Removed Simponi (golimumab)] • Removed list of applicable HCPCS codes (C9026) **Note: This correction was made to the policy on 03/30/2015*	1. Vedolizumab is **proven and medically necessary** for the treatment of ulcerative colitis (UC) when **all** of the following criteria are met:[1] A. Moderate to severe disease activity ulcerative colitis (e.g., esophageal, gastroduodenal, perianal, or rectal disease; history of colonic or small-bowel resection) **AND** B. **One** of the following: 1) History of failure, contraindication, or intolerance to at least **one** of the following conventional therapies: • Tumor necrosis factor (TNF) blocker [e.g., Humira (adalimumab), Simponi (golimumab)] • Immunomodulator (e.g., azathioprine, 6-mercaptopurine) • Corticosteroid 2) Corticosteroid dependent (e.g., unable to successfully taper corticosteroids without a return of the symptoms of UC) **AND** C. Patient is not receiving vedolizumab in combination with either of the following: 1) Tumor necrosis factor (TNF) blocker [e.g., Humira (adalimumab), Simponi (golimumab)] 2) Tysabri (natalizumab) 2. Vedolizumab is **proven and medically necessary** for the treatment of active Crohn's disease (CD) when **all** of the following criteria are met:[1] A. Moderate to severe disease activity Crohn's disease (e.g., esophageal, gastroduodenal, perianal, or rectal disease; history of colonic or small-bowel resection) **AND** B. **One** of the following: 1) History of failure, contraindication, or intolerance to at least **one** of the following conventional therapies: i. Tumor necrosis factor (TNF) blocker [e.g., Humira (adalimumab), Cimzia (certolizumab)] ii. Immunomodulator (e.g., azathioprine, 6-mercaptopurine) iii. Corticosteroid 2) Corticosteroid dependent (e.g., unable to successfully taper corticosteroids without a return of the symptoms of UC) **AND**

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Entyvio (Vedolizumab) *(continued)*	Jun. 1, 2015		C. Patient is not receiving vedolizumab in combination with either of the following: 1) Tumor necrosis factor (TNF) blocker [e.g., Humira (adalimumab), Cimzia (certolizumab)] 2) Tysabri (natalizumab) **Centers for Medicare and Medicaid Services (CMS):** Medicare does not have a National Coverage Determination (NCD) for vedolizumab (Entyvio™). Local Coverage Determinations (LCDs) do not exist at this time. Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf. (Accessed October 7, 2014)
Oncology Medication Clinical Coverage Policy	Jul. 1, 2015	• Updated description of "NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)" • Updated benefit considerations; added language for *Essential Health Benefits for Individual and Small Group* plans to indicate: ○ 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),	**Description** 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®). 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. **Coverage Rationale** 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*.) UnitedHealthcare will cover all chemotherapy agents for individuals under the

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Oncology Medication Clinical Coverage Policy *(continued)*	Jul. 1, 2015	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 enrollee specific benefit document to determine benefit coverage	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. **Additional Information** 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 47 individual panels, composed of more than 950clinicians and oncology researchers from the 25 NCCN member institutions and their affiliates. **NCCN Categories of Evidence and Consensus** **Category 1**: The recommendation is based on high-level evidence (ie, 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. **Category 2A**: 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. **Category 2B**: The recommendation is based on lower level evidence, and there is nonuniform consensus that the recommendation should be made. In these instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Oncology Medication Clinical Coverage Policy *(continued)*	Jul. 1, 2015		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. **Category 3**: 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.
Rituxan (Rituximab)	Jul. 1, 2015	• Updated coverage rationale: ○ Reformatted and relocated information pertaining to medical necessity review; added language to indicate if service is "medically necessary" to applicable proven statement • Updated benefit considerations: ○ Added language for *Essential Health Benefits for Individual and Small Group* plans to indicate: ▪ 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	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. Rituximab is **proven** for the treatment of: 1. **Immune thrombocytopenic purpura (ITP)** **Additional information to support medical necessity review where applicable:** Rituximab is **medically necessary** for the treatment of immune thrombocytopenic purpura when **all** of the following criteria are met: A. Diagnosis of immune thrombocytopenic purpura (ITP) **AND** B. Documented platelet count < 50 x 10^9 / L **AND** C. **History of failure, contraindication, or intolerance to **one** of the following: 1) Corticosteroids 2) Immune globulin 3) Splenectomy 2. **Autoimmune mucocutaneous blistering diseases** 3. Rituxan is **proven and medically necessary** for the treatment of **Wegener's granulomatosis or microscopic polyangiitis (both ANCA-associated vasculidities)** when **both** of the following criteria are

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Rituxan (Rituximab) *(continued)*	Jul. 1, 2015	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 enrollee specific benefit document to determine benefit coverage ○ Removed language indicating the State of New Jersey prohibits requiring failed prior therapy or intolerance to therapy as a requirement for coverage • Updated list of applicable ICD-9 codes; added 714.89 • Updated supporting information	met: A. Diagnosis of Wegener's granulomatosis or microscopic polyangiitis **AND** B. **One** of the following: 1) Patient is receiving concurrent therapy with glucocorticoids 2) **History of contraindication or intolerance to glucocorticoids 4. **Autoimmune hemolytic anemia, including chronic cold agglutinin disease** 5. Rituxan is **proven and medically necessary** for the treatment of **rheumatoid arthritis** when **all** of the following criteria are met: A. Moderate to severe disease activity [e.g., swollen, tender joints with limited range of motion] **AND** B. **One** of the following: 1) Patient is receiving concurrent therapy with methotrexate 2) **History of contraindication or intolerance to methotrexate **AND** C. **History of failure, contraindication or intolerance to at least **one** tumor necrosis factor (TNF) inhibitors [e.g., adalimumab (Humira), etanercept (Enbrel), infliximab (Remicade)] **AND** D. Patient is not receiving rituximab in combination with either of the following: 1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] 2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] 6. **Post-transplant B-lymphoproliferative disorder** 7. **Neuromyelitis optica** Rituximab is **unproven** for the treatment of: 1. Anti-GM1 antibody-related neuropathies 2. Kaposi sarcoma-associated herpes virus-related multicentric Castleman disease 3. Pure red cell aplasia 4. Systemic lupus erythematosus 5. Acquired factor VIII inhibitors 6. Polyneuropathy associated with anti-MAG antibodies 7. Idiopathic membranous nephropathy

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Rituxan (Rituximab) *(continued)*	Jul. 1, 2015	to reflect the most current clinical evidence, FDA information and references	8. Chronic graft-versus-host disease 9. Reduction of anti-HLA antibodies in patients awaiting renal transplant 10. Multiple sclerosis 11. Dermatomyositis and polymyositis While a beneficial effect of rituximab has been reported in some of these conditions, none of them have shown positive results in large, controlled clinical trials. **Centers for Medicare and Medicaid Services (CMS):** Medicare does not have a National Coverage Determination (NCD) for rituximab. Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for Rituximab (Rituxan®) and Drugs and Biologicals: Rituximab (Rituxan ®). In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. Refer to the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, section 50 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf (Accessed February 11, 2015)
Vaccines	Jul. 1, 2015	• Updated benefit considerations; added language for *Essential Health Benefits for Individual and Small Group* plans to indicate: ○ 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),	The standard UnitedHealthcare Certificate of Coverage covers preventive health services, including immunizations, administered in a physician office. Some immunizations are excluded, e.g., immunizations that are required for travel, employment, education, insurance, marriage, adoption, military service, or other administrative reasons. An immunization that does not fall under one of the exclusions in the Certificate of Coverage is considered covered after all of the following conditions are satisfied: 1. US Food and Drug Administration (FDA) approval; 2. ACIP definitive ("shall") recommendation rather than a permissive ("may") recommendation published in the Morbidity & Mortality Weekly Report (MMWR) of the Centers for Disease Control and Prevention (CDC). Implementation will typically occur within 60 days after publication in the MMWR. Please also refer to UnitedHealthcare's Preventive Care Services Guideline for

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UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Vaccines *(continued)*	Jul. 1, 2015	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 enrollee specific benefit document to determine benefit coverage	additional information on vaccines covered as preventive services. **Centers for Medicare and Medicaid Services (CMS):** Medicare does not have a National Coverage Determination (NCD) for Immunizations. Local Coverage Determinations (LCDs) do exist; refer to the LCDs for Immunizations. For specific coverage information of immunizations under the Medicare Part B program, refer to the Medicare Benefit Policy Manual (Pub. 100-2) Chapter 15 Covered Medical and Other Health Services Section 50.4.4.2 Immunizations available at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf. (Accessed February 3, 2015)

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Maximum Dosage Policy	Jul. 1, 2015	• Revised coverage rationale: ○ Added J code based maximum dosage information for zoledronic acid (brand) ○ Added maximum allowed quantity for National Drug Code (NDC) billing for Neulasta (pegfilgrastim) and zoledronic acid ○ Updated CMS information • Updated benefit considerations; added language for *Essential Health Benefits for Individual*	Refer to the policy for complete details on Maximum Dosage guidelines.

Drug and Biologics Policy Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Maximum Dosage Policy *(continued)*	Jul. 1, 2015	*and Small Group* plans to indicate: ○ 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 enrollee specific benefit document to determine benefit coverage • Updated applicable codes; added NDC listings for zoledronic acid	

Drug and Biologics Policy Updates

REVISED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors	Jul. 1, 2015	• Revised coverage rationale:
		  ○ Added langage to indicate the proven uses are "medically necessary"
		  ○ Updated list of proven/medically necessary indications for treatment with Eylea (aflibercept) and Lucentis (ranibizumab); added diabetic retinopathy in patients with diabetic macular edema (DME)
		  ○ Updated CMS information
		• Updated supporting information to reflect the most current clinical evidence, FDA information and references
			This policy provides information about the use of certain specialty pharmacy medications administered by the intravitreal route for ophthalmologic conditions.
			
			This policy refers to the following drug products, all of which are vascular endothelial growth factor (VEGF) inhibitors:
			• aflibercept (Eylea™)
			• bevacizumab (Avastin®)
			• pegaptanib (Macugen®)
			• ranibizumab (Lucentis®)
			
			Proven Uses
			Eylea (aflibercept) is proven and medically necessary for the treatment of:
			1. Neovascular age-related macular degeneration (AMD)
			2. Diabetic macular edema (DME)
			3. Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)
			4. Diabetic retinopathy in patients with diabetic macular edema (DME)
			
			Avastin (bevacizumab) is proven and medically necessary for the treatment of:
			1. Neovascular age-related macular degeneration (AMD)
			2. Diabetic macular edema
			3. Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)
			4. Proliferative diabetic retinopathy
			5. Neovascular glaucoma
			6. Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome (OHS)
			
			Macugen (pegaptanib) is proven and medically necessary for the treatment of:
			1. Neovascular age-related macular degeneration (AMD)
			2. Diabetic macular edema
			
			Lucentis (ranibizumab) is proven and medically necessary for the treatment of:

Drug and Biologics Policy Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors *(continued)*	Jul. 1, 2015		1. Neovascular age-related macular degeneration (AMD) 2. Diabetic macular edema (DME) 3. Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) 4. Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome (OHS) 5. Diabetic retinopathy in patients with diabetic macular edema (DME) **Unproven Use** Aflibercept, bevacizumab, pegaptanib, and ranibizumab are **unproven** for the treatment of retinopathy of prematurity. Because VEGF is involved in a wide variety of physiologic processes, the ocular and systemic safety of anti-VEGF agents is of prime concern in neonates. **Additional Information** Bevacizumab is supplied in sterile vials containing a solution of 25 mg/mL. Doses utilized in ophthalmic conditions generally range from 6.2 mcg to 2.5 mg. Therefore, bevacizumab in vials is often divided into single-dose, prefilled syringes for intravitreal use by compounding pharmacies. Compounding pharmacies must comply with United States Pharmacopeia (USP) Chapter 797, which sets standards for the compounding, transportation, and storage of compounded sterile products (CSP). The Pharmacy Compounding Accreditation Board can verify that the pharmacy is adhering to these standards. The American Society of Retinal Specialists (ASRS) is committed to ensuring that retina specialists have access to compounded drugs (such as Avastin) that are prepared with high-quality material following good quality controls and sound engineering design by appropriately trained personnel. Please refer to their information page at https://www.asrs.org/advocacy-practice/access-to-safe-compounded-agents for resources pertaining to access of safe compounded agents. Please refer to the US Food and Drug Administration (FDA) Section of this policy for information related to contamination of compounded bevacizumab. In an effort to guard against contamination during the compounding process,

Drug and Biologics Policy Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors *(continued)*	Jul. 1, 2015		the United States Veterans Health Administration (USVHA) requires that only USVHA pharmacies may dispense bevacizumab for intravitreal administration to Veterans Administration beneficiaries. The medication must be dispensed directly to the VA ophthalmologist, who will then be responsible for preparing and administering the bevacizumab dose for each patient. In addition to strict labeling and storage requirements, the ophthalmologist is required to prepare only one dose of medication from each vial; if both eyes are to be treated, a separate vial and syringe must be utilized. **Centers for Medicare and Medicaid Services (CMS):** Medicare does not have a National Coverage Determination (NCD) for bevacizumab (Avastin®), Aflibercept (Eylea™), Ranibizumab (Lucentis ®) or Macugen. There are Local Coverage Determinations (LCDs) for Avastin®, Lucentis ®, Eylea™ and Macugen. Refer to the LCDs for Drugs and Biologicals: Antiangiogenic Therapy for Ophthalmic Conditions, Drugs and Biologics (Non-chemotherapy), Drugs and Biologicals, Coverage of, for Label and Off-Label Uses, Drugs and Biologicals: Bevacizumab (Avastin®), Intravitreal Bevacizumab (Avastin®), Ranibizumab (Lucentis ®) and Macugen (pegaptanib sodium injection). In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf. (Accessed February 26, 2015)

Coverage Determination Guideline (CDG) Updates

UPDATED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Breast Reduction Surgery	Jun. 1, 2015	• Routine review; no change to coverage determination guidelines	**Benefit Document Language** Before using this guideline, please check the enrollee specific benefit document and any federal or state mandates, if applicable. **Essential Health Benefits for Individual and Small Group:** For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee specific benefit document to determine benefit coverage. **Indications for Coverage** Breast reduction surgery following mastectomy to achieve symmetry is covered as part of the Women's Health and Cancer Rights Act (WHCRA). Please refer to the Coverage Determination Guideline titled Breast Reconstruction Post Mastectomy for additional information. **Criteria for a Coverage Determination as Reconstructive:** Breast reduction surgery is considered reconstructive and medically necessary when the following criteria are met: A. Macromastia is the primary etiology of the member's functional impairment or impairments (as defined in the *Definitions* section). The following are examples of functional impairments that must be attributable to macromastia to be considered (not an all-inclusive list): • Severe skin excoriation/intertrigo unresponsive to medical management • Severe restriction of physical activities that meets the definition of functional impairment • Signs and symptoms of nerve compression that are unresponsive to medical management (e.g. ulnar paresthesias) • Acquired kyphosis that is attributed to macromastia • Chronic breast pain due to weight of the breasts

Coverage Determination Guideline (CDG) Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Breast Reduction Surgery *(continued)*	Jun. 1, 2015		• Upper back, neck, or shoulder pain • Shoulder grooving from bra straps • Headache **and** B. The amount of tissue to be removed plots above the 22nd percentile; or C. If the amount of tissue to be removed plots between the 5th and 22nd percentiles, the procedure may be either reconstructive or cosmetic; the determination is based on the review of the information provided; and D. Diagnostic tests, if done, have ruled out other causes of the functional impairment; and E. The proposed procedure is likely to result in significant improvement of the functional impairment The following documentation may be requested as part of the review: Reduction Mammoplasty documentation should include the evaluation and management note for the date of service and the note for the day the decision to perform surgery was made. The enrollee's medical record must contain, and be available for review on request, the following information: • Height and weight • Body Surface Area (BSA) • Photographs that document macromastia **Coverage Limitations and Exclusions** Some states require benefit coverage for services that UnitedHealthcare considers cosmetic procedures, such as repair of external congenital anomalies in the absence of a functional impairment. Please refer to enrollee specific benefit documents. 1. Cosmetic Procedures are excluded from coverage. Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures. The fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure. 2. Any procedure that does not meet the reconstructive criteria above in the Indications for Coverage section, e.g. psychological or social reasons, breast size asymmetry unless post mastectomy, exercise. 3. Breast reduction surgery is cosmetic when done to improve appearance without improving a functional/physiologic impairment.

Coverage Determination Guideline (CDG) Updates

UPDATED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Breast Reduction Surgery *(continued)*	Jun. 1, 2015		4. The use of liposuction as the sole procedure for breast reduction surgery is considered cosmetic. **Appendix** This Schnur chart may be used to assess whether the amount of tissue that will be removed is reasonable for the body habitus, and whether the procedure is cosmetic or reconstructive in nature. 1. If the amount plots above the 22nd percentile and the member has a functional impairment, the procedure is reconstructive. 2. If the amount plots below the 5th percentile, the procedure is cosmetic. 3. If the amount plots between the 5th and 22nd percentiles, the procedure may be either reconstructive or cosmetic based on review of information. To calculate body surface area (BSA) see http://www-users.med.cornell.edu/~spon/picu/calc/bsacalc.htm **OR** BSA = ($W^{0.425}$ x $H^{0.725}$) x 0.007184 (weight is in kilograms and the height is in centimeters.) **Modified Schnur Nomogram Chart**

Body Surface (m2)	Lower 5th Percentile	Lower 22nd Percentile
1.35	127	199
1.40	139	218
1.45	152	238
1.50	166	260
1.55	181	284
1.60	198	310
1.65	216	338
1.70	236	370
1.75	258	404
1.80	282	441
1.85	308	482
1.90	336	527
1.95	367	575
2.00	401	628

Coverage Determination Guideline (CDG) Updates

UPDATED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Breast Reduction Surgery *(continued)*	Jun. 1, 2015		2.05 439 687 2.10 479 750 2.15 523 819 2.20 572 895 2.25 625 978 2.30 682 1,068 2.35 745 1,167 2.40 814 1,275 2.45 890 1,393 2.50 972 1,522 2.55 1,062 1,662
Clinical Trials	Jul. 1, 2015	• Updated coverage rationale: **Indications for Coverage** ○ Reformatted *Criteria for Approved Clinical Trials*; removed sub-header for "Federally Funded Trials" ○ Modified language pertaining to *Routine Patient Costs During Clinical Trials*; replaced references to "investigational item or service" with "experimental or investigational service or item" **Coverage Limitations and Exclusions** ○ Updated list of applicable coverage limitations and exclusions; added language to clarify benefit coverage is not provided for clinical trials that do not meet the requirements listed in the *Indications for Coverage* section of the policy (an example includes, but is not	Refer to the policy for complete details on the coverage guidelines for Clinical Trials.

Coverage Determination Guideline (CDG) Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Clinical Trials *(continued)*	Jul. 1, 2015	limited to, Phase 0 drug clinical trials) • Updated definitions; removed definition of "investigational device exemption"	
Gynecomastia Treatment	Jun. 1, 2015	• Routine review; no change to coverage determination guidelines	**Benefit Document Language** Before using this guideline, please check the enrollee specific benefit document and any federal or state mandates, if applicable. **Essential Health Benefits for Individual and Small Group:** For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee specific benefit document to determine benefit coverage. **Indications for Coverage** **Criteria for a Coverage Determination that surgery is reconstructive and medically necessary:** I. Mastectomy or suction lipectomy for treatment of benign gynecomastia for a male patient under age 18 is considered reconstructive and medically necessary when all the following criteria are met: A. Gynecomastia or breast enlargement with moderate to severe chest pain that is causing a functional/physical impairment as defined in the *Definitions* section. The inability to participate in athletic events, sports or social activities is not considered to be a functional/physical or physiological impairment. B. No prior history of prescribed medications and appropriate screening(s) of non-prescription and/or recreational drugs or

Coverage Determination Guideline (CDG) Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Gynecomastia Treatment *(continued)*	Jun. 1, 2015		substances that have a known side effect of gynecomastia. (examples include but are not limited to the following, testosterone, marijuana, asthma drugs, phenothiazines, anabolic steroids, cimetidine and calcium channel blockers) C. The breast enlargement must be present for at least 2 years. If so, lab tests which might include, but are not limited to the following must be performed: 1. thyroid function studies; 2. testosterone; 3. Beta subunit HCG II. Mastectomy or suction lipectomy for treatment of benign gynecomastia for a male patient age 18 and up is considered reconstructive and medically necessary when all the following criteria are met: A. Discontinuation of medications, nutritional supplements, and non-prescription medications or substances (examples include but are not limited to the following, testosterone, marijuana, asthma drugs, phenothiazines, anabolic steroids, cimetidine and calcium channel blockers) that have a known side effect of gynecomastia or breast enlargement and the breast size did not regress after discontinuation of use as appropriate. B. Gynecomastia or breast enlargement with moderate to severe chest pain that is causing a functional/physical impairment as defined below in the Definitions section. The inability to participate in athletic events, sports or social activities is not considered to be a functional/physical or physiological impairment. C. Review of test results that have been performed to rule out certain diseases or other causes of gynecomastia (examples include but are not limited to blood tests, e.g. hormone levels estrogen, testosterone, liver and kidney function studies/enzymes) D. Glandular breast tissue is the primary cause of gynecomastia as opposed to fatty deposits and is documented on physical exam and/or mammography. **Additional Information**: In most cases breast enlargement and/or benign gynecomastia spontaneously resolves by age 18 making treatment unnecessary. Gynecomastia during puberty is not uncommon and in 90% of cases regresses within 3 years of onset.

Coverage Determination Guideline (CDG) Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Gynecomastia Treatment *(continued)*	Jun. 1, 2015		If a tumor or neoplasm is suspected, a breast ultrasound and/or mammogram may be performed. As indicated, a breast biopsy may also be performed. **Coverage Limitations and Exclusions** 1. Treatment of benign gynecomastia when specifically excluded in the enrollee specific benefit document. 2. Treatment of benign gynecomastia when not specifically excluded in the enrollee specific benefit document and the above criteria is not met. 3. Most medical and surgical treatments for benign gynecomastia are considered cosmetic. Medical treatments and surgery to alter a perceived abnormal appearance, or for psychological reasons, are considered cosmetic and are not covered. The fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of benign gynecomastia does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure.

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**

Preventive Care Services	Jul. 1, 2015	• Revised coverage rationale/indications for coverage:
		  ○ Updated language pertaining to **Cost Sharing for Non-Grandfathered Health Plans**; added language to indicate, depending on the plan, eligible expenses for services from non-network providers may not equal the provider's billed charges (refer to plan's schedule of benefits)
		• Revised list of applicable procedure codes for **Preventive Care Services**:
		  ○ Updated service description
			Refer to the policy for complete details on the coverage guidelines for Preventive Care Services.

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Jul. 1, 2015	table header to clarify "a date in this column is *when the* rating was released, not when *the benefit is* effective" ***Chlamydia Infection Screening – Females*** ○ Updated service description: ▪ Updated service title/header to indicate guidelines apply to females ▪ Replaced *USPSTF Ratings A and B (June 2007)* with *USPSTF Rating B (September 2014)* indicating: - *The* USPSTF recommends screening for chlamydia in sexually active women age 24 years and younger and in older women who are at increased risk for infection ▪ Added notation to clarify the USPSTF recommendation applies to all sexually active adolescents and adult women, including pregnant women ○ Reformatted/clarified lists of applicable diagnosis codes and claims edit criteria ***Gonorrhea Screening – Females*** ○ Updated service description:	

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Jul. 1, 2015	▪ Updated service title/header to indicate guidelines apply to females ▪ Replaced *USPSTF Rating B (May 2005)* with *USPSTF Rating B (September 2014)* indicating: - The USPSTF recommends screening for gonorrhea in sexually active women age 24 years and younger and in older women who are at increased risk for infection ○ Reformatted/clarified lists of applicable diagnosis codes and claims edit criteria ***Hepatitis B Virus Infection Screening*** ○ Reformatted/clarified lists of applicable diagnosis codes and claims edit criteria ***HIV – Human Immunodeficiency Virus – Screening for Adolescents and Adults*** ○ Reformatted/clarified lists of applicable diagnosis codes and claims edit criteria ***Syphilis Screening*** ○ Reformatted/clarified lists of applicable diagnosis codes and claims edit criteria	

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Jul. 1, 2015	***Screening Mammography*** ○ Updated service description; added reference link to the medical policy titled *Breast Imaging for Screening and Diagnosing Cancer* ○ Updated claims edit criteria; added language to clarify: ▪ This benefit only applies to screening mammography ▪ This benefit does not apply to other screening methods, including but not limited to, digital breast tomosynthesis (3-D mammography) ***Cholesterol Screening (Lipid Disorders Screening)*** ○ Reformatted list of applicable ICD-9 diagnosis codes for *Body Mass Index 40 And Over, Adult* ***Immunizations*** ○ Removed and relocated lists of applicable codes and claims edit criteria to new/separate table titled **Preventive Immunizations**: ▪ Added language to indicate: - In the case of a public health emergency (as defined by the Centers for Disease Control or state or	

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Jul. 1, 2015	local public health departments), UnitedHealthcare may choose to apply preventive benefits to a new vaccine if the vaccine has FDA approval, even if an ACIP recommendation has not been announced - Brand names/trade names are included, *when available*, as examples for convenience only; coverage pursuant to this Coverage Determination Guideline is based solely on the procedure codes - Age Group information is provided for informational use only; for purposes of this document, "adult" means age 18 years and up and "pediatric" means age 0-18 years - Benefit Limits are from FDA labeling and ACIP recommendations; codes that indicate "for applicable age	

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Jul. 1, 2015	see code description" are limited to the age(s) listed in the code description ▪ Reformatted coverage guidelines by service type category - Added CPT/HCPCS code descriptions and applicable brand/trade names (when available) - Clarified content/language pertaining to age and benefit limits ▪ Updated coverage guidelines for CPT code 90723 [Diptheria, tetanus and acellular pertussis, hepatits B, and polio inactive (DTaP-HepB-IPV); added benefit limit guideline of 0-6 years (ends on 7th birthday) ***Behavioral Counseling in Primary Care to Promote a Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults with Cardiovascular Risk Factors*** ○ Updated service description: ▪ Renamed/retitled service title/header; previously titled *Behavioral Counseling in Primary*	

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Jul. 1, 2015	*Care to Promote a Healthy Diet* ▪ Replaced *USPSTF Rating B (January 2003)* with *USPSTF Rating B (September 2014)* indicating: - The USPSTF recommends offering or referring adults who are overweight or obese and have additional cardiovascular disease (CVD) risk factors to intensive behavioral counseling interventions to promote a healthful diet and physical activity for CVD prevention ○ Updated lists of applicable diagnosis codes to align with USPSTF recommendations: ▪ Added: **Overweight** - ICD-9: 278.02, V85.21, V85.22, V85.23, V85.24, and V85.25 - ICD-10: E66.3, Z68.25, Z68.26, Z68.27, Z68.28, and Z68.29 **Body Mass Index 30.0 – 39.9**	

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Jul. 1, 2015	- ICD-9: V85.30, V85.31, V85.32, V85.33, V85.34, V85.35, V85.36, V85.37, V85.38, and V85.39 - ICD-10: Z68.30, Z68.31, Z68.32, Z68.33, Z68.34, Z68.35, Z68.36, Z68.37, Z68.38, and Z68.39 **Body Mass Index 40.0 and Over** - ICD-9: V85.41, V85.42, V85.43, V85.44, and V85.45 - ICD-10: Z68.41, Z68.42, Z68.43, Z68.44, and Z68.45 **Impaired Fasting Glucose** - ICD-9: 790.21 - ICD-10: R73.01 **Metabolic Syndrome** - ICD-9: 277.7 - ICD-10: E88.81 ▪ Changed sub-header/title for "Hyperlipidemia" to "Hyperlipidemia/Dyslipidemia" ***Behavioral Counseling to Prevent Sexually Transmitted Infections*** ○ Updated service description; replaced *USPSTF Rating B (October 2008)* with *USPSTF*	

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Jul. 1, 2015	*Rating B (August 2014)* indicating: ▪ The USPSTF recommends intensive behavioral counseling for all sexually active adolescents and for adults who are at increased risk for sexually transmitted infections (STIs) • Updated **Appendix A – USPSTF Grade Definitions**: ○ Added Grade Definitions for USPSTF Recommendations dated **after July 2012** ○ Updated Grade Definitions for USPSTF Recommendations dated **after May 2007**; revised Grade C Definition to indicate: ▪ Clinicians may provide this service to selected patients depending on individual circumstances; however, for most individuals without signs or symptoms there is likely to be only a small benefit from this service (this statement is undergoing USPSTF revision)	

Coverage Determination Guideline (CDG) Updates

REVISED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Rhinoplasty and Other Nasal Surgeries	Jul. 1, 2015	• Changed policy title; previously titled *Rhinoplasty and Repair of Vestibular Stenosis* • Revised coverage rationale/indications for coverage: **Rhinoplasty for Nasal Vestibular Stenosis or Alar Collapse** ○ Updated coverage criteria for reconstructive/medically necessary treatment: ▪ Removed criterion requiring "internal and/or external nasal valve compromise causes an anatomic mechanical nasal airway obstruction and is a primary contributing factor for obstructed nasal breathing. (e.g., large cutaneous defect, malignancy or trauma) ▪ Added criterion requiring "internal valve compromise due to collapse of the upper lateral cartilage and/or external nasal valve compromise due to collapse of the alar (lower lateral) cartilage resulting in an anatomic mechanical nasal airway obstruction that is a primary contributing factor for obstructed nasal breathing"	**Plan Document Language** Before using this guideline, please check the enrollee specific benefit document and any federal or state mandates, if applicable. **Essential Health Benefits for Individual and Small Group:** For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee specific benefit document to determine benefit coverage. **Indications for Coverage** Some states require benefit coverage for services that UnitedHealthcare considers cosmetic procedures, such as repair of external congenital anomalies in the absence of a functional impairment. Please refer to enrollee's plan specific documents. **RHINOPLASTY FOR NASAL VESTIBULAR STENOSIS OR ALAR COLLAPSE**: Repair of nasal vestibular stenosis or alar collapse is considered reconstructive and medically necessary when **all** of the following criteria are present: A. Prolonged, persistent obstructed nasal breathing due to internal and/or external nasal valve compromise (see definition), and B. Internal valve compromise due to collapse of the upper lateral cartilage and/or external nasal valve compromise due to collapse of the alar (lower lateral) cartilage resulting in an anatomic mechanical nasal airway obstruction that is a primary contributing factor for obstructed nasal breathing, and C. Other causes have been eliminated as the primary cause of nasal obstruction (eg. sinusitis, allergic rhinitis, vasomotor rhinitis, nasal

Coverage Determination Guideline (CDG) Updates

REVISED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Rhinoplasty and Other Nasal Surgeries *(continued)*	Jul. 1, 2015	**Rhinoplasty for Congenital Anomalies** ○ Reworded coverage criteria for reconstructive/medically necessary treatment to indicate rhinoplasty is considered reconstructive when performed for a nasal deformity associated with congenital craniofacial anomalies including, but not limited to Pierre Robin, Apert Syndrome, Fraser Syndrome, Binder Syndrome, Goldenhar Syndrome, Nasal dermoids, Tessier Nasal Cleft (most commonly #1) or associated with a cleft lip or cleft palate **Septal Dermatoplasty** (new to policy) ○ Added language to indicate septal dermatoplasty (CPT code 30620) is considered reconstructive when; ▪ There is a documented functional impairment (e.g., obstruction, pain or bleeding) due to diseased nasal mucosa, and ▪ The functional impairment will be eliminated by a skin graft **Lysis Intranasal Synecha** (new to policy) ○ Added language to indicate lysis intranasal synechia	polyposis, adenoid hypertrophy, nasopharyngeal masses) **RHINOPLASTY FOR CONGENITAL ANOMALIES:** The following are considered reconstructive and medically necessary when the following criteria are present: Rhinoplasty is considered reconstructive when performed for a nasal deformity associated with congenital craniofacial anomalies including, but not limited to Pierre Robin, Apert Syndrome, Fraser Syndrome, Binder Syndrome, Goldenhar Syndrome, Nasal dermoids, Tessier Nasal Cleft (most commonly #1) or associated with a cleft lip or cleft palate. **SEPTAL DERMATOPLASTY (CPT 30620):** Septal dermatoplasty is considered reconstructive when: A. There is a documented functional impairment (eg. Obstruction, pain or bleeding) due to diseased nasal mucosa, and B. The functional impairment will be eliminated by a skin graft. **LYSIS INTRANASAL SYNECHIA (CPT 30560):** Lysis intranasal synechia is considered reconstructive when: A. There is a documented functional impairment (eg. Obstruction, pain or bleeding) due to intranasal synechia (adhesions/scar bands), and B. The functional impairment will be eliminated by lysis of the synechia. **Medical Necessity Plans:** Please use the criteria above where applicable. **California Only**: This is the mandated language for Reconstructive Procedures - Reconstructive procedures to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease. Reconstructive procedures include surgery or other procedures which are associated with an Injury, Sickness or Congenital Anomaly. The primary result of the procedure is not a changed or improved physical appearance for cosmetic purposes only, but rather to improve function and/or create a normal appearance, to the extent possible. **Documentation:**

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Rhinoplasty and Other Nasal Surgeries *(continued)*	Jul. 1, 2015	(CPT code 30560) is considered reconstructive when; ▪ There is a documented functional impairment (e.g., obstruction, pain or bleeding) due to intranasal synechia (adhesions/scar bands), and ▪ The functional impairment will be eliminated by lysis of the synechia **Documentation** (new to policy) ○ Added language to indicate rhinoplasty or other nasal surgery documentation should include the evaluation and management note for the date of service and the note for the day the decision to perform surgery was made; the enrollee's medical record must contain, and be available for review on request, the following information: ▪ Physician office notes ▪ Radiologic imaging ▪ Photographs that document the nasal anomaly • Updated definitions; added definition of: ○ External nasal valve ○ Septal dermatoplasty ○ Synechia	Rhinoplasty or other nasal surgery documentation should include the evaluation and management note for the date of service and the note for the day the decision to perform surgery was made. The enrollee's medical record must contain, and be available for review on request, the following information: • Physician office notes • Radiologic imaging • Photographs that document the nasal anomaly **Coverage Limitations and Exclusions** Cosmetic Procedures are excluded from coverage, including but not limited to: A. Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures. The fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure. B. Rhinoplasty, unless rhinoplasty criteria above are met C. Any procedure that does not meet the reconstructive criteria above D. Rhinoplasty procedures performed to improve appearance (check enrollee's plan specific document)