UnitedHealthcare®

June 2016

medical policy update bulletin

Medical Policy, Drug Policy & Coverage Determination Guideline Updates

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

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

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

Overview

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

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

Tips for using the Medical Policy Update Bulletin:

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

Policy Update Classifications

New

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

Updated

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

Revised

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

Replaced

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

Retired

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

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

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Athletic Pubalgia Surgery	Jun. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Added reference link to related policy titled *Femoroacetabular Impingement Syndrome* • Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or list of applicable codes	**Surgical repair is unproven and not medically necessary for treating athletic pubalgia.** 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, 2016	• Reformatted and reorganized policy; transferred content to new template
		• Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references; no change to coverage rationale or lists of applicable codes
			Breast Imaging as an Adjunct to Mammography
			Digital mammography is proven and medically necessary for patients with dense breast tissue.
			
			Breast Magnetic Resonance Imaging (MRI)
			Breast magnetic resonance imaging (MRI) is proven and medically necessary for patients at high risk for breast cancer as defined as having any of the following:
			• Personal history of atypical breast histologies
			• Family history or genetic predisposition for breast cancer
			• Prior therapeutic thoracic radiation therapy
			• Dense breast tissue with any one of the following risk factors:
			  ○ Lifetime risk of breast cancer of ≥20%, according to risk assessment tools based on family history
			  ○ Personal history of BRCA1 or BRCA 2 gene mutations
			  ○ First-degree relative with a BRCA 1 or BRCA 2 gene mutation but not having had genetic testing themselves
			  ○ Prior therapeutic thoracic radiation therapy between ages of 10-30
			  ○ Personal history of Li Fraumeni Syndrome, Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome or a first-degree relative with one of these syndromes.
			
			Breast magnetic resonance imaging (MRI) is unproven and not medically necessary for patients with dense breast tissue not accompanied by defined risk factors as described above.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Breast Imaging for Screening and Diagnosing Cancer *(continued)*	Jun. 1, 2016		**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 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.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Breast Imaging for Screening and Diagnosing Cancer *(continued)*	Jun. 1, 2016		**Computer Aided Detection for MRI of the Breast** **Computer aided detection (CAD) is unproven and not medically necessary as an aid for radiologists to interpret contrast-enhanced magnetic resonance imaging (MRI) of the breast.** Clinical evidence has not yet demonstrated that CAD improves patient outcomes or reduces breast cancer mortality when added to contrast-enhanced MRI. There is insufficient evidence to assess whether the use of CAD systems would maintain or increase the sensitivity, specificity, and recall rates of MRI of the breast. Prospective, well-designed and executed studies are needed to determine whether or not the use of CAD provides a positive clinical benefit. **Breast Ultrasound** **Breast ultrasound is unproven and not medically necessary for routine breast cancer screening including patients with dense breast tissue.** Clinical evidence has not yet demonstrated that routine use of ultrasonography as an adjunct to screening mammography reduces the mortality rate from breast cancer. **Breast ultrasound is proven and medically necessary as an aid for radiologists to localize breast lesions and in guiding placement of instruments for cyst aspiration and percutaneous breast biopsies.** **Computer Aided Detection for Ultrasound** **Computer-aided detection (CAD) is unproven and not medically necessary as an aid for radiologists to detect breast cancer during ultrasound.** Clinical evidence has not yet demonstrated that CAD improves patient outcomes or reduces breast cancer mortality when added to ultrasonography. Future research should include better-designed studies, including prospective studies and randomized controlled trials evaluating this technology in large numbers of screening ultrasounds. **Computer Aided Tactile Breast Imaging** **Computer-aided tactile breast imaging is unproven and not medically necessary.** Clinical evidence is insufficient to determine whether tactile breast imaging

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Breast Imaging for Screening and Diagnosing Cancer *(continued)*	Jun. 1, 2016		improves outcomes for the screening or diagnosis of breast cancer. Future research should include better-designed studies, including comparative, prospective and randomized controlled trials evaluating this technology. **Automated Breast Ultrasound** **Automated breast ultrasound is unproven and not medically necessary.** Clinical evidence is insufficient to determine whether automated breast ultrasound improves the detection rate of breast cancer compared to screening mammography. Future research should include better-designed studies, including prospective studies and randomized controlled trials evaluating this technology. **Refer to the Evidence-Based Clinical Guidelines – Imaging for:** • Magnetic resonance imaging (MRI) of the breast • 3D rendering of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modalities
Corneal Hysteresis and Intraocular Pressure Measurement	Jun. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated/clarified coverage rationale: ○ Replaced language indicating "measurement of corneal hysteresis is unproven and not medically necessary for *the diagnosis and management of* corneal disorders and glaucoma" with "measurement of corneal hysteresis is unproven and not medically necessary for *evaluating and managing* corneal disorders and glaucoma" ○ Replaced language indicating "measurement of ocular	**Measurement of corneal hysteresis is unproven and not medically necessary for evaluating and managing 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. **Measurement of ocular blood flow by intraocular pressure sampling using an ocular blood flow tonometer is unproven and not medically necessary for evaluating and managing 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.

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Corneal Hysteresis and Intraocular Pressure Measurement *(continued)*	Jun. 1, 2016	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" with "measurement of ocular blood flow by intraocular pressure sampling using an ocular blood flow tonometer is unproven and not medically necessary for *evaluating and managing* glaucoma and other ocular disorders" • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information and references	**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.
Embolization of the Ovarian and Iliac Veins for Pelvic Congestion Syndrome	Jul. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated list of applicable CPT codes; modified "coding clarification" language regarding the intended use for CPT code 37241: ○ Added instruction to see CPT codes 36468–36479 for sclerosis of veins or endovenous ablation of incompetent extremity veins ○ Updated list of applicable ICD-9 diagnosis codes (discontinued Oct. 1, 2015);	**Embolization of the ovarian or internal iliac veins is considered unproven and not medically necessary for treating 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.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Embolization of the Ovarian and Iliac Veins for Pelvic Congestion Syndrome *(continued)*	Jul. 1, 2016	removed 454.1, 454.2, 454.8, 459.81 • Updated list of applicable ICD-10 diagnosis codes; removed I83.222–I83.225, I83.228, I83.229, I83.811–I83.813, I83.819, I83.891–I83.893, I83.899 and I87.2 • Updated supporting information to reflect the most current FDA and CMS information	
Gastrointestinal Motility Disorders, Diagnosis and Treatment	Jul. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated coverage rationale; added language to clarify defecography is unproven and not medically necessary for evaluating conditions other than those listed as proven/medically necessary • Updated list of applicable CPT codes; removed 43210 • Updated supporting information to reflect the most current description of services, clinical evidence, CMS information and references	**Gastric Electrical Stimulation Therapy** **Gastric electrical stimulation therapy is proven and medically necessary for treating the following conditions:** • Refractory diabetic gastroparesis that has failed other therapies • Chronic, intractable (drug-refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology when used according to U.S. Food and Drug Administration (FDA) labeled indications. See the *U.S. Food and Drug Administration* section of the policy 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.

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Gastrointestinal Motility Disorders, Diagnosis and Treatment *(continued)*	Jul. 1, 2016		**Defecography**
			Defecography is proven and medically necessary for evaluating the following conditions:
			• Intractable constipation,
			• Constipation in patients 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 evaluating all other conditions, including but not limited to:
			• 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 evaluating 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.
			
			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.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Intraoperative Hyperthermic Intraperitoneal Chemotherapy (HIPEC)	Jun. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or list of applicable codes	**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 member specific benefit plan document, coverage may be available through participation in an eligible clinical trial.
Macular Degeneration Treatment Procedures	Jun. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated supporting information to reflect the most current clinical evidence, CMS information and references; no change to coverage rationale or list of applicable codes	**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 treating patients with end-stage, age-related macular degeneration.** See the *U.S. Food and Drug Administration* section of the 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 for**

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Macular Degeneration Treatment Procedures *(continued)*	Jun. 1, 2016		**treating 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 treating 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 treating macular drusen.** Results of available studies lead to the conclusion that current prophylactic laser treatment does not benefit patients who have macular drusen.
Magnetoencephal-ography and Magnetic Source Imaging for Specific Neurological Applications	Jun. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated coverage rationale; modified list of unproven/not medically necessary indications: ○ Replaced "other neurologic disorders and psychiatric conditions *such as* schizophrenia" with "*all* other neurologic disorders and psychiatric conditions *including but not limited to* schizophrenia" • Updated supporting information to reflect the most current clinical evidence and references	**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 evaluating brain function in patients with the following indications:** • Trauma • Stroke • Learning disorders • ALL other neurologic disorders and psychiatric conditions including but not limited to schizophrenia There is insufficient evidence to conclude that the use of MEG/MSI improves health outcomes such as improved diagnostic accuracy and treatment

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Magnetoencephal-ography and Magnetic Source Imaging for Specific Neurological Applications *(continued)*	Jun. 1, 2016		planning for patients with trauma, stroke, learning disorders, or other neurologic disorders and psychiatric conditions. Further clinical trials 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.
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins	July 1, 2016	• Updated list of applicable CPT codes; modified "coding clarification" language regarding the intended use for CPT code 37241: ○ Added instruction to see CPT codes 36468–36479 for sclerosis of veins or endovenous ablation of incompetent extremity veins	**I. Varicose Vein Ablative and Stripping Procedures:** **A. Radiofrequency ablation, endovenous laser ablation, stripping, ligation and excision of the great saphenous vein and small saphenous veins are considered reconstructive and medically necessary when ALL of the following criteria are present (1, 2, 3 and 4):** 1. **Junctional Reflux** (see *Definitions* section of the policy): a. Ablative therapy for the great or small saphenous veins will be considered reconstructive and therefore medically necessary only if junctional reflux is demonstrated in these veins; or b. Ablative therapy for accessory veins will be considered reconstructive and medically necessary only if anatomically related persistent junctional reflux is demonstrated after the great or small saphenous veins have been removed or ablated. 2. **Member must have one of the following functional impairments:** a. Skin ulceration; or b. Documented episode(s) of frank bleeding of the varicose vein due to erosion of/or trauma to the skin; or c. Documented superficial thrombophlebitis or documented venous stasis dermatitis; or d. Moderate to severe pain causing functional/physical impairment. 3. **Venous Size:** a. The great saphenous vein must be 5.5 mm or greater when measured at the proximal thigh immediately below the saphenofemoral junction via duplex ultrasonography

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Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins *(continued)*	July 1, 2016		b. The small saphenous vein or accessory veins must measure 5 mm or greater in diameter immediately below the appropriate junction. 4. **Duration of reflux, in the standing or reverse Trendelenburg position that meets the following parameters:** a. Greater than or equal to 500 milliseconds (ms) for the great saphenous, small saphenous or principle tributaries b. Perforating veins > 350 ms c. Some duplex ultrasound readings will describe this as moderate to severe reflux which will be acceptable. **B. Ablation of perforator veins is considered reconstructive and medically necessary when the following criteria are present:** 1. Evidence of perforator venous insufficiency measured by recent duplex ultrasonography report (see criteria above); and 2. Perforator vein size is 3.5 mm or greater; and 3. Perforating vein lies beneath a healed or active venous stasis ulcer. **C. Endovenous mechanochemical ablation (MOCA) of varicose veins using a percutaneous infusion catheter is unproven and not medically necessary for treating venous reflux.** There is insufficient evidence in the clinical literature supporting the safety and efficacy of MOCA for treating varicose veins. Further results from large, well-designed studies are needed to support the clinical utility of this approach. **II. Ligation Procedures:** **A. Ligation of the great saphenous vein at the saphenofemoral junction, as a stand-alone procedure, is unproven and not medically necessary for treating venous reflux.** Ligation performed without stripping or ablation is associated with high long-term recurrence rates due to neovascularization. **B. Ligation of the small saphenous vein at the saphenopopliteal junction, as a stand-alone procedure, is unproven and not medically necessary for treating venous reflux.** Ligation performed without stripping or ablation is associated with high long-term recurrence rates due to neovascularization.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins *(continued)*	July 1, 2016		**C. Ligation at the saphenofemoral junction, as a stand-alone procedure, is proven and medically necessary, when used to prevent the propagation of an active clot to the deep venous system in patients with ascending superficial thrombophlebitis who fail or are intolerant of anticoagulation therapy.** **D. Ligation at the saphenofemoral junction, as an adjunct to radiofrequency ablation or endovenous laser ablation of the main saphenous veins, is unproven and not medically necessary for treating venous reflux.** Published clinical evidence has not demonstrated that the addition of saphenofemoral ligation to endovenous ablation procedures provides an additive benefit in resolving venous reflux or preventing varicose vein recurrence. Endovenous ablation is a clinically effective therapy for treating venous reflux. Adding ligation to the procedure adds clinical risk without adding clinical benefit.
Transpupillary Thermotherapy	Jun. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated supporting information to reflect the most current clinical evidence, CMS information and references; no change to coverage rationale or list of applicable codes	**Transpupillary thermotherapy is proven and medically necessary for treating retinoblastoma and choroidal melanomas.** **Transpupillary thermotherapy is unproven and not medically necessary for treating 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.

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes	Aug. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale; updated coverage guidelines for continuous glucose monitoring: ○ Changed service	**Insulin Delivery** **External insulin pumps that deliver insulin by continuous subcutaneous infusion are proven and medically necessary for the following:** • Patients with type 1 diabetes For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 20th edition, 2016, Insulin Infusion Pump

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes *(continued)*	Aug. 1, 2016	description/sub-header from "Continuous Glucose Monitors with or without Combined Insulin Pumps" to "Continuous Glucose Monitoring" ○ Updated coverage criteria for long-term continuous glucose monitoring for personal use at home to indicate this service is proven and medically necessary as a supplement to self-monitoring of blood glucose (SMBG) for patients with type 1 diabetes who have demonstrated adherence to a physician ordered diabetic treatment plan • Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references	ACG:A-0339 (AC). • Patients with type 2 diabetes who currently perform ≥4 insulin injections and ≥4 blood glucose measurements daily **Note:** Programmable disposable external insulin pumps are considered equivalent to standard insulin pumps. **Nonprogrammable transdermal insulin delivery systems are unproven and not medically necessary for treating patients with diabetes.** There is insufficient evidence in the clinical literature demonstrating the safety and efficacy of transdermal insulin delivery in the management of patients with diabetes. **Implantable insulin pumps are investigational, unproven and not medically necessary.** No implantable insulin pumps have received U.S. Food and Drug Administration (FDA) approval at this time. While some preliminary studies reported improved glycemic control and fewer episodes of hypoglycemia in carefully selected patients, complications such as catheter blockage and infection were observed. Larger, randomized controlled trials are needed to determine the long-term impact of implantable insulin pumps on diabetes management. **Insulin infuser ports are unproven and not medically necessary for insulin delivery in patients with diabetes.** There is insufficient evidence demonstrating that the use of insulin infuser ports results in improved glycemic control beyond what can be achieved by using standard insulin delivery methods. In addition, an increase in complications, such as infection at the port site, has been reported when using these devices. Further well-designed, large-scale randomized controlled trials are needed to establish the safety and efficacy of these devices. See the *Description of Services* section of the policy for further details on the various types of insulin delivery systems. **Continuous Glucose Monitoring** **Short-term (3-7 days) continuous glucose monitoring by a**

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes *(continued)*	Aug. 1, 2016		**healthcare provider for diagnostic purposes is proven and medically necessary for patients with diabetes.** **Long-term continuous glucose monitoring for personal use at home is proven and medically necessary as a supplement to self-monitoring of blood glucose (SMBG) for patients with type 1 diabetes who have demonstrated adherence to a physician ordered diabetic treatment plan.** For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 20th edition, 2016, Continuous Glucose Monitoring ACG:A-0126 (AC). **Long-term continuous glucose monitoring for personal use at home is unproven and not medically necessary for patients with type 2 diabetes or gestational diabetes.** There is insufficient evidence that the use of long-term continuous glucose monitoring leads to improvement of glycemic control in patients with type 2 or gestational diabetes. **Remote Glucose Monitoring** **Remote glucose monitoring is unproven and not medically necessary for managing patients with diabetes.** There is insufficient evidence in the clinical literature to conclude that remote glucose monitoring demonstrates improvement in clinical outcomes.
Extracorporeal Shock Wave Therapy (ESWT)	Jul. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale: ○ Added language to indicate extracorporeal shock wave therapy (ESWT), whether low energy, high energy or radial wave, is unproven and not medically necessary for ***all indications***, *including but not limited to* the indications listed	**Extracorporeal shock wave therapy (ESWT), whether low energy, high energy or radial wave, is unproven and not medically necessary for all indications, including but not limited to 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 elbow) • Medial epicondylitis (golfers elbow) • Tenosynovitis of the foot or ankle

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Extracorporeal Shock Wave Therapy (ESWT) *(continued)*	Jul. 1, 2016	○ Modified list of unproven/not medically necessary indications; replaced "lateral epicondylitis (tennis and golfers elbow)" with "lateral epicondylitis (tennis elbow)" and "medial epicondylitis (golfers elbow)" ○ Updated list of applicable CPT codes; revised description for 0300T • Updated supporting information to reflect the most current clinical evidence and references	• 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).
Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC)	Aug. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale: ○ Updated definitions; added language to indicate: ▪ A *founder mutation* is a gene mutation observed with high frequency in a group that is or was geographically or culturally isolated, in which one or more of the ancestors was a carrier of the mutant gene; this phenomenon is often called a founder effect (National Cancer Institute web site) ○ Updated coverage guidelines for genetic counseling; added language to clarify guidelines apply to benefit plans that allow for medical	**Definitions** Please note, for the purpose of this policy: 1. Close blood relatives are defined as follows: a. First degree relatives include parents, siblings and offspring b. Second degree relatives include half-brothers/sisters, aunts/uncles, grandparents, grandchildren and nieces/nephews c. affected on the same side of the family d. Third degree relatives include first cousins, great-aunts/uncles, great-grandchildren and great grandparents affected on same side of family 2. A breast cancer diagnosis includes either invasive carcinomas or non-invasive (in situ) ductal carcinoma types. 3. Ovarian cancer also includes fallopian tube cancers and primary peritoneal carcinoma. 4. Limited family history is defined as having fewer than two known first-degree or second-degree female relatives or female relatives surviving beyond 45 years of age on either or both sides of the family. (e.g., individual who is adopted) 5. Documentation of personal and family history, in the form of a pedigree drawing/diagram utilizing standardized nomenclature, should be in the contemporaneous medical records submitted with the testing request (i.e., request form). 6. For the statements that include age guidelines, a person is considered to

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Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Aug. 1, 2016	necessity review ○ Updated coverage guidelines BRCA testing: ▪ Modified BRCA testing criteria pertaining to the following individuals to indicate BRCA1 and BRCA2 testing is proven and medically necessary for; ▪ **Women and men with a personal history of pancreatic cancer** at any age and at least one close blood relative on the same side of the family *with ovarian cancer at any age or* breast *cancer* (≤ age 50 years), *or two relatives with breast*, pancreatic and/or prostate cancer (Gleason score ≥7) at any age ▪ **Men with a personal history of prostate cancer** (Gleason score ≥7) at any age and at least one close blood relative on the same side of the family with *ovarian cancer at any age or* breast *cancer* (≤ age 50 years), *or two relatives with breast*, pancreatic and/or prostate cancer (Gleason score ≥7) at any age ○ Modified notatation	be 45 years of age up until the day before their 46th birthday, and a person is considered to be 50 years of age up until the day before their 51st birthday. 7. Two breast primary cancers include cancers appearing at the same time (synchronous) and one is not a metastasis of the other; or primary cancers developing at different times (metachronous or asynchronous). The tumors may be in one or two breasts. 8. Gleason scoring is a system of grading prostate cancer tissue based on how it looks under a microscope. Gleason scores range from 2 to 10 and indicate how likely it is that a tumor will spread. A low Gleason score means the cancer tissue is similar to normal prostate tissue and the tumor is less likely to spread. A high Gleason score means the cancer tissue is very different from normal and the tumor is more likely to spread. 9. HBOC-associated malignancies include prostate cancer (Gleason score ≥7), pancreatic cancer or melanoma. The presence of these malignancies does not necessarily justify BRCA testing. For example, a female with breast cancer over age 50 whose sister had melanoma at 40 and whose father has prostate cancer (Gleason score ≥7) would meet criteria. In another example, a female with breast cancer over age 50 whose maternal aunt had pancreatic cancer and whose paternal uncle had prostate cancer (Gleason score ≥7) would not meet criteria because the aunt and uncle are on different sides of the family. 10. Triple-negative breast cancer refers to any breast cancer that does not show expression of estrogen receptors (ER), progesterone receptors (PR) or HER2/neu. This subtype of breast cancer is clinically characterized as more aggressive and less responsive to standard treatment and is associated with poorer overall patient prognosis. It is diagnosed more frequently in younger women, women with BRCA1 mutations and those belonging to African-American and Hispanic ethnic groups. 11. A founder mutation is a gene mutation observed with high frequency in a group that is or was geographically or culturally isolated, in which one or more of the ancestors was a carrier of the mutant gene. This phenomenon is often called a founder effect (National Cancer Institute website). **Genetic Counseling** For benefit plans that allow for medical necessity review, genetic counseling

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Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Aug. 1, 2016	addressing NCCN testing guidelines; replaced references to "unaffected individual" with "individual without a cancer diagnosis" • Updated list of applicable CPT codes; added 96040 • Added list of applicable HCPCS codes: S0265 • Updated supporting information to reflect the most current clinical evidence and references	is required by an independent (not employed by a genetic testing lab) genetics provider prior to genetic testing for BRCA mutations in order to inform persons being tested about the benefits and limitations of a specific genetic test as applied to a unique person. Genetics providers employed by or contracted with a laboratory that are part of an integrated health system that routinely delivers health care services beyond the laboratory testing itself are considered independent. Genetic testing for BRCA mutations requires documentation of medical necessity by **ONE** of the following who has evaluated the member and intends to engage in post-test follow-up counseling: • Board-Eligible or Board-Certified Genetic Counselor (CGC) • Advanced Genetics Nurse (AGN-BC) • Genetic Clinical Nurse (GCN) • Advanced Practice Nurse in Genetics (APNG) • A Board-Eligible or Board-Certified Clinical Geneticist • A physician with experience in cancer genetics (Defined as providing cancer risk assessment on a regular basis and having received specialized ongoing training in cancer genetics. Educational seminars offered by commercial laboratories about how to perform genetic testing are not considered adequate training for cancer risk assessment and genetic counseling.) ***Documentation Requirements*** • Three generation pedigree • UnitedHealthcare genetic counseling attestation form. **BRCA Testing Criteria** **Note**: National Comprehensive Cancer Network (NCCN) guidelines state that meeting one or more of these criteria warrants further personalized risk assessment, genetic counseling and consideration of genetic testing. Comprehensive *BRCA1*/*BRCA2* genetic testing includes sequencing of both *BRCA1* and *BRCA2* genes and analysis for large genomic rearrangements, either concurrently or sequentially. NCCN guidelines emphasize the need for comprehensive testing for individuals who meet the testing criteria for *BRCA1*/*BRCA2* and have no known familial *BRCA1*/*BRCA2* mutations who have undergone accurate risk assessment and genetic counseling.

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Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Aug. 1, 2016		I. *BRCA1* and *BRCA2* testing is proven and medically necessary for women with a personal history of breast cancer in the following situations and where gene testing results will impact medical management: A. Breast cancer diagnosed at age 45 or younger with or without family history; or B. Breast cancer diagnosed at age 50 or younger with: 1. An additional primary breast cancer; or 2. At least one close blood relative with breast cancer at any age; or 3. At least one close blood relative with pancreatic cancer; or 4. At least one close blood relative with prostate cancer (Gleason score ≥7; or 5. An unknown or limited family history (see *Definitions* section of the policy for further clarification of limited family history). C. Breast cancer diagnosed at any age with: 1. At least one close blood relative with breast cancer diagnosed at age 50 or younger; or 2. At least two close blood relatives on the same side of the family with breast cancer at any age; or 3. At least one close blood relative with ovarian cancer at any age; or 4. At least two close blood relatives on the same side of the family with pancreatic and/or prostate cancer (Gleason score ≥7) at any age; or 5. Close male blood relative with breast cancer; or 6. At least one close blood relative who has a BRCA1 or BRCA2 mutation (Testing should be targeted to the known BRCA1/BRCA2 mutation in the family. Further BRCA1/BRCA2 testing should only be pursued if the results are negative and the patient otherwise meets testing criteria); or 7. Ashkenazi Jewish or ethnic groups associated with founder mutations. Testing for Ashkenazi Jewish founder-specific mutations should be performed first. Further *BRCA1*/*BRCA2* testing should only be pursued if the results are negative and the patient otherwise meets testing criteria without considering Ashkenazi Jewish ancestry. D. Triple-negative breast cancer diagnosed at age 60 or younger. II. *BRCA1* and *BRCA2* testing is proven and medically necessary for women

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Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Aug. 1, 2016		with a personal history of ovarian cancer. III. *BRCA1* and *BRCA2* testing is proven and medically necessary for women and men with a personal history of pancreatic cancer at any age and at least one close blood relative on the same side of the family with ovarian cancer at any age or breast cancer (≤ age 50 years) or two relatives with breast, pancreatic and/or prostate cancer (Gleason score ≥7) at any age. IV. *BRCA1* and *BRCA2* testing for Ashkenazi Jewish founder-specific mutations is proven and medically necessary for women and men with a personal history of pancreatic cancer and Ashkenazi Jewish ancestry. V. *BRCA1* and *BRCA2* testing is proven and medically necessary for men with a personal history of prostate cancer (Gleason score ≥7) at any age and at least one close blood relative on the same side of the family with ovarian cancer at any age or breast cancer (≤ age 50 years) or two relatives with breast, pancreatic and/or prostate cancer (Gleason score ≥7) at any age. VI. *BRCA1* and *BRCA2* testing is proven and medically necessary for men with a personal history of breast cancer. VII. *BRCA1* and *BRCA2* screening tests are proven and medically necessary for men and women without a personal history of breast or ovarian cancer with at least one of the following familial risk factors only when there are no family members affected with a BRCA associated cancer available for testing (see note below): A. At least one first- or second-degree blood relative meeting any of the above criteria (I-VI); or B. At least one third-degree blood relative with breast cancer and/or ovarian cancer who has at least 2 close blood relatives with breast cancer (at least one with breast cancer at age 50 or younger) and/or ovarian cancer; or C. A known *BRCA1*/*BRCA2* mutation in a blood relative (defined as first-, second- or third-degree relative). Testing should be targeted to the known *BRCA1*/*BRCA2* mutation in the family. Further *BRCA1*/*BRCA2* testing should only be pursued if the results are negative and the patient otherwise meets testing criteria.

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Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Aug. 1, 2016		**Note**: NCCN guidelines state that significant limitations of interpreting test results for an individual without a cancer diagnosis should be discussed. If there are no living family members with breast or ovarian cancer available for testing, consider testing family members affected with other cancers associated with *BRCA1*/*BRCA2*, such as prostate cancer (Gleason score ≥7), pancreatic cancer or melanoma. Testing of individuals without a cancer diagnosis should only be considered when there is no affected family member available for testing (NCCN, 2016). VIII. *BRCA1* and/or *BRCA2* testing is unproven and not medically necessary for all other indications including: 1) screening for breast or ovarian cancer risk for individuals not listed in the proven indications above or 2) for risk assessment of other cancers. Further evidence is needed to establish the clinical utility of testing in other populations.
Mechanical Stretching and Continuous Passive Motion Devices	Aug. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale; updated coverage guideline for proven/medically necessary use of low-load prolonged-duration stretch devices for the treatment of existing joint contractures of the upper and lower extremities as an adjunct to therapy: ○ Replaced language requiring "patient has symptoms of significant joint motion stiffness *unresponsive to other therapies* in the immediate post-operative period" with "patient has symptoms of significant joint motion stiffness in the immediate post-operative period"	**The use of continuous passive motion (CPM) devices is proven for the prevention of joint contractures of the upper and lower extremities.** **The use of continuous passive motion devices are medically necessary for patients in the immediate post-operative phase of joint surgery as an adjunct to (and not replacement of) physical therapy to prevent contractures of the joints of the upper and/or lower extremities.** **The use of lumbar continuous passive motion device is unproven and not medically necessary.** Clinical evidence is limited to manufacturer data. There is no scientific evidence in the published peer-reviewed medical literature that these devices for patient controlled therapy are safe or effective. **The use of low-load prolonged-duration stretch devices is proven and medically necessary for the treatment of existing joint contractures of the upper and lower extremities as an adjunct to therapy in patients with symptoms of significant joint motion stiffness in the immediate post-operative period.** **The use of static progressive (SP) stretch splint devices and patient**

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Mechanical Stretching and Continuous Passive Motion Devices *(continued)*	Aug. 1, 2016		**actuated serial stretch (PASS) devices, for the treatment of joint contractures of the extremities alone or combined with standard physical therapy are unproven and not medically necessary**. Clinical evidence is not sufficient to demonstrate that use of static progressive or patient actuated devices is a safe or effective treatment option. Studies are limited to small sample sizes.
Omnibus Codes	Jul. 1, 2016	• Revised coverage rationale to reflect quarterly code edits (effective Jul. 1, 2016); added language to indicate the following procedures are unproven/not medically necessary: ○ Transperineal placement of biodegradable material, peri-prostatic (via needle) (CPT code 0438T) ○ Percutaneous cryoablation of upper/lower extremity distal/peripheral nerve(s), of nerve plexuses or of other truncal nerves (CPT codes 0440T–0442T) ○ Real time spectral analysis of prostate tissue by fluorescence spectroscopy (CPT code 0443T) ○ Placement of drug eluting ocular inserts under the eyelid(s) (CPT codes 0444T and 0445T)	Refer to the policy for complete details on the coverage guidelines for Omnibus Codes.
Preterm Labor Management	Aug. 1, 2016	• Changed policy title; previously titled Preterm Labor: Identification and Treatment • Reformatted and reorganized policy; transferred content to new template	**Tocolytic Therapy** **The use of tocolytic therapy beyond 48 hours is unproven and not medically necessary for preventing spontaneous preterm birth by prolonging pregnancy.** Available studies fail to demonstrate any benefit of maintenance tocolysis in

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Preterm Labor Management *(continued)*	Aug. 1, 2016	• Revised coverage rationale: ○ Replaced language indicating "the use of tocolytic therapy *beyond 7 days* is unproven and not medically necessary for preventing spontaneous preterm birth by prolonging pregnancy" with "the use of tocolytic therapy *beyond 48 hours* is unproven and not medically necessary for preventing spontaneous preterm birth by prolonging pregnancy" ○ Removed and relocated information pertaining to the 2011 FDA MedWatch alert warning against use of terbutaline to treat preterm labor (see *FDA* section of policy for applicable details) ○ Added language to indicate magnesium sulfate is proven and medically necessary for treating preterm labor short-term when the following criteria are met: ▪ Short-term prolongation of pregnancy (up to 48 hours) to allow for the administration of antenatal corticosteroids in pregnant women who are at risk of preterm delivery within 7 days; or ▪ Fetal neuroprotection before anticipated early	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. **Magnesium sulfate is proven and medically necessary for treating preterm labor short-term when the following criteria are met:** • Short-term prolongation of pregnancy (up to 48 hours) to allow for the administration of antenatal corticosteroids in pregnant women who are at risk of preterm delivery within 7 days; **or** • Fetal neuroprotection before anticipated early preterm (less than 32 weeks of gestation) delivery **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.

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Preterm Labor Management *(continued)*	Aug. 1, 2016	preterm (less than 32 weeks of gestation) delivery • Updated list of applicable HCPCS codes; added J3475 • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	
Sodium Hyaluronate	Jul. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Revised coverage rationale: ○ Updated list of FDA labeled indications for intra-articular injections of sodium hyaluronate for treating pain due to osteoarthritis of the knee; added "Hymovis: 2 injections" • Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references	**Intra-articular injections of sodium hyaluronate is proven and medically necessary for treating 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 Gel One: 1 injection Gel-Syn: 3 injections GenVisc 850: 3 to 5 injections Hyalgan: 5 injections Hymovis: 2 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.

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Sodium Hyaluronate *(continued)*	Jul. 1, 2016		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 treating temporomandibular joint (TMJ) disc displacement and osteoarthritis.** **Sodium hyaluronate preparations are unproven and not medically necessary for treating 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 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. **Hyaluronic acid gel preparations to improve the skin's contour and/or reduce depressions due to acne, scars, injury or wrinkles are 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.

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Remicade® (Infliximab)	Jun. 1, 2016	• Added reference link to related Utilization Review Guideline (URG) titled *Specialty Medication Administration - Site of Care Review Guidelines* • Updated coverage rationale; modified list of unproven/not medically necessary indications: ○ Replaced "adult-onset Still's disease" with "Still's disease" • Updated supporting information to reflect the most current clinical evidence, CMS information, and references	**Remicade® (Infliximab) is proven and medically necessary for the treatment of:** 1. **Ankylosing spondylitis** when the following criterion is met: a. Diagnosis of ankylosing spondylitis (AS) 2. **Crohn's disease** when the following criterion is met: **One** of the following: • Diagnosis of fistulizing Crohn's disease (Crohn's Disease Activity Index (CDAI) ≥ 220 and ≤ 400) **OR** • **Both** of the following: (a) Diagnosis of moderately to severely active adult or pediatric Crohn's disease **AND** (b) History of failure, contraindication, or intolerance to at least **one** conventional therapy (e.g., corticosteroids, 6-mercaptopurine, azathioprine, methotrexate, etc.) 3. **Noninfectious uveitis** when both of the following criteria are met: a. Diagnosis of refractory noninfectious uveitis that is causing or threatening vision loss (e.g., noninfectious uveitis associated with Behçet's or Reiter's syndromes) **AND** b. History of failure, contraindication, or intolerance to **all** of the following: (1) Topical corticosteroids (2) Systemic corticosteroids (3) Immunosuppressive drugs (e.g., azathioprine, cyclosporine, or methotrexate) 4. **Plaque psoriasis** when **both** of the following criteria are met: a. Diagnosis of chronic severe plaque psoriasis (i.e., extensive and/or disabling) **AND** b. Patient is a candidate for systemic therapy 5. **Psoriatic arthritis** when the following criterion is met: a. Diagnosis of psoriatic arthritis (PsA)

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Remicade® (Infliximab) *(continued)*	Jun. 1, 2016		6. **Rheumatoid arthritis** when **both** of the following criteria are met: a. Diagnosis of moderately to severely active rheumatoid arthritis (RA) **AND** b. **One** of the following: c. Patient is receiving concurrent therapy with methotrexate d. History of contraindication or intolerance to methotrexate 7. **Sarcoidosis** when **all** of the following criteria are met: a. Diagnosis of sarcoidosis **AND** b. History of failure, contraindication, or intolerance to corticosteroids (e.g., prednisone, methylprednisolone) **AND** c. History of failure, contraindication, or intolerance to **one** immunosuppressant (e.g., methotrexate, cyclophosphamide, azathioprine) 8. **Ulcerative colitis** when **both** of the following criteria are met: a. Diagnosis of moderately to severely active adult or pediatric ulcerative colitis (UC) **AND** b. History of failure, contraindication, or intolerance to at least **one** conventional therapy (e.g., 6-mercaptopurine, aminosalicylate, azathioprine, corticosteroids) There may be other conditions that qualify as serious, rare diseases for which the use of Remicade may be appropriate. Please refer to the *Benefit Considerations* section of the policy for additional information. **Remicade is unproven and not medically necessary for the treatment of:** • Still's disease • Sjogren's syndrome • Graft-vs-host disease • Myelodysplastic syndromes • Undifferentiated spondyloarthropathy • Reiter's syndrome • Hidradenitis suppurative • Wegener's granulomatosis

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Remicade® (Infliximab) *(continued)*	Jun. 1, 2016		• Juvenile idiopathic arthritis (juvenile rheumatoid arthritis) Remicade is unproven for the treatment of the above conditions because statistically robust randomized controlled trials are needed to address the issue of whether Remicade has sufficient superiority in clinical efficacy compared to other available treatments to justify the inherent clinical risk in the use of a monoclonal antibody anti-tumor necrosis factor agent. **Centers for Medicare and Medicaid Services (CMS):** Medicare does not have a National Coverage Determination (NCD) that specifically addresses Remicade ® (infliximab). Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for Drugs and Biologicals: Infliximab (REMICADE®) and Infliximab (Remicade ™). 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 March 18, 2016)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Lemtrada (Alemtuzumab)	Jul. 1, 2016	• Changed policy titled; previously titled *Alemtuzumab* • Revised coverage rationale; removed coverage criteria for Campath • Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references	**Lemtrada (Alemtuzumab) is proven and medically necessary for treatment of relapsing-remitting multiple sclerosis when all of the following criteria are met:** 1. Diagnosis of relapsing-remitting multiple sclerosis (RRMS) **AND** 2. **One** of the following: a. **Treatment-naïve to alemtuzumab:** (1) Patient has history of failure following a trial for at least 4 weeks **or** history of intolerance or contraindication to **two** of the following: (a) interferon β-1a (Avonex® or Rebif®) (b) interferon β-1b (Betaseron® or Extavia®) (c) glatiramer acetate (Copaxone®) (d) dimethyl fumarate (Tecfidera®) (e) teriflunomide (Aubagio®) (f) fingolimod (Gilenya®)

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Lemtrada (Alemtuzumab)	Jul. 1, 2016		(g) peginterferon beta-1a (Plegridy™) **AND** (2) Patient has not been previously treated with alemtuzumab **AND** (3) Patient is not receiving alemtuzumab in combination with another disease modifying agent (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, or teriflunomide) **AND** (4) Initial dosing is administered: 12 mg intravenously daily for 5 consecutive days **AND** (5) Regimen is administered only once within 12 months **OR** b. **Treatment-experienced with alemtuzumab:** (1) Patient has previously received treatment with alemtuzumab **AND** (2) Patient is not receiving alemtuzumab in combination with another disease modifying agent (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, or teriflunomide) **AND** (3) Retreatment dosing is administered: 12 mg intravenously daily for 3 consecutive days **AND** (4) Regimen is administered only once within 12 months Coverage of Lemtrada is limited up to two treatment courses (5 day initial and 3 day end course). Requests for additional doses/courses beyond two courses will not be approved. **Alemtuzumab is unproven for the treatment of:** a. Rheumatoid arthritis b. Autoimmune neutropenia c. Autoimmune hemolytic anemia d. Pure red cell aplasia e. Immune thrombocytopenic purpura f. Evans syndrome g. Autoimmune pancytopenia **Centers for Medicare and Medicaid Services (CMS):**

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Lemtrada (Alemtuzumab)			Medicare does not have a National Coverage Determination (NCD) for Lemtrada (alemtuzumab). However, there are Local Coverage Determinations (LCDs) at address alemtuzumab; refer to the LCDs for Chemotherapy Drugs and their Adjuncts. 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 January 28, 2016)

Coverage Determination Guideline (CDG) Updates

UPDATED

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Clinical Trials	Jun. 1, 2016	• Reformatted and reorganized policy; transferred content to new template (no change to coverage rationale or lists of applicable codes)	**Indications for Coverage** Effective for plan years starting on or after January 1, 2014, the Patient Protection and Affordable Care Act ("PPACA") requires non-grandfathered health plans to cover "Routine Patient Costs" incurred by a "Qualifying Individual" who is participating in an "Approved Clinical Trial". Benefits include the reasonable and necessary items and services used to prevent, diagnose and treat complications arising from participation in a qualifying clinical trial. Benefits are available only when the Covered Person is clinically eligible for participation in the qualifying clinical trial as defined by the researcher. I. **Approved Clinical Trial** A. An "Approved Clinical Trial" is defined as: 1. Phase I, Phase II, Phase III, or Phase IV clinical trial, 2. Being conducted in relation to the prevention, detection or treatment for Cancer or other life threatening disease or condition, and 3. That meets the requirements under Section II below. For purposes of this benefit, a "life-threatening disease or condition" is one from which the likelihood of death is probable unless the course of the disease or condition is interrupted. B. Additional Clinical Trials The following clinical trials are not currently required by PPACA. However, these clinical trials are covered under United Healthcare's clinical trial benefit. 1. Phase I, Phase II or Phase III clinical trial, 2. Being conducted in relation to the detection or treatment of non-life threatening • Cardiovascular disease (cardiac/stroke), • Surgical musculoskeletal disorders of the spine, hip and knees, and/or • Other Clinical Trials: Certain plans may allow clinical trials relating to other diseases or disorders which are not life-threatening. Please refer to the member specific benefit plan SPD for coverage. 3. That meets the requirements under Section II below.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Clinical Trials *(continued)*	Jun. 1, 2016		II. **Criteria For Approved Clinical Trials** A. The clinical trial must be described in paragraph 1, 2 or 3 below. 1. The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following: • National Institutes of Health (NIH) [Includes National Cancer Institute (NCI)] • Centers for Disease Control and Prevention (CDC) • Agency for Healthcare Research and Quality (AHRQ) • Centers for Medicare and Medicaid Services (CMS) • A cooperative group or center of any of the entities described above or the Department of Defense (DOD) or the Veterans Administration (VA) • A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants • The Department of Veterans Affairs, the Department of Defense or the Department of Energy as long as the study or investigation has been reviewed and approved through a system of peer review that is determined by the Secretary of Health and Human Services to meet both of the following criteria: ○ Comparable to the system of peer review of studies and investigations used by the National Institutes of Health. ○ Ensures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review. **or** 2. The study or investigation is conducted under an investigational new drug application reviewed by the U.S. Food and Drug Administration; **or** 3. The study or investigation is a drug trial that is exempt from having such an investigational new drug application. B. Additional Requirements 1. The clinical trial must have a written protocol that describes a scientifically sound study that has been approved by all relevant institutional review boards (*IRBs*) before participants are enrolled in the trial. We may, at any time, request documentation about

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Clinical Trials *(continued)*	Jun. 1, 2016		the trial. 2. The subject or purpose of the trial must be the evaluation of an item or service that meets the definition of a Covered Health Service and is not otherwise excluded under the Policy. III. **Qualified Individual** A. To be a qualified individual an individual must be: 1. Covered under the health plan; **and** 2. Eligible to participate in an approved clinical trial according to the trial protocol based upon: • The individual was referred to the clinical trial by an in-network health care professional who has concluded that the individual's participation would be appropriate because the individual is eligible for the trial according to its protocol, **or** • The individual provides the plan with medical and scientific information that establishes that participation would be appropriate because the individual is eligible for the trial according to its protocol. IV. **Routine Patient Costs During Clinical Trials** include: A. Covered Health Services for which Benefits are typically provided absent a clinical trial. B. Covered Health Services required solely for: 1. The provision of the Experimental or Investigational Service(s) or item (e.g., the infusion administration services to deliver an investigational drug); **and/or** 2. The clinically appropriate monitoring of the effects of the service or item (e.g., lab tests and imaging done at a frequency consistent with signs and symptoms and other standards of care for that diagnosis or treatment type); **and/or** 3. The prevention of complications. C. Covered Health Services needed for reasonable and necessary care arising from the provision of an Experimental or Investigational Service(s) or item. **Network Plans** If one or more network providers are participating in a clinical trial, then UnitedHealthcare may require that the Qualified Individual participate in the clinical trial using a network provider, as long as the network provider will

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Clinical Trials *(continued)*	Jun. 1, 2016		accept the qualifying individual as a participant in the trial. However, if an Approved Clinical Trial is conducted outside of the Qualified Individual's state of residence, then UnitedHealthcare may not deny or otherwise limit payment for Routine Patient Services solely on the basis that the trial is conducted out-of-state.
			
			Coverage Limitations and Exclusions
			Benefits for clinical trials **do not** include:
			• The Experimental or Investigational Service(s) or item that is used in the clinical trial is not covered, except for the following:
			  ○ Certain Category B devices (see definition)
			  ○ Certain promising interventions for patients with terminal illnesses
			  ○ Other items and services that, in our determination, meet specified criteria in accordance with our medical and drug policies
			• Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient. Examples include, but are not limited to:
			  ○ Laboratory tests and imaging studies done at a frequency dictated by the study protocol and not consistent with signs and symptoms and other standards of care for that diagnosis or treatment type
			• A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis
			• Items and services provided by the research sponsors free of charge for any person enrolled in the trial
			• Travel and transportation expenses are excluded from coverage. These include, but are not limited to, the following examples:
			  ○ Fees for all types of transportation (examples include, but are not limited to: personal vehicle, taxi, medical van, ambulance, commercial airline, and train)
			  ○ Rental car expenses
			  ○ Mileage reimbursement for driving a personal vehicle
			  ○ Lodging
			  ○ Meals
			• Routine patient costs obtained out-of-network where non-network benefits do not exist under the plan.
			• Clinical Trials that do not meet the requirements listed in the *Indications for Coverage* section above. An example includes, but is not limited to, Phase 0 drug clinical trials.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gynecomastia Treatment	Jun. 1, 2016	• Reformatted and reorganized policy; transferred content to new template (no change to coverage rationale or list of applicable codes)	**Indications for Coverage** **Criteria for a Coverage Determination that Surgery is Reconstructive and Medically Necessary** • 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: ○ Gynecomastia or breast enlargement with moderate to severe chest pain that is causing a functional/physical impairment as defined in the *Definitions* section of the policy. The inability to participate in athletic events, sports or social activities is not considered to be a functional/physical or physiological impairment. ○ No prior history of prescribed medications and appropriate screening(s) of non-prescription and/or recreational drugs or 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). ○ 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: ▪ Thyroid function studies ▪ Testosterone ▪ Beta subunit HCG • 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: ○ 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. ○ Gynecomastia or breast enlargement with moderate to severe chest pain that is causing a functional/physical impairment as defined in the *Definitions* section of the policy. The inability to participate in athletic events, sports or social activities is not considered to be a functional/physical or physiological impairment.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gynecomastia Treatment *(continued)*	Jun. 1, 2016		○ 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). ○ 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. 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** • Treatment of benign gynecomastia when specifically excluded in the member specific benefit plan document. • Treatment of benign gynecomastia when not specifically excluded in the member specific benefit plan document and the above criteria is not met. • 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
Breast Reduction Surgery	Aug. 1, 2016	• Reformatted and reorganized policy; transferred content to new template	**California Mandate for Medically Necessary Surgery**: The State of California requires that all breast reduction surgeries be reviewed for medical necessity. Benefits will be provided if the breast reduction meets the Criteria

Coverage Determination Guideline (CDG) Updates

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Breast Reduction Surgery *(continued)*	Aug. 1, 2016	• Revised coverage rationale/ indications for coverage: ○ Updated *Criteria for a Coverage Determination as Reconstructive*; removed criterion requiring "diagnostic tests, if done, have ruled out other causes of the functional impairment" ○ Modified language pertaining to documentation requirements; replaced language indicating " the [noted] documentation *may be requested as part of the* review" with "the [noted] documentation *should be available for* review"	for a Coverage Determination as Reconstructive identified below. **Indications for Coverage** Breast reduction surgery following mastectomy to achieve symmetry is covered as part of the Women's Health and Cancer Rights Act (WHCRA). Please refer to the Coverage Determination Guideline titled Breast Reconstruction Post Mastectomy. Breast reconstruction may be covered under certain circumstances for the surgical treatment of gender dysphoria. Please refer to the member specific benefit plan document for coverage. **All plans cover breast reduction surgeries that qualify under the Women's Health and Cancer Rights Act of 1998.** If a surgery does not qualify under the Women's Health and Cancer Rights Act of 1998, certain plans may allow breast reduction surgery which we determine to treat a physiologic functional impairment. However, certain plans exclude breast reduction surgery even if it treats a physiologic functional impairment. Refer to the member specific benefit plan document to determine coverage. ***For Plans that Cover Breast Reduction Surgery that Treat a Physiologic Functional Impairment (Including California Reviews for Medical Necessity)*** **Criteria for a Coverage Determination as Reconstructive** Breast reduction surgery is considered reconstructive and medically necessary when the following criteria are met and a physiologic functional impairment is identified: • Macromastia is the primary etiology of the member's functional impairment or impairments (as defined in the *Definitions* section of the policy). 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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Breast Reduction Surgery *(continued)*	Aug. 1, 2016		medical management (e.g., ulnar paresthesias) ○ Acquired kyphosis that is attributed to macromastia ○ Chronic breast pain due to weight of the breasts ○ Upper back, neck, or shoulder pain ○ Shoulder grooving from bra straps ○ Headache and • The amount of tissue to be removed plots above the 22nd percentile; or • If the amount of tissue to be removed plots between the 5th and 22nd percentiles, the procedure may be either reconstructive or cosmetic; the determination is based on the review of the information provided; and • The proposed procedure is likely to result in significant improvement of the functional impairment. **The Following Documentation Should be Available for Review** Reduction Mammoplasty documentation should include the evaluation and management note for the date of service and the note for the day the decision to perform surgery was made. The member's medical record must contain, and be available for review on request, the following information: • Height and weight • Body Surface Area (BSA) • Photographs that document macromastia **Coverage Limitations and Exclusions** Some states require benefit coverage for services that UnitedHealthcare considers cosmetic procedures, such as repair of external congenital anomalies in the absence of a functional impairment. Please refer to the member specific benefit plan documents. • Cosmetic Procedures are excluded from coverage. Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures. The fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure. • Any procedure that does not meet the reconstructive criteria above in the *Indications for Coverage* section (e.g., psychological or social reasons, breast size asymmetry unless post mastectomy, exercise.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Breast Reduction Surgery *(continued)*	Aug. 1, 2016		• Breast reduction surgery is cosmetic when done to improve appearance without improving a functional/physiologic impairment. • The use of liposuction as the sole procedure for breast reduction surgery is considered cosmetic. **Appendix** This Schnur chart may be used to assess whether the amount of tissue that will be removed is reasonable for the body habitus, and whether the procedure is cosmetic or reconstructive in nature. • If the amount plots above the 22nd percentile and the member has a functional impairment, the procedure is reconstructive. • If the amount plots below the 5th percentile, the procedure is cosmetic. • If the amount plots between the 5th and 22nd percentiles, the procedure may be either reconstructive or cosmetic based on review of information. To calculate body surface area (BSA), see: http://www.cornellpediatrics.org/ser_div/critical/calc/bsacalc.htm or BSA = (W 0.425 x H 0.725) x 0.007184 (weight is in kilograms and height is in centimeters) **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
2.05	439	687

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
			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
Preventive Care Services	Jul. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Revised list of applicable procedure and diagnosis codes: **Preventive Care Services** ○ Revised coverage guidelines for ***Colorectal Cancer Screening***: ▪ Updated list of applicable procedure codes for *Fecal Occult Blood Testing (FOBT), Sigmoidoscopy, or Colonoscopy: Code Group 1*; added S0285 [colonoscopy pre-op consultation (new code effective Jul. 1, 2016)] ○ Revised service description for ***Depression in Children and Adolescents (Screening)*** [previously titled *Major Depressive Disorder in Children and Adolescents (Screening)*]: ▪ Removed March 2009	Refer to the policy for complete details on the coverage guidelines for Preventive Care Services.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Jul. 1, 2016	USPSTF 'B' rating ▪ Added February 2016 USPSTF 'B' rating: - The USPSTF recommends screening for major depressive disorder (MDD) in adolescents aged 12 to 18 years; screening should be implemented with adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up **Expanded Women's Preventive Health** ○ Revised coverage guidelines for ***Contraceptive Methods (Including Sterilizations)***: ▪ Updated list of applicable procedure codes for *Tubal Ligation Followup Hysterosalpingogram: Code Group 1*; added Q9967 (contrast material) • Reformatted *Appendix A – USPSTF Grade Definitions*	

Utilization Review Guideline (URG) Updates

UPDATED

Policy Title	Effective Date	Summary of Changes	Utilization Management Guiding Principles
Specialty Medication Administration – Site of Care Review Guidelines	Jun. 1, 2016	• Reformatted and reorganized policy; transferred content to new template • Updated supporting information to reflect the most current references; no change to utilization management guidelines	**Introduction** This guideline addresses the criteria for consideration of allowing hospital outpatient facility specialty medication infusion services. This includes claim submission for hospital based services with the following CMS/AMA Place of Service codes: • 22 On Campus-Outpatient Hospital, and • 19 Off Campus-Outpatient Hospital Alternative sites of care, such as non-hospital outpatient infusion, physician office, ambulatory infusion or home infusion services are well accepted places of service for medication infusion therapy. If a patient does not meet criteria to for outpatient hospital facility infusion, alternative sites of care may be used. This Policy applies to these specialty medications that require healthcare provider administration: • Abatacept (Orencia®) • Eculizumab (Soliris®) • Golimumab (Simponi® Aria™) • Infliximab (Remicade® lyophilized concentrate for intravenous use) • Tocilizumab (Actemra® injection for intravenous use) • Vedolizumab (Entyvio®) **Review Criteria for Site of Care Selection** Outpatient hospital facility-based intravenous medication infusion is medically necessary for persons who meet any of the following criteria: • Medically unstable based upon submitted clinical history; or • Initial medication infusion of or re-initiation after more than 6 months following discontinuation of therapy; or • Previous experience of a severe adverse event following infusion. Examples include but are not limited to anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure; or • Continuing experience of adverse events that cannot be mitigated by pre-medications; or • Physically and/or cognitively impaired **and** no home caregiver available. **Additional Information**: Medical necessity criteria for administration of intravenous infusion therapy at home are addressed in MCG™ Care

Utilization Review Guideline (URG) Updates

UPDATED			
Policy Title	**Effective Date**	**Summary of Changes**	**Utilization Management Guiding Principles**
Specialty Medication Administration – Site of Care Review Guidelines *(continued)*			Guidelines, 20th edition, 2016, Home Infusion Therapy, CMT: CMT-0009(SR). **Benefit Considerations** This guideline applies to members with 2011 COC or Summary Plan Document with benefits available for health care services if medically necessary and have been approved for the requested medication clinical use. This guideline applies to UnitedHealthcare Commercial and Medicaid plans. This guideline does not apply to Medicare plans. **Supporting Information and Clinical Evidence Background** Home infusion as a place of service is well established and accepted by physicians. A 2010 home infusion provider survey by the National Home Infusion Association reported providing 1.24 million therapies to approximately 829,000 patients, including 129,071 infusion therapies of specialty medications. **Clinical Evidence** MCG™ Care Guidelines, 20th edition, 2016, Home Infusion Therapy, CMT: CMT-0009(SR) addresses criteria for home infusion therapy. Clinical patient characteristics for home suitability include: clinical stability, no need for close observation or daily nurse care, and reliable venous access. Additional criteria for home environment, infusion plan and patient ability to participate in care are summarized. **Professional Societies** The American Academy of Allergy Asthma and Immunology has published guidelines for the suitability of patients to receive treatment in various care setting including clinical characteristics of patients needing a high level of care in the hospital outpatient facility which includes patient characteristics: previous serious infusion reaction such as anaphylaxis, seizure, myocardial infarction, or renal failure, immune globulin therapy naïve, continual experience of moderate or serious infusion related adverse reactions, physical or cognitive impairment. The Hunter Syndrome European Expert Council: European recommendations for the diagnosis and multidisciplinary management of a rare disease

Utilization Review Guideline (URG) Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Utilization Management Guiding Principles**
Specialty Medication Administration – Site of Care Review Guidelines *(continued)*			published an article reviewing the collective experiences with agalsidase beta home infusion therapy and outlines how safe, patient-centered homecare can be organized in enzyme replacement therapy for patients with Fabry disease. Criteria include that "Patients must have received ERT in hospital for 3-6 months; if patients have previously had IRRs, they must be under control with premedication, and they must not have had an IRR in the 2-8 weeks before homecare is approved and premedication must be given. If a patient has significant respiratory disease (%FVC, 40% or less; or evidence of serious obstructive airway disease), homecare may not be suitable." The Agency for Healthcare Research and Quality (AHRQ) publication on Enzyme Replacement Therapy states, "Home infusion of ERT was initially studied in patients with type I Gaucher disease. It has been reported as an option for patients with Fabry disease, MPS I, and MPS II, and MPS VI. However, patients with infantile Pompe disease may not be able to transfer to home care because of an increased risk for serious adverse events during an infusion. In general, the outcomes measured in these studies and the follow-up durations were similar to those reported by disease in the clinical studies summarized under *Guiding Question 3*. Safety was the main focus of most home infusion studies, as the patients had already been receiving ERT in a more controlled setting." **Medication or Condition Specific Studies** In a trial evaluating patients with paroxysmal nocturnal hemoglobinuria, after initial 2-5 doses of eculizumab (Soliris), 79 patients received continued infusion with every 14 days in the home setting for the duration of the study – 1-98 months, mean duration of 39 months. The survival of patients treated with eculizumab was not different from age- and sex-matched normal controls (P = .46) but was significantly better than 30 similar patients managed before eculizumab (P = .030). Three patients on eculizumab, all over 50 years old, died of causes unrelated to PNH. Twenty-one patients (27%) had a thrombosis before starting eculizumab (5.6 events per 100 patient-years) compared with 2 thromboses on eculizumab (0.8 events per 100 patient-years; P < .001). Twenty-one patients with no previous thrombosis discontinued warfarin on eculizumab with no thrombotic sequelae. Forty of 61 (66%) patients on eculizumab for more than 12 months achieved transfusion independence. The 12-month mean transfusion requirement reduced from 19.3 units before eculizumab to 5.0 units in the

Utilization Review Guideline (URG) Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Utilization Management Guiding Principles**
Specialty Medication Administration – Site of Care Review Guidelines *(continued)*			most recent 12 months on eculizumab (P < .001). Eculizumab dramatically alters the natural course of PNH, reducing symptoms and disease complications as well as improving survival to a similar level to that of the general population. Infliximab has been shown to be safely infused in the community setting. A chart review of 3161 patients who received a combined 20,976 infusions in community clinics was conducted to evaluate safety across all types of patients. Infliximab infusions are safe in the community setting. Severe ADRs were rare. A total of 524 (2.5% of all infusions) acute ADRs in 353 patients (11.2%) were recorded. Most reactions (ie, ADRs) were mild (n=263 [50.2%, 1.3% of all infusions]) or moderate (n=233 [44.5%, 1.1% of all infusions]). Twenty-eight reactions (5.3%, 0.1% of all infusions) were severe. Emergency medical services were called to transport patients to hospital for seven of the severe reactions, of which none required admission. As per pre-established medical directives adrenaline was administered three times. The authrors concluded that infliximab infusions are safe in the community setting. Severe ADRs were rare. None required active physician intervention; nurses were able to treat all reactions by following standardized medical directives. Ten children were enrolled in the home infusion program if they were compliant with hospital-based infliximab infusions and other medications, had no adverse events during hospital-based infliximab infusions, were in remission and had access to experienced pediatric homecare nursing. The children received 59 home infusions with a dose range of 7.5 to 10 mg/kg/dose. Home infusions ranged from 2 to 5 hours. Since infusions could be performed any day of the week, school absenteeism was decreased. The average patient satisfaction rating for home infusions was 9 on a scale from 1 to 10 (10 = most satisfied). Three patients experienced difficulty with IV access requiring multiple attempts, but all were able to receive their infusions. One infusion was stopped because of arm pain above the IV site. This patient had his next infusion in the hospital before returning to the home infusion program. No severe adverse events (palpitations, blood pressure instability, hyperemia, respiratory symptoms) occurred during home infusions. In the carefully selected patients, infliximab infusions administered at home were safe and are cost-effective. Patients and families preferred home infusions, since time missed from school and work was reduced.