UnitedHealthcare®

January 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**

Overview

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

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

Tips for using the Medical Policy Update Bulletin:

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

Policy Update Classifications

New

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

Updated

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

Revised

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

Replaced

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

Retired

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

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

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Coverage Determination Guideline (CDG) Updates

Take Note

Annual CPT® and HCPCS Code Updates

Effective Jan. 1, 2016, all applicable Medical Policies, Drug Policies and Coverage Determination Guidelines (CDGs) have been modified to reflect the 2016 Current Procedural Terminology (CPT®) and Healthcare Common Procedure Coding System (HCPCS) code additions, revisions, and deletions. Refer to the following sources for information on the 2016 code changes:

- American Medical Association. Current Procedural Terminology: CPT® 2016
- Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System: HCPCS Level II

Policy Title	Policy Type	Summary of CPT®/HCPCS Code Edits
Abnormal Uterine Bleeding and Uterine Fibroids	Medical Policy	• Added 0404T, J7297 and J7298 • Removed J7302
Attended Polysomnography for Evaluation of Sleep Disorders	Medical Policy	• Revised description for 0383T, 0384T, 0385T and 0386T
Bariatric Surgery	Medical Policy	• Added 43210
Breast Imaging for Screening and Diagnosing Cancer	Medical Policy	• Added 0422T • Revised description for 77057
Cardiovascular Disease Risk Tests	Medical Policy	• Added 0423T and 93050 • Removed 0311T
Cochlear Implants	Medical Policy	• Revised description for L8621
Cosmetic and Reconstructive Procedures	CDG	• Added L8607
Emergency Health Services and Urgent Care	CDG	• Revised description for 99284
Fecal DNA Testing	Medical Policy	• Added 81528 • Removed S3890
Gastrointestinal Motility Disorders, Diagnosis and Treatment	Medical Policy	• Added 43210
Gene Expression Tests	Medical Policy	• Added 81493, 81525, 81540 and 81545
Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC)	Medical Policy	• Added 81162, 81432 and 81433

Take Note

Annual CPT® and HCPCS Code Updates		
Glaucoma Surgical Treatments	Medical Policy	• Removed 0123T
Hepatitis Screening	Medical Policy	• Revised description for 86708, 86709, 87340, 87341 and 87350
Home Health Care	CDG	• Added G0299 and G0300 • Removed G0154
Implanted Electrical Stimulator for Spinal Cord	Medical Policy	• Added C1822 • Revised description for C1820
Macular Degeneration Treatment Procedures	Medical Policy	• Revised description for 0308T
Molecular Profiling to Guide Cancer Treatment	Medical Policy	• Revised description for 81445, 81450 and 81455
Occipital Neuralgia and Headache Treatment	Medical Policy	• Revised description for 95972
Omnibus Codes	Medical Policy	• Added 81538, 99177, 0394T, 0395T, 0396T, 0398T, 0400T, 0401T, 0402T, 0408T, 0409T, 0410T, 0411T, 0412T 0413T, 0414T, 0415T, 0416T, 0417T, 0418T, 0421T, 0424T, 0425T, 0426T, 0427T, 0428T, 0429T, 0430T, 0431T, 0432T, 0433T, 0434T, 0435T, 0436T, L8607, Q4161, Q4162, Q4163, Q4164 and Q4165 • Revised description for 99174, 0358T, 0348T, 0349T, 0350T, 0351T, 0352T, 0353T, 0354T, Q4132, Q4133, Q4134, Q4137, Q4138, Q4139, Q4140, Q4141, Q4145, Q4147, Q4150, Q4151, Q4152, Q4153, Q4155 and Q4160 • Removed 0103T, 0182T, 0223T, 0224T, 0225T, 0233T, 0243T and 0244T
Preventive Care Services	CDG	• Added 99177, 0403T, 81162, J7297, J7298, G0296, G0297, G0475 and G0476 • Removed 90645, 90646, 90669, 90703, 90704, 90705, 90706, 90708, 90719, 90720, 90721, J7302 and S0195
Sodium Hyaluronate	Medical Policy	• Added J7328 and Q9980
Transcatheter Heart Valve Procedures	Medical Policy	• Added 33477 • Removed 0262T

Medical Policy Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Deep Brain Stimulation	Jan. 1, 2016	• Updated supporting information to reflect the most current clinical evidence, FDA information, and references; no change to coverage rationale or lists of applicable codes	**Deep brain stimulation is proven and medically necessary for treating the following:** • Idiopathic Parkinson's disease when used according to U.S. Food and Drug Administration (FDA) indications • Essential tremor when used according to U.S. Food and Drug Administration (FDA) indications • Primary dystonia* (occurs apart from any other identifiable illness) including generalized and/or segmental dystonia, hemidystonia and cervical dystonia (torticollis) when used according to the U.S. Food and Drug Administration (FDA) indications *Primary dystonia may include genetic torsion dystonia, acquired torsion dystonia (not due to drugs), spasmodic torticollis, fragments of torsion dystonia, and unspecified torticollis. **Deep brain stimulation is unproven and not medically necessary for treating secondary Parkinsonism (result of head trauma, metabolic conditions, toxicity, drugs, or other medical disorders).** Well-designed studies demonstrating the efficacy of deep brain stimulation for treating secondary Parkinsonism are not available. Clinical trials are needed to demonstrate the benefit of deep brain stimulation for this patient population. **Deep brain stimulation is unproven and not medically necessary for treating secondary dystonia (occurs with illness, after trauma or following exposure to certain medications or toxins).** There is inadequate evidence of the safety and efficacy of deep brain stimulation for treating secondary dystonia. Questions remain with regard to patient selection criteria and long-term benefits and safety compared with standard treatments. Formal comparisons, with large randomized controlled or comparative trials of pallidotomy, thalamotomy, and deep brain stimulation, are required before conclusions can be drawn regarding the use of deep brain stimulation for patients with secondary dystonia. **Deep brain stimulation is unproven and not medically necessary for treating conditions other than those listed as proven. This includes but is not limited to the following diagnoses:** • Depression • Obsessive-compulsive disorder (OCD)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Deep Brain Stimulation *(continued)*	Jan. 1, 2016		• Epilepsy • Tourette syndrome • Cluster headache • Impulsive or violent behavior • Chronic pain • Trigeminal neuralgia • Movement disorders caused by multiple sclerosis (MS) Some studies have examined the use of deep brain stimulation for treating major depression, obsessive-compulsive disorder (OCD), epilepsy, Tourette syndrome, cluster headache, impulsive or violent behavior, stroke pain, chronic pain, phantom limb pain, trigeminal neuralgia and movement disorders of multiple sclerosis (MS). However, because of limited studies, small sample sizes, weak study designs and heterogenous patient characteristics, there is insufficient data to conclude that deep brain stimulation is safe and/or effective for treating these indications.
Electrical Stimulation and Electromagnetic Therapy for Wounds	Jan. 1, 2016	• Updated supporting information to reflect the most current clinical evidence, CMS information, and references; no change to coverage rationale or list of applicable codes	**Electrical stimulation is unproven and not medically necessary for the treatment of wounds including venous stasis ulcers, arterial ulcers, diabetic foot ulcers and chronic pressure sores.** There is insufficient evidence from randomized, controlled trials that electrical stimulation, as an adjunct to standard wound care, can increase the healing rate of chronic dermal or cutaneous wounds. There were substantial methodological flaws in the available studies, which make it difficult to define the magnitude of treatment effects and to determine what types of wounds are most likely to benefit from electrical stimulation. There is also insufficient evidence to determine the type of device or form of electrical current for use in wound healing. **Electromagnetic therapy is unproven and not medically necessary for the treatment of wounds including venous stasis ulcers, arterial ulcers, diabetic foot ulcers, chronic pressure sores and soft tissue injuries.** The available evidence regarding the use of pulsed high-frequency electromagnetic energy for the treatment of chronic wounds and soft tissue injuries is insufficient to support conclusions regarding the efficacy of this technology. The data from clinical trials are insufficient to prove efficacy, to define optimal treatment protocols, to establish patient selection criteria, or to evaluate the relative efficacy of this therapy compared with other

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Electrical Stimulation and Electromagnetic Therapy for Wounds *(continued)*	Jan. 1, 2016		treatment options. The available studies involved small numbers of subjects and because significant differences were noted between intervention and control groups, it is not possible to draw valid conclusions about the efficacy of this technology.
Hysterectomy for Benign Conditions	Jan. 1, 2016	• Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or list of applicable codes	**For information regarding medical necessity review, when applicable, see the following MCG™ Care Guidelines, 19th edition, 2015:** • Hysterectomy, Abdominal, ORG: S-650 (ISC) • Hysterectomy, Vaginal, ORG: S-660 (ISC) • Hysterectomy, Laparoscopic, ORG: S-665 (ISC)
Implantable Beta-Emitting Microspheres for Treatment of Malignant Tumors	Jan. 1, 2016	• Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or lists of applicable codes	**Yttrium-90 (^{90}Y) microsphere radioembolization is proven and medically necessary for the following indications:** • unresectable metastatic liver tumors from primary colorectal cancer (CRC) • unresectable metastatic liver tumors from neuroendocrine tumors • unresectable primary hepatocellular carcinoma (HCC) **Yttrium-90 (^{90}Y) microsphere radioembolization is unproven and not medically necessary for all other indications.** Limited evidence suggests that treatment with intrahepatic microsphere radiation (IMR) might shrink tumors and relieve symptoms in some patients, sometimes enough to render some inoperable tumors operable. However, limited available evidence has not shown improved survival. In addition, the treatment's potential impact on quality of life has not been studied. No studies have yet compared the effects of IMR therapy with alternative treatments, such as chemoembolization. Randomized controlled trials are needed to determine the clinical utility of this treatment.
Infertility Diagnosis and Treatment	Jan. 1, 2016	• Updated supporting information to reflect the most current clinical evidence, CMS information, and references; no change to coverage rationale or lists of applicable codes	**Diagnostic Procedures** ***Females*** **The following tests or procedures are proven and medically necessary for diagnosing infertility in female patients:** • Antral follicle count • Clomiphene citrate challenge test

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

Infertility Diagnosis and Treatment *(continued)*	Jan. 1, 2016		• The following hormone level tests:
			  ○ antimüllerian hormone (AMH)
			  ○ estradiol
			  ○ follicle-stimulating hormone (FSH)
			  ○ luteinizing hormone (LH)
			  ○ progesterone
			  ○ prolactin
			  ○ thyroid-stimulating hormone (TSH)
			• Hysterosalpingogram (HSG)
			• Diagnostic hysteroscopy
			• Diagnostic laparoscopy with or without chromotubation
			• Pelvic ultrasound (transabdominal or transvaginal)
			• Sonohysterogram or saline infusion ultrasound
			
			The following tests are unproven and not medically necessary for diagnosing infertility in female patients:
			• Inhibin B
			• Uterine/endometrial receptivity testing (e.g., E-tegrity® and Endometrial Function Test® (EFT®))
			
			There is insufficient evidence to permit conclusions regarding the use of these tests. More studies are needed to support improved outcomes (i.e., increased successful pregnancies with delivery of liveborn children) with use of these diagnostic tests.
			
			Males
			The following tests or procedures are proven and medically necessary for diagnosing infertility in male patients:
			• Antisperm antibodies
			• The following genetic screening tests:
			  ○ cystic fibrosis gene mutations
			  ○ karyotyping for chromosomal abnormalities
			  ○ Y-chromosome microdeletions testing
			• The following hormone level tests:
			  ○ LH
			  ○ FSH
			  ○ prolactin
			  ○ testosterone (total and free)
			• Leukocyte count in semen

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Infertility Diagnosis and Treatment *(continued)*	Jan. 1, 2016		• Post-ejaculatory urinalysis • Scrotal, testicular or transrectal ultrasound • Semen analysis • Testicular biopsy • Vasography **The following tests are unproven and not medically necessary for diagnosing infertility in male patients:** • Computer-assisted sperm analysis (CASA) • Hyaluronan binding assay (HBA) • Postcoital cervical mucus penetration test • Reactive oxygen species (ROS) test • Sperm acrosome reaction test • Sperm DNA integrity/fragmentation tests (e.g. sperm chromatin structure assay (SCSA), single-cell gel electrophoresis assay (Comet), deoxynucleotidyl transferase-mediated dUTP nick end labeling assay (TUNEL), sperm chromatin dispersion (SCD) or Sperm DNA Decondensation™ Test (SDD)) • Sperm penetration assays There is insufficient evidence to permit conclusions regarding the use of these tests. More studies are needed to support improved outcomes (i.e., increased successful pregnancies with delivery of liveborn children) with use of these diagnostic tests. **Therapeutic Procedures** For medical necessity reviews, please refer to the Optum Infertility Clinical Performance Guideline. **The following procedures are unproven and not medically necessary for treating infertility:** • Co-culture of embryos • EmbryoGlue® • In vitro maturation (IVM) of oocytes Studies describe different techniques of co-culture of embryos, but no standardized method of co-culturing has been defined. The use of co-cultures may improve blastocyst development but may not result in an improved pregnancy or delivery rate.

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Infertility Diagnosis and Treatment *(continued)*	Jan. 1, 2016		There is inadequate published scientific data to permit conclusions regarding the use of EmbryoGlue. Although preliminary results with IVM are promising, studies to date show that implantation and pregnancy rates are significantly lower than those achieved with standard IVF. Further evidence from well-designed trials is needed to determine the long-term safety and efficacy of the procedure. **Cryopreservation** **Cryopreservation of sperm, semen or embryos is proven and medically necessary for individuals who are undergoing treatment with assisted reproductive technologies or are planning to undergo therapies that threaten their reproductive health, such as cancer chemotherapy.** **Cryopreservation of *mature* oocytes (eggs) is proven and medically necessary for women, under the age of 42, who are undergoing treatment with assisted reproductive technologies or are planning to undergo therapies that threaten their reproductive health, such as cancer chemotherapy.** **Cryopreservation of *immature* oocytes (eggs) is unproven and not medically necessary.** Further evidence from well-designed trials is needed to determine the long-term safety and efficacy of cryopreserving immature oocytes for future in vitro maturation. **Cryopreservation of ovarian or testicular tissue is unproven and not medically necessary.** Ovarian tissue banking remains a promising clinical technique because it avoids ovarian stimulation and provides the opportunity for preserving gonadal function in prepubertal, as well as adult patients. However, this procedure has produced very few live births. Testicular tissue or testis xenografting are in the early phases of experimentation and have not yet been successfully tested in humans.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Sodium Hyaluronate	Jan. 1, 2016	**Notice of Revision**: The following summary of changes has been modified. Revisions to the policy update announcement previously appearing in the *December 2015 Policy Update Bulletin* are outlined in red below. Please take note of the additional updates to be implemented on **Jan. 1, 2016.**
		
		• Updated coverage rationale for treatment with intra-articular injections of sodium hyaluronate for pain due to osteoarthritis of the knee; expanded list of proven/ medically necessary U.S. FDA labeled indications to include:
		  ○ Gel-Syn for 3 injections
		  ○ Genvisc 850 for 3 to 5 injections
		• Updated list of applicable HCPCS codes to reflect annual code edits (effective Jan.1, 2016); added J7328 and Q9980
		• Updated list of applicable ICD-10 diagnosis codes; removed M07.661, M07.662, M07.669, M12.861, M12.862, M12.869, M12.9, M25.561, M25.562, and M25.569
		• Updated supporting information to reflect the most current clinical evidence, FDA information, and references
			Treatment with intra-articular injections of sodium hyaluronate is proven and medically necessary for pain due to osteoarthritis of the knee when administered according to U.S. Food and Drug Administration (FDA) labeled indications.
			
			FDA Labeling*:
			
			Euflexxa: 3 injections
			Gel One: 1 injection
			Gel-Syn: 3 injections
			Genvisc 850: 3 to 5 injections
			Hyalgan: 5 injections
			Monovisc: 1 injection
			Orthovisc: 3 to 4 injections
			Supartz: 3 to 5 injections
			Synvisc: 3 injections
			Synvisc One: 1 injection
			
			*Hyaluronic acid preparations for the treatment of pain due to osteoarthritis of the knee are deemed therapeutically equivalent. The UnitedHealth Group National Pharmacy and Therapeutics Committee has defined as therapeutically equivalent, products that can be expected to produce essentially the same therapeutic outcome and toxicity.
			
			Note: *There is no evidence that use of one intra-articular hyaluronan product is superior to another.*
			
			Repeated courses of intra-articular hyaluronan injections may be considered under the following conditions:
			• Significant pain relief was achieved with the prior course of injections; **and**
			• Pain has recurred; **and**
			• At least 6 months have passed since the prior course of treatment
			
			Intra-articular injections of sodium hyaluronate are proven and medically necessary for temporomandibular joint (TMJ) disc displacement and osteoarthritis.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Sodium Hyaluronate *(continued)*	Jan. 1, 2016		**Treatment with sodium hyaluronate preparations is unproven and not medically necessary for any other indication not listed above as proven including but not limited to:** • Pain due to osteoarthritis in any joint other than the knee or TMJ • Any other form of arthritis (including rheumatoid arthritis) • Patello-femoral syndrome • Chondromalacia of the knee • Following total or partial knee joint replacement Increase in viscoelasticity of synovial fluid after sodium hyaluronate injection has not been demonstrated in patients with rheumatoid arthritis, and it has not been determined whether sodium hyaluronate is protective in joints affected by rheumatoid arthritis. Further studies are needed to determine the safety and durability of such treatment for patello-femoral syndrome and chondromalacia of the knee and whether it significantly delays the need for more invasive treatment, e.g. surgery, joint replacement or arthroplasty. There are no clinical studies evaluating the use of sodium hyaluronate in persons following total or partial knee joint replacement surgery. **Treatment with hyaluronic acid gel preparations to improve the skin's contour and/or reduce depressions due to acne, scars, injury or wrinkles is considered cosmetic.** The use of sodium hyaluronate preparations to improve the skin's contour and/or reduce depressions in the skin due to acne, scars, injury or wrinkles improves physical appearance but does not remove or improve a functional impairment of the skin.
Temporomandibular Joint Disorders	Jan. 1, 2016	• Updated supporting information to reflect the most current FDA information, CMS information, and references; no change to coverage rationale or lists of applicable codes	**The following services are proven and medically necessary for treating disorders of the temporomandibular joint (TMJ):** • Arthrocentesis • Arthroplasty [For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines®, 19th edition, 2015, Temporomandibular Joint Arthroplasty, ACG: A-0523 (AC)] • Arthroscopy (with or without FDA approved bone anchor devices) • Arthrotomy/open joint surgery (with or without FDA approved bone anchor devices) • Injections of corticosteroids for rheumatoid arthritis-related TMJ disorders

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Temporomandibular Joint Disorders *(continued)*	Jan. 1, 2016		• Physical therapy • Stabilization and repositioning splint therapy *(Does not include low-load prolonged-duration stretch (LLPS) devices discussed below)* **Partial or total joint replacement with an artificial prosthesis is proven and medically necessary for treating disorders of the temporomandibular joint (TMJ) when all other treatments have failed.** Not all services treat all TMJ disorders; specific treatments are based upon the specific diagnosis. **The following services are unproven and not medically necessary for treating disorders of the temporomandibular joint (TMJ):** • Biofeedback • Craniosacral manipulation • Passive rehabilitation therapy • Low-load prolonged-duration stretch (LLPS) devices There are limited studies evaluating biofeedback for the treatment of musculoskeletal pain, including TMJ pain. One small uncontrolled study reported positive effects, while a larger randomized controlled study failed to demonstrate any treatment effect. Well-designed randomized, blinded and placebo-controlled outcome studies published on craniosacral manipulation for TMJ are not available. For additional information regarding manipulation under anesthesia for TMJ disorders, see the Medical Policy titled Manipulation Under Anesthesia. While there are some data from several randomized trials and case series studies that certain types of passive rehabilitation techniques may improve jaw mobility early in recovery in patients who have undergone TMJ surgery, or have lost jaw mobility due to TMJ derangement or to contracture following radiation therapy, these studies all included very small numbers of patients, and did not provide blinded assessment of outcomes, long-term follow-up, or information on optimal treatment protocols. Further prospective controlled clinical trials that directly compare LLPS devices to other treatment modalities are needed.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC)	Jan. 1, 2016	**Notice of Revision**: The following summary of changes has been modified. Revisions to the policy update announcement previously appearing in the *December 2015 Policy Update Bulletin* are outlined in red below. Please take note of the additional updates to be implemented on **Jan. 1, 2016.** • Revised coverage rationale: ○ Updated/clarified definition of: ▪ Breast cancer diagnosis ▪ Documentation of personal and family history ▪ Gleason scoring system ▪ Triple-negative breast cancer ○ Added coverage criteria/ requirements for genetic counseling to indicate: ▪ Genetic counseling 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	**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 affected on the same side of the family c. 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 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.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Jan. 1, 2016	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 ~~Board-Certified~~ physician with experience in cancer genetics (defined as providing cancer risk assessment on a regular basis and	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. **Genetic Counseling** Genetic counseling 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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Jan. 1, 2016	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 include: - Three generation pedigree - UnitedHealthcare genetic counseling attestation form ○ Revised BRCA testing criteria: ▪ Added language to indicate: - 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 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. 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 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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Jan. 1, 2016	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 ▪ Revised testing criteria for **women with a personal history of breast cancer** to indicate *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	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 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 breast (≤ age 50 years), ovarian, 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 breast (≤ age 50 years), ovarian, pancreatic and/or prostate cancer (Gleason score ≥7) at any age. VI. *BRCA1* and *BRCA2* testing is proven and medically necessary for men

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Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Jan. 1, 2016	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 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	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-V); 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. **Note:** NCCN guidelines state that significant limitations of interpreting test results for an unaffected individual 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 unaffected individuals should only be considered when there is no affected family member available for testing (NCCN, 2015). 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.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Jan. 1, 2016	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	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Jan. 1, 2016	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 ▪ Revised criteria for **women and men with a personal history of pancreatic cancer** 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	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Jan. 1, 2016	and at least one close blood relative on the same side of the family with breast (≤ age 50 years), ovarian, pancreatic and/or prostate cancer (Gleason score ≥7) at any age ▪ Added criteria for **Ashkenazi Jewish founder-specific mutations to** indicate BRCA1 and BRCA2 is proven and medically necessary for women and men with a personal history of pancreatic cancer and Ashkenazi Jewish ancestry ▪ Revised criteria for **men with a personal history of prostate cancer** to indicate 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 breast (≤ age 50 years), ovarian, pancreatic and/or prostate cancer (Gleason score ≥7) at any age ▪ Revised criteria for **men and women without a personal history of breast or ovarian cancer** to indicate: - BRCA1 and BRCA2 screening tests are	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Jan. 1, 2016	proven and medically necessary 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: A. At least one first- or second-degree blood relative meeting any of the above criteria (I-V); 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*	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Jan. 1, 2016	mutation in the family • Further *BRCA1/BRCA2* testing should only be pursued if the results are negative and the patient otherwise meets testing criteria - NCCN guidelines state that significant limitations of interpreting test results for an unaffected individual 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 unaffected individuals should only be considered when there is no affected family member available for testing (NCCN,	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (HBOC) *(continued)*	Jan. 1, 2016	2015) ○ Removed criteria for large genomic rearrangement testing as this step is incorporated into comprehensive testing and may be done concurrently or sequentially • Updated list of applicable CPT codes to reflect annual code edits (effective 01/01/2016); added 81162, 81432 and 81433 • Removed "Additional Products" information listing specific genetic test device names and manufacturers • Updated supporting information to reflect the most current description of services, clinical evidence, CMS information and references	
Intensity-Modulated Radiation Therapy	Feb. 1, 2016	• Converted policy content to new template • Updated benefit considerations; removed language indicating benefit coverage for an otherwise unproven service for the treatment of serious rare diseases may occur when certain conditions are met • Revised coverage rationale; updated list of proven/medically necessary indications: ○ Added "mediastinal tumors" ○ Removed "primary or benign bone tumors" • Updated supporting information to reflect the most current	**This policy applies to persons 19 years of age and older. Intensity-modulated radiation therapy (IMRT) is covered without further review for persons 18 years and younger.** **IMRT is proven and medically necessary for treating the primary site of the following diagnoses:** • Anal cancer • Breast cancer when the patient has a separation of 25.5 cm or more in the intra-thoracic distance from the midpoint of the posterior light field border of the medial tangential field to the midpoint of the posterior light field of the lateral tangential field • Cervical cancer in patients who have had a hysterectomy • Esophageal cancer • Head and neck cancers, including the following areas: pharynx (nasopharynx, oropharynx and hypopharynx), larynx, salivary glands, oral cavity (includes the tongue), nasal cavity and paranasal sinuses • Mediastinal tumors

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Intensity-Modulated Radiation Therapy *(continued)*	Feb. 1, 2016	description of services, clinical evidence, CMS information, and references	• Pancreatic cancer • Primary or benign tumors of the central nervous system including the brain, brainstem and spinal cord • Prostate cancer • Tracheal cancer **IMRT may be covered for a diagnosis that is not listed above as proven when at least one of the following conditions is present:** • A non-IMRT technique would substantially increase the probability of clinically meaningful normal tissue toxicity. • The same or an immediately adjacent area has been previously irradiated, and the dose distribution within the patient must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue. Requests for these exceptions will be evaluated on a case-by-case basis. **The use of compensator based beam modulation treatment is proven and medically necessary when done in combination with an IMRT indication that is listed above as proven.** **IMRT used in conjunction with proton beam radiation therapy is unproven and not medically necessary.** Clinical evidence is insufficient to support the combined use of these technologies in a single treatment plan. Comparative effectiveness studies including randomized controlled trials are needed to demonstrate the safety and long-term efficacy of combined therapy. **Continuous/real-time intra-fraction localization and tracking systems are unproven and not medically necessary for use in image-guided radiation therapy.** Larger, prospective studies are needed to determine whether image-guided radiation therapy using continuous or real-time tracking systems improves health outcomes in patients receiving IMRT.
Mechanical Stretching and Continuos Passive Motion Devices	Feb. 1, 2016	• Revised coverage rationale: ○ Clarified language to indicate *the use of* specific devices is proven/medically necessary or unproven/not medically necessary	**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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Mechanical Stretching and Continuos Passive Motion Devices *(continued)*	Feb. 1, 2016	○ Added language to indicate the use of low-load prolonged-duration stretch devices are 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 unresponsive to other therapies in the **immediate** post-operative period* • Updated supporting information to reflect the most current description of services, clinical evidence, and references	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 unresponsive to other therapies in the immediate post-operative period. **The use of static progressive (SP) stretch splint devices and patient 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	Jan. 1, 2016	**Notice of Revision**: The following summary of changes has been modified. Revisions to the policy update announcement previously appearing in the *December 2015 Policy Update Bulletin* are outlined in red below. Please take note of the additional updates to be implemented on **Jan. 1, 2016.** • Updated coverage rationale for the following unproven/not medically necessary procedure: **Implantable cardiac devices for percutaneous closure (occlusion) of the left atrial appendage (LAA) (CPT code**	Refer to the policy for complete details on the coverage guidelines for Omnibus Codes.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Omnibus Codes *(continued)*	Jan. 1, 2016	**0281T)** ○ Replaced reference to "cardiac devices" with "implantable cardiac devices" • Revised coverage rationale to reflect annual code edits (effective Jan. 1, 2016): ○ Added language to indicate the following procedures are unproven/not medically necessary: ▪ Use of intra-operative kinetic balance sensor for implant stability during knee replacement arthroplasty (CPT code 0396T) ▪ Magnetic resonance image guided high intensity focused ultrasound (MRgFUS) intracranial stereotactic ablation (CPT code 0398T) ▪ Multi-spectral digital skin lesion analysis (CPT codes 0400T and 0401T) ▪ Collagen cross-linking of cornea analysis (CPT code 0402T) ▪ Cardiac contractility modulation using an implantable device (CPT codes 0408T – 0418T) ▪ Transurethral waterjet ablation of the prostate (CPT code 0421T) ▪ Implantable neurostimulation devices	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Omnibus Codes *(continued)*	Jan. 1, 2016	for the treatment of central sleep apnea (CPT codes 0424T – 0436T) ○ Updated list of applicable CPT codes for: **Instrument-based ocular screening using photoscreening** ▪ Added 99177 ▪ Revised description for 99174 ▪ Added list of allowable diagnoses **High dose rate electronic brachytherapy** ▪ Added 0394T and 0395T ▪ Removed 0182T **Serum proteomic profiling using mass spectrometry** ▪ Added 81538 **Bioelectrical impedance analysis whole body composition assessment** ▪ Revised description for 0358T **Radiostereometric analysis in bone** ▪ Revised description for 0348T, 0349T, and 0350T **Optical coherence tomography (OCT)** ▪ Revised description for 0351T, 0352T, 0353T, and 0354T ○ Updated list of applicable HCPCS codes for: **Skin substitutes** ▪ Revised description for	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Omnibus Codes *(continued)*	Jan. 1, 2016	Q4132, Q4133, Q4134, Q4137, Q4138, Q4139, Q4140, Q4141, Q4145, Q4147, Q4150, Q4151, Q4152, Q4153, Q4155, and Q4160 ○ Removed language indicating the following procedures are unproven and not medically necessary: ▪ Testing for vitamin B-12 deficiency with a quantitative Holotranscobalamin testing (CPT code 0103T) ▪ Use of computer-aided electronic auscultatory (acoustic cardiography) devices (CPT codes 0223T, 0224T, and 0225T) ▪ Use of advanced glycation end products as a diagnostic or predictive test (CPT code 0233T) ▪ Use of intermittent or continuous computerized wheeze detectors (CPT codes 0243T and 0244T) • Updated supporting information to reflect the most current clinical evidence and references	
Omnibus Codes	Feb. 1, 2016	• Revised coverage rationale: ○ Added language to indicate the following **soft-tissue bulking agent** is	Refer to the policy for complete details on the coverage guidelines for Omnibus Codes.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Omnibus Codes *(continued)*	Feb. 1, 2016	proven/medically necessary in certain circumstances: ▪ Injectable bulking agent for vocal cord medialization (HCPCS code L8607) ○ Added language to indicate the following **skin substitutes** are unproven/not medically necessary: ▪ AmnioGen-A™, AmnioGen-C™, AmnioGen-45™, or AmnioGen-200™ (HCPCS codes Q4162 and Q4163) ▪ AmnioPro™, BioRenew™, BioSkin™, or WoundEx™ (HCPCS code Q4163) ▪ AmnioPro™ Flow, BioRenew™ Flow, BioSkin™ Flow, or WoundEx™ Flow (HCPCS code Q4162) ▪ Bio-ConneKt® (HCPCS code Q4161) ▪ Helicoll™ (HCPCS code Q4164) ▪ Keramatrix® (HCPCS code Q4165) ▪ Plurivest (HCPCS code Q4153) • Updated supporting information to reflect the most current clinical evidence and references	
Surgical Treatment for Spine Pain	Feb. 1, 2016	• Revised coverage rationale:	**Spinal fusion using extreme lateral interbody fusion (XLIF®) or direct lateral interbody fusion (DLIF) is proven.**

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical Treatment for Spine Pain *(continued)*	Feb. 1, 2016	○ Updated language pertaining to clinical evidence/study findings for minimally invasive lumbar decompression (MILD®) to indicate: ▪ Current clinical evidence is insufficient to permit conclusions about whether any beneficial effect from minimally invasive lumbar decompression provides a significant advantage over surgical decompression ▪ In addition, the complication rates and reoperation rates for this procedure compared with those of decompression surgery is unknown • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	Coding Clarification • The North American Spine Society (NASS) recommends that anterior or anterolateral approach techniques performed via an open approach should be billed with CPT codes 22554 – 22585. These codes should be used to report the use of extreme lateral interbody fusion (XLIF) and direct lateral interbody fusion (DLIF) procedures (NASS, 2010). • Laparoscopic approaches should be billed with an unlisted procedure code. For information regarding medical necessity review, when applicable, see the following MCG™ Care Guidelines, 19th edition, 2015: • Cervical Diskectomy or Microdiskectomy, Foraminotomy, Laminotomy, S-310 (ISC) • Lumbar Diskectomy, Foraminotomy, or Laminotomy S-810 (ISC) • Cervical Laminectomy S-340 (ISC) • Lumbar Laminectomy S-830 (ISC) • Cervical Fusion, Anterior S-320 (ISC) • Cervical Fusion, Posterior S-330 (ISC) • Lumbar Fusion S-820 (ISC) **The following spinal procedures are unproven:** A. **Spinal fusion**, when performed via the following methods: 1. **Laparoscopic anterior lumbar interbody fusion (LALIF**) 2. **Transforaminal lumbar interbody fusion (TLIF)** which utilizes only endoscopy visualization (such as a percutaneous incision with video visualization) 3. **Axial lumbar interbody fusion (AxiaLIF)** 4. **Interlaminar lumbar instrumented fusion (ILIF)** This includes interbody cages, screws, and pedicle screw fixation devices with any of the above procedures. Clinical evidence is limited primarily to retrospective studies and case series. Randomized, controlled trials comparing these procedures to standard procedures are needed to determine impact on health outcomes and long-term efficacy. B. **Spinal Decompression and Interspinous Process Decompression**

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical Treatment for Spine Pain *(continued)*	Feb. 1, 2016		**Systems** 1. **Interspinous process decompression (IPD) systems**, for the treatment of spinal stenosis 2. **Minimally invasive lumbar decompression (MILD®)** Current clinical evidence is insufficient to permit conclusions about whether any beneficial effect from minimally invasive lumbar decompression provides a significant advantage over surgical decompression. In addition, the complication rates and reoperation rates for this procedure compared with those of decompression surgery is unknown. C. **Spinal Stabilization** 1. **Stabilization systems** for the treatment of degenerative spondylolisthesis 2. **Total facet joint arthroplasty, including facetectomy, laminectomy, foraminotomy, vertebral column fixation** The current published evidence is insufficient to determine whether facet arthroplasty is as effective or as safe as spinal fusion, the current standard for surgical treatment of degenerative disc disease. In addition, no devices have received approval from the U.S. Food and Drug Administration for use outside the clinical trial setting. 3. **Percutaneous sacral augmentation (sacroplasty)** with or without a balloon or bone cement for the treatment of back pain The available clinical evidence shows that percutaneous sacroplasty, may alleviate the pain and functional impairment of sacral insufficiency fractures (SIF) in most patients with few and predominantly minor adverse effects, suggesting that this procedure may be relatively safe and efficacious for treatment of SIF. Despite these promising findings, the overall quality of the body of evidence is low given that the available studies were limited by methodological flaws (e.g., retrospective design, small sample size, subjective outcome measures, lack of a control group, and inadequate follow-up). Before reliable recommendations may be made, higher-quality studies are required that entail large populations with sufficient statistical power. D. **Stand alone facet fusion without an accompanying decompressive**

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Surgical Treatment for Spine Pain *(continued)*	Feb. 1, 2016		**procedure**. This includes procedures performed with or without bone grafting and/or the use of posterior intrafacet implants such as fixation systems, facet screw systems or anti-migration dowels. Clinical evidence is limited primarily to case series and nonrandomized studies. Randomized, controlled trials comparing facet fusion to standard procedures are needed to determine impact on health outcomes and long-term efficacy.

Drug and Biologics Policy Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Alemtuzumab	Feb. 1, 2016	• Updated list of applicable HCPCS codes to reflect annual code edits: ○ Added J0202 ○ Removed J9019 and Q9979	This drug policy will ONLY be updated for ***non-oncology indications***. Please refer to the Oncology Medication Clinical Coverage Policy for updated information based on the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium for oncology indications associated with Campath (alemtuzumab) only. Campath (alemtuzumab) is **proven** for the treatment of:* 1. Patients undergoing peripheral blood stem cell (PBSC) and/or bone marrow transplantation 2. Patients undergoing solid organ transplantation * Effective September 4th, 2012, Campath (alemtuzumab) will no longer be available commercially, but will be provided through the Campath Distribution Program free of charge. Additional details about this program may be found at www.campath.com. UnitedHealthcare will not provide coverage of Campath in relapsing-remitting multiple sclerosis (RRMS). 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 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®) 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

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Alemtuzumab *(continued)*	Feb. 1, 2016		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** a. **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. UnitedHealthcare will not provide coverage of Lemtrada for indications other than relapsing-remitting multiple sclerosis RRMS. Alemtuzumab is **unproven** for the treatment of: 1) Rheumatoid arthritis 2) Autoimmune neutropenia 3) Autoimmune hemolytic anemia 4) Pure red cell aplasia 5) Immune thrombocytopenic purpura 6) Evans syndrome 7) Autoimmune pancytopenia **Centers for Medicare and Medicaid Services (CMS):**

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Alemtuzumab *(continued)*	Feb. 1, 2016		Medicare does not have a National Coverage Determination (NCD) for alemtuzumab (Campath®). Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for Alemtuzumab (Campath®) and 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.
Anemia Drugs: Darbepoetin Alfa, Epoetin Alfa, and Methoxy Polyethylene Glycol-Epoetin Beta	Feb. 1, 2016	• Updated list of applicable HCPCS codes to reflect annual code edits; removed J0886	This policy addresses the following erythropoiesis stimulating agents (ESAs): Aranesp® (darbepoetin alfa) Epogen® (epoetin alfa) Mircera® (methoxy polyethylene glycol-epoetin beta [MPG-epoetin beta]) Procrit® (epoetin alfa) For the purposes of the coverage rationale, all hematocrit (Hct) values are either pretreatment (for the first 4-6 weeks of therapy) or obtained during treatment to assess ongoing titration and safety. 1. **Anemia Due to Chronic Kidney Disease:** a. Patients receiving dialysis **Aranesp, Epogen, Mircera** and **Procrit** are **proven** for the treatment of anemia of chronic kidney disease (CKD) when **all** of the following criteria are met: (1) Patient is on dialysis; **AND** (2) Hematocrit is less than or equal to 30% at initiation of therapy. ESAs are **unproven** to treat anemia of CKD in patients on dialysis for a hematocrit greater than or equal to 33%. b. Patients **not** receiving dialysis **Aranesp, Epogen, Mircera** and **Procrit** are **proven** for the treatment of anemia of chronic kidney disease (CKD) when **all** of the following criteria are met: (1) Patient is **not** on dialysis; **AND** (2) Hematocrit less than or equal to 30% at initiation of therapy; **AND** (3) The rate of hematocrit decline indicates the likelihood of

Drug and Biologics Policy Updates

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Anemia Drugs: Darbepoetin Alfa, Epoetin Alfa, and Methoxy Polyethylene Glycol-Epoetin Beta *(continued)*	Feb. 1, 2016		requiring a red blood cell (RBC) transfusion. **AND** (4) Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. ESAs are **unproven** to treat anemia of CKD in patients **not** on dialysis for a hematocrit greater than 30%. 2. **Anemia Due to Cancer Chemotherapy:** a. **Aranesp, Epogen,** and **Procrit** are **proven** when used to treat anemia in cancer chemotherapy with a hematocrit less than 30% at initiation of therapy, and there is a minimum of two additional months of planned chemotherapy. Mircera is **unproven** for the treatment of anemia due to cancer chemotherapy. ESAs are **unproven** to treat anemia in patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure. 3. **Anemia Associated with Myelodysplastic Disease:** a. **Aranesp, Epogen,** and **Procrit** are **proven** to treat anemia associated with myelodysplastic disease (MDS) in those patients with a serum erythropoietin level ≤ 500 mUnits/mL or a hematocrit less than or equal to 30% at the initiation of therapy until a target hematocrit of less than or equal to 36% is achieved. 4. **Anemia Associated with Zidovudine Treatment in HIV-Infected Patients:** a. **Epogen** and **Procrit** are **proven** to treat anemia of zidovudine administered at ≤ 4200 mg/week in HIV-infected patients with endogenous serum erythropoietin level ≤ 500 mUnits/mL. 5. **Anemia in Patients with Hepatitis C with Ribavirin and Interferon Therapy:** a. **Epogen** and **Procrit** are **proven** to treat anemia associated with hepatitis C virus infection in those patients receiving ribavirin and interferon therapy and have a hematocrit less than or equal to 30% at initiation of therapy until a target hematocrit of 36% is achieved. 6. **Preoperative Use for Reduction of Allogeneic Blood Transfusions in Surgery Patients:** a. **Epogen** and **Procrit** are **proven** perioperatively to reduce the need for allogeneic blood transfusions in patients with perioperative Hct

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Anemia Drugs: Darbepoetin Alfa, Epoetin Alfa, and Methoxy Polyethylene Glycol-Epoetin Beta *(continued)*	Feb. 1, 2016		greater than 30% and less than or equal to 39% who are at high risk for blood loss from noncardiac, nonvascular, elective surgery. Epogen and Procrit are **unproven** for patients who are willing to donate autologous blood pre-operatively or in patient undergoing cardiac or vascular surgery. **Note:** For the purposes of this policy, a conversion factor of 3 should be used to estimate hematocrit when only the hemoglobin is measured, e.g., hemoglobin of 10 g/dL is approximately equal to a hematocrit of 30%, a hemoglobin of 11 g/dL is approximately equal to a hematocrit of 33%, and a hemoglobin of 12 g/dL is approximately equal to a hematocrit of 36%. ESAs are **unproven** for: 1. Patients undergoing curative chemotherapy. For information regarding use of ESAs in patients receiving cancer chemotherapy, please refer to information in the National Comprehensive Cancer Network (NCCN) Practice Guideline, Cancer- and Chemotherapy-Induced Anemia, as referenced in the *Professional Societies* section of the policy. 2. Patients with cancer receiving hormonal agents, biologic products or radiotherapy (unless also receiving concomitant myelosuppressive chemotherapy). 3. Patients who require an immediate correction of anemia as a substitute for RBC transfusions. 4. Patients undergoing cardiac or vascular surgery. 5. Patients scheduled for surgery who will donate autologous blood. **Centers for Medicare and Medicaid Services (CMS):** Medicare covers Erythropoiesis Stimulating Agents (ESA) for the treatment of anemia for patients who meet the coverage criteria. Refer to the Medicare Benefit Policy Manual, Pub. 100-2, Chapter 15, § 50.5.2 Erythropoietin (EPO) at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf; also see the Medicare Benefit Policy Manual, Pub.100-2, Chapter 11, § 20.3.A Drug Categories Always Considered to be for the Treatment of ESRD at http://www.cms.hhs.gov/manuals/Downloads/bp102c11.pdf. Medicare covers ESA treatment for anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Anemia Drugs: Darbepoetin Alfa, Epoetin Alfa, and Methoxy Polyethylene Glycol-Epoetin Beta *(continued)*	Feb. 1, 2016		lymphocytic leukemia when criteria met. See the National Coverage Determination (NCD) for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21). Local Coverage Determinations (LCDs) for ESA exist. Refer to the LCDs for Erythropoiesis Stimulating Agents - Epoetin alfa, Darbepoetin alfa, Peginesatide, Erythropoiesis Stimulating Agents, and Drugs and Biologicals: Erythropoietin Analogues.
Clotting Factors and Coagulant Blood Products	Feb. 1, 2016	• Updated list of applicable HCPCS codes to reflect annual code edits: ○ Added J7188 and J7205 ○ Removed Q9975	Refer to the policy for complete details on the coverage guidelines for Clotting Factors and Coagulant Blood Products.
Entyvio (Vedolizumab)	Feb. 1, 2016	• Added list of applicable HCPCS codes: J3380 • Updated list of applicable ICD-10 diagnosis codes; removed duplicate code listings for K51.80 and K51.00	Entyvio (vedolizumab) is **proven and medically necessary** for the treatment of: 1. **Crohn's disease** when **all** of the following criteria are met: a. Diagnosis of moderately to severely activite Crohn's disease (CD); **AND** b. **One** of the following: (1) History of failure, contraindication, or intolerance to at least **one** of the following conventional therapies: a. Tumor necrosis factor (TNF) blocker [e.g., Humira (adalimumab), Cimzia (certolizumab)] b. Immunomodulator (e.g., azathioprine, 6-mercaptopurine) c. Corticosteroid (2) Corticosteroid dependent (e.g., unable to successfully taper corticosteroids without a return of the symptoms of CD); **AND** a. Entyvio is initiated and titrated according to US Food and Drug Administration labeled dosing for Crohn's disease up to a maximum of 300mg every 8 weeks (or equivalent dose and interval schedule); **AND** b. Patient is **not** receiving Entyvio in combination with either of the following: 1. Tumor necrosis factor (TNF) blocker [e.g., Humira (adalimumab), Cimzia (certolizumab)]

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Entyvio (Vedolizumab) *(continued)*	Feb. 1, 2016		2. Tysabri (natalizumab) 2. **Ulcerative colitis** when **all** of the following criteria are met: a. Diagnosis of moderately to severely active ulcerative colitis (UC); **AND** b **One** of the following: (1) History of failure, contraindication, or intolerance to at least **one** of the following conventional therapies: a. Tumor necrosis factor (TNF) blocker [e.g., Humira (adalimumab), Simponi (golimumab)] b. Immunomodulator (e.g., azathioprine, 6-mercaptopurine) c. Corticosteroid (2) Corticosteroid dependent (e.g., unable to successfully taper corticosteroids without a return of the symptoms of UC); **AND** c. Entyvio is initiated and titrated according to US Food and Drug Administration labeled dosing for ulcerative colitis up to a maximum of 300mg every 8 weeks (or equivalent dose and interval schedule); **AND** d. Patient is **not** receiving Entyvio in combination with either of the following: (1) Tumor necrosis factor (TNF) blocker [e.g., Humira (adalimumab), Simponi (golimumab)] (2) Tysabri (natalizumab) **Centers for Medicare and Medicaid Services (CMS):** Medicare does not have a National Coverage Determination (NCD) for vedolizumab (Entyvio™). Local Coverage Determinations (LCDs) do not exist at this time. However, Local Coverage Articles (LCAs) do exist. Refer to the LCAs for Entyvio™ (VEDOLIZUMAB). 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.
Hereditary Angioedema (HAE), Treatment and Prophylaxis	Feb. 1, 2016	• Updated list of applicable HCPCS codes to reflect annual code edits; added J0596 • Updated list of applicable ICD-10	This policy refers to the following drug products: C1 Esterace Inhibitor [human] • Berinert® • Cinryze®

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Hereditary Angioedema (HAE), Treatment and Prophylaxis *(continued)*	Feb. 1, 2016	diagnosis codes; removed D81.810	C1 Esterace Inhibitor [recombinant] • Ruconest® Plasma Kallikrein Inhibitor [human] • Kalbitor® (ecallantide) 1. Berinert, Ruconest, and Kalbitor are **proven and medically necessary** for the treatment of hereditary angioedema (HAE) when **both** of the following are met: a. Used for treatment of an acute HAE attack; **AND** b. Not used in combination with other approved treatments for acute HAE attacks (e.g. Berinert, Cinryze, Firazyr, Kalbitor or Ruconest) 2. Cinryze is **proven** for the treatment of **Hereditary angioedema** (HAE) when **one** of the following are met: a. Used for **prophylaxis** against HAE attacks **OR** b. **Both** of the following: (1) Used for treatment of an acute HAE attack; **AND** (2) Not used in combination with other approved treatments for acute HAE attacks (e.g. Berinert, Cinryze, Firazyr, Kalbitor or Ruconest) **Additional information to support medical necessity review for Cinryze where applicable:** Cinryze is **medically necessary** for the treatment of **hereditary angioedema** (HAE) when **both** of the following are met: a. **One** of the following: (1) **Both** of the following: (a) For prophylaxis against HAE attacks **AND** (b) **One** of the following: i. For continuation of prior therapy; **OR** ii. History of failure, contraindication, or intolerance of **one** of the following: (i) 17-alpha alkylated androgen (e.g., danazol, oxandrolone); **OR** (ii) Antifibrinolytics (e.g., aminocaproic acid, tranexamic

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Hereditary Angioedema (HAE), Treatment and Prophylaxis *(continued)*	Feb. 1, 2016		acid); **OR** (2) **Both** of the following: (a) Used for treatment of an acute HAE attack; **AND** (b) Not used in combination with other approved treatments for acute HAE attacks (e.g. Berinert, Firazyr, Kalbitor or Ruconest) **AND** b. Prescribed by **one** of the following (1) immunologist (2) allergist (3) rheumatologist **Centers for Medicare and Medicaid Services (CMS):** Medicare does not have a National Coverage Determination (NCD) that specifically address the use of Cinryze™, Berinert®, Ruconest® or Kalbitor® the treatment of Hereditary Angioedema (HAE). Local Coverage Determinations (LCDs) do not exist at this time. In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, section 50 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf
Lupron Depot/Lupron Depot-Ped (Leuprolide Acetate)	Feb. 1, 2016	• Updated list of applicable ICD-10 diagnosis codes; added E22.8	Please refer to the Oncology Medication Clinical Coverage Policy for updated information based on the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®) for oncology indications. This policy refers to the following leuprolide acetate drug products: • Lupron Depot • Lupron Depot-Ped Lupron Depot is **proven** for: 1. **Central precocious puberty** **Additional information to support medical necessity review where applicable:**

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Lupron Depot/Lupron Depot-Ped (Leuprolide Acetate) *(continued)*	Feb. 1, 2016		Lupron Depot is **medically necessary** for the treatment of central precocious puberty when **all** of the following criteria are met: a. Diagnosis of central precocious puberty (idiopathic or neurogenic) **AND** b. Onset of secondary sexual characteristics in **one** of the following: (1) Females ≤ 8 years of age (2) Males ≤ 9 years of age **AND** c. Confirmation of diagnosis as defined by **one** of the following: (1) A pubertal luteinizing hormone response to a GnRH stimulation test (2) Bone age advanced one year beyond the chronological age The Lupron Depot label states that treatment should be discontinued at the appropriate age of onset of puberty at the discretion of the physician. Give consideration to discontinuing treatment before 11 years of age in girls and 12 years of age in boys. 2. **Endometriosis** **Additional information to support medical necessity review where applicable:** Lupron Depot is **medically necessary** for the treatment of endometriosis when **both** of the following criteria are met: a. Diagnosis of endometriosis; **AND** b. **One** of the following: (1) Contraindication, intolerance, or failure of initial treatment with oral contraceptives and non-steroidal anti-inflammatory drugs (NSAIDs). (2) Patient has had surgical ablation to prevent recurrence The Lupron Depot label states that the duration of initial treatment or retreatment for endometriosis should be limited to 6 months. For recurrence of symptoms, leuprolide may be used in combination with norethindrone acetate for 6 months; greater than one retreatment period is not recommended. Lupron Depot monotherapy is not recommended for retreatment. 3. **Uterine leiomyomata (fibroids)** **Additional information to support medical necessity review where applicable:**

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Lupron Depot/Lupron Depot-Ped (Leuprolide Acetate) *(continued)*	Feb. 1, 2016		Lupron Depot is **medically necessary** for the treatment of uterine leiomyomata when **one** of the following criteria is met: a. **All** of the following: (1) For the treatment of anemia; **AND** (2) Anemia is caused by uterine leiomyomata; **AND** (3) Patient did not respond to iron therapy of one month duration; **AND** (4) For use prior to surgery **OR** b. For use prior to surgery to reduce the size of fibroids to facilitate a surgical procedure (e.g., myomectomy, hysterectomy) The recommended duration of therapy for the treatment of uterine leiomyomata is ≤ 3 months. 4. **Fertility preservation** **Additional information to support medical necessity review where applicable:** Lupron Depot is **medically necessary** for fertility preservation when the following criteria are met: a. **Both** of the following: (1) For use in pre-menopausal women; **AND** (2) Patient is receiving a cytotoxic agent that is associated with causing primary ovarian insufficiency (premature ovarian failure) [e.g., Cytoxan (cyclophosphamide), procarbazine, vinblastine, cisplatin] Lupron Depot therapy should be discontinued upon the completion of cytotoxic treatment. **Unproven:** Lupron Depot is **unproven and not medically necessary** for puberty suppression in patients with gender identity disorder due to the lack of long-term safety data. Statistically robust randomized controlled trials are needed to address the issue of whether the benefits outweigh the substantial inherent clinical risk in its use. **Centers for Medicare and Medicaid Services (CMS):** Medicare does not have a National Coverage Determination (NCD) for Lupron or for Luteinizing Hormone-Releasing Hormone (LHRH) Analogs. Local

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Lupron Depot/Lupron Depot-Ped (Leuprolide Acetate) *(continued)*	Feb. 1, 2016		Coverage Determinations (LCDs) do exist. Refer to the LCDs for Luteinizing Hormone-Releasing Hormone (LHRH) Analogs. 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 May 19, 2015)
Xolair (Omalizumab)	Feb. 1, 2016	• Updated list of applicable ICD-9 diagnosis codes (discontinued 10/01/15); removed 493.92 and 708.9 • Updated list of applicable ICD-10 diagnosis codes: ○ Added L50.0 and L50.1 ○ Removed J45.901	Refer to the policy for complete details on the coverage guidelines for Xolair (Omalizumab).

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG)	Feb. 1, 2016	• Revised coverage rationale: ○ Updated and reformatted list of applicable intravenous (IV) and subcutaneous (SC) immune globulin (IG) products (not all-inclusive); removed Flebogamma® (IV) ○ Added list of diagnoses addressed in policy: ▪ Asthma (severe, persistent, high-dose steroid-dependent) ▪ Autoimmune bullous diseases ▪ Autoimmune uveitis ▪ Bone marrow	Refer to the policy for complete details on the coverage guidelines for Immune Globulin (IVIG and SCIG).

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) *(continued)*	Feb. 1, 2016	transplantation (BMT) ▪ Chronic inflammatory demyelinating polyneuropathy ▪ Chronic lymphocytic leukemia (CLL), prevention of infection in B-cell CLL Cytomegalovirus (CMV) induced pneumonitis in solid organ transplants ▪ Dermatomyositis or polymyositis ▪ Diabetes mellitus ▪ Enteroviral meningoencephalitis ▪ Fetomaternal alloimmune thrombocytopenia ▪ Graves' ophthalmopathy ▪ Guillain-Barré syndrome (GBS) ▪ HIV-infection, prevention of bacterial infection in pediatric HIV ▪ Idiopathic thrombocytopenic purpura (ITP) ▪ IgM antimyelin-associated glycoprotein paraprotein-associated peripheral neuropathy ▪ Kawasaki disease ▪ Lambert-Eaton myasthenic syndrome (LEMS) ▪ Lennox Gastaut syndrome ▪ Lymphoproliferative	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) *(continued)*	Feb. 1, 2016	disease, treatment of bacterial infections ▪ Monoclonal gammopathy ▪ Multifocal motor neuropathy (MMN) ▪ Multiple sclerosis, relapsing remitting (RRMS) ▪ Myasthenic exacerbation Neuromyeltis optica ▪ Paraproteinemic neuropathy ▪ Posttransfusion purpura Primary immunodeficiency syndromes ▪ Rasmussen syndrome ▪ Renal transplantation, prevention of acute humoral rejection Rheumatoid arthritis, severe ▪ Rotaviral enterocolitis ▪ Staphylococcal toxic shock Stiff-person syndrome ▪ Thrombocytopenia, secondary to HCV, HIV, and ▪ Toxic epidermal necrolysis or Stevens-Johnson syndrome Urticaria, delayed pressure ▪ Unproven Uses ○ Revised general requirements pertaining to medical necessity review for continuation of therapy;	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) *(continued)*	Feb. 1, 2016	added criterion for long term treatment requiring documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response ○ Reformatted/consolidated clinical criteria for bone marrow transplantation, renal transplantation, and treatment of secondary thrombocytopenia ○ Relocated and revised list of proven indications [primary immunodeficiency diseases (PIDs)] for immune globulin (not all inclusive); added "chronic mucocutaneous moniliasis (CMC or APCED)" and "polyendocrinopathy and enteropathy (IPEX)" ○ Added language to indicate the unproven indications are "not medically necessary" • Updated list of applicable HCPCS codes; added J1575 • Updated list of applicable ICD-9 diagnosis codes (discontinued 10/01/15) • Updated list of applicable ICD-10 diagnosis codes: ○ Added A87.0, A87.8, A87.9, A88.8, D80.6, D80.7, D82.4, D83.1, D84.8, D89.82, E31.0, G40.811, G40.812, G40.813, G40.814, G61.89, G62.89, and J45.51	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) *(continued)*	Feb. 1, 2016	○ Removed A52.15, B25.1, B25.2, B25.8, B25.9, C88.8, C91.90, C94.40, C94.41, C94.42, C94.6, D47.1, D47.Z9, D70.8, D71, D82.8, D82.9, D89.89, D89.9, G04.91, G37.4, G40.309, G40.311, G40.319, G40.409, G40.411, G58.8, G58.9, G59, G63, G65.1, G65.2, G73.3, I78.0, J44.0, J45.20, J45.22, J45.30, J45.32, J45.40, J45.42, J45.50, J45.902, J45.909, L10.1, L10.3, L10.4, L10.5, L10.81, L10.89, L10.9, L12.31, L12.8, L12.9, L14, L50.5, L50.6, M05.721, M05.722, M05.729, M05.731,M05.732, M05.739, M05.741,M05.742, M05.749, M05.751,M05.752, M05.759, M05.761,M05.762, M05.769, M05.771,M05.772, M05.779, M05.79, M05.80, M05.811, M05.812,M05.819, M05.821, M05.822,M05.829, M05.831, M05.832,M05.839, M05.841, M05.842,M05.849, M05.851, M05.852,M05.859, M05.861, M05.862,M05.869, M05.871, M05.872,M05.879, M05.89, M05.9, M06.00, M06.011, M06.012,M06.019, M06.021, M06.022,M06.029, M06.031, M06.032,M06.039, M06.041, M06.042,M06.049, M06.051, M06.052,M06.059, M06.061, M06.062,M06.069, M06.071, M06.072,M06.079,	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) *(continued)*	Feb. 1, 2016	M06.08, M06.09, M06.20, M06.211, M06.212,M06.219, M06.221, M06.222,M06.229, M06.231, M06.232,M06.239, M06.241, M06.242,M06.249, M06.251, M06.252,M06.259, M06.261, M06.262,M06.269, M06.271, M06.272,M06.279, M06.28, M06.29, M06.30, M06.311, M06.312,M06.319, M06.321, M06.322,M06.329, M06.331, M06.332,M06.339, M06.341, M06.342,M06.349, M06.351, M06.352,M06.359, M06.361, M06.362,M06.369, M06.371, M06.372,M06.379, M06.38, M06.39, M06.80, M06.811, M06.812,M06.819, M06.821, M06.822,M06.829, M06.831, M06.832,M06.839, M06.841, M06.842,M06.849, M06.851, M06.852,M06.859, M06.861, M06.862,M06.869, M06.871, M06.872,M06.879, M06.88, M06.89, M06.9, M34.83, M35.9, O36.8210, O36.8211, O36.8212, O36.8213, O36.8214, O36.8215, O36.8219, O36.8220, O36.8221, O36.8222, O36.8223, O36.8224, O36.8225, O36.8229, O36.8230, O36.8231, O36.8232, O36.8233, O36.8234, O36.8235, O36.8239, O36.8290, O36.8291, O36.8292, O36.8293, O36.8294, O36.8295,	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) *(continued)*	Feb. 1, 2016	O36.8299, O98.411, O98.412, O98.413, O98.419, O98.42, O98.43, O98.711, O98.712, O98.713, O98.72, O99.355, P61.8, P61.9, Q81.8, Q81.9, T86.90, T86.91, T86.92, T86.93, and T86.99 • Updated supporting information to reflect the most current clinical evidence, CMS information, and references	

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services	Jan. 1, 2016	**Notice of Revision**: The following summary of changes has been modified. Revisions to the policy update announcement previously appearing in the *December 2015 Policy Update Bulletin* are outlined in red below. Please take note of the additional updates to be implemented on **Jan. 1, 2016.** Revised coverage rationale/ indications for coverage: **Women's Health Coverage** ○ Added language for plan years that begin on or after Sept. 23, 2010 to indicate: ▪ For most benefit plans, prior authorization requirements apply to BRCA lab screening ▪ For medical necessity benefit plans, genetic counseling from an Independent Genetics Provider (see *Definitions* section of policy) is required before UnitedHealthcare will approve prior authorization requests (effective Jan. 1, 2016) **Related Services** ○ Revised language pertaining to **preventive colonoscopy** to indicate: ▪ All services for a preventive colonoscopy (e.g., associated facility,	Refer to the policy for complete details on the coverage guidelines for Preventive Care Services.

Coverage Determination Guideline (CDG) Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Jan. 1, 2016	anesthesia, pathologist, and physician fees) ▪ The preventive benefit does not include a *post*-operative examination ▪ Effective Jan. 1, 2016, the preventive benefit includes a *pre*-operative examination/consultation prior to a preventive colonoscopy • Updated definitions; added definition of "independent genetics provider (for medical necessity benefit plans)" • Revised list of applicable procedure and diagnosis codes: **Preventive Care Services** *HIV – Human Immunodeficiency Virus – Screening for Adolescents and Adults* ○ Updated list of applicable HCPCS codes for HIV – Human Immunodeficiency Virus – Screening to reflect annual code edits (effective Jan. 1, 2016); added G0475 *Genetic Counseling and Evaluation for BRCA Testing; and BRCA Lab Screening* ○ Updated list of applicable CPT codes for BRCA Lab Screening to reflect annual code edits (effective Jan. 1, 2016); added 81162 ○ Revised claims edit criteria for Genetic Counseling and Evaluation; added language	

Coverage Determination Guideline (CDG) Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Jan. 1, 2016	to indicate Medical Necessity plans require genetic counseling before BRCA Lab Screening *Colorectal Cancer Screening* ○ Updated lists of applicable codes for Fecal Occult Blood Testing (FOBT), Sigmoidoscopy, or Colonoscopy; added Code Group 5: ▪ CPT codes: 99201, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, and 99245 ▪ ICD-10 diagnosis codes: Z12.10, Z12.11, Z12.12, Z80.0, Z83.71, and Z83.79 ○ Revised claims edit criteria for Fecal Occult Blood Testing, Sigmoidoscopy, or Colonoscopy to indicate as of 1/1/16, Code Group 5 is paid as Preventive if billed with one of the Code Group 5 diagnosis codes *Wellness Examinations (well baby, well child, well adult)* ○ Updated list of applicable HCPCS codes for Counseling Visit [to Discuss the Need for Lung Cancer Screening (LDCT) Using Low Dose CT Scan] to reflect annual code edits (effective Jan. 1, 2016); added G0296	

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Jan. 1, 2016	○ Added claims edit criteria for HCPCS code G0296 to indicate a benefit age limit of "age 55 to 80 years (ends on 81st birthday)" applies *Behavioral Counseling in Primary Care to Promote a Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults with Cardiovascular Risk Factors* ○ Updated list of applicable CPT codes for Behavioral Counseling or Therapy to reflect annual code edits (effective Jan. 1, 2016); added 0403T ○ Revised claims edit criteria; added language to indicate a listed diagnosis code is required for CPT code 0403T *Tobacco Smoking Cessation in Adults, including Pregnant Women: Behavioral and Pharmacotherapy Interventions* ○ Updated service title/ heading; previously titled Counseling and Interventions to Prevent Tobacco Use and Tobacco-Caused Disease in Adults and Pregnant Women Counseling and Interventions (Adults) ○ Revised service description: ▪ Removed April 2009 USPSTF 'A' rating ▪ Added September 2015 USPSTF 'A' rating: - The USPSTF	

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Jan. 1, 2016	recommends that clinicians ask all pregnant women about tobacco use, advise them to stop using tobacco, and provide behavioral interventions for cessation to pregnant women who use tobacco - The USPSTF recommends that clinicians ask all adults about tobacco use, advise them to stop using tobacco, and provide behavioral interventions and U.S. Food and Drug Administration (FDA)–approved pharmacotherapy for cessation to adults who use tobacco o Reformatted list of applicable procedure codes; added heading titled *Behavioral Interventions* *Screening for Visual Impairment in Children* o Updated list of applicable CPT codes to reflect annual code edits (effective Jan. 1, 2016); added 99177 o Added claims edit criteria for CPT code 99177 to indicate: ▪ A benefit age limit of	

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Jan. 1, 2016	"less than age 6 years (ends on 6th birthday)" applies ▪ Refer to the Medical Policy titled *Omnibus Codes* for allowable diagnoses *Screening for Lung Cancer with Low-Dose Computed Tomography* ○ Updated list of applicable HCPCS codes to reflect annual code edits (effective Jan. 1, 2016); added G0297 *TB Testing (Bright Futures)* ○ Updated claims edit criteria; added language to clarify CPT code 99211 is only payable as preventive with ICD-10 diagnosis codes R76.11, R76.12, and Z11.1 **Preventive Immunizations** ○ Updated list of applicable CPT/HCPCS codes to reflect annual code edits (effective Jan. 1, 2016): ▪ Haemophilus influenza b (Hib): Removed 90645 and 90646 ▪ Human Papilloma Virus (HPV): Revised description for 90651 ▪ Pneumococcal conjugate: Removed 90669 and S0195 ▪ Tetanus: Removed 90703 ▪ Measles, Mumps, Rubella	

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Jan. 1, 2016	(MMR): Removed 90704, 90705, 90706, 90707 and 90708 ▪ Diphtheria: Removed 90719, 90720 and 90721 ○ Revised claims edit criteria for seasonal influenza ('flu'); changed benefit age limit for CPT code 90673 to "age 18 years and up" ○ Updated list of applicable trade names for CPT code 90696 (diphtheria, tetanus toxoids, acellular pertussis vaccine and inactivated poliovirus vaccine); added Quadracel® **Diabetes Diagnosis Code List** ○ Corrected formatting error in list applicable ICD-10 diagnosis codes; changed service heading/classification for E10.630, E10.638, E10.641, E10.649, E10.65, E10.69, E10.8, E10.9 from "Type 2 Diabetes Mellitus " to "Type 1 Diabetes Mellitus" **Expanded Women's Preventive Health** *Human Papillomavirus DNA Testing (HPV)* ○ Updated list of applicable HCPCS codes to reflect annual code edits (effective Jan. 1, 2016); added G0476 *Contraceptive Methods (Including Sterilizations)*	

Coverage Determination Guideline (CDG) Updates

REVISED			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services *(continued)*	Jan. 1, 2016	○ Replaced notation indicating "certain *health plans sponsored by religious* employers may qualify for an exemption from covering contraceptive methods and sterilizations" with "certain employers may qualify for an exemption from covering contraceptive methods and sterilizations *on account of religious objections*" ○ Revised list of applicable HCPCS codes for contraceptive methods/ intrauterine devices (IUDs) to reflect annual code edits (effective Jan. 1, 2016): ▪ Updated Code Group 1 for IUD (other): - Added J7297 ▪ Updated Code Group 2 for IUDs: - Added J7298 - Removed J7302	