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Medical Policy Update Bulletin: November 2021

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Updated

Policy Title	Effective Date	Summary of Changes
Abnormal Uterine Bleeding and Uterine Fibroids	Dec. 1, 2021	**Applicable Codes** • Removed CPT codes 58578 and 58999 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
Total Artificial Disc Replacement for the Spine	Nov. 1, 2021	**Coverage Rationale** • Added language to clarify cervical artificial disc replacement at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent), *as part of the same surgical plan*, is unproven and not medically necessary due to insufficient evidence of efficacy **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Breast Imaging for Screening and Diagnosing Cancer	Jan. 1, 2022	**Coverage Rationale**
		• Added instruction to refer to the *Cardiology and Radiology Imaging Guidelines – Breast Imaging Guidelines* for 3D rendering of the breast
		Unproven and Not Medically Necessary
		• Added language to indicate computed tomography (CT) of the breast is unproven and not medically necessary
		• Updated list of examples of molecular breast imaging; added "Breast Specific Gamma Imaging"
		Definitions
		• Added definition of "Computed
			Note: This policy does not address preventive benefit for breast cancer screening (including mammography); refer to the Coverage Determination Guideline titled Preventive Care Services for more information.
			
			The following are proven and medically necessary for the following individuals:
			• Digital mammography for individuals with dense breast tissue
			• Diagnostic breast ultrasound
			• Breast magnetic resonance imaging (MRI) for individuals who are high risk for breast cancer as defined as having any of the following:
			  ○ Prior thoracic radiation therapy between the ages 10 and 30
			  ○ Lifetime risk estimated at greater than or equal to 20% as defined by models that are largely dependent on family history (e.g., Gail, Claus, Tyrer-Cuzick or BRCAPRO)
			  ○ Personal history of breast cancer (not treated with bilateral mastectomy)
			  ○ Personal history with any of the following:
			  ▪ Li-Fraumeni Syndrome (TP53 mutation)
			  ▪ Confirmed BRCA 1 or BRCA 2 gene mutations

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Breast Imaging for Screening and Diagnosing Cancer (continued)	Jan. 1, 2022	Tomography (CT)" Supporting Information • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	▪ Peutz-Jehgers Syndrome (STK11, LKB1 gene variations) ▪ PTEN gene mutation ○ Family history with any of the following: ▪ At least one first-degree relative who has a BRCA1 or BRCA2 mutation ▪ First-degree relative who carries a genetic mutation in the TP53 or PTEN genes (Li-Fraumeni syndrome and Cowden and Bannayan-Riley-Ruvalcaba syndromes, or Peutz-Jehgers Syndrome) ▪ At least two first-degree relatives with breast or ovarian cancer ▪ One first-degree relative with bilateral breast cancer, or both breast and ovarian cancer ▪ First or second-degree male relative (father, brother, uncle, grandfather) diagnosed with breast cancer The following are unproven and not medically necessary due to insufficient evidence of efficacy: • Automated breast ultrasound system • Breast magnetic resonance imaging (MRI) for individuals with dense breast tissue not accompanied by defined risk factors as described above • Computer-aided detection (CAD) • Computer-aided tactile breast imaging • Computed tomography (CT) of the breast • Electrical impedance scanning (EIS) • Magnetic resonance elastography (MRE) • Molecular breast imaging (e.g., Breast Specific Gamma Imaging, Scintimammography, positron emission mammography) Note: For breast computed tomography (CT) and 3D rendering of the breast, or additional indications for breast MRI, refer to the Cardiology and Radiology Imaging Guidelines – Breast Imaging Guidelines.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Hereditary Cancer Genetic Testing for Hereditary Cancer (continued)	Dec. 1, 2021	**Coverage Rationale** • Added language to indicate single gene testing and known mutation testing for familial cancer is proven and medically necessary • Replaced language indicating "*genetic testing for BRCA1 and BRCA2 or Multi-Gene* hereditary cancer Panels with RNA testing is unproven and not medically necessary for all indications" with "RNA Panel testing for hereditary cancers is unproven and not medically necessary for all indications" ***Hereditary Breast and Ovarian Cancer Panel Testing*** • Replaced references to "genetic testing for *BRCA1 and BRCA2*" with "genetic testing *Panels* for *High Penetrance Breast Cancer Susceptibility Genes*" • Revised list of proven and medically necessary indications for: **Individuals With a Personal History of a BRCA-Related Cancer** ○ Added "women with a personal history of lobular breast cancer with personal or family history of diffuse gastric cancer" ○ Removed "a known	Genetic counseling is strongly recommended prior to these tests in order to inform persons being tested about the advantages and limitations of the test as applied to a unique person. Single gene testing and known mutation testing for familial cancer is proven and medically necessary. **Hereditary Breast and Ovarian Cancer Panel Testing** Genetic testing Panels for High Penetrance Breast Cancer Susceptibility Genes for individuals with a personal history of a BRCA-Related Cancer are proven and medically necessary in the following situations: • At least one first- or second-degree relative with a BRCA-Related Cancer; or • Ashkenazi Jewish ancestry; or • An unknown or Limited Family History; or • A BRCA 1/2 pathogenic mutation detected in tumor tissue; or • A personal history of pancreatic cancer; or • Men with a personal history of Breast Cancer; or • Men with a personal history of metastatic prostate cancer; or • Women with a personal history of Ovarian Cancer; or • Women with a personal history of Breast Cancer in any of the following situations: ○ Metastatic Breast Cancer; or ○ Breast Cancer diagnosed at age 45 or younger; or ○ An additional Breast Cancer primary (prior diagnosis or bilateral cancer); or ○ Triple-Negative Breast Cancer diagnosed at any age; or ○ Lobular breast cancer with personal or family history of diffuse gastric cancer; or • Individual has a Tyrer-Cuzick, BRCAPro or Penn11 Score of 2.5% or greater for a *BRCA1/2* pathogenic variant.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Hereditary Cancer (continued)	Dec, 1, 2021	BRCA1/BRCA2 mutation in a Close Blood Relative" ○ Replaced "women with a personal history of Triple-Negative Breast Cancer diagnosed at age *60 or younger*" with "women with a personal history of Triple-Negative Breast Cancer diagnosed at *any* age" **Individuals Without a Personal History of a Related Cancer** ○ Removed "a known BRCA1/BRCA2 mutation in a Close Blood Relative" ***Other Hereditary Cancer Syndrome Multi-Gene Panel Testing*** • Replaced language indicating: ○ "Genetic testing with a Multi-Gene hereditary cancer Panel in individuals with a personal history of cancer is proven and medically necessary if all the [listed] criteria are met" with "genetic testing with a Multi-Gene hereditary cancer Panel in individuals with a personal history of *a primary solid tumor* cancer is proven and medically necessary if all the [listed] criteria are met"	Genetic testing Panels for High Penetrance Breast Cancer Susceptibility Genes for individuals without a personal history of a related cancer are proven and medically necessary in the following situations: • At least one first- or second-degree relative with a BRCA-Related Cancer; or • Ashkenazi Jewish ancestry and at least one Close Blood Relative with a BRCA-Related Cancer; or • Individual has a Tyrer-Cuzick, BRCAPro or Penn11 Score of 5% or greater for a BRCA1/2 pathogenic variant Genetic testing Panels for High Penetrance Breast Cancer Susceptibility Genes are unproven and not medically necessary for all other indications including: • Screening for cancer risk for individuals not listed in the proven indications above; or • Risk assessment of other cancers; or • Confirmation of direct to consumer genetic testing without meeting any of the proven indications above. **Other Hereditary Cancer Syndrome Multi-Gene Panel Testing** Genetic testing with a Multi-Gene hereditary cancer Panel in individuals with a personal history of a primary solid tumor cancer is proven and medically necessary if all the following criteria are met: • The suspected hereditary cancer syndromes can be diagnosed by testing two or more genes included in the specific hereditary cancer panel; and ○ A personal history of at least two different primary solid tumor cancers ; or ○ A personal history of BRCA-related cancer diagnosed at age 40 or younger; or ○ A personal history of BRCA-related cancer and at least one Close Blood Relative with a cancer associated with Lynch Syndrome; or ○ At least one Close Blood Relative diagnosed with a BRCA-Related Cancer at age 40 or younger; or

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Hereditary Cancer (continued)	Dec. 1, 2021	○ "Genetic testing with a Multi-Gene hereditary cancer Panel in individuals without a personal history of cancer is proven and medically necessary if all the [listed] criteria are met" with "genetic testing with a Multi-Gene hereditary cancer Panel in individuals without a personal history of *a primary solid tumor* cancer is proven and medically necessary if all the [listed] criteria are met" • Revised coverage criteria: Individuals With a Personal History of a Primary Solid Tumor Cancer ○ Replaced criterion requiring: ▪ "A personal history of at least two different cancers *(e.g., Breast and Ovarian)*" with "a personal history of at least two different *primary solid tumor* cancers" ▪ "At least *three* Close Blood Relatives *(in addition to affected individual)* on the same side of the family diagnosed with any *primary solid tumor* cancer" with "at least *two* Close Blood Relatives on the same side	○ At least two Close Blood Relatives (in addition to affected individual) on the same side of the family diagnosed with any primary solid tumor cancer; or ○ A personal history of cancer associated with Lynch Syndrome; or ○ A personal history of cancer where tumor testing results demonstrate that the cancer was MSI-high or had immunohistochemical staining showing the absence of one or more mismatch repair proteins (MLH1, MSH2, MSH6 or PMS2); or ○ A personal history of colorectal polyposis with at least 10 adenomatous polyps, at least 2 hamartomatous polyps or at least 5 serrated polyps/lesions proximal to the rectum; or ○ The individual has a PREMM5, MMRpro or MMRpredict Score of 2.5% or greater for having a Lynch syndrome gene mutation. Genetic testing with a Multi-Gene hereditary cancer Panel in individuals without a personal history of a primary solid tumor cancer is proven and medically necessary if all the following criteria are met: • The suspected hereditary cancer syndromes can be diagnosed by testing two or more genes included in the specific hereditary cancer Panel; and ○ At least one first-degree relative diagnosed with at least two different primary solid tumor cancers; or ○ At least one first- or second-degree relative diagnosed with a BRCA-Related Cancer at age 40 or younger; or ○ At least three Close Blood Relatives, on the same side of the family, diagnosed with any primary solid tumor cancer; or ○ At least one first-degree relative with a cancer associated with Lynch Syndrome; or ○ At least one second-degree relative with a cancer associated with Lynch Syndrome diagnosed at age 50 or younger; or ○ At least one second-degree relative with at least two cancers associated with Lynch Syndrome; or ○ Two or more second-degree relatives with a cancer associated with Lynch Syndrome; or

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Hereditary Cancer (continued)	Dec. 1, 2021	of the family diagnosed with any cancer" **Individuals Without a Personal History of a Primary Solid Tumor Cancer** ○ Added criterion requiring at least one first-degree relative diagnosed with at least two different primary solid tumor cancers ○ Replaced criterion requiring: ▪ "At least three Close Blood Relatives, on the same side of the family, diagnosed with any cancer" with "at least three Close Blood Relatives, on the same side of the family, diagnosed with any *primary solid tumor* cancer" ▪ "At least one *first- or* second-degree relative with a cancer associated with Lynch Syndrome diagnosed at age 50 or younger" with "at least one second-degree relative with a cancer associated with Lynch Syndrome diagnosed at age 50 or younger" ▪ "At least one *first- or* second-degree relative	○ At least one first- or second-degree relative with a clinical diagnosis of Familial Adenomatous Polyposis, Attenuated Familial Adenomatous Polyposis, Juvenile Polyposis Syndrome or Peutz-Jeghers Syndrome; or ○ The individual has a PREMM5, MMRpro or MMRpredict Score of 5% or greater for having a Lynch syndrome gene mutation. Genetic testing with a Multi-Gene hereditary cancer Panel in individuals diagnosed with cancer at age 18 or younger is proven and medically necessary. Multi-Gene hereditary cancer Panels are unproven and not medically necessary for all other indications. RNA Panel testing for hereditary cancers is unproven and not medically necessary for all indications.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Hereditary Cancer (continued)	Dec. 1, 2021	with at least two cancers associated with Lynch Syndrome" with "at least one second-degree relative with at least two cancers associated with Lynch Syndrome" ▪ "Two or more *first- or* second-degree relatives with a cancer associated with Lynch Syndrome" with "two or more second-degree relatives with a cancer associated with Lynch Syndrome" Documentation Requirements • Updated list of applicable CPT codes with associated documentation requirements; removed 81212, 81215, and 81217 Definitions • Added definition of "High Penetrance Breast Cancer Susceptibility Genes" Applicable Codes *BRCA1 and BRCA2* • Removed CPT codes 81212, 81215, and 81217 *Multi-Gene Panel* • Added CPT code 81479 Supporting Information • Updated *Description of Services*,	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Hereditary Cancer (continued)	Dec. 1, 2021	*Clinical Evidence*, and *References* sections to reflect the most current information	

Infertility Diagnosis and Treatment	Jan. 1, 2022	**Coverage Rationale**
		• Added language to indicate sperm capacitation test is unproven and not medically necessary for diagnosing or treating Infertility
		Applicable Codes
		• Added CPT code 0255U
		Supporting Information
		• Updated *Clinical Evidence* and *References* sections to reflect the most current information
			For medical necessity reviews, refer to the Clinical Guideline titled Fertility Solutions Medical Necessity Clinical Guideline: Infertility.
			
			The following tests or procedures are proven and medically necessary for diagnosing or treating Infertility:
			• Antisperm antibodies
			• Antral follicle count
			• Cryopreservation of sperm, semen, or embryos 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) 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
			• Genetic screening tests:
			  ○ Cystic fibrosis gene mutations
			  ○ Karyotyping for chromosomal abnormalities
			  ○ Y-chromosome microdeletion testing
			• Hormone level tests:
			  ○ Antimüllerian hormone (AMH)
			  ○ Estradiol
			  ○ Follicle-stimulating hormone (FSH)
			  ○ Luteinizing hormone (LH)
			  ○ Progesterone
			  ○ Prolactin
			  ○ Testosterone (total and free)
			  ○ Thyroid-stimulating hormone (TSH)
			• Hysterosalpingogram (HSG)
			• Diagnostic hysteroscopy

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Infertility Diagnosis and Treatment (continued)	Jan. 1, 2022		• Diagnostic laparoscopy with or without chromotubation • Leukocyte count in semen • Pelvic ultrasound (transabdominal or transvaginal) • Post-ejaculatory urinalysis • Scrotal, testicular or transrectal ultrasound • Semen analysis • Sonohysterogram or saline infusion ultrasound • Testicular biopsy • Vasography Due to insufficient evidence of efficacy, the following are unproven and not medically necessary for diagnosing or treating Infertility: • Co-culture of embryos • Computer-assisted sperm analysis (CASA) • Cryopreservation of *immature* oocytes (eggs), ovarian tissue, or testicular tissue • EmbryoGlue® • Hyaluronan binding assay (HBA) • In vitro maturation (IVM) of oocytes • Inhibin B • Postcoital cervical mucus penetration test • Reactive oxygen species (ROS) test • Sperm acrosome reaction test • Sperm capacitation 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 • Uterine/endometrial receptivity testing • Treatments to improve uterine/endometrial receptivity (e.g., immunotherapy, endometrial scratching, uterine artery vasodilation)

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Omnibus Codes	Jan. 1, 2022	Coverage Rationale • Added guidelines for: *3D Volumetric Imaging and Reconstruction of Breast or Axillary Lymph Node Tissue (CPT code 0694T)* (new to policy) ○ Added language to indicate three-dimensional (3D) volumetric imaging and reconstruction of breast or axillary lymph node tissue is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy *Comprehensive Full-Body Motion Analysis (CPT code 0693T)* (new to policy) ○ Added language to indicate comprehensive full-body, computer-based, markerless 3D kinematic and kinetic motion analysis is unproven and not medically necessary for all indications due to insufficient evidence of safety and/or efficacy *External Upper Limb Tremor Stimulators of the Peripheral Nerves of the Wrist (CPT codes K1018 and K1019)* (new to policy) ○ Added language to indicate external upper limb tremor stimulators of the peripheral nerves of the wrist and the related monthly supplies to treat essential tremor are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy *PureWick™ Female External Catheter and the PureWick™ Urine Collection System (CPT code K1006)* (new to policy) ○ Added language to indicate the PureWick™ Female External Catheter and the PureWick™ Urine Collection System are unproven and not medically necessary for managing urinary incontinence due to insufficient evidence of efficacy *Radiofrequency (RF) Therapy (CPT codes 0672T, 53860, 53899, and 58999)* (new to policy) ○ Added language to indicate radiofrequency (RF) therapy, including but not limited to cryogen-cooled monopolar radiofrequency (CMRF), monopolar RF, multipolar RF, RF-lifting and temperature controlled RF therapies for the treatment of stress urinary incontinence (SUI) is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy • Updated list of applicable CPT codes for: *Aquapheresis (Ultrafiltration) (CPT codes 0692T, 37799, and 90999)* ○ Added 0692T (annual edit) *UroCuff Test (CPT codes 53899 and 55899)* ○ Added 55899 Supporting Information	

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Omnibus Codes (continued)	Jan. 1, 2022	• Updated *Clinical Evidence* and *References* sections to reflect the most current information for Implantable Cardiac Devices for Percutaneous Closure (Occlusion) of the Left Atrial Appendage (LAA) (CPT codes 33340 and 33999)	
Pharmacogenetic Testing	Jan. 1, 2022	**Coverage Rationale** • Added language to indicate the use of the PrismRA® molecular signature test is unproven and not medically necessary for evaluating likelihood of inadequate response to anti-TNF therapies for rheumatoid arthritis due to insufficient evidence of efficacy **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	The use of pharmacogenetic Multi-Gene Panels to guide therapy decisions is proven and medically necessary for antidepressant and antipsychotic medications when all the following criteria are met: • The individual has a diagnosis of major depressive disorder or generalized anxiety disorder; and • The individual has failed at least one prior medication to treat their condition; and • The Multi-Gene Panel has no more than 15 relevant genes The use of pharmacogenetic Multi-Gene Panels for genetic polymorphisms for any other indication, including but not limited to pain management, cardiovascular drugs, anthracyclines, or polypharmacy, is unproven and not medically necessary for evaluating drug-metabolizer status due to insufficient evidence of efficacy. Examples of these Panels include, but are not limited to the following: • GeneSight® Analgesic • GeneSight® ADHD • SureGene Test • Pain Medication DNA Insights® • PharmacoDx The use of the PrismRA® molecular signature test is unproven and not medically necessary for evaluating likelihood of inadequate response to anti-TNF therapies for rheumatoid arthritis due to insufficient evidence of efficacy.

Retired

Policy Title	Effective Date	Summary of Changes
Chemosensitivity and Chemoresistance Assays in Cancer	Nov. 1, 2021	• Policy retired; chemosensitivity and chemoresistance assays no longer require clinical review

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Clotting Factors, Coagulant Blood Products & Other Hemostatics	Dec. 1, 2021	**Template Update** • Removed *CMS* section **Coverage Rationale** • Revised list of applicable products; removed: ○ Monoclate-P® [antihemophilic factor (human)] ○ Bebulin® [factor IX complex (human)] ***Von Willebrand Disease (VWD)*** **Alphanate** • Revised coverage criteria; removed criterion allowing coverage for: ○ Diagnosis of severe VWD ○ Treatment of bleeding episodes **Wilate** • Revised coverage criteria: ○ Added criterion to allow coverage for routine prophylactic treatment ○ Replaced criterion allowing coverage for "peri-operative management of bleeding" with "peri-operative management of *surgical* bleeding" ***Congenital Factor VII Deficiency*** **NovoSeven RT** • Revised coverage criteria; removed criterion allowing coverage for peri-operative management of surgical bleeding	This policy refers to the following products: Factor VIIa (recombinant): NovoSeven® RT [coagulation factor VIIa (recombinant)]; Sevenfact™ [coagulation factor VIIa (recombinant)-jncw] Factor XIII (plasma-derived): Corifact® [factor XIII concentrate (human)] Factor VIII (plasma-derived): Hemofil M® [antihemophilic factor (human)]; Koāte®-DVI [antihemophilic factor (human)] Factor VIII (plasma-derived) / von Willebrand Factor Complex (plasma-derived): Alphanate® [antihemophilic factor (human)]; Humate-P® [antihemophilic factor (human)]; Wilate® [antihemophilic factor (human)] Factor VIII (recombinant): Advate® [antihemophilic factor (recombinant)]; Helixate® FS [antihemophilic factor (recombinant)]; Kogenate® FS [antihemophilic factor (recombinant)]; Kovaltry® [antihemophilic factor (recombinant)]; Novoeight® [antihemophilic factor (recombinant)]; Nuwiq® [antihemophilic factor (recombinant)]

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale	
Clotting Factors, Coagulant Blood Products & Other Hemostatics (continued)	Dec. 1, 2021	*Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)* • Removed language indicating Monoclate-P® is proven and medically necessary for the treatment of hemophilia A Wilate • Added language to indicate Factor VIII (plasma-derived)/von Willebrand Factor Complex (plasma-derived) [Wilate] is proven and medically necessary when both of the following criteria are met: ○ Diagnosis of hemophilia A; and ○ One of the following: ▪ Routine prophylactic treatment; or ▪ Treatment of bleeding episodes Eloctate • Revised coverage criteria: ○ Removed criterion for proven indications requiring the prescribed dosage and interval utilized is within range as defined by the prescribing information ○ Replaced medical necessity criterion requiring "PK testing results suggest that dosing more frequently than every *3.5* days is required" with "PK		Recombinate® [antihemophilic factor (recombinant)]
				Xyntha® [antihemophilic factor (recombinant)]
				Xyntha® Solofuse™ [antihemophilic factor (recombinant)]
			Factor IX (plasma-derived)	AlphaNine® SD [coagulation factor IX (human)]
				Mononine® [coagulation factor IX (human)]
				Profilnine SD® [factor IX complex human)]
			Factor IX (recombinant)	BeneFIX® [coagulation factor IX (recombinant)]
				Ixinity® [coagulation factor IX (recombinant)]
				Rixubis® [coagulation factor IX (recombinant)]
			Factor IX (recombinant), long-acting	Alprolix® [coagulation factor IX (recombinant), Fc fusion protein]
				Idelvion® [coagulation factor IX (recombinant), albumin fusion protein]
				Rebinyn® [coagulation factor IX (recombinant), GlycoPEGylated]
			Anti-Inhibitor Coagulant Complex (plasma-derived)	FEIBA® [anti-inhibitor coagulant complex (human)]
			Fibrinogen Concentrate (plasma-derived)	RiaSTAP® [fibrinogen concentrate (human)]
				Fibryga® [fibrinogen (human)]

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale	
Clotting Factors, Coagulant Blood Products & Other Hemostatics (continued)	Dec. 1, 2021	testing results suggest that dosing more frequently than every *3 to 5* days is required" Jivi • Revised coverage criteria for proven indications; removed criterion requiring the prescribed dosage and interval utilized is within range as defined by the prescribing information NovoSeven RT • Revised coverage criteria; removed criterion allowing coverage for routine prophylactic treatment Sevenfact • Revised coverage criteria: ○ Removed criterion requiring documentation of inhibitors (e.g., Bethesda inhibitor assay) ○ Replaced criterion allowing coverage for "*routine prophylactic treatment or peri-operative management of surgical bleeding or* treatment of bleeding episodes" with "treatment *and control* of bleeding episodes" *Hemophilia B (i.e., Congenital Factor IX Deficiency, Christmas Disease)* • Removed language indicating Bebulin® is proven and medically	Factor XIII A-subunit (recombinant)	Tretten® [coagulation factor XIII A-subunit (recombinant)]
			Factor VIII (recombinant), long-acting	Adynovate® [antihemophilic factor (recombinant), PEGylated]
				Afstyla® [antihemophilic factor (recombinant)]
				Eloctate® [antihemophilic factor (recombinant), Fc fusion protein]
				Esperoct® [antihemophilic factor (recombinant), glycopegylated-exei]
				Jivi® [antihemophilic factor (recombinant), PEGylated-aucl]
			Factor VIII (recombinant), porcine sequence	Obizur® [antihemophilic factor (recombinant), porcine sequence]
			Factor X (plasma-derived)	Coagadex® [coagulation factor X (human)]
			Von Willebrand Factor (recombinant)	Vonvendi® [von Willebrand factor (recombinant)]
			Bispecific factor IXa- and factor X-directed antibody	Hemlibra® (emicizumab-kxwh)
			Refer to the policy for complete details.	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Clotting Factors, Coagulant Blood Products & Other Hemostatics (continued)	Dec. 1, 2021	necessary for the treatment of hemophilia B AlphaNine SD, Mononine, and Profilnine SD • Revised coverage criteria; replaced criterion allowing coverage for "*prevention and* treatment of bleeding episodes" with "*routine prophylactic treatment or* treatment of bleeding episodes" BeneFIX, Rixubis, Alprolix, and Idelvion • Revised coverage criteria; replaced criterion allowing coverage for "control and prevention of bleeding episodes or prevention of bleeding in surgical interventions (i.e., surgical prophylaxis)" with "*routine prophylactic* treatment or *peri-operative management of* surgical *bleeding* or *treatment of* bleeding episodes" Ixinity and Rebinyn • Revised medically necessity criteria; replaced criterion allowing coverage for: ○ "Routine prophyla*xis of to prevent or reduce the frequency of bleeding episodes*" with "routine prophyla*ctic treatment*" ○ "Peri-operative management"	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Clotting Factors, Coagulant Blood Products & Other Hemostatics (continued)	Dec. 1, 2021	with "peri-operative management *of surgical bleeding*" ○ "*Control and prevention* of bleeding episodes" with "*treatment* of bleeding episodes" NovoSeven RT • Revised coverage criteria; removed criterion allowing coverage for routine prophylactic treatment *Fibrinogen Deficiency (i.e., Factor I Deficiency)* Fibryga and RiaSTAP • Revised coverage criteria; removed criterion allowing coverage for: ○ Routine prophylactic treatment ○ Peri-operative management of surgical bleeding *Congenital Factor X Deficiency* Coagadex • Revised coverage criteria; added criterion to allow coverage for routine prophylactic treatment Supporting Information • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Complement Inhibitors (Soliris® & Ultomiris®)	Jan. 1, 2022	Coverage Rationale • Revised medical necessity criteria for: *Paroxysmal Nocturnal Hemoglobinuria (PNH)* ○ Added criterion requiring: Initial Therapy ▪ One of the following: – History of failure of, contraindication, or intolerance to Empaveli (pegcetacoplan) therapy (Note: Preferred therapy criteria is not applicable for Medicare Advantage members; refer to the CMS section of the policy); or – Patient is < 18 years of age; or – Patient is pregnant ▪ Patient is not receiving Soliris or Ultomiris in combination with Empaveli (pegcetacoplan) Continuation of Therapy ▪ One of the following: – Patient is < 18 years of age; or – Patient is pregnant; or	This policy refers to the following complement inhibitor drug products: • Soliris (eculizumab) • Ultomiris (ravulizumab-cwvz) Refer to the policy for complete details.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Complement Inhibitors (Soliris® & Ultomiris®) (continued)	Jan. 1, 2022	– Both of the following: • Patient has a hemoglobin level greater than 10.5 g/dL; and • Patient has not required red blood cell transfusions to maintain a hemoglobin level greater than 10.5 g/dL or – Both of the following: • Prescriber attests that the patient has been counseled on alternative chronic treatment options for PNH; and • Prescriber attests that the patient has shared in decision-making on their PNH therapy plan ▪ Patient is not receiving Soliris or Ultomiris in combination with Empaveli (pegcetacoplan) *Myasthenia Gravis*	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Complement Inhibitors (Soliris® & Ultomiris®) (continued)	Jan. 1, 2022	○ Added language to indicate preferred therapy criteria is not applicable for Medicare Advantage members; refer to the CMS section of the policy Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information	
Maximum Dosage and Frequency	Dec. 1, 2021	Coverage Rationale • Revised list of: *Maximum Allowed Quantities by HCPCS Units* Simponi Aria (golimumab) ○ Changed maximum allowed amount from "*256* HCPCS units" to "*300* HCPCS units" Xolair (omalizumab) ○ Added: ▪ Diagnosis: Nasal polyps ▪ Maximum Dosage Per Administration: 600 mg ▪ HCPCS Code: J2357 ▪ Maximum Allowed: 120 HCPCS units (5 mg per unit) *Maximum Allowed Quantities for National Drug Code (NDC) Billing* Rituxan (rituximab) ○ Replaced NDC "50242-0051-*01*" with "50242-0051-*10*"	This policy provides information about the maximum dosage per administration and dosing frequency for certain medications administered by a medical professional. Most medications have a maximum dosage and frequency based upon body surface area or patient weight or a set maximal dosage and frequency independent of patient body size. **Drug Products** • abatacept (Orencia®) • aflibercept (Eylea®) • bevacizumab (Avastin®) • bevacizumab-awwb (Mvasi™) • bevacizumab-bvzr (Zirabev®) • brolucizumab-dbll (Beovu®) • certolizumab pegol (Cimzia®) • denosumab (Prolia® & Xgeva®) • eculizumab (Soliris®) • emicizumab-kxwh (Hemlibra®) • golimumab (Simponi Aria®) • infliximab (Remicade®) • infliximab-axxq (Avsola™) • infliximab-dyyb (Inflectra®) • infliximab-abda (Renflexis®) • nivolumab (Opdivo®) • omalizumab (Xolair®)

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Maximum Dosage and Frequency (continued)	Dec. 1, 2021	(code correction only) Reclast/Zometa (zoledronic acid) ○ Replaced NDC "00078-*0425*-61" with "00078-*0435*-61" (code correction only) Xolair (omalizumab) *Asthma* ○ Revised values for: ▪ NCD 50242-0040-62: Replaced *Maximum Allowed* amount of "*2* vials" with "*3* vials" ▪ NCD 50242-0214-01: – Changed *How Supplied* value from "75 mg PFS" to "75 mg/*1 mL* PFS" – Changed maximum allowed amount from "*1* mL" to "*0.5* mL" ▪ NCDs 50242-0215-01 and 50242-0215-86: Changed *How Supplied* value from "150 mg PFS" with "150 mg/*1 mL* PFS" *Chronic Urticaria* ○ Removed NDC 0242-0214-01 ○ Revised NCDs 50242-0215-01 and 50242-0215-86: Changed *How Supplied* value from "150	• patisiran (Onpattro®) • pegaptanib sodium (Macugen®) • pegfilgrastim (Neulasta®) • pegfilgrastim-apgf (Nyvepria™) • pegfilgrastim-cbqv (Udenyca®) • pegfilgrastim-jmdb (Fulphila™) • pegfilgrastim-bmez (Ziextenzo®) • ranibizumab (Lucentis®) • ravulizumab-cwvz (Ultomiris®) • rituximab (Rituxan®) • rituximab-pvvr (Ruxience™) • rituximab-abbs (Truxima®) • rituximab and hyaluronidase (Rituxan Hycela®) • testosterone cypionate (Depo-Testosterone®) • testosterone enanthate • testosterone pellets (Testopel®) • testosterone undecanoate (Aveed®) • tildrakizumab-asmn (Ilumya™) • tocilizumab (Actemra®) • trastuzumab (Herceptin®) • trastuzumab-anns (Kanjinti™) • trastuzumab-dkst (Ogivri™) • trastuzumab-dttb (Ontruzant®) • trastuzumab-pkrb (Herzuma®) • trastuzumab-qyyp (Trazimera™) • ustekinumab (Stelara®) • vedolizumab (Entyvio®) • zoledronic acid (zoledronic acid, Reclast®, and Zometa® The use of medications included in this policy when given within the maximum dosage and/or frequency based upon body surface area or patient weight or a set of maximal dosage and/or frequency independent of patient body size are proven when used according to labeled indications or when

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Maximum Dosage and Frequency (continued)	Dec. 1, 2021	mg PFS" to "150 mg/1 mL PFS" *Nasal Polyps* ○ Added: ▪ NDC 50242-0040-62: – How Supplied: 150 mg vials – Maximum Allowed: 4 vials ▪ NDC 50242-0214-01: – How Supplied: 75 mg/0.5 mL pre-filled syringe (PFS) – Maximum Allowed: 0.5 mL ▪ NDC 50242-0215-01: – How Supplied: 150 mg/1 mL PFS – Maximum Allowed: 4 mL *Maximum Allowed Frequencies* Simponi Aria (golimumab) ○ Added maximum frequency for the diagnosis of juvenile idiopathic arthritis to allow administration at 0, 4, then every 8 weeks thereafter Xolair (omalizumab) ○ Added maximum frequency for the diagnosis of nasal polyps to allow administration once	otherwise supported by published clinical evidence. The medications included in this policy when given beyond maximum dosages and/or frequency based upon body surface area or patient weight or a set maximal dosage independent of patient body size are not supported by package labeling or published clinical evidence and are unproven. This policy creates an upper dose limit based on the clinical evidence and the 95th percentile for adult body weight (128 kg) and body surface area (2.59 meters^2) in the U.S. (adult male, 30 to 39 years, Fryar, 2016). In some cases, the maximum allowed units and/or vials may exceed the upper level limit as defined within this policy due to an individual patient body weight > 128 kg or body surface area > 2.59 meters. Refer to the policy for complete details.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Maximum Dosage and Frequency (continued)	Dec. 1, 2021	every 2 or 4 weeks, depending on body weight and IgE levels **Supporting Information** • Updated *References* section to reflect the most current information	
Saphnelo™ (Anifrolumab-Fnia)	Jan. 1, 2022	**Coverage Rationale** • Removed reference link to the Medical Benefit Drug Policy titled *Review at Launch for New to Market Medications* • Revised medical necessity criteria; added criterion requiring: *Initial Therapy* ○ The patient has a contraindication, intolerance, or failure to Benlysta Note: Preferred therapy criteria is not applicable for Medicare Advantage members; refer to the CMS section of the policy ○ Saphnelo (anifrolumab-fnia) is prescribed by or in consultation with a rheumatologist *Continuation of Therapy* ○ Saphnelo (anifrolumab-fnia) is prescribed by or in consultation with a rheumatologist **Supporting Information** • Added *CMS* section • Updated *References* section to	Saphnelo (anifrolumab-fnia) is proven for the treatment of moderate to severe systemic lupus erythematosus (SLE) when all of the following criteria are met: • For initial therapy, all of the following: ○ Diagnosis of moderate to severe systemic lupus erythematosus, without severe active central nervous system lupus or severe active lupus nephritis; and ○ Laboratory testing has documented the presence of autoantibodies [e.g., ANA, Anti-dsDNA, Anti-Sm, Anti-Ro/SSA, Anti-La/SSB]; and ○ Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic; and ○ Patient is not receiving Saphnelo in combination with a biologic agent or Benlysta; and ○ Saphnelo is dosed according to US FDA labeled dosing for SLE; and ○ Initial authorization is for no more than 6 months. • For continuation of therapy, all of the following: ○ Patient has previously received Saphnelo injection for intravenous infusion; and ○ Documentation of positive clinical response; and ○ Patient is without severe active central nervous system lupus or severe active lupus nephritis; and ○ Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic; and ○ Patient is not receiving Saphnelo in combination with a biologic agent or Benlysta; and ○ Saphnelo is dosed according to US FDA labeled dosing for SLE; and ○ Authorization is for no more than 12 months.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Saphnelo™ (Anifrolumab-Fnia) (continued)	Jan. 1, 2022	reflect the most current information	Saphnelo (anifrolumab-fnia) is medically necessary for the treatment of moderate to severe systemic lupus erythematosus (SLE) when all of the following criteria are met: • For initial therapy, all of the following: ○ Diagnosis of moderate to severe systemic lupus erythematosus, without severe active central nervous system lupus or severe active lupus nephritis; and ○ Laboratory testing has documented the presence of autoantibodies [e.g., ANA, Anti-dsDNA, Anti-Sm, Anti-Ro/SSA, Anti-La/SSB]; and ○ Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic; and ○ Patient has a contraindication, intolerance, or failure to Benlysta (for Medicare reviews, refer to the *CMS* section of the policy); and ○ Patient is not receiving Saphnelo in combination with a biologic agent or Benlysta; and ○ Saphnelo is dosed according to US FDA labeled dosing for SLE; and ○ Prescribed by or in consultation with a rheumatologist; and ○ Initial authorization is for no more than 6 months. • For continuation of therapy, all of the following: ○ Patient has previously received Saphnelo injection for intravenous infusion; and ○ Documentation of positive clinical response; and ○ Patient is without severe active central nervous system lupus or severe active lupus nephritis; and ○ Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic; and ○ Patient is not receiving Saphnelo in combination with a biologic agent or Benlysta; and ○ Saphnelo is dosed according to US FDA labeled dosing for SLE; and ○ Prescribed by or in consultation with a rheumatologist; and ○ Authorization is for no more than 12 months.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Saphnelo™ (Anifrolumab-Fnia) (continued)	Jan. 1, 2022		Saphnelo is unproven and not medically necessary for: • Severe active lupus nephritis • Severe active central nervous system (CNS) lupus • Use in combination with other biologics
Xolair® (Omalizumab)	Dec. 1, 2021	Applicable Codes • Revised list of Maximum Allowed Quantities by National Drug Code (NDC) Units; added values for: *NCD 50242-0214-01* Moderate to Severe Asthma and Nasal Polyps ○ How Supplied: 75 mg/0.5 mL pre-filled syringe (PFS) ○ Maximum Allowed: 0.5 mL *NCD 50242-0215-01* and *NCD 50242-0215-86* Chronic Urticaria and Moderate to Severe Asthma ○ How Supplied: 150 mg/1 mL PFS ○ Maximum Allowed: 2 mL Nasal Polyps ○ How Supplied: 150 mg/1 mL PFS ○ Maximum Allowed: 4 mL	This policy refers to Xolair (omalizumab) subcutaneous injection for administration by a healthcare professional. Xolair (omalizumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit. Refer to the policy for complete details.

Coverage Determination Guideline Updates

Updated

Policy Title	Effective Date	Summary of Changes
Breast Reconstruction Post Mastectomy and Poland Syndrome	Nov. 1, 2021	**Related Policies** • Added reference link to the Coverage Determination Guideline titled *Gynecomastia Treatment* **Coverage Rationale** • Updated list of examples of a dermal matrix; replaced "Allomax" with "Cortiva® (AlloMax™)" **Documentation Requirements** • Updated list of applicable CPT codes with associated documentation requirements; added 11970
Breast Repair/Reconstruction Not Following Mastectomy	Dec. 1, 2021	**Related Policies** • Added reference link to the Coverage Determination Guideline titled *Gynecomastia Treatment* **Documentation Requirements** • Updated list of *Required Clinical Information*

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements	Dec. 1, 2021	**Coverage Rationale** *Ventilators and Respiratory Assist Devices* • Added language to indicate the coverage guidelines in this section of the policy apply to individuals 2 years of age and older • Replaced language indicating "ventilators are not covered when used to deliver continuous or intermittent positive airway pressure" with "ventilators are not covered when used *only* to deliver continuous or intermittent positive airway pressure *for adults and children 2 years of age and older*" **Supporting Information** • Updated *References* section to reflect the most current information	**Indications for Coverage** Durable Medical Equipment (DME) is a Covered Health Care Service when the member has a DME benefit, the equipment is ordered by a physician to treat an injury or sickness (illness) and the equipment is not otherwise excluded in the member benefit plan document. DME must be: • Not consumable or disposable except as needed for the effective use of covered DME; • Not of use to a person in the absences of a disease or disability; • Ordered or provided by a physician for outpatient use primarily in a home setting; and • Used for medical purposes ***Breast Pumps*** Breast pumps may be covered under the preventive care services benefit. Refer to the Coverage Determination Guideline titled Preventive Care Services for breast pump coverage indications. ***Contact Lenses & Scleral Bandages (Shells)***

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (continued)	Dec. 1, 2021		Contact lenses or scleral shells that are used to treat an injury or disease (e.g., corneal abrasion, keratoconus or severe dry eye) are not considered DME and may be covered as a therapeutic service. In these situations, contact lenses and scleral shells are not subject to a plan's contact lens exclusion. ***Cranial Remolding Orthosis*** Cranial molding helmets (cranial remolding orthosis, billed with S1040) are excluded except when used to avoid the need for surgery, and/or to facilitate a successful post-surgical outcome are covered as DME and are not subject to the orthotic device exclusion. For all indications, refer to the Medical Policy titled Plagiocephaly and Craniosynostosis Treatment. Note: A protective helmet (HCPCS code A8000–A8004) is not a cranial remolding device. It is considered a safety device worn to prevent injury to the head rather than a device needed for active treatment; see Coverage Limitations and Exclusions. ***Enteral Pumps*** Enteral pumps are covered as DME. Refer to the Coverage Determination Guideline titled Enteral Nutrition for information regarding formula. ***Implanted Devices*** Any device, appliance, pump, machine, stimulator, or monitor that is fully implanted into the body is not covered as DME. (If covered, the device is covered as part of the surgical service.) Note: Cochlear Implant Benefit Clarification: The external components (i.e., speech processor, microphone, and transmitter coil) are considered under the DME benefit, and the implantable components are considered under the medical-surgical benefit. The member specific benefit plan document must be referenced to determine if there are DME benefits for repair or replacement of external components.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (continued)	Dec. 1, 2021		***Insulin Pumps*** Insulin pumps, disposable and durable are covered. For state specific information on mandated coverage of diabetes supplies, check state mandates. Refer to the Medical Policy titled Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes. ***Lymphedema Stockings for the Arm*** Post-mastectomy lymphedema stockings for the arm are covered on an unlimited basis as to number of items and dollar amounts covered consistent with the requirements of the Women's Health and Cancer Rights Act (WHCRA) of 1998. ***Medical Supplies*** • Medical Supplies that are used with covered DME are covered when the supply is necessary for the effective use of the item/device (e.g., oxygen tubing or mask, batteries for power wheelchairs and prosthetics, or tubing for a delivery pump). • Ostomy Supplies are limited to the following: ○ Irrigation sleeves, bags and ostomy irrigation catheters ○ Pouches, face plates and belts ○ Skin barriers Note: Benefits are not available for deodorants, filters, lubricants, tape, appliance cleaners, adhesive, adhesive remover, or other items not listed above (check the member specific benefit plan document for coverage of ostomy supplies). • Urinary Catheters: ○ Benefits for Indwelling and Intermittent Urinary Catheters for incontinence or retention. ○ Benefits include related urologic supplies for indwelling catheters limited to: ▪ Urinary drainage bag and insertion tray (kit) ▪ Anchoring device

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (continued)	Dec. 1, 2021		▪ Irrigation tubing set ○ Documentation should include the number and type of catheters that are needed. Note: • Certain plans may exclude coverage for Urinary Catheters (e.g., test, drug, device, or procedure). Refer to the member specific benefit plan document to determine if this exclusion applies. • For additional supply information, refer to the Coverage Limitations and Exclusions section. ***Mobility Devices*** • Mobility Devices including manual wheelchairs, electric wheelchairs, transfer chairs, scooters/power-operated vehicles (POV), canes and walkers, are a Covered Health Care Service when Medically Necessary. Check the member specific benefit plan document for coverage. • Proof of the home evaluation is not required at the time of prior authorization. The on-site home evaluation can be performed prior to, or at the time of, delivery of a power Mobility Device. The written report of the home evaluation must be available on request post-delivery. ***Oral Appliances*** Oral appliances for snoring are excluded. For oral appliances for sleep apnea (HCPCS E0485 and E0486) refer to the Medical Policy titled Obstructive Sleep Apnea Treatment. • A letter of referral or prescription to the dentist for the appliance must be received from the treating physician; and • A polysomnography must be completed documenting Obstructive Sleep Apnea ***Orthotic Braces*** Orthotic braces that stabilize an injured body part and braces to treat curvature

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (continued)	Dec. 1, 2021		of the spine are considered DME (see Coverage Limitations and Exclusions). Examples of orthotic braces include but are not limited to: • Ankle Foot Orthotic (AFO) • Knee orthotics (KO) • Lumbar-sacral orthotic (LSO) • Necessary adjustments to shoes to accommodate braces • Thoracic-lumbar-sacral orthotic (TLSO) Note: There are specific codes that are defined by HCPCS as orthotics that UnitedHealthcare covers as DME. ***Pleurx Bottles and Tubing*** Pleurx bottles and tubing are covered as DME. ***Repair, Replacement, and Upgrade*** Repair, replacement and upgrade of DME is covered when the member has a DME benefit and any of the following: Repair The repairs, including the replacement of essential accessories, such as hoses, tubes, mouth pieces, etc., for necessary DME are covered when necessary to make the item/device serviceable Replacement Replacement of DME is for the same or similar type of equipment which is beyond its reasonable useful life span and has become irreparable. Upgrade The physician provides documentation that the condition of the member changes (e.g., impaired function necessitates an upgrade to a power wheelchair from a manual one)

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

Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (continued)	Dec. 1, 2021		**General Criteria**
			• Routine wear on the equipment renders it non-functional and the member still requires the equipment.
			  ○ Vendors/manufacturers are responsible for repairs, replacements, and maintenance for rented equipment and for purchased equipment covered by warranty
			  ○ Coverage includes DME obtained in a physician's office, DME vendor, or any other provider authorized to provide/dispense DME
			• Unless otherwise stated, DME has a Reasonable Useful Lifetime (RUL) of 5 years
			• Pediatric DME must allow room for growth adjustments to a minimum of 2 inches in seat width and 3 inches of seat depth.
			
			Note:
			  ○ Growth method may not mean ordering equipment that it is too large for current needs.
			  ○ A new prescription isn't needed if the needs of the patient are the same.
			
			Equipment Upgrades
			• A change in the member's medical condition and equipment needs requires the same documentation as a new request
			• Equipment upgrades are equivalent to a new service
			
			Safety Enclosure with Beds
			Safety enclosure with beds (e.g., pediatric enclosed bed, adult bed, safety enclosure) are covered as DME for individuals that have a risk for safety in bed when all of the following criteria are met:
			• Use of equipment is required due to a diagnosis related to cognitive impairment (e.g., traumatic brain injury, cerebral palsy, seizure disorder) or a severe behavioral disorder
			• There is a safety risk that includes but is not limited to any of the following:
			  ○ Claustrophobia

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (continued)	Dec. 1, 2021		○ High risk of falls due to a clinical condition ○ Uncontrolled movements ○ Violent or self-destructive behaviors such as uncontrolled head banging • Less restrictive alternatives methods such as the following have been tried and have not been successful or are contraindicated; ○ A mattress on the floor ○ Protective helmet ○ Side rails ○ Weighted blankets The physician documentation must include: • A signed physicians order for the enclosed bed • Behavioral Management Program, if applicable • Evaluation for contraindications to use of the equipment • Member assessment for physical, environmental, and behavioral factors • Name and model of protective or enclosure bed with a valid HCPCS code • Physician directed written monitoring plan • The medical, neurologic, or behavioral diagnosis Refer to the Coverage Determination Guideline titled Beds and Mattresses for additional information regarding beds. ***Speech Generating Devices*** Dedicated Speech Generating Devices are covered as DME when: • The device(s) are not explicitly excluded from coverage in the member specific benefit plan document (COC or SPD); and • The treating physician determines that the member has either a severe speech impairment (impediment) or lack of speech resulting from Sickness or Injury; and • The medical condition warrants the use of a device based upon the definitions below The physician attestation must be consistent with and based upon the

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (continued)	Dec. 1, 2021		recommendation of a qualified speech and language pathologist. The speech and language pathology evaluation must reach all of the following conclusions: • The member's medical condition is one resulting in a severe expressive speech impairment (impediment) or lack of speech directly related to Sickness or Injury; • The member's speaking needs cannot be met using natural communication methods; • Other forms of treatment have been attempted or considered and ruled out. Examples of a Dedicated Speech Generating Device are: o Freedom o Prentke Romich (or PRC) o Say-it!™ o Tobii Dynavox Note: Most benefit plans require a 3-month rental period before a purchase can be made. ***Trachea-Esophageal and Voice Aid Prosthetics*** Trachea-esophageal prosthetics and voice aid prosthetics are covered as DME. ***Ventilators and Respiratory Assist Devices applies for 2 years of age and older*** Ventilators are covered to treat neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease. Ventilators are not covered when used only to deliver continuous or intermittent positive airway pressure for adults and children 2 years of age and older. For adult or pediatric members, UnitedHealthcare uses the Medicare policy for coverage determinations for home ventilators. Home ventilators are: • Not covered for non-life-threatening conditions • Not covered when used as Respiratory Assistance Devices (RAD)

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (continued)	Dec. 1, 2021		For member's 2 years of age and older, any type of ventilator would not be Medically Necessary for any of the conditions described in the Medicare RAD criteria even though the ventilator may have the capability of operating in a bi-level PAP (E0470, E0471) mode. • The conditions that qualify for use of a RAD are not life-threatening conditions where interruption of respiratory support would quickly lead to serious harm or death. • Ventilators, such as Trilogy mechanical ventilators, (E0465, E0466) used for the treatment of conditions described in the Medicare RAD criteria that deliver continuous or intermittent positive airway pressure are not Medically Necessary . Bi-level PAP devices (E0470, E0471) are considered as Medically Necessary in those clinical scenarios. • Ventilators must not be billed using codes for CPAP (E0601) or bi-level PAP (E0470, E0471, and E0472). The use of CPAP or bi-level PAP HCPCS codes to bill a ventilator is incorrect coding, even if the ventilator is only being used in CPAP or bi-level mode. **PAP Therapy** Note: For the evaluation of PAP therapy, hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in airflow and with at least a 3% decrease in oxygen saturation from pre-event baseline or the event is associated with an arousal (AASM Scoring Manual, 2017). **Medical Necessity Plans** In the absence of a related policy or coverage indication from above, UnitedHealthcare uses available criteria from the DME MAC. DME, related supplies, and orthotics are Medically Necessary when: • Ordered by a physician; and • The item(s) meets the plans Medically Necessary definition (refer to the member specific benefit plan document); and • CMS DME MAC criteria are met (see above link); and

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

Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (continued)	Dec. 1, 2021		• The item is not otherwise excluded from coverage
			
			Coverage Limitations and Exclusions
			When more than one piece of DME can meet the member's functional needs, benefits are available only for the item that meets the minimum specifications for member needs. Examples include but are not limited to:
			• Standard electric wheelchair vs. custom wheelchair
			• Standard bed vs semi-electric bed vs fully electric or flotation system
			  ○ This limitation is intended to exclude coverage for deluxe or additional components of a DME item which are not necessary to meet the member's minimal specifications to treat an Injury or Sickness.
			
			When the member rents or purchases a piece of DME that exceeds this guideline, the member will be responsible for any cost difference between the piece he/she rents or purchases and the piece we have determined is the most cost-effective.
			
			The following services are excluded from coverage:
			• Additional accessories to DME items or devices which are primarily for the comfort or convenience of the member are not covered. Examples include but are not limited to:
			  ○ Air conditioners
			  ○ Air purifiers and filters
			  ○ Batteries for non-medical equipment (e.g., flashlights, smoke detectors, telephones, watches, weight scales)
			  ○ Humidifiers
			  ○ Non-medical mobility devices (e.g., commercial stroller) This exclusion does not apply to pediatric wheelchairs.
			  ○ Remodeling or modification to home or vehicle to accommodate DME or patient condition (e.g., Ramps, stair lifts and stair glides, wheelchair lifts, bathroom modifications, door modifications)
			• Cranial molding helmets and cranial banding except when used to avoid the need for surgery and/or to facilitate a successful surgical outcome.

Coverage Determination Guideline Updates

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

Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (continued)	Dec. 1, 2021		• Dental braces. Check the member specific benefit plan document and State Mandates.
			• Devices and computers to assist in communication and speech. However, see Indications for Coverage section for information on Dedicated Speech Generating Devices.
			• Devices used specifically as safety items or to affect performance in sports-related activities.
			• Diagnostic or monitoring equipment purchased for home use (e.g., blood pressure monitor, oximeters) unless otherwise described as a Covered Health Care Service (e.g., oximeter use with a ventilator).
			• Elastic splints, sleeves or bandages, unless part of a Covered Health Care Service (e.g., sleeve used in conjunction with a lymphedema pump or bandages used with complex decongestive therapy).
			• Oral appliances for snoring. See Indications for Coverage section for oral appliances for sleep apnea.
			• Orthotic braces that straighten or change the shape of a body part.
			• Personal Care, Comfort and Convenience items and supplies. Check the member specific benefit plan document for the list of excluded items.
			• Powered and non-powered exoskeleton devices.
			• Prescribed or non-prescribed publicly available devices, software applications and/or monitors that can be used for non-medical purposes (e.g., smart phone applications, software applications).
			• Replacement of items due to malicious damage, neglect or abuse.
			• Replacement of lost or stolen items.
			• Routine periodic maintenance (e.g., testing, cleaning, regulating and checking of equipment) for which the owner or vendor is generally responsible.
			• The following items and supplies:
			  ○ DME and supplies that are explicitly excluded in the member specific benefit plan document.
			  ○ Medical Supplies (except those described above under Indications for Coverage). This includes, but is not limited to bandages, gauze, dressings, cotton balls and alcohol wipes.

Coverage Determination Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (continued)	Dec. 1, 2021		○ Items and supplies that do not meet the definition of a Covered Health Care Service. ○ Ostomy Supplies unless specifically stated as covered. Check the member specific benefit plan document. See the Indications for Coverage section. ○ Urinary catheters unless specifically stated as covered. Check the member specific benefit plan document. • The following items are excluded even if prescribed by a physician. Refer to the member specific benefit plan document. ○ Blood pressure cuff/monitor ○ Enuresis alarm ○ Non-wearable external defibrillator ○ Trusses or girdle ○ Ultrasonic nebulizers • Upgrade or replacement of DME when the existing equipment is still functional. Refer to the Repair, Replacement, and Upgrade section.

Retired

Policy Title	Effective Date	Summary of Changes
Therapeutic Shoes and Inserts for Diabetics	Nov. 1, 2021	• Policy retired; refer to the member specific benefit plan document for coverage details for therapeutic shoes and inserts for individuals with diabetes

Utilization Review Guideline Updates

Updated

Policy Title	Effective Date	Summary of Changes
Elective Inpatient Services	Nov. 1, 2021	Coverage Rationale • Replaced notation indicating "this policy does not apply to *obstetric conditions*" with "this policy does not apply to an obstetric *member during pregnancy, childbirth, or the post-partum period*"
Observation Services	Nov. 1, 2021	Coverage Rationale • Replaced notation indicating "this policy does not apply to *obstetric conditions*" with "this policy does not apply to an obstetric *member during pregnancy, childbirth, or the post-partum period*"

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Outpatient Surgical Procedures – Site of Service	Feb. 1, 2022	Coverage Rationale • Revised list of medically necessary indications for planned surgical procedures performed in a hospital outpatient department; replaced "brittle diabetes" with "uncontrolled diabetes with recurrent diabetic ketoacidosis (DKA) or severe hypoglycemia" Definitions • Removed definition of "Brittle Diabetes" • Updated definition of "Obstructive Sleep Apnea (OSA)" Applicable Codes • Revised lists of CPT/HCPCS codes requiring site of service medical necessity review: *Commercial Plans* ○ Removed 11000, 11626, 11646, 12037, 13152, 15260, 19020, 21365, 21385, 21390, 21407, 21554, 30117, 40530, 41105, 41116, 42820, 42825,	UnitedHealthcare members may choose to receive surgical procedures in an ambulatory surgical center (ASC) or other locations. We are conducting site of service medical necessity reviews, however, to determine whether the outpatient hospital department is medically necessary, in accordance with the terms of the member's benefit plan. If the outpatient hospital department is not considered medically necessary, this location will not be covered under the member's plan. Certain planned surgical procedures performed in a hospital outpatient department are considered medically necessary for an individual who meets any of the following criteria: • Advanced liver disease (MELD Score > 8) • Advance surgical planning determines an individual requires overnight recovery and care following a surgical procedure • Anticipated need for transfusion • Bleeding disorder requiring replacement factor or blood products or special infusion products to correct a coagulation defect • Cardiac arrhythmia (symptomatic arrhythmia despite medication) • Chronic obstructive pulmonary disease (COPD) (FEV1 <50%) • Coronary artery disease ([CAD]/peripheral vascular disease [PVD]) (ongoing cardiac ischemia requiring medical management or recently placed [within 1 year] drug eluting stent) • Developmental stage or cognitive status warranting use of a hospital outpatient department • End stage renal disease ([hyperkalemia above reference range] receiving peritoneal or hemodialysis)

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Outpatient Surgical Procedures – Site of Service (continued)	Feb. 1, 2022	42830, 43240, 43265, 43274, 43275, 43276, 45389, 46040, 46045, 46050, 46060, 49900, 57288, 59150, 59151, 64435, 64910, 65275, 67015, and 69666 **Supporting Information** • Updated *References* section to reflect the most current information	• History of cerebrovascular accident (CVA) or transient ischemic attack (TIA) (recent event [< 3 months]) • History of myocardial infarction (MI) (recent event [< 3 months]) • Individuals with drug eluting stents (DES) placed within one year or bare metal stents (BMS) or plain angioplasty within 90 days unless acetylsalicylic acid and antiplatelet drugs will be continued by agreement of surgeon, cardiologist and anesthesia • Ongoing evidence of myocardial ischemia • Poorly Controlled asthma (FEV1 < 80% despite medical management) • Pregnancy • Prolonged surgery (> 3 hours) • Resistant hypertension (Poorly Controlled) • Severe valvular heart disease • Sleep apnea (moderate to severe Obstructive Sleep Apnea (OSA) • Uncompensated chronic heart failure (CHF) (NYHA class III or IV) • Uncontrolled diabetes with recurrent diabetic ketoacidosis (DKA) or severe hypoglycemia • Under 18 years of age A planned surgical procedure performed in a hospital outpatient department is considered medically necessary if there is an inability to access an ambulatory surgical center for the procedure due to any one of the following: • There is no geographically accessible ambulatory surgical center that has the necessary equipment for the procedure; or • There is no geographically accessible ambulatory surgical center available at which the individual's physician has privileges; or • An ASC's specific guideline regarding the individual's weight or health conditions that prevents the use of an ASC **Planned Surgical Procedures List** Site of service medical necessity reviews will be conducted for surgical procedures on the Applicable Codes List only when performed in an outpatient hospital setting.

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Provider Administered Drugs – Site of Care	Jan. 1, 2022	**Related Policies** • Added reference link to the Medical Benefit Drug Policy titled: ○ *Ryplazim® (Plasminogen, Human-Tvmh)* ○ *Saphnelo™ (Anifrolumab-Fnia)* **Coverage Rationale** • Revised list of applicable specialty medications that require healthcare provider administration; added: ○ Nexviazyme™ (avalglucosidase alfa-ngpt) ○ Ryplazim® (plasminogen, human-tvmh) ○ Saphnelo™ (anifrolumab-fnia) **Documentation Requirements** • Updated list of specialty medications with associated documentation requirements; added: ○ Nexviazyme™ (avalglucosidase alfa-ngpt) (HCPCS codes C9399, J3490, and J3590) ○ Ryplazim® (plasminogen, human-tvmh) (HCPCS codes C9399, J3490, and J3590) ○ Saphnelo™ (anifrolumab-fnia) (HCPCS codes C9399, J3490, and J3590)	This guideline addresses the criteria for consideration of allowing hospital outpatient facility specialty medication infusion services. This includes claim submission for hospital-based services with the following CMS/AMA Place of Service codes: • 19 Off Campus-Outpatient Hospital; and • 22 On Campus-Outpatient Hospital Alternative sites of care, such as non-hospital outpatient infusion, physician office, ambulatory infusion or home infusion services are well accepted places of service for medication infusion therapy. If an individual does not meet criteria for outpatient hospital facility infusion, alternative sites of care may be used. Outpatient hospital facility-based intravenous medication infusion is medically necessary for individuals who meet at least one of the following criteria (submission of medical records is required): • Documentation that the individual is medically unstable for administration of the prescribed medication at the alternative sites of care as determined by any of the following: ○ The individual's complex medical status or therapy requires enhanced monitoring and potential intervention above and beyond the capabilities of the office or home infusion setting; or ○ The individual's documented history of a significant comorbidity (e.g., cardiopulmonary disorder) or fluid overload status that precludes treatment at an alternative site of care; or ○ Outpatient treatment in the home or office setting presents a health risk due to a clinically significant physical or cognitive impairment; or ○ Difficulty establishing and maintaining patent vascular access; or ○ To initiate, re-initiate products for a short duration (e.g., 4 weeks) or • Documentation (e.g., infusion records, medical records) of episodes of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) that have not been responsive to acetaminophen, steroids, diphenhydramine, fluids,

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Provider Administered Drugs – Site of Care (continued)	Jan. 1, 2022		infusion rate reductions, or other pre-medications, thereby increasing risk to the individual when administration is in the home or office setting; or • Initial infusion or re-initiation of therapy after more than 6 months; or • Homecare or infusion provider has deemed that the individual, home caregiver, or home environment is not suitable for home infusion therapy (if the prescriber cannot infuse in the office setting). Ongoing outpatient hospital facility-based infusion duration of therapy will be no more than 6 months to allow for reassessment of the individual's ability to receive therapy at an alternative site of care. • Actemra® (tocilizumab) • Adakveo® (crizanlizumab-tmca) • Aldurazyme® (laronidase) • Amondys 45™ (casimersen) • Aralast NP® (A1-PI) • Avsola™ (infliximab-axxq) • Benlysta® (belimumab) • Cabenuva (cabotegravir; rilpiverine) • Cerezyme® (imiglucerase) • Cimzia® (certolizumab pegol) • Cinqair® (reslizumab) • Crysvita® (burosumab-twza) • Elaprase® (idursulfase) • Elelyso® (taliglucerase) • Entyvio® (vedolizumab) • Evkeeza™ (evinacumab) • Exondys 51® (eteplirsen) • Fabrazyme® (agalsidase beta) • Fasenra® (benralizumab) • Givlaari® (givosiran) • Glassia® (A1-PI) • Ilaris® (canakinumab) • Ilumya™ (tildrakizumab-asmn)

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Provider Administered Drugs – Site of Care (continued)	Jan. 1, 2022		• Inflectra® (infliximab-dyyb) • Kanuma® (sebelipase alfa) • Lumizyme® (alglucosidase alfa) • Mepsevii™ (vestronidase alfa-vjbk) • Naglazyme® (galsulfase) • Nexviazyme™ (avalglucosidase alfa-ngpt) • Nucala® (mepolizumab) • Nulibry™ (fosdenopterin) • Onpattro® (patisiran) • Orencia® (abatacept) • Oxlumo™ (lumasiran) • Prolastin®-C™ (A1-PI) • Prolia® (denosumab) • Radicava® (edaravone) • Reblozyl® (luspatercept-aamt) • Remicade® (infliximab) • Renflexis® (infliximab-abda) • Revcovi® (elapegademase-lvlr) • Ryplazim® (plasminogen, human-tvmh) • Saphnelo™ (anifrolumab-fnia) • Simponi Aria® (golimumab) • Soliris® (eculizumab) • Stelara® (ustekinumab) • Tepezza® (teprotumumab-trbw) • Trogarzo® (ibalizumab-uiyk) • Ultomiris® (ravulizumab-cwvz) • Uplizna™ (inebilizumab-cdon) • Viltepso™ (Viltolarsen) • Vimizim® (elosulfase alfa) • VPRIV® (velaglucerase) • Vyepti™ (eptinezumab-jjmr) • Vyondys 53™ (golodirsen) • Zemaira® (A1-PI)

General Information

The inclusion of a health service (e.g., test, drug, device or procedure) in this bulletin indicates only that UnitedHealthcare is adopting a new policy and/or updated, revised, replaced or retired an existing policy; it does not imply that UnitedHealthcare provides coverage for the health service. Note that most benefit plan documents exclude from benefit coverage health services identified as investigational or unproven/not medically necessary. Physicians and other health care professionals may not seek or collect payment from a member for services not covered by the applicable benefit plan unless first obtaining the member's written consent, acknowledging that the service is not covered by the benefit plan and that they will be billed directly for the service.

Note: The absence of a policy does not automatically indicate or imply coverage. As always, coverage for a health service 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.

UnitedHealthcare respects the expertise of the physicians, health care professionals, and their staff who participate in our network. Our goal is to support you and your patients in making the most informed decisions regarding the choice of quality and cost-effective care, and to support practice staff with a simple and predictable administrative experience. The Medical Policy Update Bulletin was developed to share important information regarding UnitedHealthcare Medical Policy, Medical Benefit Drug Policy, Coverage Determination Guideline, and Utilization Review Guideline updates. When information in this bulletin conflicts with applicable state and/or federal law, UnitedHealthcare follows such applicable federal and/or state law.

Policy Update Classifications

New

New clinical coverage criteria have been adopted for a health service (e.g., test, drug, device or procedure)

Updated

An existing policy has been reviewed and changes have not been made to the clinical coverage criteria; 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

Replaced

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

Retired

The health service(s) addressed 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

The complete library of UnitedHealthcare Medical Policies, Medical Benefit Drug Policies, Coverage Determination Guidelines, and Utilization Review Guidelines is available at UHCprovider.com > Policies and Protocols > Commercial Policies > Medical & Drug Policies and Coverage Determination Guidelines.