UnitedHealthcare®

August 2018

medical policy update bulletin

Medical Policy, Medical Benefit 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, Medical Benefit Drug Policy, Coverage Determination Guideline, Utilization Review Guideline, and Quality of Care Guideline 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, Medical Benefit Drug Policy, Coverage Determination Guideline (CDG), Utilization Review Guideline (URG), and/or Quality of Care Guideline (QOCG) updates. The inclusion of a health service (e.g., test, drug, device 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 health service. In the event of an inconsistency or conflict between the information provided in this bulletin and the posted policy, the provisions of the posted policy will prevail. Note that most benefit plan documents exclude from benefit coverage health services identified as investigational or unproven/not medically necessary. Physicians and other health care professionals may not seek or collect payment from a member for services not covered by the applicable benefit plan unless first obtaining the member's written consent, acknowledging that the service is not covered by the benefit plan and that they will be billed directly for the service.

The complete library of UnitedHealthcare Medical Policies, Medical Benefit Drug Policies, CDGs, URGs, and QOCGs is available at **UHCprovider.com** > *Policies and Protocols > Commercial Policies > 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 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 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 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

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.

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Medical Policy Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Abnormal Uterine Bleeding and Uterine Fibroids	Aug. 1, 2018	• Updated coverage rationale; modified language pertaining to clinical evidence/study findings for treatment of uterine fibroids: ○ Replaced language indicating "the effects of uterine artery embolization (UAE) on ovarian and uterine function and on fertility *are relatively unknown [and]* further studies of safety and/or efficacy in published, peer-reviewed medical literature *are necessary*" with "the effects of UAE on ovarian and uterine function and on fertility *require* further studies of safety and/or efficacy in published, peer-reviewed medical literature" ○ Replaced language indicating "further *studies* are needed to determine the long-term efficacy of laparoscopic ultrasound-guided radiofrequency ablation for treating uterine fibroids" with "further *well-designed randomized controlled trials* are needed to determine the long-term efficacy of laparoscopic ultrasound-guided radiofrequency ablation for treating uterine fibroids" • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references
Carrier Testing for Genetic Diseases	Sep. 1, 2018	• Updated list of applicable CPT codes; added 81479 • Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references
Chemosensitivity and Chemoresistance Assays in Cancer	Aug. 1, 2018	• Updated coverage rationale: ○ Replaced language indicating "[the listed service] is unproven *and* not medically necessary" with "[the listed service] is unproven *and/or* not medically necessary" ○ Replaced references to "patients" with "individuals" • Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references
Discogenic Pain Treatment	Sep. 1, 2018	• Updated coverage rationale: ○ Replaced language indicating "[the listed services] are unproven *and* not medically necessary" with "[the listed services] are unproven *and/or* not medically necessary" ○ Modified language pertaining to clinical evidence/study findings for percutaneous discectomy and decompression procedures: ▪ Removed language indicating available clinical studies are weakened by the lack of randomization, lack comparator groups, and lack of long-term follow-up ▪ Replaced language indicating "well-designed studies with larger *patient* populations are needed" with "well-designed studies with larger populations *and long term follow-up* are needed" ○ Replaced reference to "patients" with "members" • Updated list of applicable CPT codes; added 22899 • Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references

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Policy Title	Effective Date	Summary of Changes
UPDATED		
Electrical and Ultrasound Bone Growth Stimulators	Sep. 1, 2018	• Updated coverage rationale to clarify electrical and electromagnetic bone growth stimulators are proven and/or medically necessary in certain circumstances; see MCG™ Care Guidelines, 22nd edition, 2018 for applicable clinical coverage criteria • Updated supporting information to reflect the most current CMS information
Electrical Bioimpedance for Cardiac Output Measurement	Aug. 1, 2018	• Updated coverage rationale; replaced language indicating "[the listed service] is unproven *and* not medically necessary" with "[the listed service] is unproven *and/or* not medically necessary" • Replaced reference to: ○ "*Patient* selection criteria" with "selection criteria" ○ "Patient" with "individual" • Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references
Gender Dysphoria Treatment	Aug. 1, 2018	• Updated coverage rationale; replaced language indicating "[the listed services] are considered cosmetic *and* not medically necessary" with "[the listed services] are considered cosmetic *and/or* not medically necessary" • Updated supporting information to reflect the most current description of services, clinical evidence, and references
Hysterectomy for Benign Conditions	Sep. 1, 2018	• Updated coverage rationale to clarify hysterectomy is proven and/or medically necessary in certain circumstances; see MCG™ Care Guidelines, 22nd edition, 2018 for applicable clinical coverage criteria • Updated supporting information to reflect the most current CMS information
Occipital Neuralgia and Headache Treatment	Sep. 1, 2018	• Updated coverage rationale and clinical evidence; replaced references to "*greater* occipital nerve blocks" with "occipital nerve blocks"
Pharmacogenetic Testing	Oct. 1, 2018	• Updated coverage rationale: ○ Replaced language indicating "[the listed service] is unproven *and* not medically necessary" with "[the listed service] is unproven *and/or* not medically necessary" ○ Replaced reference to "pharmacogenetic testing panels" with "pharmacogenetic *multigene* testing panels" • Updated list of applicable CPT codes; added 0029U • Updated supporting information to reflect the most current clinical evidence, CMS information, and references
Spinal Ultrasonography	Aug. 1, 2018	• Updated coverage rationale; replaced language indicating: ○ "[The listed service] is proven *and* medically necessary" with "[the listed service] is proven *and/or* medically necessary" ○ "[The listed service] is unproven *and* not medically necessary" with "[the listed service] is unproven *and/or* not medically necessary" • Updated supporting information to reflect the most current clinical evidence and references

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UPDATED		
Whole Exome and Whole Genome Sequencing	Oct. 1, 2018	• Updated list of applicable CPT codes; added 0036U • Updated supporting information to reflect the most current description of services, clinical evidence, and references

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Genetic Testing for Hereditary Cancer	Oct. 1, 2018	• Reorganized and revised coverage rationale: ○ Replaced language indicating: ▪ "[The listed services] are proven *and* medically necessary" with "[the listed services] are proven *and/or* medically necessary" ▪ "[The listed services] are unproven *and* not medically necessary" with "[the listed services] are unproven *and/or* not medically necessary" ○ Replaced references to "patient" with "individual" **Hereditary Breast and Ovarian Cancer (BRCA1/BRCA2)** • Modified list of proven and/or medically necessary indications for genetic testing for BRCA1 and BRCA2 for individuals **with** a personal history of a related cancer: ○ Added "individuals with a BRCA 1/2 pathogenic mutation detected in tumor tissue" ○ Revised coverage criteria for	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. **Hereditary Breast and Ovarian Cancer (*BRCA1/BRCA2*)** **Genetic testing for *BRCA1* and *BRCA2* for individuals with a personal history of a related cancer is proven and/or medically necessary in the following situations**: • Men with a personal history of Breast Cancer • Women with a personal history of ovarian cancer • Women with a personal history of Breast Cancer in any the following situations: ○ Metastatic Breast Cancer and may be a candidate for treatment with a PARP inhibitor (e.g., olaparib) ○ Breast Cancer diagnosed at any age in an individual with at least one close (1st-, 2nd-, and 3rd-degree relative) blood relative who has a *BRCA1* or *BRCA2* mutation ○ Breast Cancer diagnosed at any age in an individual with Ashkenazi Jewish ancestry ○ Breast Cancer diagnosed at any age with any one of the following: ▪ At least one close blood relative with ovarian cancer; or ▪ At least one close male blood relative with Breast Cancer; or ▪ At least one close blood relative with Breast Cancer diagnosed at age 50 or younger; or ▪ At least two close blood relatives on the same side of the family with with Breast Cancer, pancreatic cancer, or prostate cancer at any age; or ▪ An unknown or Limited Family History (see *Definitions* section of the policy for further clarification of Limited Family History) ○ Breast Cancer diagnosed at age 45 or younger ○ "Triple-Negative" (Her2 negative, ER negative and PR negative) Breast Cancer diagnosed at age 60 or younger

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REVISED			
Genetic Testing for Hereditary Cancer *(continued)*	Oct. 1, 2018	**women with a personal history of Breast Cancer** diagnosed at any age: ▪ Removed language indicating 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 ▪ Added language to indicate genetic testing for BRCA1 and BRCA2 is proven and/or medically necessary when there is an unknown or Limited Family History ○ Revised coverage criteria for **individuals with a personal history of pancreatic cancer** diagnosed at any age: ▪ Added criterion requiring "at least one Close Blood Relative who has a known BRCA1 or BRCA2 mutation" ▪ Added language to indicate genetic testing for BRCA1 and BRCA2 is proven and/or medically necessary when there is an unknown or Limited Family History ○ Revised coverage criteria for	○ Breast Cancer diagnosed at age 50 or younger with any of the following: ▪ An additional Breast Cancer primary (prior diagnosis or bilateral cancer); or ▪ At least one close blood relative with Breast Cancer or pancreatic cancer or prostate cancer; or ▪ An unknown or Limited Family History (see *Definitions* section of the policy for further clarification of Limited Family History) • A personal history of pancreatic cancer in the any of the following situations: ○ Pancreatic cancer diagnosed at any age in an individual with at least one close blood relative who has a known *BRCA1* or *BRCA2* mutation ○ Pancreatic cancer diagnosed at any age with any one of the following: ▪ At least one close relative with ovarian cancer; or ▪ At least one close relative with Breast Cancer diagnosed with at age 50 or younger; or ▪ At least two close blood relatives on the same side of the family with Breast Cancer, pancreatic cancer, or prostate cancer; or ▪ An unknown or Limited Family History • Men with a personal history of prostate cancer in any of the following situations: ○ Metastatic prostate cancer (radiographic evidence of metastases or biopsy-proven disease) diagnosed at any age ○ High Risk prostate cancer(Gleason Score at least7) diagnosed at any age with any of the following: ▪ At least one close blood relative with ovarian cancer at any age; or ▪ At least one close blood relative with Breast Cancer diagnosed at age 50 or younger; or ▪ At least two close relatives on the same side of the family with breast, pancreatic and/or prostate cancer; or ▪ An unknown or Limited Family History • Individuals with a *BRCA 1/2* pathogenic mutation detected in tumor tissue **Genetic testing for *BRCA1* and *BRCA2* for individuals *without* a personal history of a related cancer is proven and/or medically necessary in the following situations**:

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Genetic Testing for Hereditary Cancer *(continued)*	Oct. 1, 2018	**men with a personal history of prostate cancer** diagnosed at any age: ▪ Added criterion requiring "metastatic prostate cancer (radiographic evidence of metastases or biopsy-proven disease)" ▪ Modified criteria pertaining to men with a personal history of high risk prostate cancer: - Replaced criterion requiring: • "Gleason Score ≥ 7" with "Gleason Score *at least 7*" • "At least one Close Blood Relative with Breast Cancer *(≤ age 50 years)*" with "at least one Close Blood Relative with Breast Cancer *diagnosed at age 50 or younger*" - Added language to indicate genetic testing for BRCA1 and BRCA2 is proven and/or medically necessary for men with a personal history of high risk	• When there is a known *BRCA1*/*BRCA2* mutation in a close blood relative (defined as first-, second-, or third-degree relative) • When there is at least one of the following familial risk factors: ○ At least one first- or second-degree blood relative meeting any of the above criteria for individuals with a personal history of a related cancer; or ○ At least one third-degree blood relative with Breast Cancer and/or ovarian cancer who has at least two close blood relatives with Breast Cancer (at least one with Breast Cancer at age 50 or younger) and/or ovarian cancer **Genetic testing for *BRCA1* and/or *BRCA2* testing is unproven and/or not medically necessary for all other indications including**: • Screening for breast or ovarian 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 Further evidence is needed to establish the clinical utility of testing in other populations. **Multi-Gene Hereditary Cancer Panel Testing Criteria** **Genetic testing with a multi-gene hereditary cancer panel in individuals with an indication for testing for hereditary breast and ovarian cancer is proven and/or medically necessary if all of the following criteria are met**: • The suspected hereditary cancer syndromes can be diagnosed by testing of one or more genes included in the specific hereditary cancer panel; and • The results of testing will directly impact this patient's medical management; and • The individual meets at least one of the criteria in Hereditary Breast and Ovarian Cancer (*BRCA1/BRCA2*) (see above section); and • The individual has a family history or personal history that is strongly suggestive of **more than one** hereditary cancer syndrome including at least one of the following: ○ A personal history of at least two different cancers (e.g., Breast Cancer and ovarian cancer)

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Genetic Testing for Hereditary Cancer *(continued)*	Oct. 1, 2018	prostate cancer when there is an unknown or Limited Family History • Modified list of proven and/or medically necessary indications for genetic testing for BRCA1 and BRCA2 for individuals **without** a personal history of a related cancer: ○ Removed language indicating 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 • Added language to indicate genetic testing for *BRCA1* and/or *BRCA2* testing is unproven and/or not medically necessary for confirmation of direct to consumer genetic testing without meeting any of the proven indications [listed in the policy] **Multi-Gene Hereditary Cancer Panel Testing Criteria** • Revised coverage criteria for proven and/or medically necessary genetic testing with a multi-gene hereditary cancer panel in individuals with an indication for testing for **hereditary breast and ovarian cancer**: ○ Expanded criterion	○ A personal history of cancer diagnosed at age 40 or younger ○ A personal history of cancer and at least one relative with a cancer associated with Lynch Syndrome (i.e., brain, colorectal, endometrial, gastric, ovarian, pancreatic, renal pelvis, small intestine, or ureter cancers, sebaceous adenomas, sebaceous carcinomas, and keratoacanthomas) ○ At least one close blood relative diagnsosed with Breast Cancer, ovarian cancer, prostate cancer or pancreatic cancer at age 40 or younger ○ At least three close blood relatives on the same side of the family diagnosed with any cancer **Genetic testing with a multi-gene cancer panel in individuals with an indication for testing for hereditary colorectal cancer is proven and/or medically necessary in the following situations**: • The suspected hereditary cancer syndromes can be diagnosed by testing of one or more genes included in the specific hereditary cancer panel; and • The results of testing will directly impact this individual's medical management; and • The individual has a personal or family history with at least one of the following criteria for Hereditary Colorectal Cancer/Lynch Syndrome Cancer or colorectal polyposis syndrome: ○ Men with a personal history of colorectal cancer or women with a personal history of colorectal or endometrial cancer diagnosed at age 50 or younger ○ Men with a personal history of colorectal cancer or women with a personal history of colorectal or endometrial cancer diagnosed at age 51 or later with at least one of the following criteria: ▪ A personal history of another cancer associated with Lynch Syndrome (i.e., brain, gastric, ovarian, pancreatic, renal pelvis, small intestine, or ureter cancers, sebaceous adenomas, sebaceous carcinomas, and keratoacanthomas); or ▪ Tumor testing results showing that their colorectal or endometrial cancer was MSI-high or had immunohistochemical (IHC) staining showing the absence of one or more mismatch repair proteins (*MLH1, MSH2, MSH6 or PMS2*) ○ A personal history of colorectal polyposis with at least 10 adenomatous polyps, at least 2 hamartomatous polyps, or at least 5

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Genetic Testing for Hereditary Cancer *(continued)*	Oct. 1, 2018	pertaining to individuals with a family or personal history that is strongly suggestive of more than one hereditary cancer syndrome to indicate at least one of the following is required: ▪ A personal history of at least two different cancers (e.g., Breast Cancer and Ovarian Cancer) ▪ A personal history of cancer diagnosed at age 40 or younger ▪ A personal history of cancer and at least one relative with a cancer associated with Lynch Syndrome (i.e., brain, colorectal, endometrial, gastric, ovarian, pancreatic, renal pelvis, small intestine, or ureter cancers, sebaceous adenomas, sebaceous carcinomas, and keratoacanthomas) ▪ At least one Close Blood Relative diagnosed with Breast Cancer, Ovarian Cancer, prostate cancer, or pancreatic cancer at age 40 or younger ▪ At least three Close Blood Relatives on the same side of the family diagnosed with any cancer	serrated polyps ○ At least one close blood relative with a diagnosis of colorectal cancer or endometrial cancer at age 50 or younger ○ At least one close blood relative with at least two cancers associated with Lynch Syndrome (i.e., brain, colorectal, endometrial, gastric, ovarian, pancreatic, renal pelvis, small intestine, or ureter cancers, sebaceous adenomas, sebaceous carcinomas, and keratoacanthomas) ○ Two or more close blood relatives with a cancer associated with Lynch Syndrome (i.e., brain, colorectal, endometrial, gastric, ovarian, pancreatic, renal pelvis, small intestine, or ureter cancers, sebaceous adenomas, sebaceous carcinomas, and keratoacanthomas), with at least one diagnosed at age 50 or younger ○ Three or more close blood relatives with a cancer associated with Lynch Syndrome (i.e., brain, colorectal, endometrial, gastric, ovarian, pancreatic, renal pelvis, small intestine, or ureter cancers, sebaceous adenomas, sebaceous carcinomas, and keratoacanthomas) diagnosed at any age ○ At least one close blood relative with a clinical diagnosis of Familial Adenomatous Polyposis, Attenuated Familial Adenomatous Polyposis, Juvenile Polyposis Syndrome, or Peutz-Jeghers Syndrome ○ A PREMM5, PREMM1,2,6, 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 without an indication for testing for hereditary breast and ovarian cancer or colorectal cancer is proven and/or medically necessary in the following situations**: • The suspected hereditary cancer syndromes can be diagnosed by testing of one or more genes included in the specific hereditary cancer panel; and • The results of testing will directly impact this individual's medical management; and • The individual has a family history or personal history that is strongly suggestive of **more than one** hereditary cancer syndrome **Genetic testing with a multi-gene hereditary cancer panel in individuals diagnosed with cancer at age 18 or younger is proven and**

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Genetic Testing for Hereditary Cancer *(continued)*	Oct. 1, 2018	• Revised coverage criteria for **hereditary colorectal cancer** to indicate genetic testing with a multi-gene cancer panel in individuals with an indication for testing for hereditary colorectal cancer is proven and/or medically necessary in the following situations: ○ The suspected hereditary cancer syndromes can be diagnosed by testing of one or more genes included in the specific hereditary cancer panel; and ○ The results of testing will directly impact this individual's medical management; and ○ The individual has a personal or family history with at least one of the following criteria for Hereditary Colorectal Cancer/Lynch Syndrome Cancer or colorectal polyposis syndrome: ▪ Men with a personal history of colorectal cancer or women with a personal history of colorectal or endometrial cancer diagnosed at age 50 or younger ▪ Men with a personal history of colorectal cancer or women with a personal history of colorectal or endometrial	**medically necessary**. **Genetic testing with a multi-gene cancer panel is proven and/or medically necessary in a individual who has previously tested negative (indeterminate) for the high Penetrance genes that are most likely to explain the personal or family history of cancer (e.g., *BRCA1/2* for Breast Cancer and ovarian cancer)in the following situations**: • The suspected hereditary cancer syndromes can be diagnosed by testing of one or more genes included in the specific hereditary cancer panel; and • The results of testing will directly impact this individual's medical management; and • The individual's personal and family history remains strongly suggestive of an inherited susceptibility that can be diagnosed by testing of one or more genes included in the specific hereditary cancer panel including at least one of the following: ○ A personal history of at least two different cancers (e.g., Breast Cancer and ovarian cancer) ○ A personal history of cancer diagnosed at age 40 or younger ○ A personal history of cancer and at least one relative with a cancer associated with Lynch Syndrome (i.e., brain, colorectal, endometrial, gastric, ovarian, pancreatic, renal pelvis, small intestine, or ureter cancers, sebaceous adenomas, sebaceous carcinomas, and keratoacanthomas) ○ At least one close blood relative diagnsosed with Breast Cancer, ovarian cancer, prostate cancer or pancreatic cancer at age 40 or younger ○ At least three close blood relatives on the same side of the family diagnosed with any cancer **Multi-gene hereditary cancer panels are unproven and/or not medically necessary for all other indications**.

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Genetic Testing for Hereditary Cancer *(continued)*	Oct. 1, 2018	cancer diagnosed at age 51 or later with at least one of the following criteria: - A personal history of another cancer associated with Lynch Syndrome (i.e., brain, gastric, ovarian, pancreatic, renal pelvis, small intestine, or ureter cancers, sebaceous adenomas, sebaceous carcinomas, and keratoacanthomas); or - Tumor testing results showing that their colorectal or endometrial cancer was MSI-high or had immunohisto-chemical (IHC) staining showing the absence of one or more mismatch repair proteins (MLH1, MSH2, MSH6 or PMS2) ▪ A personal history of colorectal polyposis with at least 10 adenomatous polyps, at least 2 hamartomatous polyps, or at least 5 serrated polyps ▪ At least one close blood	

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Genetic Testing for Hereditary Cancer *(continued)*	Oct. 1, 2018	relative with a diagnosis of colorectal cancer or endometrial cancer at age 50 or younger ▪ At least one close blood relative with at least two cancers associated with Lynch Syndrome (i.e., brain, colorectal, endometrial, gastric, ovarian, pancreatic, renal pelvis, small intestine, or ureter cancers, sebaceous adenomas, sebaceous carcinomas, and keratoacanthomas) ▪ Two or more close blood relatives with a cancer associated with Lynch Syndrome (i.e., brain, colorectal, endometrial, gastric, ovarian, pancreatic, renal pelvis, small intestine, or ureter cancers, sebaceous adenomas, sebaceous carcinomas, and keratoacanthomas), with at least one diagnosed at age 50 or younger ▪ Three or more close blood relatives with a cancer associated with Lynch Syndrome (i.e., brain, colorectal, endometrial, gastric, ovarian, pancreatic, renal pelvis, small	

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Genetic Testing for Hereditary Cancer *(continued)*	Oct. 1, 2018	intestine, or ureter cancers, sebaceous adenomas, sebaceous carcinomas, and keratoacanthomas) diagnosed at any age ▪ At least one close blood relative with a clinical diagnosis of Familial Adenomatous Polyposis, Attenuated Familial Adenomatous Polyposis, Juvenile Polyposis Syndrome, or Peutz-Jeghers Syndrome ▪ A PREMM5, PREMM1,2,6, MMRpro, or MMRpredict Score of 5% or greater for having a Lynch syndrome gene mutation • Added language to indicate genetic testing with a multi-gene hereditary cancer panel in individuals diagnosed with cancer at age 18 or younger is proven and/or medically necessary • Revised coverage criteria for proven and/or medically necessary genetic testing with a multi-gene cancer panel in an individual who has previously tested negative (indeterminate) for the high Penetrance genes that are most likely to explain the personal or family history of cancer (e.g., BRCA1/2 for Breast Cancer and Ovarian Cancer): ○ Added criterion requiring	

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REVISED			
Genetic Testing for Hereditary Cancer *(continued)*	Oct. 1, 2018	"the suspected hereditary cancer syndromes can be diagnosed by testing of one or more genes included in the specific hereditary cancer panel" ○ Expanded criterion pertaining to individuals with a personal and family history remains strongly suggestive of an inherited susceptibility that can be diagnosed by testing of one or more genes included in the specific hereditary cancer panel to indicate at least one of the following is required: ▪ A personal history of at least two different cancers (e.g., Breast Cancer and Ovarian Cancer) ▪ A personal history of cancer diagnosed at age 40 or younger ▪ A personal history of cancer and at least one relative with a cancer associated with Lynch Syndrome (i.e., brain, colorectal, endometrial, gastric, ovarian, pancreatic, renal pelvis, small intestine, or ureter cancers, sebaceous adenomas, sebaceous carcinomas, and keratoacanthomas) ▪ At least one Close Blood	

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Genetic Testing for Hereditary Cancer *(continued)*	Oct. 1, 2018	Relative diagnosed with Breast Cancer, Ovarian Cancer, prostate cancer or pancreatic cancer at age 40 or younger ▪ At least three Close Blood Relatives on the same side of the family diagnosed with any cancer **Definitions** • Added definition of: ○ Age Guidelines ○ Breast Cancer ○ Close Blood Relatives ○ Founder Mutation ○ Gleason Scoring ○ Limited Family History ○ Lynch Syndrome Cancers ○ Ovarian Cancer ○ Penetrance ○ Personal and Family History Documentation ○ Triple-Negative Breast Cancer • Removed definition of "1st, 2nd, and 3rd Degree Relatives" **Applicable Codes** • Updated and reorganized list of applicable CPT codes; added 81435, 81436, 81437, and 81438 **Supporting Information** • Updated supporting information to reflect the most current description of services, clinical evidence, and references	

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REVISED			
Manipulative Therapy	Aug. 1, 2018	• Revised coverage rationale: ○ Replaced language indicating manipulative therapy is unproven and/or not medically necessary for: ▪ "Treating non-musculoskeletal disorders, *including but not limited to* lungs (e.g., asthma), internal organs (e.g., intestinal), *neurological (e.g., headaches),* and *ear, nose, and throat* (e.g., otitis media)" with "treating non-musculoskeletal disorders (e.g., asthma, *otitis media, infantile colic, etc.) and* internal organ *disorders* (e.g., *gallbladder, spleen,* intestinal, *kidney*, or lung *disorders*)" ▪ "Preventive *or* maintenance care" with "prevention/ maintenance/*custodial care*" ○ Removed language indicating the role of manipulative therapy in preventive or maintenance care has not been established in scientific literature; a beneficial impact on health outcomes has not been established	**Manipulative therapy is proven and/or medically necessary for treating musculoskeletal disorders, except as noted below**. **Manipulative therapy is unproven and/or not medically necessary for treating**: • Non-musculoskeletal disorders (e.g., asthma, otitis media, infantile colic, etc.) • Prevention/maintenance/custodial care • Internal organ disorders (e.g., gallbladder, spleen, intestinal, kidney, or lung disorders) • Temporomandibular joint (TMJ) disorder • Scoliosis **Craniosacral therapy (cranial manipulation/Upledger technique) or manipulative services that utilize nonstandard techniques including but not limited to applied kinesiology, National Upper Cervical Chiropractic Association (NUCCA), and neural organizational technique are unproven and/or not medically necessary for any indication**. The role of manipulation for the above has not been established in scientific literature. A beneficial impact on health outcomes, e.g., improved physical function, durable pain relief, has not been established. **Manipulative therapy is unproven and/or not medically necessary when ANY of the following apply:** • The member's condition has returned to the pre-symptom state. • Little or no improvement is demonstrated within 30 days of the initial visit despite modification of the treatment plan. • Concurrent manipulative therapy, for the same or similar condition, provided by another health professional whether or not the healthcare professional is in the same professional discipline. This policy does not address manipulation under anesthesia; refer to the policy titled Manipulation Under Anesthesia.

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REVISED			
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions	Oct. 1, 2018	• Reorganized and revised coverage rationale: ○ Added language to indicate: ▪ Molecular profiling of thyroid nodules (e.g., Afirma, ThyraMIR, Thyroseq) is proven and/or medically necessary when all of the following criteria are met: - Follicular pathology on fine needle aspiration is indeterminate - The results of the test will be used for making decisions about further surgery ▪ Use of more than one molecular profile test in an individual with a thyroid nodule is unproven and/or not medically necessary ▪ Molecular profiling using chromosomal microarray analysis is considered proven and/or medically necessary for individuals with acute leukemia ▪ Whole Exome Sequencing (WES) and Whole Genome Sequencing (WGS) of tumors is considered unproven and/or not medically necessary for	**Breast Cancer** **The use of one of the following gene expression tests listed below is considered proven and/or medically necessary to make a treatment decision regarding adjuvant chemotherapy in females or males with non-metastatic breast cancer when all of the following criteria are met**. **Use of more than one gene expression test for the same tumor in an individual with breast cancer is unproven and/or not medically necessary**. **MammaPrint (also referred to as the "Amsterdam signature" or "70-gene signature"), is considered proven and/or medically necessary to assess distant recurrence of disease in individuals with recently diagnosed non-metastatic breast cancer when all the following criteria are met**: • High clinical risk of recurrence based on at least one of the following criteria: ○ Lymph node positive (pN1-2); or ○ Tumor size greater than 2 cm; or ○ Poorly differentiated or undifferentiated histology (grade 3) AND tumor size greater than 1 cm; and • Hormone receptor-positive (estrogen receptor positive, progesterone receptor positive or both); and • HER2 receptor negative; and • Adjuvant chemotherapy is not precluded due to any other factor (e.g., advanced age and/or significant co-morbidities); and • Individual and treating physician have had a discussion prior to testing regarding the potential results of the test and determined to use the results to guide therapy. **Mammaprint is considered unproven and/or not medically necessary for all other indications**. **Oncotype Dx Breast, Prosigna PAM-50 Breast Cancer Prognostic Gene Signature Assay, EndoPredict and the Breast Cancer Index gene expression tests for intermediate and low risk breast cancer are considered proven and/or medically necessary to assess use of adjuvant chemotherapy in individuals with recently diagnosed non-**

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REVISED			
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions *(continued)*	Oct. 1, 2018	all indications ○ Updated list of unproven and/or not medically necessary indications for molecularly profiling using gene expression profiling or multi-gene cancer panels: ▪ Added: – Bladder Cancer (e.g., CytoScan® DX Assay) – Breast cancer other than those previously described as covered – Leukemia other than those described as covered (e.g., FoundationOne® Heme) – Plasma detection of cell-free DNA (e.g., Guardant, Colonsentry) ▪ Updated list of examples of tests associated with cancers of unknown primary site; added "Pathfinder TG" ▪ Replaced "*cutaneous* melanoma" with "melanoma" ○ Removed language pertaining to clinical evidence/study findings for the following unproven and/or not medically necessary indications: ▪ Breast cancer treatment	**metastatic breast cancer when all of the following criteria are met**: • Lymph node negative (pN0) or axillary lymph node micrometastasis less than 2mm (pN1mi); and • Hormone receptor positive (estrogen receptor positive, progesterone receptor positive or both); and • HER2 receptor negative; and • Adjuvant chemotherapy is not precluded due to any other factor (e.g., advanced age and/or significant co-morbidities); and • Individual and treating physician have had a discussion prior to testing regarding the potential results of the test and determined to use the results to guide therapy. **Oncotype Dx Breast, Prosigna PAM-50 Breast Cancer Prognostic Gene Signature Assay, EndoPredict, and the Breast Cancer Index are considered unproven and/or not medically necessary for all other indications**. **Gene expression profiling assays for breast cancer treatment other than those previously described as covered are considered unproven and/or not medically necessary, including but not limited to**: • BluePrint (also referred to as "80-gene profile") • Breast Cancer Gene Expression Ratio (also known as Theros H/I) • BreastNext • BreastOncPX • BreastPRS • Insight DX Breast Cancer Profile • Mammostrat • NexCourse Breast IHC4 • NuvoSelect eRx 200-Gene Assay • Oncotype DX DCIS • SYMPHONY Genomic Breast Cancer Profile • TargetPrint • TheraPrint • The 41-gene signature assay • The 76-gene "Rotterdam signature" assay **Thyroid Cancer** **Molecular profiling of thyroid nodules (e.g., Afirma, ThyraMIR, Thyroseq) is proven and/or medically necessary when all of the**

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions *(continued)*	Oct. 1, 2018	other than those described [in the policy] as covered ▪ Identification of the tissue of origin for cancers of unknown primary site ▪ Cutaneous and uveal melanoma ▪ Colorectal cancer (CRC) risk assessment or management ▪ Evaluation or management of multiple myeloma ▪ Screening, detection and management of prostate cancer ○ Removed language indicating topographic genotyping is unproven and/or not medically necessary • Added definition of: ○ Comparative Genome Hybridization (CGH) ○ Gene Expression Testing ○ Next Generation Sequencing (NGS) ○ Variant of Unknown Significance (VUS) ○ Whole Exome Sequencing (WES) ○ Whole Genome Sequencing (WGS) • Updated list of applicable CPT codes; added 0018U, 0026U, 0036U, 0037U, 0045U, 0047U, 0048U, 0050U, 0056U, and	**following criteria are met**: • Follicular pathology on fine needle aspiration is indeterminate • The results of the test will be used for making decisions about further surgery **Use of more than one molecular profile test in an individual with a thyroid nodule is unproven and/or not medically necessary**. **Leukemia** **Molecular profiling using chromosomal microarray analysis is considered proven and/or medically necessary for individuals with acute leukemia**. **Lung Cancer** **Molecular profiling of tumors using a multi-gene cancer panel of up to 50 genes is considered proven and/or medically necessary for individuals with metastatic non-small cell lung cancer (NSCLC)**. **Use of more than one gene multi-gene cancer panel for the same individual with non-small cell lung cancer is unproven and/or not medically necessary**. **Molecular Profiling Tests for Other Indications or Cancers** **Whole Exome Sequencing (WES) and whole genomic sequencing (WGS) of tumors is considered unproven and/or not medically necessary for all indications**. **Multi-gene cancer panels of greater than 50 genes are considered unproven and/or not medically necessary for all indications**. **Molecularly profiling using gene expression profiling or multi-gene cancer panels is considered unproven and/or not medically necessary for all other indications, including but not limited to:** • Bladder Cancer (e.g., CytoScan® DX Assay) • Breast cancer other than those previously described as covered • Cancers of Unknown Primary Site (e.g., Response Dx, CancerTYPE ID, Rosetta Cancer Origin, ProOnc, SourceDX, Pathfinder TG) • Colorectal Cancer (e.g., Oncotype DX Colon Cancer Assay, Colorectal Cancer DSA, GeneFx Colon, OncoDefender CRC)

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REVISED			
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions *(continued)*	Oct. 1, 2018	0057U • Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references	• Leukemia other than those previously described as covered (e.g., FoundationOne® Heme) • Melanoma (e.g., Decision Dx – Melanoma, Decision Dx-UM) • Multiple myeloma (e.g., MyPRS/MyPRS Plus) • Plasma detection of cell free DNA (e.g., Guardant, Colonsentry) • Prostate cancer (e.g., Oncotype DX Prostate Cancer Assay, TMPRSS2 fusion gene, Prolaris Prostate Cancer Test, Decipher Prostate Cancer Classifer) • Uveal melanoma (e.g., Decision Dx-UM)
Omnibus Codes	Oct. 1, 2018	• Added coverage guidelines for: **Pulse-Echo Ultrasound Bone Density Measurement (CPT code 0508T)** ○ Added language to indicate the use of pulse-echo ultrasound bone density measurement is unproven and/or not medically necessary due to insufficient clinical evidence of safety and/or efficacy in published peer-reviewed medical literature **Refined Autologous Adipose Cell Transfer for the Treatment of Meniscal Tears (CPT code 27599)** ○ Added language to indicate refined autologous adipose cell transfer is unproven and/or not medically necessary for the treatment of meniscal tears due to insufficient clinical evidence of safety and/or efficacy in published peer-reviewed medical literature **Absorbable Nasal Implants**	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
REVISED			
Omnibus Codes *(continued)*	Oct. 1, 2018	**(CPT codes 30999 and L8699)** ○ Added language to indicate absorbable nasal implants [e.g., Latera Absorbable Nasal Implant (Spirox®)] are unproven and/or not medically necessary for supporting nasal upper and lower lateral cartilage due to insufficient clinical evidence of safety and/or efficacy in published peer-reviewed medical literature **Multi-Biomarker Disease Activity (MBDA) Test (CPT code 81490)** ○ Added language to indicate the use of a multi-biomarker disease activity (MBDA) test is unproven and/or not medically necessary for managing individuals with rheumatoid arthritis (RA) due to insufficient evidence of safety and/or efficacy in the published peer-reviewed medical literature • Revised coverage guidelines for: **All Services** ○ Replaced language indicating: ▪ "[The listed services] are proven *and* medically necessary" with "[the listed services] are proven *and/or* medically necessary" ▪ "[The listed services] are	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Omnibus Codes *(continued)*	Oct. 1, 2018	unproven *and* not medically necessary" with "[the listed services] are unproven *and/or* not medically necessary" **Computer-Assisted Musculoskeletal Surgical Navigational for Orthopedic Procedures (CAOS) (CPT codes 0054T, 0055T, 0396T, and 20985)** ○ Updated list of applicable CPT codes; revised description for 20985 **Pillcam Colon2 Capsule Endoscopy System (CPT code 0355T)** ○ Replaced reference to "Pillcam Colon 2" with "Pillcam Colon2 capsule endoscopy system" **Transurethral Waterjet Ablation of the Prostate, also known as Aquablation (CPT code 0421T)** ○ Modified language pertaining to clinical evidence/study findings to indicate there is a lack of high quality evidence demonstrating the beneficial impact of transurethral waterjet ablation in patients with benign prostatic hyperplasia (BPH); therefore, it is not possible to conclude whether this new technology has a beneficial effect on health outcomes	

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Omnibus Codes *(continued)*	Oct. 1, 2018	**Implantable Neurostimulation Devices for the Treatment of Central Sleep Apnea (CPT codes 0424T, 0425T, 0426T, 0427T, 0428T, 0429T, 0430T, 0431T, 0432T, 0433T, 0434T, 0435T, and 0436T)** ○ Replaced language indicating "implantable neurostimulation devices for the treatment of central sleep apnea are investigational, unproven and/or not medically necessary due to *lack of U.S. Food and Drug Administration (FDA) approval and* insufficient clinical evidence" with "implantable neurostimulation devices for the treatment of central sleep apnea are investigational, unproven and/or not medically necessary due to insufficient clinical evidence" ○ Removed language indicating: ▪ Coverage may be available through participation in an eligible clinical trial depending on the member specific benefit plan document ▪ Implantable neurostimulation devices	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Omnibus Codes *(continued)*	Oct. 1, 2018	have not yet received FDA approval and are limited to investigational use ○ Added instruction to refer to the policy titled *Obstructive Sleep Apnea Treatment* for additional information on treatment of central sleep apnea **Cooled Radiofrequency Ablation (RFA) (CPT codes 22899, 27299, 27599, and 64999)** ○ Updated list of applicable CPT codes; revised description for 22899, 27299, 27599, and 64999 **Percutaneous Cryoablative Therapy of Pulmonary Tumors (CPT code 32994)** ○ Replaced language indicating "percutaneous cryoablative therapy of pulmonary tumors, including the pleura or chest wall when involved by tumor extension, is unproven" with "percutaneous cryoablative therapy of pulmonary tumors, including the pleura or chest wall when involved by tumor extension, is unproven *and/or not medically necessary*" **Optical Endomicroscopy (CPT codes 0397T, 43206, 43252, and 88375)** ○ Updated list of applicable	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
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Omnibus Codes *(continued)*	Oct. 1, 2018	CPT codes; added 0397T and 88375 **Surgical Treatment of a Tarlov Cyst from the Sacrum (CPT code 64999)** ○ Removed information pertaining to medical necessity review **Intraoperative Radiation Therapy Using Low-Energy X-Rays or Electrons (CPT codes 19294, 77424, 77425, and 77469)** ○ Updated list of applicable CPT codes; added 19294 **Multifocal Electroretinogram (mfERG) and Pattern Electroretinogram (PERG) or Pattern Electroretinogram Optimized for Glaucoma Screening (PERGLA) (CPT code 92499)** ○ Updated list of applicable CPT codes; revised description for 92499 **Microscopic Examination of Hair to Determine Telogen and Anagen Counts or Structural Hair Shaft Abnormality (CPT code 96902)** ○ Replaced language indicating "microscopic *analysis* of hair is unproven *and* not medically necessary" with "microscopic *examination* of hair *to determine telogen and anagen counts or structural hair shaft*	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Omnibus Codes *(continued)*	Oct. 1, 2018	*abnormality* is unproven *and/or* not medically necessary" **Kinesio Taping (CPT codes 29799, 97139, and 97799)** ○ Updated list of applicable CPT codes; added 97799 **Instrument-Based Ocular Screening Using Photoscreening (CPT codes 99174 and 99177)** ○ Replaced reference to "children" with "individuals" ○ Updated and reformatted list of applicable ICD-10 diagnosis codes: ▪ Transferred content to embedded Excel file format ▪ Added I69.010, I69.011, I69.012, I69.013, I69.014, I69.015, I69.018, I69.019, I69.110, I69.111, I69.112, I69.113, I69.114, I69.115, I69.118, I69.119, I69.210, I69.211, I69.212, I69.213, I69.214, I69.215, I69.218, I69.219, I69.310, I69.311, I69.312, I69.313, I69.314, I69.315, I69.318, I69.319, I69.810, I69.811, I69.812, I69.813, I69.814, I69.815, I69.818, I69.819,	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Omnibus Codes *(continued)*	Oct. 1, 2018	I69.910, I69.911, I69.912, I69.913, I69.914, I69.915, I69.918, I69.919, and R41.840 ▪ Removed H54.0, I69.1, I69.11, I69.21, I69.31, I69.81, and I69.91 **Digestive Enzyme Cartridges for Use with Enteral Tube Feeding (HCPCS codes B4104, B9998, and Q9994)** ○ Updated list of applicable CPT codes; added Q9994 **Upper Limb Orthotic Known As MyoPro™ (HCPCS codes E1399 and L3999)** ○ Updated list of applicable CPT codes; added E1399 **Three-Dimensional (3-D) Printed Cranial Implants (HCPCS code L8699)** ○ Removed reference to specific product names (OssDsign® Cranial Patient-Specific Implant and OsteoFab™ Patient Specific Cranial Device) ○ Added language to indicate 3D printing of implants may be performed with other procedures such as 3D rendering with interpretation and reporting of imaging; for additional information regarding these imaging procedures, refer to the Imaging: Evidence-Based Clinical Guidelines	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Omnibus Codes *(continued)*	Oct. 1, 2018	**Prolaryn, Prolaryn Plus, Radiesse, and Sculptra (HCPCS codes L8607, Q2026, and Q2028)** ○ Added language to indicate uses of Radiesse other than for treating facial defects due to facial lipidatrophy in persons with human immunodeficiency virus (HIV) may be cosmetic • Removed coverage guidelines for: ○ Breath testing for a measure of heart transplant rejection (CPT code 0085T) (no longer requires clinical review) ○ Intravascular catheter-based spectroscopy to assess coronary artery plaque vulnerability (CPT code 0205T) (no longer requires clinical review) ○ Two-lead, computerized, resting electrocardiography (ECG) analysis to diagnose heart disease (CPT code 0206T) (no longer requires clinical review) ○ Nocturnal epilepsy monitoring systems that record external heart rate and accelerometer motion data (CPT/HCPCS codes 0381T, 0382T, 0383T, 0384T, 0385T, and 0386T) (no longer requires clinical review) ○ Cardiac contractility	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Omnibus Codes *(continued)*	Oct. 1, 2018	modulation using an implantable device (CPT codes 0408T, 0409T, 0410T, 0411T, 0412T, 0413T, 0414T, 0415T, 0416T, 0417T, and 0418T) (no longer requires clinical review) ○ Inert gas rebreathing for measuring cardiac output (CPT codes 93799 and 94799) (no longer requires clinical review) ○ Testing for Thymol turbidity (HCPCS code P2033) (no longer requires clinical review) ○ Testing for blood mucoprotein (HCPCS code P2038) (no longer requires clinical review) ○ Skin and soft tissue substitutes (HCPCS codes Q4100, Q4115, Q4123, Q4131, Q4132, Q4133, Q4134, Q4135, Q4136, Q4137, Q4138, Q4139, Q4140, Q4141, Q4142, Q4143, Q4145, Q4146, Q4147, Q4148, Q4149, Q4150, Q4151, Q4152, Q4153, Q4154, Q4155, Q4156, Q4157, Q4158, Q4159, Q4160, Q4161, Q4162, Q4163, Q4164, Q4165, Q4166, Q4167, Q4168, Q4169, Q4170, Q4171, Q4172, Q4173, Q4174, Q4175, Q4176,	

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Omnibus Codes *(continued)*	Oct. 1, 2018	Q4177, Q4178, Q4179, Q4180, Q4181, and Q4182); refer to the policy titled Skin and Soft Tissue Substitutes for applicable coverage guidelines • Updated supporting information to reflect the most current clinical evidence and references	
Skin and Soft Tissue Substitutes	Oct. 1, 2018	• Reformatted policy; content previously located in the policy titled *Omnibus Codes* • Added reference links to related policies • Revised coverage rationale: ○ Replaced language indicating: ▪ "[The listed service] is proven *and* medically necessary" with "[the listed service] is proven *and/or* medically necessary" ▪ "[The listed services] are unproven *and* not medically necessary due to insufficient clinical evidence of safety and/or efficacy in published peer-reviewed medical literature" with "[the listed services] are unproven *and/or* not medically necessary" ○ Added language to indicate: ▪ The following skin and soft tissue substitutes are unproven and/or not	**TransCyte™** **TransCyte is proven and/or medically necessary for treating surgically excised Full-Thickness Thermal Burn wounds and deep Partial-Thickness Thermal Burn wounds in individuals who require such a covering before autograft placement**. **TransCyte is unproven and/or not medically necessary for all other indications**. Additional studies are needed to evaluate the safety and effectiveness of TransCyte for other indications. **Other Skin and Soft Tissue Substitutes** **The following skin and soft tissue substitutes are unproven and/or not medically necessary for any indication**: • Affinity® • Alloskin® • Allowrap® • Amnio Wound™ • Amnioband® • Amnioexcel™ or Biodexcel™ • AmnioFix® • Amniomatrix™ or Biodmatrix™ • Architect Extracellular Matrix® • Artacent® • ArthroFLEX® • Bio-ConneKt® • Biodfence™ or Biodfence Dryflex™ • BioSkin™ • BioSkin™ Flow

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Skin and Soft Tissue Substitutes *(continued)*	Oct. 1, 2018	medically necessary for any indication: ArthroFLEX®, Cymetra™, DermACELL®, DermaSpan™, GammaGraft™, HYALOMATRIX®, Integra® Flowable Wound Matrix, InteguPly®, MatriStem®, MemoDerm™, PriMatrix®, Strattice™, Talymed®, TheraSkin®, and TranZgraft® ▪ Additional studies are needed to evaluate the safety and effectiveness of TransCyte for other indications ▪ Due to limited studies, small sample sizes, and weak study designs, there is insufficient clinical evidence to conclude that these skin substitutes have an improved health outcome over standard therapies; well-designed, randomized comparative clinical trials are needed to demonstrate the efficacy and safety of these products ○ Removed language indicating: ▪ AmnioGen-A™, AmnioGen-C™, AmnioGen-45™, or	• Biovance® • Clarix® • Clarix® Flo • Conexa™ Reconstructive Matrix • CorMatrix® • Cygnus™ • Cymetra™ • Cytal™ • DermACELL® • Dermapure™ • DermaSpan™ • Dermavest® or Plurivest® • Epicord™ • Epifix® • Excellagen® • Ez-derm® • Floweramnioflo™ or FlowerFlo™ • Floweramniopatch™ or FlowerPatch™ • FlowerDerm™ • GammaGraft™ • Grafix® • GrafixPL® • Guardian • Helicoll™ • Hmatrix® • HYALOMATRIX® • Integra® Flowable Wound Matrix • InteguPly® • Interfyl™ • Keramatrix® • Kerecis™ Omega3 • MatriStem® • Mediskin™ • MemoDerm™ • Miroderm™ • NeoPatch™ • Neox® • Neox Flo® • Nushield®

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Skin and Soft Tissue Substitutes *(continued)*	Oct. 1, 2018	AmnioGen-200™ are unproven and/or not medically necessary for any indication ○ Replaced reference to: ▪ "Persons" with "individuals" ▪ "Kerecis™ *or Marigen*™" with "Kerecis™ *Omega3*" • Added definition of: ○ Acellular Matrix ○ Allogeneic Matrix ○ Composite Matrix ○ Full-Thickness Thermal Burn (Third Degree Burn) ○ Human Skin Allograft ○ Partial-Thickness Thermal Burn (Second Degree Burn) • Updated list of applicable HCPCS codes; added Q4110, Q4111, Q4112, Q4114, Q4117, Q4118, Q4121, Q4122, Q4125, Q4126, Q4127, and Q4130 • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	• PalinGen® Amniotic Tissue Allograft and PalinGen® Flow products • PriMatrix® • ProMatrX™ • PuraPly™ or PuraPly™ Antimicrobial • Repriza® • Revita™ • Revitalon® • Strattice™ • Talymed® • Tensix® • TheraSkin® • TranZgraft® • Truskin™ • WoundEx™ • WoundEx™ Flow • Xcm Biologic Tissue Matrix® Due to limited studies, small sample sizes, and weak study designs, there is insufficient clinical evidence to conclude that these skin substitutes have an improved health outcome over standard therapies. Well-designed, randomized comparative clinical trials are needed to demonstrate the efficacy and safety of these products.

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Entyvio® (Vedolizumab)	Aug. 1, 2018	• Updated coverage rationale; reformatted coverage criteria for initial therapy of Crohn's disease to clarify intent

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Enzyme Replacement Therapy	Aug. 1, 2018	• Revised coverage rationale: ○ Replaced language indicating "[the listed drug products] are *medically necessary* for the treatment of [the listed conditions]" with "[the listed drugs product] are *proven* for the treatment of [the listed conditions]" ○ Added language to indicate [the listed drug products] are *medically necessary* when the [listed] *additional* criteria are met	Refer to the policy for complete details on the coverage guidelines for Enzyme Replacement Therapy.
Erythropoiesis-Stimulating Agents	Aug. 1, 2018	• Changed policy title; previously titled *Anemia Drugs: Darbepoetin Alfa, Epoetin Alfa, and Methoxy Polyethylene Glycol-Epoetin Beta* • Revised coverage rationale; added "Retacrit™ (epoetin alfa)" to the list of erythropoiesis-stimulating agents (ESAs) addressed in the policy • Updated list of applicable HCPCS codes; added Q5105 and Q5106 • Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references	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) • Retacrit™ (epoetin alfa) "ESAs" will be used to refer to all erythropoiesis stimulating agents, unless otherwise specified. 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. **Anemia Due to Chronic Kidney Disease** ***Patients Receiving Dialysis*** I. **ESAs are proven for the treatment of anemia of chronic kidney disease (CKD) when ALL of the following criteria are met:**

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Erythropoiesis-Stimulating Agents *(continued)*	Aug. 1, 2018		A. Patient is on dialysis; **and** B. Hematocrit is less than 30% at initiation of therapy. II. **ESAs are unproven to treat anemia of CKD in patients on dialysis for a hematocrit greater than or equal to 33%.** ***Patients NOT Receiving Dialysis*** I. **ESAs are proven for the treatment of anemia of chronic kidney disease (CKD) when ALL of the following criteria are met**: A. Patient is **not** on dialysis; **and** B. Hematocrit less than 30% at initiation of therapy; **and** C. The rate of hematocrit decline indicates the likelihood of requiring a red blood cell (RBC) transfusion; **and** D. Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. II. **ESAs are unproven to treat anemia of CKD in patients NOT on dialysis for a hematocrit greater than 30%.** **Anemia Due to Cancer Chemotherapy** I. **Aranesp, Epogen, Procrit,** and **Retacrit are proven when used to treat anemia in cancer chemotherapy when BOTH of the following criteria are met**: A. Hematocrit less than 30% at initiation of therapy; **and** B. There is a minimum of two additional months of planned chemotherapy. II. **Mircera is unproven for the treatment of anemia due to cancer chemotherapy**. III. **ESAs are unproven to treat anemia in patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure**. IV. **ESAs are unproven to treat anemia in patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion.** **Anemia Associated with Myelodysplastic Disease** I. **Aranesp, Epogen, Procrit, and Retacrit are proven to treat anemia associated with myelodysplastic disease (MDS) when BOTH of the following criteria are met**: A. **One** of the following: 1. Serum erythropoietin level ≤ 500 mUnits/mL; **or**

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REVISED			
Erythropoiesis-Stimulating Agents *(continued)*	Aug. 1, 2018		2. Hematocrit is less than or equal to 30% at the initiation of therapy; **and** B. For **continuation of therapy**, the hematocrit remains less than 36%. **Anemia Associated with Zidovudine Treatment in HIV-Infected Patients** I. **Epogen, Procrit, and Retacrit are proven to treat anemia in HIV-infected patients when BOTH of the following criteria are met**: A. Patient is receiving zidovudine administered at ≤ 4200 mg/week; **and** B. Endogenous serum erythropoietin level ≤ 500 mUnits/mL; **and** C. Hematocrit is less than 30% at initiation of therapy. **Anemia in Patients with Hepatitis C with Ribavirin and Interferon Therapy** I. **Epogen, Procrit, and Retacrit are proven to treat anemia associated with hepatitis C virus infection when ALL of the following criteria are met**: A. Patient is receiving ribavirin and interferon therapy; **and** B. Hematocrit is less than or equal to 30% at initiation of therapy; **and** C. For **continuation of therapy**, the hematocrit remains less than 36%. **Preoperative Use for Reduction of Allogeneic Blood Transfusions in Surgery Patients** I. **Epogen, Procrit, and Retacrit are proven perioperatively to reduce the need for allogeneic blood transfusions when ALL of the following criteria are met**: A. Perioperative Hct is greater than 30% and less than or equal to 39%; **and** B. Patient is at high risk for blood loss during surgery; **and** C. Patient is unable or unwilling to donate autologous blood; **and** D. Surgery procedure is elective, noncardiac, and nonvascular. II. **ESAs are unproven for patients who are willing to donate autologous blood pre-operatively or in patient undergoing cardiac or vascular surgery**. **Additional Information** For the purposes of this policy, a conversion factor of 3 should be used to

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Erythropoiesis-Stimulating Agents *(continued)*	Aug. 1, 2018		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% **Unproven** **ESAs are unproven for**: • 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 • Patients with cancer receiving hormonal agents, biologic products or radiotherapy (unless also receiving concomitant myelosuppressive chemotherapy) • Patients who require an immediate correction of anemia as a substitute for RBC transfusions • Patients undergoing cardiac or vascular surgery • Patients scheduled for surgery who will donate autologous blood • Patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure • Patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion
Soliris® (Eculizumab)	Aug. 1, 2018	• Revised coverage rationale; replaced language indicating "Soliris is proven *and/or medically necessary* for the treatment of generalized myasthenia gravis when all of the [listed] criteria are met" with "Soliris is proven for the treatment of generalized myasthenia gravis; *Soliris is medically necessary* when all of the [listed] criteria are met" • Updated supporting information to reflect the most current references	**Soliris (eculizumab) is proven for the treatment of:** I. **Atypical hemolytic uremic syndrome (aHUS)** **Soliris is medically necessary when all of the following criteria are met**: A. **Initial Therapy:** 1. Documentation supporting the diagnosis of aHUS by ruling out **both** of the following: a. Shiga toxin E. coli-related hemolytic uremic syndrome (STEC-HUS) b. Thrombotic thrombocytopenia purpura (TTP) (e.g., rule out ADAMTS13 deficiency) **and** 2. Soliris is initiated and titrated according to the US FDA labeled dosing for aHUS, up to a maximum of 1200 mg every 2 weeks;

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Soliris® (Eculizumab) *(continued)*	Aug. 1, 2018		**and** 3. Prescribed by or in consultation with a hematologist; **and** 4. Initial authorization will be for no more than 6 months. B. **Continuation Therapy**: 1. Patient has previously been treated with Soliris; **and** 2. Documentation demonstrating a positive clinical response from baseline (e.g., reduction of plasma exchanges, reduction of dialysis, increased platelet count, reduction of hemolysis); **and** 3. Soliris is dosed according to the US FDA labeled dosing for aHUS: 1200 mg every 2 weeks; **and** 4. Prescribed by or in consultation with a hematologist; **and** 5. Reauthorization will be for no more than 12 months. II. **Paroxysmal nocturnal hemoglobinuria (PNH)** **Soliris is medically necessary when all of the following criteria are met**: A. **Initial Therapy:** 1. Documentation supporting the diagnosis of PNH with at least **one** of the following criteria: a. At least 10% PNH type III red cells b. Greater than 50 % of glycosylphosphatidylinositol-anchored proteins (GPI-AP)-deficient poly-morphonuclear cells (PMNs) **and** 2. **One** of the following: a. Patient is transfusion dependent as defined as **one** of the following: i. Hemoglobin ≤ 7 g/dL ii. **Both** of the following 1) Hemoglobin ≤ 9 g/dL 2) Patient is experiencing symptoms of anemia **or** b. Patient has a documented history of major adverse vascular events from thromboembolism **and** 3. Soliris is initiated and titrated according to the US FDA labeled dosing for PNH, up to a maximum of 900 mg every 2 weeks; **and** 4. Prescribed by or in consultation with a hematologist; **and** 5. Initial authorization will be for no more than 6 months. B. **Continuation Therapy**:

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Soliris® (Eculizumab) *(continued)*	Aug. 1, 2018		1. Patient has previously been treated with Soliris; **and** 2. Documentation demonstrating a positive clinical response from baseline (e.g., increased or stabilization of hemoglobin levels, reduction in transfusions, etc.); **and** 3. Soliris is dosed according to the US FDA labeled dosing for PNH: 900 mg every 2 weeks; **and** 4. Prescribed by or in consultation with a hematologist; **and** 5. Reauthorization will be for no more than 12 months. III. **Generalized myasthenia gravis**: **Soliris is medically necessary when all of the following criteria are met:** A. For **initial therapy, all** of the following: 1. Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of generalized myasthenia gravis (gMG) by a neurologist or in consultation with a neurologist confirming **all** of the following: a. Patient has not failed a previous course of Soliris therapy; **and** b. Positive serologic test for anti-AChR antibodies; **and** c. **One** of the following: i. History of abnormal neuromuscular transmission test demonstrated by single-fiber electromyography (SFEMG) or repetitive nerve stimulation ii. History of positive anticholinesterase test, e.g., edrophonium chloride test iii. Patient has demonstrated improvement in MG signs on oral cholinesterase inhibitors, as assessed by the treating neurologist **and** d. Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy; **and** e. Patient has a Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score ≥ 6 at initiation of therapy; **and** 2. **Both** of the following: a. History of failure of at least **two** immunosuppressive agent over the course of at least 12 months [e.g., azathioprine,

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Soliris® (Eculizumab) *(continued)*	Aug. 1, 2018		methotrexate, cyclosporine, mycophenylate, etc.]; **and** b. Patient has required 2 or more courses of plasmapheresis/ plasma exchanges and/or intravenous immune globulin for at least 12 months without symptom control **and** 3. Patient is currently on a stable dose (at least 2 months) of immunosuppressive therapy; **and** 4. Soliris is initiated and titrated according to the US FDA labeled dosing for gMG, up to a maximum of 1200 mg every 2 weeks; **and** 5. Prescribed by or in consultation with a Neurologist; **and** 6. Initial authorization will be for no more than 6 months. B. For **continuation therapy, all** of the following**:** 1. Patient has previously been treated with Soliris; **and** 2. Submission of medical records (e.g., chart notes, laboratory tests) to demonstrate a positive clinical response from baseline as demonstrated by at least **all** of the following: a. Improvement and/or maintenance of at least a 3 point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline. b. Reduction in signs and symptoms of myasthenia gravis c. Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Soliris.* ***Note:** Add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on Soliris therapy will be considered as treatment failure. **and** 3. Soliris is dosed according to the US FDA labeled dosing for gMG: up to a maximum of 1200 mg every 2 weeks; **and** 4. Prescribed by or in consultation with a Neurologist; **and** 5. Reauthorization will be for no more than 12 months. **Soliris is unproven and not medically necessary for treatment of Shiga toxin E. coli-related hemolytic uremic syndrome (STEC-HUS).**

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Home Health Care	Aug. 1, 2018	• Updated list of applicable CPT codes; revised description for 99602 • Updated list of applicable HCPCS codes; revised description for S5523, S9211, S9212, S9348, S9494, S9503, S9504, S9542, and S9559
Skilled Care and Custodial Care Services	Aug. 1, 2018	• Added language to indicate the definitions listed in the policy may not apply to all plans; refer to the member specific benefit plan document for applicable definitions • Updated supporting information to reflect the most current references; no change to coverage rationale or lists of applicable codes