

UnitedHealthcare Oxford Policy Update Bulletin: November 2023

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Policy Title	Effective Date	Summary of Changes
Infertility Diagnosis, Treatment, and Fertility Preservation	Jan. 1, 2024	<p>Documentation Requirements</p> <ul style="list-style-type: none"> Updated list of CPT codes with associated documentation requirements; removed 0568T <p>Applicable Codes</p> <ul style="list-style-type: none"> Removed CPT code 0568T; refer to the Clinical Policy titled <i>Omnibus Codes</i>
Pharmacogenetic Panel Testing	Jan. 1, 2024	<p>Coverage Rationale</p> <ul style="list-style-type: none"> Removed list of examples of pharmacogenetic Multi-Gene Panels (5 or more genes) for genetic polymorphisms <p>Documentation Requirements</p> <ul style="list-style-type: none"> Updated list of CPT codes with associated documentation requirements; added 0029U, 0411U, and 0419U <p>Applicable Codes</p> <ul style="list-style-type: none"> Removed CPT codes 0286U, 0290U, 0291U, 0929U, and 0293U <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current information
Plagiocephaly and Craniosynostosis Treatment	Nov. 1, 2023	<p>Related Policies</p> <ul style="list-style-type: none"> Removed reference link to the Clinical Policy titled <i>Upper Extremity Myoelectric Prosthetic Devices</i> <p>Documentation Requirements</p> <ul style="list-style-type: none"> Updated list of required clinical information; replaced: <ul style="list-style-type: none"> “Diagnosis and <i>reason</i> for the <i>orthotic</i>” with “diagnosis and <i>indication(s)</i> for <i>cranial orthosis</i>” “Physical exam <i>related to support the need of the orthotic; include the neurological, circulatory, skin, and musculoskeletal examination that supports the request, as well as</i> presence or absence of torticollis” with “<i>general physical exam including presence or absence of torticollis</i>” “Documentation of treatments tried, failed, or contraindicated; include the dates and reason for discontinuation” with “documentation of treatments tried, failed, or contraindicated; include the dates, <i>duration</i>, and reason for discontinuation” “Orthotist notes to include equipment quote with billing codes <i>and cost</i>” with “orthotist notes to include equipment quote with billing codes” “Date <i>and type of injury/surgery</i>, if applicable” with “date <i>of planned or completed craniosynostosis surgery</i>, if applicable” “Provide [the listed additional criteria] for a <i>replacement</i> request” with “provide [the listed additional criteria] for a request <i>for continuation of treatment with a new cranial orthotic</i>”

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Surgery of the Elbow	Nov. 1, 2023	<p>Documentation Requirements</p> <ul style="list-style-type: none"> Updated list of CPT codes with associated documentation requirements; added 29835 and 29836 Updated list of required clinical information; replaced “prior therapies/treatments tried, failed, or contraindicated; include the dates and reason for discontinuation” with “prior therapies/treatments tried, failed, or contraindicated; include the dates, <i>duration</i>, and reason for discontinuation”
Surgery of the Shoulder	Nov. 1, 2023	<p>Documentation Requirements</p> <ul style="list-style-type: none"> Updated list of required clinical information: <ul style="list-style-type: none"> Replaced: <ul style="list-style-type: none"> “Severity of pain <i>as documented on a validated pain scale</i> and functional disability(ies) <i>as documented on a validated functional disability scale or described as interfering with activities of daily living (preparing meals, dressing, driving, walking)</i>” with “severity of pain and <i>details of functional disability(ies) interfering with activities of daily living (ADLs)</i>” “Upon request, we may require the specific diagnostic image(s) <i>that documents the severity of joint disease using a validated scale (e.g., Walch classification of primary glenohumeral osteoarthritis)</i> and that shows the abnormality for which surgery is being requested” with “upon request, we may require the specific diagnostic image(s) that shows the abnormality for which surgery is being requested” “Therapies tried (<i>including dates</i>) and failed <i>as documented by a lack of clinically significant improvement between at least two measurements concurrent to the therapy, on validated pain or functional disability scale(s) or quantifiable symptoms; these therapies could include: nonoperative therapy (i.e., orthotics, medications/injections, physical therapy, other pain management procedures, etc.) and/or surgery</i>” with “<i>prior therapies/ treatments tried, failed, or contraindicated; include the dates, duration, and reason for discontinuation</i>” “If the location is being requested as an inpatient stay, provide medical notes to support <i>at least one of the following: surgery is bilateral, member has significant co-morbidities, and/or the member does not have appropriate resources to support post-operative care after an outpatient procedure</i>” with “if the location is being requested as an inpatient stay, provide medical notes to support <i>site of service</i>” Removed: <ul style="list-style-type: none"> Advanced joint disease using a validated scale (e.g., Walch classification of primary glenohumeral osteoarthritis) <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Clinical Evidence, FDA, and References</i> sections to reflect the most current information

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Surgical Treatment of Lymphedema	Nov. 1, 2023	<p>Definitions</p> <ul style="list-style-type: none"> Updated definition of “Liposuction/Lipectomy” <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current information 	
Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Electroretinography	Jan. 1, 2024	<p>Title Change/Template Update</p> <ul style="list-style-type: none"> Relocated and reformatted content previously included in the Clinical Policy titled <i>Omnibus Codes</i> <p>Supporting Information</p> <ul style="list-style-type: none"> Added <i>Description of Services</i> and <i>FDA</i> sections Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information 	<p>Multifocal Electroretinogram (mfERG)</p> <p>Multifocal electroretinogram (mfERG) is proven and medically necessary for chloroquine (CQ) and hydroxychloroquine (HCQ) retinopathy screening.</p> <p>Multifocal electroretinogram (mfERG) is unproven and not medically necessary for all other indications due to insufficient evidence of safety and/or efficacy.</p> <p>Pattern Electroretinogram (PERG)/Pattern Electroretinogram Optimized for Glaucoma Screening (PERGLA)</p> <p>Pattern electroretinogram (PERG) or pattern electroretinogram optimized for glaucoma screening (PERGLA) are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.</p>
Injectables for Reconstructive Procedures	Jan. 1, 2024	<p>Title Change/Template Update</p> <ul style="list-style-type: none"> Relocated and reformatted content previously included in the Clinical Policy titled <i>Omnibus Codes</i> <p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised language to indicate: <ul style="list-style-type: none"> Radiesse and Sculptra are proven, medically necessary, and reconstructive for treating facial defects due to facial lipoatrophy in persons with human immunodeficiency virus 	<p>Dermal Filler Injections</p> <p>Radiesse and Sculptra are proven, medically necessary and reconstructive for treating facial defects due to facial lipoatrophy in persons with human immunodeficiency virus (HIV). The use of other dermal filler products is considered cosmetic.</p> <p>Injectable Bulking Agents</p> <p>Injectable bulking agents (e.g., Prolaryn, Prolaryn Plus®) are proven, medically necessary and reconstructive for treatment of vocal fold insufficiency/dysfunction when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and</p>

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Injectables for Reconstructive Procedures (continued)	Jan. 1, 2024	<p>(HIV); the use of other dermal filler products is considered cosmetic</p> <ul style="list-style-type: none"> ○ Injectable bulking agents (e.g., Prolaryn, Prolaryn Plus®) are proven, medically necessary, and reconstructive for treatment of vocal fold insufficiency/dysfunction when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions <p>Documentation Requirements (new to policy)</p> <ul style="list-style-type: none"> ● Added language to indicate HCPCS code Q2026 requires medical notes documenting the following, when applicable: <ul style="list-style-type: none"> ○ History of medical conditions requiring treatment or surgical intervention which includes a well-defined physical/physiologic abnormality resulting in a medical condition that requires treatment to prove medical necessity ○ High-quality color photograph(s): <ul style="list-style-type: none"> ▪ All photographs must be labeled with the: 	precautions.

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Injectables for Reconstructive Procedures (continued)	Jan. 1, 2024	<ul style="list-style-type: none"> - Date taken - Applicable case number obtained at time of notification, or the member's name and ID number on the photograph(s) ▪ Submission of color image(s) are required and can be submitted via the external portal at uhcprovider.com/paan; faxes will not be accepted <p>Supporting Information</p> <ul style="list-style-type: none"> • Added <i>Description of Services</i> and <i>FDA</i> sections • Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information 	
Light and Laser Therapy	Jan. 1, 2024	<p>Coverage Rationale</p> <ul style="list-style-type: none"> • Added language to indicate: <ul style="list-style-type: none"> ○ Laser hair removal is proven and medically necessary for the treatment of pilonidal sinus disease that has been or is being treated with surgery performed to debride an accumulation of fluid or pus causing the formation of a cyst or abscess ○ Fractional ablative laser fenestration [e.g., carbon dioxide (CO₂) laser, Erbium 	<p>Pulsed dye laser therapy is proven and medically necessary for treating the following:</p> <ul style="list-style-type: none"> • Port-wine stains • Cutaneous hemangioma/hemangiomata <p>Laser hair removal is proven and medically necessary for the treatment of pilonidal sinus disease that has been or is being treated with surgery performed to debride an accumulation of fluid or pus causing the formation of a cyst or abscess.</p> <p>Fractional ablative laser fenestration [e.g., carbon dioxide (CO₂) laser, Erbium Yttrium Aluminum Garnet (Er:YAG) laser] of hypertrophic burn scars is proven and medically necessary when both of the following criteria are met:</p>

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Light and Laser Therapy (continued)	Jan. 1, 2024	<p>Yttrium Aluminum Garnet (Er:YAG) laser] of hypertrophic burn scars is proven and medically necessary when both of the following criteria are met:</p> <ul style="list-style-type: none"> ▪ The burn scar is causing functional impairment (i.e., limiting range of motion) and the treatment can be reasonably expected to improve the functional impairment ▪ The individual has tried and failed at least one conventional treatment (e.g., hypoallergenic paper tape, pressure garments, or silicone kits with gel/sheeting) <ul style="list-style-type: none"> ○ Neodymium: Yttrium-Aluminum-Garnet (Nd:YAG) and excimer are unproven and not medically necessary for treating rosacea, rhinophyma, and acne vulgaris <ul style="list-style-type: none"> • Removed language indicating laser hair removal is unproven and not medically necessary for treating pilonidal sinus disease due to insufficient evidence of efficacy • Replaced language indicating “pulsed dye laser therapy is proven 	<ul style="list-style-type: none"> • The burn scar is causing functional impairment (i.e., limiting range of motion) and the treatment can be reasonably expected to improve the functional impairment; and • The individual has tried and failed at least one conventional treatment (e.g., hypoallergenic paper tape, pressure garments or silicone kits with gel/sheeting) <p>Light and laser therapy including, but not limited to, intense pulsed light, light phototherapy, photodynamic therapy, Neodymium: Yttrium-Aluminum-Garnet (Nd:YAG), excimer, and pulsed dye laser are unproven and not medically necessary for treating the following due to insufficient evidence of efficacy:</p> <ul style="list-style-type: none"> • Rosacea • Rhinophyma • Acne vulgaris

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Light and Laser Therapy (continued)	Jan. 1, 2024	<p>and medically necessary for treating cutaneous hemangiomas with “pulsed dye laser therapy is proven and medically necessary for treating cutaneous <i>hemangioma</i>/hemangiomas”</p> <p>Documentation Requirements</p> <ul style="list-style-type: none"> Revised list of required clinical information; added: <ul style="list-style-type: none"> Specific location and size of the lesion Treatments tried, failed, contraindicated, or on-going; include the dates, duration, and reason for discontinuation Submission of color image(s) are required and can be submitted via the external portal at uhcprovider.com/paan; faxes will not be accepted <p>Applicable Codes</p> <ul style="list-style-type: none"> Added CPT codes 0479T, 0480T, and 17999 Added ICD-10 diagnosis codes L05.01, L05.02, L05.91, L05.92, L90.5, and L91.0 Removed ICD-10 diagnosis codes Q85.81, Q85.82, Q85.83, and Q85.9 <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, <i>FDA</i>, and 	

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Light and Laser Therapy (continued)	Jan. 1, 2024	<p><i>References</i> sections to reflect the most current information</p> <ul style="list-style-type: none"> Removed <i>Benefit Considerations</i> section 	
Minimally Invasive Procedures for Gastric and Esophageal Diseases	Jan. 1, 2024	<p>Title Change</p> <ul style="list-style-type: none"> Previously titled <i>Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) and Achalasia</i> <p>Coverage Rationale</p> <ul style="list-style-type: none"> Replaced language indicating “per oral endoscopic myotomy (POEM) is <i>considered</i> unproven and not medically necessary for all other indications [not listed as proven and medically necessary] (e.g., Zenker’s diverticula)” with “per oral endoscopic myotomy (POEM) is unproven and not medically necessary for all other indications [not listed as proven and medically necessary] (e.g., Zenker’s diverticula)” Added language to indicate: <ul style="list-style-type: none"> Gastric peroral endoscopic myotomy (G-POEM) is unproven and not medically necessary for the treatment of gastroparesis Functional lumen imaging probe technology is unproven and not medically necessary for diagnosing achalasia 	<p>The per oral endoscopic myotomy (POEM) procedure is proven and medically necessary for Achalasia or Diffuse Esophageal Spasm.</p> <p>Per oral endoscopic myotomy (POEM) is unproven and not medically necessary for all other indications (e.g., Zenker’s diverticula) due to insufficient evidence.</p> <p>Gastric peroral endoscopic myotomy (G-POEM) is unproven and not medically necessary for the treatment of Gastroparesis.</p> <p>The following are unproven and not medically necessary for treating Gastroesophageal Reflux Disease (GERD) due to insufficient evidence of efficacy:</p> <ul style="list-style-type: none"> Endoscopic therapies Injection or implantation techniques LINX Reflux Management System <p>Functional lumen imaging probe technology is unproven and not medically necessary for diagnosing Achalasia.</p> <p>Endoluminal therapy with GERDx™ is investigational, unproven, and not medically necessary for treating GERD as it has not received U.S. Food and Drug Administration (FDA) approval.</p> <p>Refer to the Clinical Policy titled Bariatric Surgery for information regarding endoscopic therapies for the treatment of obesity.</p>

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Minimally Invasive Procedures for Gastric and Esophageal Diseases (continued)	Jan. 1, 2024	<p>Definitions</p> <ul style="list-style-type: none"> Added definition of “Gastroparesis” Updated definition of “Diffuse Esophageal Spasm” <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services, Clinical Evidence, FDA, and References</i> sections to reflect the most current information 	
Molecular Oncology Companion Diagnostic Testing	Jan. 1, 2024	<p>Title Change/Template Update</p> <ul style="list-style-type: none"> Relocated and reformatted content previously included in the Clinical Policy titled <i>Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions</i> <p>Related Policies</p> <ul style="list-style-type: none"> Added reference link to the Clinical Policy titled: <ul style="list-style-type: none"> <i>Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and Treatment Decisions</i> <i>Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions</i> <p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised language to indicate: <ul style="list-style-type: none"> Companion Diagnostic Tests using Comprehensive Genomic Profiling (CGP) are 	<p>Companion Diagnostic Tests using Comprehensive Genomic Profiling (CGP) are considered proven and medically necessary when used for the appropriate oncology indication when all of the following criteria are met:</p> <ul style="list-style-type: none"> Indication has a corresponding diagnostic test and biomarker on the List of Cleared or Approved Companion Diagnostic Devices FDA No Comprehensive Genomic Profiling (CGP) has been performed previously for this tumor type and stage If testing is done via Liquid Biopsy [e.g., FoundationOne® Liquid CDx (CPT code 0239U) or Guardant360® CDx (CPT code 0242U)], one of the following criteria must be met: <ul style="list-style-type: none"> The individual undergoing testing is not medically fit for invasive biopsy; or Tumor tissue testing is not feasible; or Circulating tumor DNA (ctDNA) testing is the proven method for detection of the specific biomarker (e.g., <i>ESR1</i> resistance mutations) <p>Companion Diagnostic Tests using Comprehensive Genomic Profiling (CGP) which do not meet the above requirements are considered unproven and not medically necessary.</p> <p>Note: For anaplastic thyroid cancer, refer to the Clinical Policy titled Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions. For acute myeloid leukemia, refer to the Clinical Policy titled Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and</p>

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Molecular Oncology Companion Diagnostic Testing (continued)	Jan. 1, 2024	<p>considered proven and medically necessary when used for the appropriate oncology indication when all of the following criteria are met:</p> <ul style="list-style-type: none"> ▪ Indication has a corresponding diagnostic test and biomarker on the <i>FDA List of Cleared or Approved Companion Diagnostic Devices</i> ▪ No Comprehensive Genomic Profiling (CGP) has been performed previously for this tumor type and stage ▪ If testing is done via Liquid Biopsy [e.g., FoundationOne® Liquid CDx (CPT code 0239)] or Guardant360® CDx (CPT code 0242U)], one of the following criteria must be met: <ul style="list-style-type: none"> – The individual undergoing testing is not medically fit for invasive biopsy – Tumor tissue testing is not feasible – Circulating tumor DNA (ctDNA) testing is the proven method for 	Treatment Decisions.

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Molecular Oncology Companion Diagnostic Testing (continued)	Jan. 1, 2024	<p>detection of the specific biomarker (e.g., ESR1 resistance mutations)</p> <ul style="list-style-type: none"> ○ Companion Diagnostic Tests using Comprehensive Genomic Profiling (CGP) which do not meet the above requirements are considered unproven and not medically necessary ○ For anaplastic thyroid cancer, refer to the Clinical Policy titled <i>Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions</i> ○ For acute myeloid leukemia, refer to the Clinical Policy titled <i>Molecular Oncology Testing for Hematological Cancer Diagnosis, Prognosis, and Treatment Decisions</i> <p>Documentation Requirements</p> <ul style="list-style-type: none"> ● Updated list of CPT codes with associated documentation requirements to indicate 0022U, 0037U, 0179U, 0239U, 0242U, 81445, 81449, 81450, 81451, 81455, 81479, and 81599 require medical notes documenting the following, when applicable: <ul style="list-style-type: none"> ○ Cancer type and stage 	

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Molecular Oncology Companion Diagnostic Testing (continued)	Jan. 1, 2024	<ul style="list-style-type: none"> ○ Results of prior comprehensive genomic profiling, if applicable ○ Proposed treatment based on results of genetic testing (if available) <p>Definitions</p> <ul style="list-style-type: none"> ● Added definition of: <ul style="list-style-type: none"> ○ Advanced Cancer ○ Companion Diagnostic Test ● Removed definition of: <ul style="list-style-type: none"> ○ Comparative Genome Hybridization (CGH) ○ Chromosome Microarray Analysis (CMA) ○ Favorable Intermediate-Risk Prostate Cancer ○ Gene Expression Profiling (GEP) ○ Low-Risk Prostate Cancer ○ Predictive Molecular Markers ○ Prognostic Molecular Markers ○ Very Low-Risk Prostate Cancer ○ Whole Exome Sequencing (WES) ○ Whole Genome Sequencing (WGS) ● Updated definition of: <ul style="list-style-type: none"> ○ Liquid Biopsy <p>Applicable Codes</p> <ul style="list-style-type: none"> ● Updated list of applicable CPT codes to reflect/include 0022U, 0037U, 0179U, 0239U, 0242U, 81445, 81449, 81450, 81451, 	

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Molecular Oncology Companion Diagnostic Testing (continued)	Jan. 1, 2024	<p>81455, 81456, 81479, and 81599</p> <ul style="list-style-type: none"> Removed list of applicable ICD-10 diagnosis codes <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, <i>FDA</i>, and <i>References</i> sections to reflect the most current information 	
Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and Treatment Decisions	Jan. 1, 2024	<p>Title Change/Template Update</p> <ul style="list-style-type: none"> Relocated and reformatted content previously included in the Clinical Policy titled <i>Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions</i> <p>Related Policies</p> <ul style="list-style-type: none"> Added reference link to the Clinical Policy titled: <ul style="list-style-type: none"> <i>Molecular Oncology Companion Diagnostic Testing</i> <i>Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions</i> <p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised language to indicate: <ul style="list-style-type: none"> The use of multigene panels (50 genes or fewer) at initial diagnosis and/or recurrence or relapse is proven and medically necessary when ordered by a hematologist or 	<p>The use of multigene panels (50 genes or fewer) at initial diagnosis and/or recurrence or relapse is proven and medically necessary when ordered by a hematologist or oncologist for individuals with:</p> <ul style="list-style-type: none"> Acute lymphoblastic leukemia; or Acute myeloid leukemia; or Multiple myeloma; or Myelodysplastic syndrome or myeloproliferative neoplasm is strongly suspected (as evidenced by order from hematologist/oncologist). <p>The use of Comprehensive Genomic Profiling (CGP) in an individual with relapsed/recurrent acute myeloid leukemia is proven and medically necessary (e.g., FoundationOne® Heme).</p> <p>Clonality assessment with clonoSEQ® Clonality ID at initial diagnosis and Measurable Residual Disease (MRD) testing with clonoSEQ® MRD are proven and medically necessary when ordered by a hematologist or oncologist for individuals with:</p> <ul style="list-style-type: none"> Acute lymphoblastic leukemia; or Multiple myeloma <p>Due to insufficient evidence of efficacy, all other molecular testing for hematologic cancer is unproven and not medically necessary. For companion diagnostic testing, refer to the Clinical Policy titled Molecular Oncology Companion Diagnostic Testing.</p>

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Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Jan. 1, 2024	<p>oncologist for individuals with:</p> <ul style="list-style-type: none"> ▪ Acute lymphoblastic leukemia ▪ Acute myeloid leukemia ▪ Multiple myeloma ▪ Myelodysplastic syndrome or myeloproliferative neoplasm is strongly suspected (as evidenced by order from hematologist/oncologist) <ul style="list-style-type: none"> ○ The use of Comprehensive Genomic Profiling (CGP) in an individual with relapsed/recurrent acute myeloid leukemia is proven and medically necessary (e.g., FoundationOne® Heme) ○ Clonality assessment with clonoSEQ® Clonality ID at initial diagnosis and Measurable Residual Disease (MRD) testing with clonoSEQ® MRD are proven and medically necessary when ordered by a hematologist or oncologist for individuals with: <ul style="list-style-type: none"> ▪ Acute lymphoblastic leukemia ▪ Multiple myeloma ○ Due to insufficient evidence of efficacy, all other molecular testing for hematologic cancer 	

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Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Jan. 1, 2024	<p>is unproven and not medically necessary; for companion diagnostic testing, refer to the Clinical Policy titled <i>Molecular Oncology Companion Diagnostic Testing</i></p> <p>Documentation Requirements</p> <ul style="list-style-type: none"> • Updated list of CPT codes with associated documentation requirements to indicate 0050U, 0171U, 0364U, 81450, 81451, 81455, 81479, and 81599 require medical notes documenting the following, when applicable: <ul style="list-style-type: none"> ○ Confirmed or suspected hematologic cancer type and stage, if available, date of diagnosis ○ Results of other diagnostic testing (e.g., blood smear, flow cytometry, FISH), if applicable ○ Proposed treatment based on results of genetic testing (if available) <p>Definitions</p> <ul style="list-style-type: none"> • Added definition of: <ul style="list-style-type: none"> ○ Measurable Residual Disease (MRD) • Removed definition of: <ul style="list-style-type: none"> ○ Comparative Genome Hybridization (CGH) ○ Chromosome Microarray Analysis (CMA) 	

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Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Jan. 1, 2024	<ul style="list-style-type: none"> ○ Favorable Intermediate-Risk Prostate Cancer ○ Gene Expression Profiling (GEP) ○ Liquid Biopsy ○ Low-Risk Prostate Cancer ○ Predictive Molecular Markers ○ Prognostic Molecular Markers ○ Very Low-Risk Prostate Cancer ○ Whole Exome Sequencing (WES) ○ Whole Genome Sequencing (WGS) <p>Applicable Codes</p> <ul style="list-style-type: none"> ● Updated list of applicable CPT codes to reflect/include 0017M, 0050U, 0120U, 0171U, 0285U, 0296U, 0331U, 0364U, 81450, 81451, 81455, 81456, 81479, and 81599 ● Removed list of applicable ICD-10 diagnosis codes <p>Supporting Information</p> <ul style="list-style-type: none"> ● Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, <i>FDA</i>, and <i>References</i> sections to reflect the most current information 	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions	Jan. 1, 2024	<p>Title Change</p> <ul style="list-style-type: none"> Previously titled <i>Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions</i> <p>Related Policies</p> <ul style="list-style-type: none"> Added reference link to the Clinical Policy titled: <ul style="list-style-type: none"> <i>Molecular Oncology Companion Diagnostic Testing</i> <i>Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and Treatment Decisions</i> <p>Coverage Rationale</p> <ul style="list-style-type: none"> Added language to indicate this policy applies to tests that have not been granted approval as an FDA cleared or approved Companion Diagnostic Removed language pertaining to: <ul style="list-style-type: none"> Companion Diagnostics; refer to the Clinical Policy titled <i>Molecular Oncology Companion Diagnostic Testing</i> Hematological cancer testing; refer to the Clinical Policy titled <i>Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and Treatment Decisions</i> Revised list of unproven and not medically necessary gene 	<p>This policy applies to tests that have not been granted approval as an FDA cleared or approved Companion Diagnostic.</p> <p>Breast Cancer Gene Expression Profiling (GEP)</p> <p>The use of one of the following GEP tests: MammaPrint®, Oncotype Dx® Breast, Prosigna® Breast Cancer Prognostic Gene Signature Assay (formerly PAM-50), Breast Cancer Index™ (BCI), and EndoPredict® is proven and medically necessary when used to inform treatment decisions in individual with invasive breast cancer in the following situations:</p> <ul style="list-style-type: none"> Newly diagnosed (within the last 6 months) when all the following criteria are met: <ul style="list-style-type: none"> Lymph node negative (including lymph node with micrometastases no greater than 2 mm) or 1-3 positive ipsilateral axillary lymph nodes diagnosed via surgical resection of tumor (not biopsy); and No distant metastases; 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); or Currently receiving adjuvant hormonal therapy (e.g., Tamoxifen or an aromatase inhibitor) for a breast cancer when all of the following criteria are met: <ul style="list-style-type: none"> Hormone receptor-positive (estrogen receptor positive, progesterone receptor positive or both); and HER2 receptor negative; 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 a decision regarding extended adjuvant hormonal therapy. <p>The use of more than one predictive GEP for the same tumor in an individual</p>

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Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Jan. 1, 2024	<p>expression profiling (GEP), multigene Next Generation Sequencing (NGS) panels, and/or comprehensive genomic profiling (CGP) for molecular testing of solid tumors:</p> <ul style="list-style-type: none"> ○ Added “whole genome methylation testing for tumors” ○ Removed “Prolaris® Prostate Cancer Test” ○ Replaced “tumor-informed assays (e.g., Invitae Personalized Cancer Monitoring, Signatera™, RaDaR®) and MRD <i>monitoring for solid tumors</i> (e.g., Guardant Reveal™)” with “tumor-informed <i>and tumor-naïve</i> minimal residual disease (MRD) assays (e.g., Invitae Personalized Cancer Monitoring, Signatera™, RaDaR®, Guardant Reveal™, <i>Guardant Response™</i>)” <p>Lung Cancer</p> <ul style="list-style-type: none"> ● Added reference link to the Clinical Policy titled <i>Molecular Oncology Companion Diagnostic Testing</i> <p>Prostate Cancer Gene Expression Profiling (GEP)</p> <ul style="list-style-type: none"> ● Revised language to indicate: <ul style="list-style-type: none"> ○ The use of the Oncotype DX® Genomic Prostate Score (GPS) is proven and medically 	<p>with breast cancer is unproven and not medically necessary due to insufficient evidence of efficacy.</p> <p>Note: This does not apply to BCI testing, which can be used once in the evaluation of the role of extended endocrine therapy in a breast cancer that may have already had GEP to determine the role of adjuvant chemotherapy.</p> <p>Due to insufficient evidence of efficacy, GEP for breast cancer for indications [including ductal carcinoma in situ (DCIS)] or treatment decisions other than those previously described as proven are unproven and not medically necessary. Such tests may include, but are not limited to:</p> <ul style="list-style-type: none"> ● BluePrint ● DCISionRT® ● Oncotype DX Breast DCIS Score® test <p>Lung Cancer</p> <p>Molecular profiling of solid tumor tissue in metastatic non-small cell lung cancer is proven and medically necessary when the following criteria are met:</p> <ul style="list-style-type: none"> ● No prior molecular profiling has been performed on the same tumor; and ● One of the following: <ul style="list-style-type: none"> ○ The multigene Next Generation Sequencing (NGS) panel selected has no more than 50 genes; or ○ Individual meets criteria for companion diagnostic testing* <p>Liquid Biopsy [cell-free DNA (cfDNA) or circulating tumor DNA (ctDNA)] molecular profiling tests of non-small cell lung cancer are proven and medically necessary when the following criteria are met:</p> <ul style="list-style-type: none"> ● No prior molecular profiling has been performed on the same tumor; and ● The individual is not medically fit for invasive biopsy or tumor tissue testing is not feasible; and ● One of the following: <ul style="list-style-type: none"> ○ The multigene NGS panel selected has no more than 50 genes; or

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Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Jan. 1, 2024	<p>necessary for individuals with biopsy-proven, untreated, localized adenocarcinoma of the prostate (no clinical evidence of metastasis or lymph node involvement) when:</p> <ul style="list-style-type: none"> ▪ Test is ordered by a physician specializing in the treatment of organ confined prostate cancer including surgical oncology/urology, radiation oncology or medical oncology ▪ Results will be used to assist with treatment decision-making when the individual has not yet received treatment for prostate cancer and is a candidate for either active surveillance or definitive therapy and all of the following: <ul style="list-style-type: none"> – Life expectancy is greater than 10 years – Risk group is one of the following: <ul style="list-style-type: none"> • Very Low-Risk Prostate Cancer • Low-Risk Prostate Cancer 	<ul style="list-style-type: none"> ○ Individual meets criteria for companion diagnostic testing* <p>*Refer to the Clinical Policy titled Molecular Oncology Companion Diagnostic Testing.</p> <p>Prostate Cancer Gene Expression Profiling (GEP)</p> <p>The use of the Oncotype DX® Genomic Prostate Score (GPS) is proven and medically necessary for individuals with biopsy-proven, untreated, localized adenocarcinoma of the prostate (no clinical evidence of metastasis or lymph node involvement) when:</p> <ul style="list-style-type: none"> • Test is ordered by a physician specializing in the treatment of organ confined prostate cancer including surgical oncology/urology, radiation oncology or medical oncology; and • Results will be used to assist with treatment decision-making when the individual has not yet received treatment for prostate cancer and is a candidate for either active surveillance or definitive therapy and all of the following: <ul style="list-style-type: none"> ○ Life expectancy is greater than 10 years; and ○ Risk group is one of the following: <ul style="list-style-type: none"> ▪ Very Low-Risk Prostate Cancer; or ▪ Low-Risk Prostate Cancer; or ▪ Favorable Intermediate-Risk Prostate Cancer. <p>The use of the Prolaris® Biopsy prostate cancer prognostic test or Decipher® Prostate Biopsy genomic classifier is proven and medically necessary for individuals with biopsy-proven, untreated, localized adenocarcinoma of the prostate (no clinical evidence of metastasis or lymph node involvement) when:</p> <ul style="list-style-type: none"> • Test is ordered by a physician specializing in the treatment of organ confined prostate cancer including surgical oncology/urology, radiation oncology or medical oncology; and • Results will be used to assist with treatment decision-making when the individual has not yet received treatment for prostate cancer and is a

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Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Jan. 1, 2024	<ul style="list-style-type: none"> • Favorable Intermediate-Risk Prostate Cancer ○ The use of the Prolaris[®] Biopsy prostate cancer prognostic test or Decipher[®] Prostate Biopsy genomic classifier is proven and medically necessary for individuals with biopsy-proven, untreated, localized adenocarcinoma of the prostate (no clinical evidence of metastasis or lymph node involvement) when: <ul style="list-style-type: none"> ▪ Test is ordered by a physician specializing in the treatment of organ confined prostate cancer including surgical oncology/urology, radiation oncology or medical oncology ▪ Results will be used to assist with treatment decision-making when the individual has not yet received treatment for prostate cancer and is a candidate for either active surveillance or definitive therapy and all of the following: <ul style="list-style-type: none"> – Life expectancy 	<p>candidate for either active surveillance or definitive therapy and all of the following:</p> <ul style="list-style-type: none"> ○ Life expectancy greater than 10 years; and ○ Risk group is one of the following: <ul style="list-style-type: none"> ▪ Very Low-Risk Prostate Cancer; or ▪ Low-Risk Prostate Cancer; or ▪ Favorable Intermediate-Risk Prostate Cancer; or ▪ Unfavorable Intermediate-Risk Prostate Cancer; or ▪ High-Risk Prostate Cancer <p>The use of Decipher Prostate RP genomic classifier is proven and medically necessary to inform adjuvant treatment after radical prostatectomy for either of the following:</p> <ul style="list-style-type: none"> • Adverse features are found (e.g., high-grade disease, Gleason score 8 or higher, extracapsular extension, positive surgical margins, seminal vesicle invasion); or • PSA is greater than zero at any point following prostatectomy. <p>Molecular screening panel tests for prostate cancer are unproven and not medically necessary due to insufficient evidence of efficacy (e.g., ExoDx[™] Prostate Test, My Prostate Score[™], Confirm MDx[™], Select MDx[™]).</p> <p>Thyroid Cancer or Indeterminate Thyroid Nodule Testing</p> <p>The use of GEP testing for thyroid nodules with indeterminate cytology [e.g., Afirma[®] Genomic Sequencing Classifier (GSC), ThyroSeq[®] V3, ThyGeNEXT[®]/ThyraMIR[®]] is proven and medically necessary when all of the following criteria are met:</p> <ul style="list-style-type: none"> • Follicular pathology on fine needle aspiration is indeterminate (Bethesda III/IV); and • The results of the test will be used for making decisions about further surgery. <p>Due to insufficient evidence of efficacy, molecular tests for indeterminate</p>

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Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Jan. 1, 2024	<ul style="list-style-type: none"> greater than 10 years – Risk group is one of the following: <ul style="list-style-type: none"> • Very Low-Risk Prostate Cancer • Low-Risk Prostate Cancer • Favorable Intermediate-Risk Prostate Cancer • Unfavorable Intermediate-Risk Prostate Cancer • High-Risk Prostate Cancer ○ The use of Decipher Prostate RP genomic classifier is proven and medically necessary to inform adjuvant treatment after radical prostatectomy for either of the following: <ul style="list-style-type: none"> ▪ Adverse features are found (e.g., high-grade disease, Gleason score 8 or higher, extracapsular extension, positive surgical margins, seminal vesicle invasion) ▪ PSA is greater than zero at any point following prostatectomy ○ Molecular screening panel tests for prostate cancer are 	<p>thyroid nodules other than those previously described as proven are unproven and not medically necessary, including but not limited to:</p> <ul style="list-style-type: none"> • Afirma® Xpression Atlas (XA) • Comprehensive Genomic Profiling (CGP) (e.g., NeoTYPE® Thyroid Profile). <p>The use of more than one molecular profile test in an individual with an indeterminate thyroid nodule is unproven and not medically necessary due to insufficient evidence of efficacy.</p> <p>CGP of confirmed anaplastic thyroid cancer is proven and medically necessary.</p> <p>Uveal Melanoma Gene Expression Profiling (GEP) GEP (e.g., DecisionDx®-UM) is considered proven and medically necessary when used to assist with predicting disease severity and making treatment decisions in the following situations:</p> <ul style="list-style-type: none"> • Individual has primary, localized uveal melanoma; and • There is no evidence of metastatic disease; and • Individual has not previously had DecisionDx-UM testing for current diagnosis. <p>Due to insufficient evidence of efficacy, all other molecularly testing of solid tumors with GEP, multi-gene NGS panels and/or CGP is unproven and not medically necessary, including but not limited to:</p> <ul style="list-style-type: none"> • NGS panels of > 50 genes unless otherwise specified • Decipher® Bladder • Response-Dx Tissue of Origin™, CancerTYPE ID®, Rosetta Cancer Origin™, ProOnc • Oncotype DX® colon cancer assay, Colorectal Cancer DSA™, Genefx™ Colon (also known as ColDx), OncoDefender™-CRC, ColoPrint®) • Decision Dx®-Melanoma, DermTech PLA™, myPath®-Melanoma) • MyPRS®/MyPRS Plus™ • Multi-cancer early detection/screening tests (e.g., Galleri®)

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Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Jan. 1, 2024	<p>unproven and not medically necessary due to insufficient evidence of efficacy (e.g., ExoDx™ Prostate Test, My Prostate Score™, Confirm MDx™, Select MDx™)</p> <p>Thyroid Cancer or Indeterminate Thyroid Nodule Testing</p> <ul style="list-style-type: none"> Removed instruction to refer to the criteria for FoundationOne® CDx for all other primary thyroid cancers <p>Documentation Requirements</p> <ul style="list-style-type: none"> Updated list of CPT codes with associated documentation requirements to reflect/include 0018U, 0022U, 0026U, 0037U, 0047U, 0048U, 0179U, 0211U, 0239U, 0242U, 0244U, 0245U, 0250U, 0285U, 0287U, 0288U, 0306U, 0307U, 0326U, 0332U, 0334U, 0379U, 0388U, 0391U, 0409U, 81445, 81449, 81455, 81479, 81518, 81519, 81520, 81521, 81522, 81523, 81541, 81542, 81546, 81552, and 81599 <p>Definitions</p> <ul style="list-style-type: none"> Added definition of: <ul style="list-style-type: none"> High-Risk Prostate Cancer Unfavorable Intermediate-Risk Prostate Cancer Very High-Risk Prostate Cancer Removed definition of: 	<ul style="list-style-type: none"> TMPRSS2 fusion gene, ExoDx™ Prostate Test, MiPS (Mi Prostate Score Urine test), MyProstateScore (MPS, formerly MiPS), Confirm MDx™, Select MDx™ Tumor-informed and tumor-naïve MRD assays (e.g., Invitae Personalized Cancer Monitoring, Signatera™, RaDaR®, Guardant Reveal™, Guardant Response™) Percepta® GSC for suspicious lung nodules Solid tumor profiling that includes Whole Exome, Whole Genome or whole transcriptome Sequencing (e.g., Caris MI Tumor Seek™, Caris MI Profile™, Tempus xE) Whole genome methylation testing for tumors

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Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Jan. 1, 2024	<ul style="list-style-type: none"> ○ Chromosome Microarray Analysis (CMA) ○ Predictive Molecular Markers ○ Prognostic Molecular Markers ● Updated definition of: <ul style="list-style-type: none"> ○ Favorable Intermediate-Risk Prostate Cancer ○ Liquid Biopsy ○ Low-Risk Prostate Cancer ○ Very Low-Risk Prostate Cancer <p>Applicable Codes</p> <ul style="list-style-type: none"> ● Removed CPT codes 0017M, 0021U, 0050U, 0118U, 0120U, 0171U, 0331U, 0364U, 81228, 81229, 81277, 81425, 81426, 81427, 81450, 81451, 86152, and 86153 ● Removed list of applicable ICD-10 diagnosis codes <p>Supporting Information</p> <ul style="list-style-type: none"> ● Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current information 	
Omnibus Codes	Jan. 1, 2024	<p>Coverage Rationale</p> <ul style="list-style-type: none"> ● Added coverage guidelines for: <p><i>Automated Visual Evoked Potentials (VEPs) for Visual Acuity Screening (CPT code 0333T)</i></p> <ul style="list-style-type: none"> ○ Added language to indicate the use of automated visual 	Refer to the policy for complete details.

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Omnibus Codes (continued)	Jan. 1, 2024	<p>evoked potentials (VEPs) for visual acuity screening is unproven and not medically necessary due to insufficient clinical evidence of safety and/or efficacy</p> <p><i>Electrocardiographic Body Surface Mapping (CPT codes 0695T and 0696T)</i></p> <ul style="list-style-type: none"> ○ Added language to indicate electrocardiographic body surface mapping is unproven and not medically necessary for the evaluation or treatment of cardiac disorders <p><i>Eye-Movement Analysis Without Spatial Calibration (CPT code 0615T)</i></p> <ul style="list-style-type: none"> ○ Added language to indicate eye-movement analysis without spatial calibration is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy <p><i>Implantable Cardioverter-Defibrillator System with a Substernal (Extravascular) Electrode (CPT codes 0571T, 0572T, 0573T, 0574T, 0575T, 0576T, 0577T, 0578T, 0579T, 0580T, and 0614T)</i></p>	

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Omnibus Codes (continued)	Jan. 1, 2024	<ul style="list-style-type: none"> ○ Added language to indicate insertion, repositioning, programming, interrogation, and evaluation of implantable cardioverter-defibrillator system with a substernal (extravascular) electrode are considered unproven and not medically necessary due to insufficient evidence of efficacy <p><i>Insertion of Iris Prosthesis (CPT/HCPCS codes 0616T, 0617T, 0618T, and C1839)</i></p> <ul style="list-style-type: none"> ○ Added language to indicate insertion of iris prosthesis is unproven and considered not medically necessary due to insufficient evidence of safety and/or efficacy <p><i>Irreversible Electroporation (IRE) Ablation (CPT codes 0600T and 0601T)</i></p> <ul style="list-style-type: none"> ○ Added language to indicate: <ul style="list-style-type: none"> ▪ Percutaneous irreversible electroporation (IRE) ablation is unproven because there are insufficient studies supporting the safety and efficacy of the procedure and demonstrating improvement in health 	

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Omnibus Codes (continued)	Jan. 1, 2024	<p>outcomes compared to other standard treatments</p> <ul style="list-style-type: none"> ▪ Open irreversible electroporation (IRE) ablation is unproven due to insufficient clinical evidence of safety and efficacy <p><i>Osteotomy, Humerus with Insertion of an Externally Controlled Intramedullary Lengthening Device (CPT code 0594T)</i></p> <ul style="list-style-type: none"> ○ Added language to indicate osteotomy, humerus, with insertion of an externally controlled intramedullary lengthening device, including intraoperative imaging, initial and subsequent alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device, is considered unproven and not medically necessary due to insufficient evidence of efficacy <p><i>Radiostereometric Analysis (RSA) (CPT codes 0347T, 0348T, 0349T, and 0350T)</i></p> <ul style="list-style-type: none"> ○ Added language to indicate 	

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Omnibus Codes (continued)	Jan. 1, 2024	<p>radiostereometric analysis (RSA) is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy</p> <p>Remote Monitoring of an External Continuous Pulmonary Fluid Monitoring System (CPT codes 0607T and 0608T)</p> <ul style="list-style-type: none"> Added language to indicate remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-hyphen derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (e.g., ECG data), transmitted to a remote 24-hour attended surveillance center, as well as the analysis of data received and transmission of reports to the physician or other qualified health care professional, is unproven due to insufficient clinical evidence of safety and efficacy <p>Sonosalpingography (CPT code 0568T)</p>	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Omnibus Codes (continued)	Jan. 1, 2024	<ul style="list-style-type: none"> Added language to indicate sonosalpingography, when used with a mixture of saline and air to confirm fallopian tube occlusion, is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy <p><i>Transcatheter Intracoronary Infusion of Supersaturated Oxygen in Conjunction with Percutaneous Coronary Revascularization During Acute Myocardial Infarction (CPT code 0659T)</i></p> <ul style="list-style-type: none"> Added language to indicate transcatheter intracoronary infusion of supersaturated oxygen in conjunction with percutaneous coronary revascularization during acute myocardial infarction is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy <p><i>Transcatheter Placement of Extracranial Vertebral Artery Stent(s) (CPT codes 0075T and 0076T)</i></p> <ul style="list-style-type: none"> Added language to indicate transcatheter placement of 	

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Omnibus Codes (continued)	Jan. 1, 2024	<p>extracranial vertebral artery stent(s) is considered unproven and not medically necessary due to insufficient evidence of efficacy</p> <p><i>Transluminal Peripheral Atherectomy of Visceral, Renal, Abdominal, or Brachiocephalic Arteries (CPT codes 0234T, 0235T, 0236T, and 0237T)</i></p> <ul style="list-style-type: none"> ○ Added language to indicate transluminal peripheral atherectomy of visceral, renal, abdominal, or brachiocephalic arteries is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy ● Revised guidelines for: <p><i>Biomarker Panel Based Algorithmic Analysis Test to Screen for Colorectal Cancer or Advanced Adenomas (CPT code 0163U)</i></p> <ul style="list-style-type: none"> ○ Replaced reference to “BeScreened” with “BeScreened™-CRC” <p><i>External Upper Limb Tremor Stimulators of the Peripheral Nerves of the Wrist (HCPCS</i></p> 	

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Omnibus Codes (continued)	Jan. 1, 2024	<p>codes K1018 and K1019)</p> <ul style="list-style-type: none"> ○ Added language to indicate external upper limb tremor stimulators of the peripheral nerves of the wrist and the related monthly supplies to treat postural and kinetic hand tremor symptoms in adults with Parkinson’s disease are unproven and not medically necessary <p>Myringotomy and Tympanostomy Tube Placement Under Iontophoresis Local Anesthesia (Tula) System (CPT code 0583T)</p> <ul style="list-style-type: none"> ○ Replaced reference to “Tube Placement Under Local Anesthesia (TULA) System” with “Tube Placement Under Iontophoresis Local Anesthesia (Tula) System” <ul style="list-style-type: none"> ● Updated list of applicable CPT/HCPCS codes for: <p>Contact or Non-Contact Near-Infrared Spectroscopy (NIRS) (CPT codes 0640T, 0641T, 0642T, and 93998)</p> <ul style="list-style-type: none"> ○ Revised description for CPT code 0641T 	

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Omnibus Codes (continued)	Jan. 1, 2024	<p><i>Intraoperative Radiation Therapy Using Low-Energy X-Rays or Electrons (CPT codes 0735T, 19294, 77424, 77425, and 77469)</i></p> <ul style="list-style-type: none"> ○ Added CPT code 0735T <p><i>Pulse-Echo Ultrasound Bone Density Measurement (CPT code 0508T)</i></p> <ul style="list-style-type: none"> ○ Added CPT code 0508T ○ Removed CPT code 0584T <p><i>Transcutaneous Magnetic Stimulation (tMS) (CPT codes 0766T, 0767T, 0768T, and 0769T)</i></p> <ul style="list-style-type: none"> ○ Revised description for CPT codes 0766T and 0767T <p><i>Use of Robotic Lower Body Exoskeleton Device (CPT/HCPCS codes 97799, E1399, K1007, and L2999)</i></p> <ul style="list-style-type: none"> ○ Added CPT code 97799 <p><i>UroCuff Test (CPT code 55899)</i></p> <ul style="list-style-type: none"> ○ Removed CPT code 53899 <ul style="list-style-type: none"> ● Removed guidelines for: <p><i>Autologous Pancreatic Islet Cell Transplantation and Allogeneic Islet Cell Transplantation (CPT/HCPCS</i></p> 	

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Omnibus Codes (continued)	Jan. 1, 2024	<p>codes 0584T, 0585T, 0586T, 48160, 48999, 60659, G0341, G0342, G0343, and S2102)</p> <ul style="list-style-type: none"> Refer to the Optum Clinical Guidelines titled Solid Organ Transplantation <p>Bioimpedance Spectroscopy for Lymphedema Assessment (CPT code 93702)</p> <ul style="list-style-type: none"> CPT code 93702 no longer requires clinical review <p>Cerebral Computed Tomography Perfusion (CTP) (CPT code 0042T)</p> <ul style="list-style-type: none"> The use of cerebral computed tomography perfusion (CTP) is managed by eviCore healthcare on behalf of UnitedHealthcare <p>Corticosteroid Drug-Eluting Punctal Plugs or Implants (CPT code 68841)</p> <ul style="list-style-type: none"> Refer to the Medical Benefit Drug Policy titled <i>Intravitreal Corticosteroid Implants</i> <p>Digestive Enzyme Cartridges (e.g., Relizorb™) (HCPCS code B4105)</p> <ul style="list-style-type: none"> HCPCS code B4105 no longer requires clinical review <p>Fractional Carbon Dioxide</p>	

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Omnibus Codes (continued)	Jan. 1, 2024	<p>Laser Treatment (CPT codes 0479T and 0480T)</p> <ul style="list-style-type: none"> Refer to the Clinical Policy titled <i>Light and Laser Therapy</i> <p>Multifocal Electroretinogram (mfERG) and Pattern Electroretinogram (PERG)/Pattern Electroretinogram Optimized for Glaucoma Screening (PERGLA) (CPT codes 0509T and 92274)</p> <ul style="list-style-type: none"> Refer to the Clinical Policy titled <i>Electroretinography</i> <p>Radiesse, Sculptra, Prolaryn, and Prolaryn Plus (HCPCS codes G0429, L8607, Q2026, and Q2028)</p> <ul style="list-style-type: none"> Refer to the Clinical Policy titled <i>Injectables for Reconstructive Procedures</i> <p>Right Ventricular Leadless Pacemakers (CPT codes 33274 and 33275)</p> <ul style="list-style-type: none"> Right ventricular leadless pacemakers are managed by eviCore healthcare on behalf of UnitedHealthcare <p>Vacuum Pumps for Residual Limb Volume Management</p>	

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Omnibus Codes (continued)	Jan. 1, 2024	<p>and Moisture Evacuation Systems Among Amputees (HCPCS codes L5781 and L5782)</p> <ul style="list-style-type: none"> Refer to the Clinical Policy titled <i>Lower Extremity Prosthetics</i> <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information 	
Preventive Care Services	Jan. 1, 2024	<p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised list of applicable: <ul style="list-style-type: none"> Covered Breastfeeding Equipment <ul style="list-style-type: none"> Added “breastmilk storage bags (HCPCS code K1005)” Coverage Limitations and Exclusions <ul style="list-style-type: none"> Replaced “breastmilk storage bags, ice-packs, labels, labeling lids, and other similar products” with “breastmilk storage accessories such as ice-packs, labels, labeling lids, and other similar products; <i>the breastmilk storage accessories exclusion does not apply to breastmilk storage bags (HCPCS code K1005)</i>” <p>Applicable Codes</p>	Refer to the policy for complete details.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Preventive Care Services (continued)	Jan. 1, 2024	<p>Preventive Care Services</p> <p>Latent Tuberculosis Infection in Adults: Screening</p> <ul style="list-style-type: none"> Revised service description: <ul style="list-style-type: none"> Removed Sep. 2016 USPSTF “B” rating Added May 2023 USPSTF “B” rating to indicate the USPSTF recommends screening for latent tuberculosis infection (LTBI) in populations at increased risk; this recommendation applies to asymptomatic adults 18 years or older at increased risk for tuberculosis (TB) <p>Expanded Women’s Preventive Health</p> <p>Breastfeeding Services and Supplies</p> <ul style="list-style-type: none"> Updated list of applicable HCPCS codes for Breast Pump Supplies; added K1005 <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>References</i> section to reflect the most current information 	
Sacroiliac Joint Interventions	Jan. 1, 2024	<p>Coverage Rationale</p> <p>Sacroiliac Joint (SI) Injections</p> <ul style="list-style-type: none"> Revised language pertaining to medical necessity clinical coverage criteria; replaced reference to the “InterQual® <i>Client Defined</i>, CP: 	<p>Note: This policy addresses intraarticular Sacroiliac Joint injections and fusion. This policy does not address radiofrequency ablation of the Sacroiliac Joint. For coverage criteria for radiofrequency ablation of the Sacroiliac Joint, refer to the Clinical Policy titled Ablative Treatment for Spinal Pain.</p> <p>Sacroiliac Joint (SI) injections are proven and medically necessary in certain</p>

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Sacroiliac Joint Interventions (continued)	Jan. 1, 2024	<p>Procedures, Sacroiliac (SI) Joint <i>Interventions (Custom) – UHG</i> with “InterQual® CP: Procedures, Sacroiliac (SI) Joint <i>Injection</i>”</p> <p>Open Sacroiliac Joint Fusion</p> <ul style="list-style-type: none"> Revised language to indicate open Sacroiliac Joint Fusion is proven and medically necessary for treating the following indications: <ul style="list-style-type: none"> Stabilization of a traumatic, severe disruption, or fracture of the pelvic ring Management of sacral tumor (e.g., sacrectomy or partial sacrectomy related to tumors involving the sacrum) As an adjunctive to medical treatment for sacroiliac joint infection or sepsis When performed as part of multisegmental spinal constructs for the correction of spinal deformity (e.g., idiopathic scoliosis, neuromuscular scoliosis) <p>Minimally Invasive Joint Fusion</p> <ul style="list-style-type: none"> Revised language to indicate minimally invasive joint fusion using a Titanium Triangular Implant for is proven and medically necessary when all the following criteria are met: <ul style="list-style-type: none"> Individual has undergone and 	<p>circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Sacroiliac (SI) Joint Injection.</p> <p>Click here to view the InterQual® criteria.</p> <p>Open Sacroiliac Joint Fusion is proven and medically necessary for treating the following indications:</p> <ul style="list-style-type: none"> Stabilization of a traumatic, severe disruption, or fracture of the pelvic ring. Management of sacral tumor (e.g., sacrectomy or partial sacrectomy related to tumors involving the sacrum). As an adjunctive to medical treatment for Sacroiliac Joint infection or sepsis. When performed as part of multisegmental spinal constructs for the correction of spinal deformity (e.g., idiopathic scoliosis, neuromuscular scoliosis). <p>Minimally invasive joint fusion using a Titanium Triangular Implant is proven and medically necessary when all the following criteria are met.</p> <ul style="list-style-type: none"> Have undergone and failed a minimum 6 months of intensive nonoperative treatment that includes all of the following: <ul style="list-style-type: none"> Medication optimization (unless contraindicated). Activity modification. Active therapeutic exercise targeted at the lumbar spine, pelvis, Sacroiliac Joint (SIJ) and hip. Individual reports nonradicular, typically, unilateral pain that is maximal below the L5 vertebrae, localized over the posterior SIJ, and consistent with SIJ pain. A physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin’s point, i.e., at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) or the absence of tenderness elsewhere (e.g., greater trochanter, lumbar spine, coccyx) that would explain the patient’s symptoms. Positive response to a cluster of at least 3 Provocative Tests (1. Patrick’s or FABER, 2. Gaenslen, 3. thigh thrust, 4. sacral thrust, 5. distraction, 6.

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Sacroiliac Joint Interventions (continued)	Jan. 1, 2024	<p>failed a minimum 6 months of intensive nonoperative treatment that includes all of the following:</p> <ul style="list-style-type: none"> ▪ Medication optimization (unless contraindicated) ▪ Activity modification ▪ Active therapeutic exercise targeted at the lumbar spine, pelvis, Sacroiliac Joint (SIJ), and hip <ul style="list-style-type: none"> ○ Individual reports nonradicular, typically, unilateral pain that is maximal below the L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain ○ A physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin’s point, i.e., at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) or the absence of tenderness elsewhere (e.g., greater trochanter, lumbar spine, coccyx) that would explain the patient’s symptoms ○ Positive response to a cluster of at least 3 provocative tests (1. Patrick’s or FABER, 2. 	<p>compression). Note that the thrust tests may not be recommended in pregnant patients or those with connective tissue disorders.</p> <ul style="list-style-type: none"> • Absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g. fibromyalgia). • Diagnostic imaging studies that include ALL of the following: <ul style="list-style-type: none"> ○ Imaging (plain radiographs and a CT or MRI) of the SI joint that excludes the presence of destructive lesions (e.g., tumor, infection), or autoimmune arthropathy that would not be properly addressed by percutaneous SIJ fusion. ○ Imaging of the pelvis (anteriorposterior plain radiograph) to rule out concomitant hip pathology that would better explain the patient’s symptoms. ○ Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that, in combination with the patient’s history, physical, and other testing would more likely be the source of their low back or buttock pain. • At least 75% reduction of pain, documented by pain diary, for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on 2 separate occasions. • A trial of at least one therapeutic intra-articular SIJ injection (i.e., corticosteroid injection).

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Sacroiliac Joint Interventions (continued)	Jan. 1, 2024	<p>Gaenslen, 3. thigh thrust, 4. sacral thrust, 5. distraction, 6. compression); note that the thrust tests may not be recommended in pregnant patients or those with connective tissue disorders.</p> <ul style="list-style-type: none"> ○ Absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia) ○ Diagnostic imaging studies that include all of the following: <ul style="list-style-type: none"> ▪ Imaging (plain radiographs and a CT or MRI) of the SI joint that excludes the presence of destructive lesions (e.g., tumor, infection), or autoimmune arthropathy that would not be properly addressed by percutaneous SIJ fusion ▪ Imaging of the pelvis (anterior posterior plain radiograph) to rule out concomitant hip pathology that would better explain the patient's symptoms ▪ Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that, in 	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Sacroiliac Joint Interventions (continued)	Jan. 1, 2024	<p>combination with the patient’s history, physical, and other testing, would more likely be the source of their low back or buttock pain</p> <ul style="list-style-type: none"> ○ At least 75% reduction of pain, documented by pain diary, for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on 2 separate occasions ○ A trial of at least one therapeutic intra-articular SIJ injection (i.e., corticosteroid injection) <p>Documentation Requirements</p> <ul style="list-style-type: none"> ● Updated list of required clinical information to reflect/include (when applicable): <ul style="list-style-type: none"> ○ Condition requiring procedure ○ History and co-morbid medical condition(s), including presence or absence of somatoform disorder or generalized pain disorders ○ Member’s symptoms including pain, location, severity, and interference with activities of daily living (ADLs) ○ Physical exam, including: 	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Sacroiliac Joint Interventions (continued)	Jan. 1, 2024	<ul style="list-style-type: none"> ▪ Specific location of tenderness ▪ Presence or absence of acute neurological deficits ▪ Results of at least three tests: <ul style="list-style-type: none"> – Compression test – Distraction test – Patrick’s or FABER test – Gaenslen’s test – Thigh thrust test – Reports of all recent imaging studies and applicable diagnostics ○ Treatments tried, failed, or contraindicated; include the dates, duration, and reason for discontinuation ○ Results of the fluoroscopically guided diagnostic intra-articular SIJ block(s) using local anesthetic <p>Definitions</p> <ul style="list-style-type: none"> ● Added definition of: <ul style="list-style-type: none"> ○ Provocative Tests ○ Sacrectomy/Partial Sacrectomy ○ Sacroiliac Joint Fusion (Arthrodesis) <p>Supporting Information</p> <ul style="list-style-type: none"> ● Updated <i>Description of Services, Clinical Evidence, and References</i> 	

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Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Sacroiliac Joint Interventions (continued)	Jan. 1, 2024	sections to reflect the most current information	

Administrative Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Autism Spectrum Disorder and Developmental Disabilities	Dec. 1, 2023	<p>Coverage Rationale</p> <p>New York Products</p> <ul style="list-style-type: none"> Revised coverage guidelines for Applied Behavioral Analysis (ABA) Therapy; added language to indicate prescriptions or orders for behavioral health treatment provided by a licensed behavior analyst shall be limited to providing treatment to individuals with behavioral health conditions that appear in the <i>Diagnostic and Statistical Manual of Mental Disorders</i>, published by the American Psychiatric Association, or an equivalent classification system as determined by the department <p>Definitions</p> <p>Connecticut (CT) Products Only</p> <ul style="list-style-type: none"> Updated definition of “Autism Spectrum Disorder” <p>New Jersey (NJ) Products Only</p> <ul style="list-style-type: none"> Updated definition of: <ul style="list-style-type: none"> Autism Spectrum Disorder Behavioral Interventions Based on Applied Behavioral Analysis (ABA) <p>Applicable Codes</p> <p>Other Developmental Disability for CT and NJ Products</p> <ul style="list-style-type: none"> Added ICD-10 diagnosis codes 	Refer to the policy for complete details.

Administrative Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Autism Spectrum Disorder and Developmental Disabilities (continued)	Dec. 1, 2023	<p>G11.5, G11.6, G23.3, G31.80, G31.86, G40.C01, G40.C09, G40.C11, G40.C19, G93.42, G93.43, G93.44, and Q93.52</p> <ul style="list-style-type: none"> Removed ICD-10 diagnosis codes F78 and Q93.5 <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>References</i> section to reflect the most current information 	
Succeeding Carrier for Inpatient Admissions	Dec. 1, 2023	<p>Title Change</p> <ul style="list-style-type: none"> Previously titled <i>Extended Benefits for Total Disability & Succeeding Carrier for Inpatient Admissions</i> <p>Purpose</p> <ul style="list-style-type: none"> Removed language indicating this policy outlines the guidelines for extended benefits for total disability <p>Definitions</p> <ul style="list-style-type: none"> Removed definition of “Extended Benefits” <p>Policy</p> <ul style="list-style-type: none"> Removed language pertaining to extended benefits 	<p>This policy outlines the guidelines for when a Member changes carriers while confined in an inpatient facility (acute care hospital, substance abuse or mental health facility, physical rehabilitation, or skilled nursing facility).</p> <p>Refer to the policy for complete details.</p>

General Information

The inclusion of a health service (e.g., test, drug, device or procedure) in this bulletin indicates only that UnitedHealthcare Oxford® is adopting a new policy and/or updated, revised, replaced or retired an existing policy; it does not imply that UnitedHealthcare Oxford® 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 Oxford® reserves the right to review the clinical evidence supporting the safety and effectiveness of a medical technology prior to rendering a coverage determination.

UnitedHealthcare Oxford® 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 Policy Update Bulletin was developed to share important information regarding UnitedHealthcare Oxford® Clinical, Administrative, and Reimbursement Policy updates. When information in this bulletin conflicts with applicable state and/or federal law, UnitedHealthcare Oxford® 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



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