United Healthcare Community Plan

UnitedHealthcare Community Plan
Medical Policy Update Bulletin: August 2026

In This Issue

Take Note

Medical Policy Updates

Updated

Revised

Retired

Medical Benefit Drug Policy Updates

Updated

In This Issue

Revised

Take Note

Quarterly CPT Code Updates

Effective **Aug. 1, 2026**, the following Medical Policies have been updated to reflect the quarterly Current Procedural Terminology (CPT®) code additions, revisions, and deletions. Refer to the American Medical Association: Current Procedural Terminology: CPT® for information on the code updates.

Policy Title	Summary of Changes
Cell-Free Fetal DNA Testing	• Added CPT codes 0632U and 0633U
FDA Cleared or Approved Companion Diagnostic Testing	• Added CPT code 0648U
Genetic Testing for Hereditary Cancer	**Multigene Panel** • Added CPT code 0651U
Pharmacogenetic Panel Testing	• Added CPT codes 0650U and 0652U • Removed CPT codes 0029U and 0423U
Transcatheter Procedures for Heart Valve Conditions	• Revised description for CPT codes 0805T and 0806T
Whole Exome and Whole Genome Sequencing (Non-Oncology Conditions)	• Added CPT codes 0657U, 0658U, and 0659U

Medical Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes

Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes	Aug. 1, 2026	**Coverage Rationale**
		Insulin Delivery
		• Added language to clarify:
		  ○ External continuous subcutaneous insulin infusion pumps *(including Omnipod)* are proven and medically necessary in certain circumstances when used according to U.S. Food and Drug Administration (FDA)–labeled indications, contraindications, warnings, and precautions
		  ○ External continuous subcutaneous insulin infusion pumps are medically necessary for managing individuals with diabetes due to causes, *other than type 1, type 2, or gestational diabetes,* that require intensive insulin therapy (insulin-treated at least three times a day)
		Supporting Information
		• Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information

Habilitation and Rehabilitation Therapy (Occupational, Physical, and Speech)	Aug. 1, 2026	**Coverage Rationale** ***Re-Evaluations*** • Updated list of required documentation for a therapy re-evaluation report; replaced "*compliance* to home program" with "*adherence* to home program" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information

Private Duty Nursing Services (for Florida Only)	Aug. 1, 2026	**Medical Records Documentation Used for Reviews**
		• Added language to indicate:
		  ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service
		  ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested
		  ○ The patient's medical record must contain documentation that fully supports the medical necessity for the requested services
		  ○ This documentation includes but is not limited to relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures
		  ○ Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request

Sinus Surgeries and Interventions	Aug. 1, 2026	**Definitions**
		• Added definition of "Acute Bacterial Rhinosinusitis"
		• Removed definition of:
		  ○ Draf Classification System for Endoscopic Frontal Sinus Drainage
		  ○ Rhinitis Medicamentosa (RM)
		• Updated definition of:

Medical Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Sinus Surgeries and Interventions (continued)	Aug. 1, 2026	○ Acute Rhinosinusitis ○ Chronic Rhinosinusitis ○ Functional Endoscopic Sinus Surgery ○ Modified Lund-Mackay Scoring System ○ Recurrent Acute Rhinosinusitis **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Brow Ptosis and Eyelid Repair	Oct. 1, 2026	**Coverage Rationale** • Replaced language indicating "lid retraction surgery (CPT code 67911) is considered reconstructive and medically necessary when all of the [listed] criteria are present" with "lid retraction surgery (CPT code 67911) is considered reconstructive and medically necessary *for conditions other than thyroid eye disease* when all the [listed] criteria are present" ***Thyroid Eye Disease*** • Revised coverage guidelines to indicate lid retraction surgery (CPT code 67911) for thyroid eye disease is considered reconstructive and medically necessary when either of the following criteria are met: ○ Moderate to severe disease where all the following apply: ▪ The disease is stable or inactive, and euthyroidism has been	**Note:** The InterQual® criteria below only applies to persons 18 years of age or older. **Brow ptosis repair and repair of the eyelid are considered reconstructive and medically necessary in certain circumstances.** For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures: • Blepharoplasty • Ectropion Repair • Entropion Repair • Eyelid Lesion Excision, +/- Reconstruction • Eyelid Reconstruction • Ptosis Repair Click here to view the InterQual® criteria. **Note**: If multiple procedures are requested, criteria for each individual procedure must be met. **Internal Browpexy for any condition is considered cosmetic and not medically necessary.** **Eyelid surgery for correction of Lagophthalmos is considered reconstructive and medically necessary when the upper eyelid is not providing complete closure to the eye, resulting in dryness and other complications.**

Revised

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Brow Ptosis and Eyelid Repair (continued)	Oct. 1, 2026	achieved and maintained ▪ Other causes of lid retraction have been eliminated (e.g., use of dilating eye drops or glaucoma medications) ▪ There is a functional impairment (e.g., dry eyes, pain/discomfort, tearing, blurred vision) ○ Severe, sight-threatening thyroid eye disease (to address subluxation) **Definitions** • Removed definition of "Marginal Reflex Distance -1 (MRD-1)" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	**Lid retraction surgery (CPT code 67911) is considered reconstructive and medically necessary for conditions other than thyroid eye disease when all the following criteria are present:** • Other causes have been eliminated as the reason for the lid retraction such as use of dilating eye drops or glaucoma medications; and • There is a functional impairment (e.g., dry eyes, pain/discomfort, tearing, blurred vision); and • Tried and failed conservative treatments **For thyroid eye disease, lid retraction surgery (CPT code 67911) is considered reconstructive and medically necessary, when either of the following criteria are met:** • Moderate to severe disease where all the following apply ○ The disease is stable or inactive, and euthyroidism has been achieved and maintained; and ○ Other causes of lid retraction have been eliminated (e.g., use of dilating eye drops or glaucoma medications); and ○ There is a functional impairment (e.g., dry eyes, pain/discomfort, tearing, blurred vision) or • Severe, sight-threatening thyroid eye disease to address subluxation **Canthoplasty/Canthopexy (CPT codes 21280, 21282, and 67950) are considered reconstructive and medically necessary when all the following criteria are present:** • There is a functional impairment; and • Repair of ectropion or entropion will not correct condition; and • At least one of the following is present: ○ Epiphora (excess tearing) not resolved by conservative measures; or ○ Corneal dryness unresponsive to lubricants; or ○ Corneal ulcer **Repair of Floppy Eyelid Syndrome (CPT codes 67961 and 67966) is considered reconstructive and medically necessary when all the following are present and have been documented and confirmed by history and examination:** • Subjective symptoms must include eyelids spontaneously "flipping over"

Revised			
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Brow Ptosis and Eyelid Repair (continued)	Oct. 1, 2026		when the member sleeps due to rubbing on the pillow and one of the following: ○ Eye pain or discomfort; or ○ Excess tearing; or ○ Eye irritation, ocular redness, and discharge • Physical examination that documents all the following: ○ Both of the following: ▪ Eyelash ptosis; and ▪ Significant upper eyelid laxity and ○ One of the following: ▪ Presence of giant papillary conjunctivitis; or ▪ Corneal findings such as one of the following: – Superficial punctate erosions; or – Corneal abrasion (documentation of a history of corneal abrasion or recurrent erosion syndrome is considered sufficient); or – Microbial keratitis • Clear, high-quality, clinical photographs that clearly document Floppy Eyelid Syndrome and demonstrate both of the following: ○ Lids must be everted in the photographs; and ○ Conjunctival surface (underbelly) of the lids must be clearly visible • Documentation that conservative treatment has been tried and failed; examples may include: ○ Ocular lubricants both drops (daytime) and ointments (bedtime) ○ Short trial of antihistamines ○ Topical steroid drops ○ Eye shield and/or taping the lids at bedtime • Infections of the eye have been ruled out; examples may include: ○ Allergic conjunctivitis ○ Atopic keratoconjunctivitis ○ Blepharitis ○ Contact lens complication (e.g., giant papillary conjunctivitis) ○ Superior limbic keratoconjunctivitis
Genetic Testing for Cardiac Disease	Oct. 1, 2026	**Related Policies** • Removed reference link to the Medical Policy titled *FDA Cleared*	**Note**: For chromosome microarray testing related to isolated, severe congenital heart disease, refer to the Medical Policy titled Chromosome Microarray Testing (Non-Oncology Conditions). For cardiomyopathies that

Revised			
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Genetic Testing for Cardiac Disease (continued)	Oct. 1, 2026	*or Approved Companion Diagnostic Testing* **Coverage Rationale** • Added instruction to refer to the Medical Policy titled: ○ *Chromosome Microarray Testing (Non-Oncology Conditions)* for chromosome microarray testing related to isolated, severe congenital heart disease ○ *Genetic Testing for Neurological Disorders* for cardiomyopathies that present primarily as neuromuscular disorders • Replaced language indicating "pretest genetic counseling is *strongly* recommended *in order* to inform persons being tested about the advantages and limitations of the test as applied to *a* unique *person*" with "pretest genetic counseling is recommended to inform persons being tested about the advantages and limitations of the test as applied to *their* unique *situation*" ***Arrhythmias*** • Replaced language indicating "*multi-gene* panel testing for the diagnosis of a *hereditary* arrhythmia syndrome is proven and medically necessary in individuals with a confirmed or suspected diagnosis	present primarily as neuromuscular disorders, refer to the Medical Policy titled Genetic Testing for Neurological Disorders. Pretest genetic counseling is recommended to inform persons being tested about the advantages and limitations of the test as applied to their unique situation. **Arrhythmias** **Targeted Panel testing of five or more genes for the diagnosis of a heritable arrhythmia syndrome is proven and medically necessary in an individual with a confirmed or suspected diagnosis of any of the following conditions:** • Brugada syndrome • Catecholaminergic polymorphic ventricular tachycardia • Long QT syndrome (LQTS) when acquired causes have been ruled out and any of the following criteria are met: ○ Prolonged corrected QT interval (≥ 460 ms) on exercise or ambulatory electrocardiogram (Holter monitoring) or during pharmacological provocation testing; or ○ T-wave abnormalities on electrocardiogram that are suggestive of LQTS (e.g., torsades de pointes, T-wave alternans, notched T wave in three leads); or ○ Profound congenital, bilateral sensorineural hearing loss and prolonged corrected QT interval; or ○ Schwartz Score of ≥ 1.5 points • Short QT syndrome **Cardiomyopathies** **Targeted Panel testing of five or more genes for the diagnosis of a heritable cardiomyopathy is proven and medically necessary in an individual with a confirmed or suspected diagnosis of any of the following conditions:** • Arrhythmogenic right ventricular dysplasia/cardiomyopathy • Dilated cardiomyopathy, without an identifiable cause, when either of the following criteria are met: ○ Individual has cardiac conduction disease, such as atrioventricular

Revised			
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Genetic Testing for Cardiac Disease (continued)	Oct. 1, 2026	of any of the [listed] conditions" with "*Targeted* Panel testing *of five or more genes* for the diagnosis of a *heritable* arrhythmia syndrome is proven and medically necessary in an individual with a confirmed or suspected diagnosis of any of the [listed] conditions" • Replaced reference to "*familial* long QT syndrome" with "long QT syndrome" ***Cardiomyopathies*** • Replaced language indicating "*multi-gene* panel testing for the diagnosis of a *hereditary* cardiomyopathy is proven and medically necessary in individuals with a confirmed or suspected diagnosis of any of the [listed] conditions" with "*Targeted* Panel testing *of five or more genes* for the diagnosis of a *heritable* cardiomyopathy is proven and medically necessary in an individual with a confirmed or suspected diagnosis of any of the [listed] conditions" • Revised list of proven and medically necessary conditions; replaced "dilated cardiomyopathy, without an identifiable cause, when an individual has cardiac conduction disease *(first-, second-, or third-degree block)*" with "dilated cardiomyopathy, without an identifiable cause,	block; or ○ Sudden cardiac death in a First-Degree Relative or Second-Degree Relative at age 45 years or younger • Hypertrophic cardiomyopathy without an identifiable cause (e.g., valvular disease, hypertension, infiltrative or neuromuscular disorder) • Left ventricular noncompaction cardiomyopathy **Thoracic Aortic Disease** **Targeted Panel testing of five or more genes is proven and medically necessary for either of the following:** • Individual has confirmed thoracic aortic disease; or • Thoracic aortic disease is suspected based on family history of thoracic aortic disease in a First-Degree Relative or Second-Degree Relative **Testing Based Only on Family History** **Targeted Panel testing of five or more genes for the diagnosis of a heritable arrhythmia syndrome or cardiomyopathy is proven and medically necessary for either of the following:** • An asymptomatic individual who has a First-Degree Relative or Second-Degree Relative with any of the following conditions: ○ Arrhythmogenic right ventricular dysplasia/cardiomyopathy ○ Brugada syndrome ○ Catecholaminergic polymorphic ventricular tachycardia ○ Familial dilated cardiomyopathy ○ Hypertrophic cardiomyopathy ○ Left ventricular noncompaction cardiomyopathy ○ LQTS ○ Short QT syndrome • An asymptomatic individual with a First-Degree Relative who experienced sudden cardiac death or near sudden death at age 45 years or younger **Comprehensive Panel tests that are intended to evaluate multiple genes associated with multiple categories of clinically distinct cardiomyopathies, arrhythmias, and/or aortic vascular disorders are unproven and not medically necessary due to insufficient evidence of**

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Genetic Testing for Cardiac Disease (continued)	Oct. 1, 2026	when an individual has cardiac conduction disease *such as atrioventricular block*" ***Thoracic Aortic Disease*** • Replaced language indicating "*multi-gene* panel testing is proven and medically necessary for either of the [listed conditions]" with "*Targeted* Panel testing *of five or more genes* is proven and medically necessary for either of the [listed conditions]" ***Testing Based Only on Family History*** • Replaced language indicating: ○ "*Multi-gene* panel testing for the diagnosis of *inherited* arrhythmic *disorders* or cardiomyopathy is proven and medically necessary in asymptomatic individuals who have *one* of the [listed] conditions" with "*Targeted* Panel testing *of five or more genes* for the diagnosis of *a heritable* arrhythmia *syndrome* or cardiomyopathy is proven and medically necessary in asymptomatic individuals who have *either* of the [listed] conditions" ○ "All other genetic testing for cardiomyopathies, arrhythmias, or aortic vascular disease [not listed in the policy as proven and medically necessary] is	**efficacy.** **All other genetic testing for cardiomyopathies, arrhythmias, or aortic vascular disease is unproven and not medically necessary due to insufficient evidence of efficacy.** **Coronary Artery Disease** **Genetic testing for coronary artery disease risk is unproven and not medically necessary due to insufficient evidence of efficacy, including but not limited to the following:** • Gene expression tests • Microarray, polygenic risk scores, or other genetic profiles, such as: ○ Allelica PRS ○ CARDIO inCode-Score ○ Epi+Gen CHD ○ PrecisionCHD

Revised			
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Genetic Testing for Cardiac Disease (continued)	Oct. 1, 2026	unproven and not medically necessary due to insufficient evidence of efficacy *(this does not apply to chromosome microarray analysis for isolated severe congenital heart disease)*" with "all other genetic testing for cardiomyopathies, arrhythmias, or aortic vascular disease [not listed in the policy as proven and medically necessary] is unproven and not medically necessary due to insufficient evidence of efficacy" • Replaced reference to "*congenital* long QT syndrome (LQTS)" with "long QT syndrome (LQTS)" • Added language to indicate Comprehensive Panel tests that are intended to evaluate multiple genes associated with multiple categories of clinically distinct cardiomyopathies, arrhythmias, and/or aortic vascular disorders are unproven and not medically necessary due to insufficient evidence of efficacy ***Coronary Artery Disease*** • Added language to clarify genetic testing for coronary artery disease *risk* is unproven and not medically necessary • Revised list of unproven and not medically necessary indications; replaced "microarray or other	

Revised

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Genetic Testing for Cardiac Disease (continued)	Oct. 1, 2026	genetic profiles *for cardiac disease risk (e.g., Cardiac DNA Insight®, Cardiac Healthy Weight DNA Insight®, Cardio IQ® gene tests and panels)*" with "microarray, *polygenic risk scores*, or other genetic profiles *such as Allelica PRS, CARDIO inCode-Score, Epi+Gen CHD, or PrecisionCHD*" **Definitions** • Added definition of: ○ Comprehensive Panel ○ Targeted Panel • Removed definition of "Multi-Gene Panel" **Applicable Codes** • Added HCPCS code S3865 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	
Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions	Oct. 1, 2026	**Coverage Rationale** • Added language to clarify this policy applies *only* to tests that have not been granted approval as a U.S. FDA-cleared or -approved companion diagnostic *test* ***Breast Cancer*** • Revised listed of Gene Expression Profiling (GEP) tests; replaced: ○ "Oncotype Dx® Breast" with "Oncotype DX Breast	This policy applies only to tests that have not been granted approval as a U.S. Food and Drug Administration–cleared or –approved companion diagnostic test. **Breast Cancer** **The use of one of the following Gene Expression Profiling (GEP) tests – MammaPrint®, Oncotype DX Breast Recurrence Score®, Prosigna® Breast Cancer Assay, Breast Cancer Index™, and EndoPredict® – is proven and medically necessary when used to inform treatment decisions in individuals with invasive breast cancer in the following situations:** • Newly diagnosed (within the last 6 months) when all the following criteria are met:

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Oct. 1, 2026	*Recurrence Score®*" ○ "Prosigna® Breast Cancer *Prognostic Gene Signature* Assay *(formerly PAM 50)*" with "Prosigna® Breast Cancer Assay" ***Colorectal Cancer*** • Added language to indicate blood-based colorectal cancer (CRC) screening using Shield™ is proven and medically necessary when all the following criteria are met: ○ The individual agrees to undergo a follow-up colonoscopy if Shield results are abnormal ○ The individual has no lower gastrointestinal pain, blood in stool, or other signs or symptoms suggestive of colorectal disease ○ The individual is of average risk for developing CRC, defined as both of the following: ▪ No personal history of adenomatous polyps, CRC, or inflammatory bowel disease (e.g., Crohn disease, ulcerative colitis) ▪ No first-degree relative(s) with CRC, adenomatous polyps, familial adenomatous polyposis, or Lynch syndrome	○ Lymph node negative (including lymph nodes with micrometastases no greater than 2 mm) or one to three positive ipsilateral axillary lymph nodes; 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 comorbidities) or • Currently receiving adjuvant hormonal therapy (e.g., tamoxifen or an aromatase inhibitor) for breast cancer when all the following criteria are met: ○ 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 **The use of more than one predictive GEP for the same tumor in an individual with breast cancer is unproven and not medically necessary due to insufficient evidence of efficacy.** **Note**: This limitation does not apply to Breast Cancer Index 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. **Colorectal Cancer** **Blood-based colorectal cancer (CRC) screening using Shield™ is proven and medically necessary when all the following criteria are met:** • The individual agrees to undergo a follow-up colonoscopy if Shield results are abnormal; and • The individual has no lower gastrointestinal pain, blood in stool, or other signs or symptoms suggestive of colorectal disease; and

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Oct. 1, 2026	(hereditary nonpolyposis CRC) ○ One of the following: ▪ The individual is aged 45 to 75 years and has not been screened with Shield or a U.S. Preventive Services Task Force–recommended CRC screening during the recommended screening interval, including but not limited to: – Shield in the past 3 years – Guaiac-based fecal occult blood test in the past year – Fecal immunochemical test in the past year – Multitargeted stool DNA test in the past 3 years – Colonoscopy in the past 10 years – Computed tomography colonography in the past 5 years – Flexible sigmoidoscopy in the past 5 years ▪ The individual is aged 76 to 85 years, has never been screened for CRC	• The individual is of average risk for developing CRC, defined as both of the following: ○ No personal history of adenomatous polyps, CRC, or inflammatory bowel disease (e.g., Crohn disease, ulcerative colitis); and ○ No first-degree relative(s) with CRC, adenomatous polyps, familial adenomatous polyposis, or Lynch syndrome (hereditary nonpolyposis CRC) and • One of the following: ○ The individual is aged 45 to 75 years; and ▪ Has not been screened with Shield or a U.S. Preventive Services Task Force–recommended CRC screening during the recommended screening interval, including but not limited to: – Shield in the past 3 years – Guaiac-based fecal occult blood test in the past year – Fecal immunochemical test in the past year – Multitargeted stool DNA test in the past 3 years – Colonoscopy in the past 10 years – Computed tomography colonography in the past 5 years – Flexible sigmoidoscopy in the past 5 years or ○ The individual is aged 76 to 85 years; and ▪ Has never been screened for CRC by any method; and ▪ Is healthy enough to undergo treatment if CRC is detected; and ▪ Does not have comorbid conditions that would significantly limit life expectancy **Lung Cancer** **Multigene molecular profiling panels that include no more than 50 genes are medically necessary for non-small cell lung cancer.** **Prostate Cancer** **The use of the Genomic Prostate Score® test 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:**

Revised

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Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Oct. 1, 2026	by any method, is healthy enough to undergo treatment if CRC is detected, and does not have comorbid conditions that would significantly limit life expectancy ***Lung Cancer*** • Replaced language indicating "multigene molecular profiling (*including* no more than 50 genes, *or for more than 50 genes only when used in a manner consistent with the Medical Policy titled FDA Cleared or Approved Companion Diagnostic Testing) performed using tumor tissue or via Liquid Biopsy [cell-free DNA (cfDNA) or circulating tumor DNA (ctDNA)]* is proven and medically necessary for non-small cell lung cancer" with "multigene molecular profiling *panels that include* no more than 50 genes are medically necessary for non-small cell lung cancer" ***Prostate Cancer*** • Replaced reference to "Genomic Prostate Score® test *(previously Oncotype DX® GPS)*" with "Genomic Prostate Score® test" ***Indeterminate Thyroid Nodules*** • Replaced language indicating "the use of more than one molecular *profile* test *in an individual with an indeterminate* thyroid nodule is unproven and	• Test is ordered by a physician specializing in the treatment of organ-confined prostate cancer, including surgical oncology/urology, radiation oncology, and 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 the following: ○ Life expectancy is greater than 10 years; and ○ Risk group is one of the following: ▪ Very Low-Risk Prostate Cancer; or ▪ Low-Risk Prostate Cancer; or ▪ 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:** • Test is ordered by a physician specializing in the treatment of organ-confined prostate cancer, including surgical oncology/urology, radiation oncology, and 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 the following: ○ Life expectancy is greater than 10 years; and ○ Risk group is one of the following: ▪ 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 **The use of the Decipher Prostate RP genomic classifier is proven and medically necessary to inform adjuvant treatment after radical prostatectomy for either of the following:** • Adverse features are found (e.g., high-grade disease, Gleason score of 8

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Oct. 1, 2026	not medically necessary" with "the use of more than one molecular test *on a single* thyroid nodule is unproven and not medically necessary" ***Unproven Molecular Tests*** • Revised language to indicate all other molecular oncology testing for solid tumor cancer [not listed in the policy as proven and medically necessary] is unproven and not medically necessary due to insufficient evidence of efficacy, including but not limited to: ○ Next-Generation Sequencing panels or Comprehensive Genomic Profiling unless otherwise specified, such as: ▪ OncoDEEP ○ Testing of breast cancers and ductal carcinoma in situ unless otherwise specified [in the policy], such as: ▪ BluePrint ▪ DCISionRT ▪ Oncotype DX Breast DCIS Score ○ Testing of thyroid cancer or thyroid nodules unless otherwise specified [in the policy], such as: ▪ Afirma Xpression Atlas ▪ NeoTYPE Thyroid Profile ○ Testing for the purpose of identifying tumor origin or primary site, such as:	or higher, extracapsular extension, positive surgical margins, seminal vesicle invasion); or • Prostate-specific antigen is greater than 0 at any point following prostatectomy **Anaplastic Thyroid Cancer** **Comprehensive Genomic Profiling of confirmed anaplastic thyroid cancer is proven and medically necessary.** **Indeterminate Thyroid Nodules** **Molecular testing of thyroid nodules [e.g., Afirma® Genomic Sequencing Classifier (GSC), ThyroSeq® V3, ThyGeNEXT®/ThyraMIR®] is proven and medically necessary when all the following criteria are met:** • 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 **The use of more than one molecular test on a single thyroid nodule is unproven and not medically necessary due to insufficient evidence of efficacy.** **Uveal Melanoma** **GEP (e.g., DecisionDx®-UM) is considered proven and medically necessary when used to assist with predicting disease severity and making treatment decisions when all the following criteria are met:** • 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 **Unproven Molecular Tests** **All other molecular oncology testing for solid tumor cancer is unproven and not medically necessary due to insufficient evidence of efficacy, including but not limited to:**

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Oct. 1, 2026	▪ CancerTYPE ID ○ Blood-based CRC screening tests unless otherwise specified [in the policy], such as: ▪ ColoHealth ▪ ColonSentry ▪ FirstSight ▪ Signal-C ▪ Shield for individuals aged < 45 years and > 85 years ○ Testing of bladder cancer, including for early detection of bladder cancer, such as: ▪ Bladder EpiCheck ▪ Cxbladder Triage ▪ Cxbladder Monitor ▪ Decipher Bladder Genomic Classifier ○ Testing of cutaneous cancers and head and neck cancers, including circulating tumor tissue–modified human papillomavirus DNA analysis, such as: ▪ DecisionDx-Melanoma ▪ DiffDx-Melanoma ▪ DecisionDx-SCC ▪ DermTech PLA ▪ Merlin ▪ MyPath Melanoma ▪ NavDx ○ Testing of prostate cancers, including for early detection of prostate cancer, unless otherwise specified [in the	• Next-Generation Sequencing panels or Comprehensive Genomic Profiling unless otherwise specified, such as: ○ OncoDEEP • Testing of breast cancers and ductal carcinoma in situ unless otherwise specified above, such as: ○ BluePrint ○ DCISionRT ○ Oncotype DX Breast DCIS Score • Testing of thyroid cancer or thyroid nodules unless otherwise specified above, such as: ○ Afirma Xpression Atlas ○ NeoTYPE Thyroid Profile • Testing for the purpose of identifying tumor origin or primary site, such as: ○ CancerTYPE ID • Blood-based CRC screening tests unless otherwise specified above, such as: ○ ColoHealth ○ ColonSentry ○ FirstSight ○ Signal-C ○ Shield for individuals aged < 45 years and > 85 years • Testing of bladder cancer, including for early detection of bladder cancer, such as: ○ Bladder EpiCheck ○ Cxbladder Triage ○ Cxbladder Monitor ○ Decipher Bladder Genomic Classifier • Testing of cutaneous cancers and head and neck cancers, including circulating tumor tissue–modified human papillomavirus DNA analysis, such as: ○ DecisionDx-Melanoma ○ DiffDx-Melanoma ○ DecisionDx-SCC ○ DermTech PLA ○ Merlin ○ MyPath Melanoma

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Oct. 1, 2026	policy], such as: ▪ Confirm mdx ▪ ExoDx Prostate ▪ MyProstateScore 2.0 ▪ ProsTAV ▪ Select mdx ○ Measurable Residual Disease assays, whether tumor informed or tumor naive, such as: ▪ Geneseeq Shielding ULTRA ▪ Geneseeq Vanguard ▪ Guardant Reveal ▪ Haystack MRD ▪ Invitae Personalized Cancer Monitoring ▪ Oncodetect ▪ Personalis NeXT Personal ▪ Plasma Detect ▪ RaDaR ▪ Signatera ○ Multicancer detection/screening tests, such as: ▪ Cancerguard ▪ Galleri ▪ Geneseeq Mercury ○ Testing of CRCs, such as: ▪ Oncotype DX Colon Recurrence Score ▪ GeneFx Colon (also known as ColDx) ▪ OnkoSight Advanced Colorectal Cancer ○ Testing of lung cancers or	○ NavDx • Testing of prostate cancers, including for early detection of prostate cancer, unless otherwise specified above, such as: ○ Confirm mdx ○ ExoDx Prostate ○ MyProstateScore 2.0 ○ ProsTAV ○ Select mdx • Measurable Residual Disease assays, whether tumor informed or tumor naive, such as: ○ Geneseeq Shielding ULTRA ○ Geneseeq Vanguard ○ Guardant Reveal ○ Haystack MRD ○ Invitae Personalized Cancer Monitoring ○ Oncodetect ○ Personalis NeXT Personal ○ Plasma Detect ○ RaDaR ○ Signatera • Multicancer detection/screening tests, such as: ○ Cancerguard ○ Galleri ○ Geneseeq Mercury • Testing of CRCs, such as: ○ Oncotype DX Colon Recurrence Score ○ GeneFx Colon (also known as ColDx) ○ OnkoSight Advanced Colorectal Cancer • Testing of lung cancers or lung nodules unless otherwise specified above, such as: ○ Percepta Genomic Sequencing Classifier • Solid tumor profiling that includes Whole-Exome Sequencing, Whole-Genome Sequencing, or whole-transcriptome sequencing, such as: ○ CancerVision ○ Caris Assure ○ Tempus xE ○ Tempus xR

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Oct. 1, 2026	lung nodules unless otherwise specified [in the policy], such as: ▪ Percepta Genomic Sequencing Classifier ○ Solid tumor profiling that includes Whole-Exome Sequencing, Whole-Genome Sequencing, or whole-transcriptome sequencing, such as: ▪ CancerVision ▪ Caris Assure ▪ Tempus xE ▪ Tempus xR ▪ OncoExTra ○ Tempus Immune Profile Score ○ Whole-genome methylation profiling ○ EpiSwitch Checkpoint inhibitor Response Test **Medical Records Documentation Used for Reviews** • Updated list of Medical Records Documentation Used for Reviews to reflect/include: ○ Name and specialty of the provider ordering the testing ○ Primary cancer diagnosis, pathology, tumor size, and nodal status ○ Results and dates of prior testing or screening, such as hormone receptor status, biopsy, fine needle aspiration,	○ OncoExTra • Tempus Immune Profile Score • Whole-genome methylation profiling • EpiSwitch Checkpoint inhibitor Response Test

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions (continued)	Oct. 1, 2026	or genetic testing ○ How clinical management will be impacted based on the results of this [service] **Definitions** • Removed definition of: ○ Comparative Genome Hybridization (CGH) ○ Very High-Risk Prostate Cancer • Updated definition of: ○ Favorable Intermediate-Risk Prostate Cancer ○ High-Risk Prostate Cancer ○ Measurable Residual Disease ○ Unfavorable Intermediate-Risk Prostate Cancer ○ Whole-Exome Sequencing **Applicable Codes** • Added CPT/HCPCS codes 0285U, 0405U, 0534U, 0560U, 0561U, 0620U, 0630U, 0631U, 0641U, 0642U, 0643U, 0646U, 0647U, and S3854 • Removed CPT codes 0022U, 0037U, 0211U, 0239U, 0242U, 0523U, and 0592U **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	
Skin and Soft Tissue Substitutes	Oct. 1, 2026	**Coverage Rationale** • Revised list of skin and soft tissue substitutes that are unproven and not medically necessary for any indication; added:	**EPIFIX® or GRAFIX® (GRAFIX PL, GRAFIX PRIME, and GRAFIX PL PRIME) (Noninjectable)** **EPIFIX or GRAFIX is proven and medically necessary for treating a diabetic foot ulcer when all the following criteria are met:**

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Skin and Soft Tissue Substitutes (continued)	Oct. 1, 2026	○ A/C Wrap ○ BIOBRANE or BIOBRANE Glove ○ BioLab Membrane Wrap Flow, BioLab Membrane Wrap Flow Solo, BioLab Membrane Wrap-Lite Flow, or BioLab Tri-Membrane Wrap Flow ○ CuraMatrix ○ DermaBind CH N or CH X, DermaBind DL N, DL+, or DL X, or DermaBind SL N, SL+, or SL X ○ DermaBind TL+ or TL X ○ Foundation Dermal Regeneration Scaffold (DRS) + Duo or DRS + Solo ○ Instagraft ○ NOVASHIELD or NovoGen Wound Matrix ○ Omeza Complete Matrix ○ Pretect ○ Renati Membrane and Renati AC Membrane ○ Revival AC ○ Revive FT or Revive TL ○ Suprello **Applicable Codes** • Added HCPCS codes A2040, A2041, A2042, A2043, A2044, A2045, Q4418, Q4419, Q4421, Q4422, Q4423, Q4424, Q4425, Q4426, Q4427, Q4428, Q4429, Q4435, Q4436, Q4437, Q4438, Q4439, and Q4440	• Adequate circulation to the affected extremity, as indicated by one or more of the following: ○ Pedal pulses palpable or pulses confirmed with Doppler examination ○ Ankle-Brachial Index between 0.7 and 1.2 • Glycated hemoglobin test < 12% (within the last 90 days) • Ulcer has failed to demonstrate adequate healing, with at least 4 weeks of standard wound care, which includes **all** of the following: ○ Application of dressings to maintain a moist wound environment ○ Debridement of necrotic tissue if present ○ Offloading • No known contraindications, which may include but are not limited to the following: ○ Active Charcot deformity or major structural abnormalities of the affected foot ○ Chronic infection to the ulcer site ○ Known or suspected malignancy of the current ulcer being treated ○ Ulcer being treated does not extend to tendon, muscle, capsule, or bone **Due to insufficient evidence of efficacy, EPIFIX and/or GRAFIX are unproven and not medically necessary for all other indications.** **TransCyte®** **TransCyte is proven and medically necessary for treating surgically excised Full-Thickness Thermal Burn wounds and deep Partial-Thickness Thermal Burn wounds before autograft placement.** **TransCyte is unproven and not medically necessary for all other indications due to insufficient evidence of efficacy.** **Other Skin and Soft Tissue Substitutes** Refer to the policy for a list of skin and soft tissue substitutes that are unproven and not medically necessary for any indication due to insufficient evidence of efficacy.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Skin and Soft Tissue Substitutes (continued)	Oct. 1, 2026	• Revised description for HCPCS codes A2014 and A2037 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	Refer to the Medical Policy titled Breast Reconstruction for information about coverage for skin and soft tissue substitutes used during post mastectomy breast reconstruction procedures. **Note**: Refer to the *Clinical Evidence* section of the policy for specific product information.

Surgery of the Foot	Oct. 1, 2026	**Coverage Rationale**
		Interposition/Interpositional Arthroplasty
		• Added language to indicate Interposition/Interpositional Arthroplasty of the first or second metatarsophalangeal joint, using any method, is unproven and not medically necessary for treating limitations in motion or degenerative changes due to insufficient evidence of efficacy
		Definitions
		• Updated definition of "Interposition/Interpositional Arthroplasty"
		Supporting Information
		• Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information
			Surgery of the foot is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures:
			• Arthrodesis or Arthroplasty, Interphalangeal Joint, Second-Fifth Toes
			• Exostectomy, First Metatarsophalangeal (MTP) Joint (Bunionectomy)
			• Osteotomy, Distal Transpositional, First Metatarsal (MT) (Bunionectomy)
			• Osteotomy, Proximal, First Metatarsal (MT) (Bunionectomy)
			• Osteotomy, Proximal Phalanx, First Toe ±Bunionectomy
			• Plantar Fascial Release
			
			Click here to view the InterQual® criteria.
			
			Hallux Limitus or Rigidus (Correction Without Implant)
			Correction of the first metatarsophalangeal joint with cheilectomy, debridement, and capsular release without implant is proven and medically necessary when all the following criteria are met:
			• Diagnosis of hallux limitus or hallux rigidus to include the following:
			  ○ Radiographic imaging to confirm a mild to moderate pathology (i.e., a grading scale such as the Coughlin and Shurnas or Hattrup and Johnson Classification may be used)
			• Persistent pain despite a reasonable trial of conservative treatment, including one or more of the following:
			  ○ Orthotics, shoe modification (e.g., high and wide toe box, rocker bottom sole), and/or shoe inserts
			  ○ Medical therapy (nonsteroidal anti-inflammatory drugs, analgesics, or intra-articular injections)
			  ○ Activity modification
			  ○ Debridement of hyperkeratotic lesions, if present

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

Surgery of the Foot (continued)	Oct. 1, 2026		**Correction of the first metatarsophalangeal joint with cheilectomy, debridement, and capsular release without implant is unproven and not medically necessary for severe hallux rigidus (i.e., a grading scale such as the Coughlin and Shurnas or Hattrup and Johnson Classification may be used) due to insufficient evidence of efficacy.**
			
			Hallux Rigidus (Correction With Implant)
			Correction of the first metatarsophalangeal joint with cheilectomy, debridement, and capsular release with implant (Hemi-Implant Arthroplasty or Total Implant Arthroplasty) is proven and medically necessary when all the following criteria are met:
			• Diagnosis of hallux rigidus to include the following:
			  ○ Radiographic imaging to confirm a moderate to severe pathology (i.e., a grading scale such as the Coughlin and Shurnas or Hattrup and Johnson Classification may be used)
			• Persistent pain despite a reasonable trial of conservative treatment, including one or more of the following:
			  ○ Orthotics, shoe modification (e.g., high and wide toe box, rocker bottom sole), and/or shoe inserts
			  ○ Medical therapy (nonsteroidal anti-inflammatory drugs, analgesics, or intra-articular injections)
			  ○ Activity modification
			  ○ Debridement of hyperkeratotic lesions, if present
			
			Interposition/Interpositional Arthroplasty
			Due to insufficient evidence of efficacy, Interposition/Interpositional Arthroplasty of the first or second metatarsophalangeal joint, using any method, is unproven and not medically necessary for treating limitations in motion or degenerative changes.
			
			Osteochondral Allograft or Autograft Transplant
			Osteochondral allograft or autograft transplant is unproven and not medically necessary for treating cartilage defects of the foot due to insufficient evidence of efficacy.

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgery of the Hip	Oct. 1, 2026	**Coverage Rationale** • Revised language pertaining to medical necessity clinical coverage criteria; removed reference to the InterQual® CP: Procedures, Arthroscopy, Diagnostic, +/- Synovial Biopsy, Hip **Definitions** • Updated definition of "Hip Disability and Osteoarthritis Outcome Score (HOOS)" **Applicable Codes** • Removed CPT code 29860 • Revised description for CPT codes 27299 and 29999 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	**Surgery of the hip and surgical treatment for Femoroacetabular Impingement Syndrome is proven and medically necessary in certain circumstances.** For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures: • Arthroscopy, Surgical, Hip • Arthroscopy, Surgical, Hip (Pediatric) • Arthrotomy, Hip • Hemiarthroplasty, Hip • Removal and Replacement, Total Joint Replacement (TJR), Hip • Total Joint Replacement (TJR), Hip Click here to view the InterQual® criteria. **Surgical treatment for Femoroacetabular Impingement Syndrome is unproven and not medically necessary in the presence of advanced osteoarthritis (i.e., Tönnis Grade 2 or 3) and/or severe cartilage damage (i.e., Outerbridge Grade III or IV).**

Surgery of the Shoulder	Oct. 1, 2026	**Coverage Rationale**
		• Revised language pertaining to medical necessity clinical coverage criteria; removed reference to the InterQual® CP: Procedures, Arthroscopy, Diagnostic, +/- Synovial Biopsy, Shoulder
		Applicable Codes
		• Removed CPT code 29805
			Surgery of the shoulder is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the:
			• InterQual® CP: Procedures:
			  ○ Arthroscopy or Arthroscopically Assisted Surgery, Shoulder
			  ○ Arthroscopy or Arthroscopically Assisted Surgery, Shoulder (Adolescent)
			  ○ Joint Replacement, Shoulder
			  ○ Removal and Replacement or Revision, Joint Replacement, Shoulder
			
			Click here to view the InterQual® criteria.
			
			Subacromial balloon spacers for the treatment of rotator cuff tears are unproven and not medically necessary due to insufficient evidence of efficacy.

Medical Policy Updates

Retired		
Policy Title	**Effective Date**	**Summary of Changes**
Cytological Examination of Breast Fluids for Cancer Screening or Diagnosis	Aug. 1, 2026	• Retired policy; cytological examination of breast fluids for cancer screening or diagnosis no longer requires clinical review
Embolization of the Ovarian and Iliac Veins for Pelvic Congestion Syndrome	Aug. 1, 2026	• Retired policy; embolization of the ovarian and iliac veins for pelvic congestion syndrome no longer requires clinical review

Medical Benefit Drug Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Roctavian® (Valoctocogene Roxaparvovec-Rvox)	Aug. 1, 2026	**Application** ***Texas*** • Removed language indicating this Medical Benefit Drug Policy does not apply to the state of Texas
Skyrizi® (Risankizumab-Rzaa)	Aug. 1, 2026	**Coverage Rationale** • Replaced references to "targeted immunomodulator" with "systemic targeted immunomodulator" • Updated coverage criteria; added language to clarify the patient must not be receiving Skyrizi in combination with another systemic targeted immunomodulator *for treatment of the same indication* **Supporting Information** • Updated *References* section to reflect the most current information
White Blood Cell Colony Stimulating Factors	Sep. 1, 2026	**Application** • Added language to indicate the *Preferred Product* language and the *Preferred Product Criteria* do not apply to the state of Virginia; refer to the Virginia DMAS' *Common Core Formulary* for preferred product criteria **Coverage Rationale** • Revised list of applicable white blood cell colony stimulating factors (CSFs); added Armlupeg® (pegfilgrastim-unne) • Added language to indicate coverage for Armlupeg will be provided contingent on the criteria in the *Preferred Product Criteria* and *Diagnosis-Specific Criteria* sections [of the policy] • Removed language indicating the long-acting and short-acting preferred product criteria in the *Preferred Product Criteria* sections [of the policy] apply to the states of Minnesota (MN) and Virginia (VA) **Applicable Codes** • Added HCPCS code Q5169 **Supporting Information** • Updated *Background*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab	Sep. 1, 2026	**Coverage Rationale** • Revised list of applicable denosumab products; added: ○ Aukelso™ (denosumab-kyqq) ○ Bosaya™ (denosumab-kyqq) ○ Enoby™ (denosumab-qbde) ○ Ospomyv™ (denosumab-dssb) ○ Xbryk™ (denosumab-dssb)	This policy refers to the following denosumab products: • Aukelso™ (denosumab-kyqq) • Bildyos® (denosumab-nxxp) • Bilprevda® (denosumab-nxxp) • Bomyntra® (denosumab-bnht) • Bosaya™ (denosumab-kyqq) • Conexxence® (denosumab-bnht) • Enoby™ (denosumab-qbde) • Jubbonti® (denosumab-bbdz)

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab (continued)	Sep. 1, 2026	○ Xtrenbo™ (denosumab-qbde) • Added language to indicate: ○ Enoby and Xtrenbo are preferred denosumab products; coverage will be provided for Enoby and Xtrenbo contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ Aukelso, Bosaya, Ospomyv, and Xbryk are non-preferred products; coverage for Aukelso, Bosaya, Ospomyv, and Xbryk is contingent on the *Preferred Product Criteria* and *Diagnosis-Specific Criteria* [sections of the policy] • Revised preferred product criteria and diagnosis-specific criteria to include Aukelso, Bosaya, Enoby, Ospomyv, Xbryk, and Xtrenbo • Replaced language indicating "denosumab, *denosumab-bbdz, denosumab-bmwo, denosumab-bnht, and denosumab-nxxp* are unproven and not medically necessary for the [listed] indications" with "denosumab is unproven and not medically necessary for the [listed] indications" **Applicable Codes** • Added HCPCS codes Q5159, Q5161, and Q5167	• Osenvelt® (denosumab-bmwo) • Ospomyv™ (denosumab-dssb) • Prolia® (denosumab) • Stoboclo® (denosumab-bmwo) • Wyost® (denosumab-bbdz) • Xbryk™ (denosumab-dssb) • Xgeva® (denosumab) • Xtrenbo™ (denosumab-qbde) • Any U.S. Food and Drug Administration (FDA)–approved denosumab biosimilar not listed here Refer to the policy for complete details.

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Denosumab (continued)	Sep. 1, 2026	**Supporting Information** • Updated *Background*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Factor Mimetics and Rebalancing Agents for Hemophilia	Oct. 1, 2026	**Coverage Rationale** • Replaced language indicating "marstacimab-hncq (Hympavzi) is medically necessary for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with hemophilia A *without factor VIII inhibitors*/hemophilia B *without factor IX inhibitors*" with "marstacimab-hncq (Hympavzi) is medically necessary for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with hemophilia A/hemophilia B" • Revised coverage criteria: ○ Replaced criterion requiring "[the drug product is] prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)" with "[the drug product is] prescribed for the prevention *or reduction in frequency* of bleeding episodes (i.e., routine prophylaxis)" Marstacimab-hncq (Hympavzi) ○ Added criterion for initial therapy to allow coverage when both of the following are met:	This policy refers to the following products: • Antithrombin-directed small interfering ribonucleic acid (siRNA): Qfitlia® (fitusiran) • Bispecific factor IXa- and factor X-directed antibody: Hemlibra® (emicizumab-kxwh) • Tissue factor pathway inhibitor (TFPI) antagonist: Alhemo® (concizumab-mtci) and Hympavzi® (marstacimab-hncq) Refer to the policy for complete details.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Factor Mimetics and Rebalancing Agents for Hemophilia (continued)	Oct. 1, 2026	▪ Diagnosis of hemophilia A/hemophilia B ▪ The patient has developed high-titer factor VIII/factor IX inhibitors [i.e., patient has developed factor VIII/factor IX inhibitors greater than or equal to 5 Bethesda units (BU)] ○ Replaced criterion requiring: ▪ "The patient is ***12*** years of age or older" with "the patient is ***6*** years of age or older" ▪ "The patient cannot self-inject and does not have a caretaker who can be trained to administer Hympavzi" with "*the patient is less than 12 years of age* ***or*** the patient *is 12 years of age or older and* cannot self-inject and does not have a caretaker who can be trained to administer Hympavzi" **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information	
FcRn Blockers	Oct. 1, 2026	**Coverage Rationale** ***Generalized Myasthenia Gravis*** • Replaced criterion requiring: ○ "Positive serologic test for anti-AChR antibodies" with	This policy refers to the following drug products for administration by a healthcare professional: • Imaavy™ (nipocalimab-aahu) for intravenous (IV) route • Rystiggo® (rozanolixizumab-noli) for subcutaneous (SC) route • Vyvgart® (efgartigimod alfa-fcab) for intravenous (IV) route

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
FcRn Blockers (continued)	Oct. 1, 2026	"*One of the following:* positive serologic test for anti-AChR antibodies, *positive serologic test for anti-MuSK antibodies, positive serologic test for anti-LRP4 antibodies, or negative serologic test for anti-AChR, anti-MuSK, and anti-LRP4 antibodies (triple seronegative)*" ○ "One of the following: the patient has a history of failure of at least two immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.), or the patient has a history of failure of at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/plasma exchanges and/or immune globulin over the course of at least 12 months without symptom control" with "*if anti-AChR antibody positive, anti-LRP4 antibody positive, or triple seronegative,* one of the following: the patient has a history of failure of at least two immunosuppressive agents over the course of at least 12 months (e.g.,	• Vyvgart Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc) vial for subcutaneous (SC) route Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) prefilled syringe for self-administered subcutaneous injection is obtained under the pharmacy benefit. Refer to the policy for complete details.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
FcRn Blockers (continued)	Oct. 1, 2026	azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.), or the patient has a history of failure of at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/plasma exchanges and/or immune globulin over the course of at least 12 months without symptom control • Added criterion requiring the patient has a history of failure of at least one immunosuppressive agent over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.) if anti-muscle-specific tyrosine kinase (MuSK) antibody positive **Applicable Codes** • Added ICD-10 diagnosis code G70.0 **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Medical Therapies for Enzyme Deficiencies	Oct. 1, 2026	**Application** ***Indiana*** • Replaced reference link to the state-specific version with language to indicate: ○ This Medical Benefit Drug	This policy refers to the following medical therapies for enzyme deficiency products: • Aldurazyme® (laronidase) • Avlayah™ (tividenofusp alfa-eknm) • Elaprase® (idursulfase) • Elfabrio® (pegunigalsidase alfa-iwxj)

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Medical Therapies for Enzyme Deficiencies (continued)	Oct. 1, 2026	Policy does not apply for Lumizyme (HCPCS code J0221), Nexviazyme (HCPCS code J0219), and Pombiliti (HCPCS code J1203); refer to the state's Medicaid clinical policy ○ This Medical Benefit Drug Policy applies for all other drug products [not listed above] **Coverage Rationale** • Revised list of applicable medical therapies for enzyme deficiency products; added: ○ Avlayah™ (tividenofusp alfa-eknm) ○ Loargys® (pegzilarginase-nbln) • Added language to indicate: ○ Coverage for Avlayah and Loargys is contingent on criteria in the *Drug-Specific Criteria* section [of the policy] ○ **Avlayah (tividenofusp alfa)** is medically necessary for the treatment of neurologic manifestations of Hunter syndrome (Mucopolysaccharidosis type II, MPS II) when the following criteria are met: ***Initial Therapy*** ▪ Diagnosis of MPS II confirmed by one of the following: – Deficiency in	• Fabrazyme® (agalsidase beta) • Kanuma® (sebelipase alfa) • Lamzede® (velmanase alfa-tycv) • Loargys® (pegzilarginase-nbln) • Lumizyme® (alglucosidase alfa) • Mepsevii™ (vestronidase alfa-vjbk) • Naglazyme® (galsulfase) • Nexviazyme™ (avalglucosidase alfa-ngpt) • Nulibry™ (fosdenopterin) • Pombiliti™ (cipaglucosidase alfa-atga) • Revcovi™ (elapegademase-lvlr) • Vimizim® (elosulfase alfa) • Xenpozyme™ (olipudase alfa-rpcp) Refer to the policy for complete details.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Medical Therapies for Enzyme Deficiencies (continued)	Oct. 1, 2026	iduronate 2-sulfatase enzyme activity as measured in fibroblasts or leukocytes combined with normal enzyme activity level of another sulfatase – Molecular genetic testing for deletion or mutations in the iduronate 2-sulfatase gene ▪ Presence of clinical signs and symptoms of the disease (e.g., hepatosplenomegaly, skeletal deformities, dysostosis, neurocognitive decline, cardiovascular disorders, etc.) ▪ Avlayah is not being used to treat MPS II in combination with Elaprase ▪ Dosing is in accordance with the U.S. FDA-approved labeling ▪ Initial authorization will be for no more than 12 months ***Continuation of Therapy*** ▪ Patient has previously received treatment with tividenofusp alfa ▪ Patient has experienced	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Medical Therapies for Enzyme Deficiencies (continued)	Oct. 1, 2026	a positive clinical response to tividenofusp alfa therapy (e.g., improved hearing, improved functional capacity, improved neurological symptoms, reduced spleen volume, reduced urine glycosaminoglycan excretion, etc.) ▪ Avlayah is not being used to treat MPS II in combination with Elaprase ▪ Dosing is in accordance with the U.S. FDA-approved labeling ▪ Reauthorization will be for no more than 12 months ○ **Loargys (pegzilarginase)** is medically necessary for the treatment of hyperargininemia when the following criteria are met: ***Initial Therapy*** ▪ Diagnosis of hyperargininemia (arginase 1 deficiency) confirmed by one of the following: – Absence or deficiency of arginase 1 enzyme activity – Genetic variants in the *ARG1* gene	

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Medical Therapies for Enzyme Deficiencies (continued)	Oct. 1, 2026	▪ Presence of clinical signs and symptoms of the disease (e.g., loss of motor skills, intellectual disability, developmental delay) ▪ Dosing is in accordance with the U.S. FDA-approved labeling ▪ Initial authorization will be for no more than 12 months ***Continuation of Therapy*** ▪ Patient has previously received treatment with pegzilarginase therapy ▪ Patient has experienced a positive clinical response to pegzilarginase therapy (e.g., improved motor function, improved pulmonary function) ▪ Dosing is in accordance with the U.S. FDA-approved labeling ▪ Reauthorization will be for no more than 12 months • Revised coverage criteria for Elaprase (idursulfase) for the treatment of mucopolysaccharidosis II (MPS II, Hunter syndrome); added criterion requiring Elaprase is not being used to treat MPS II in combination with Avlayah	

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Medical Therapies for Enzyme Deficiencies (continued)	Oct. 1, 2026	**Applicable Codes** ***Avlayah*** • Added HCPCS codes C9399, J3490, and J3590 • Added ICD-10 diagnosis code E76.1 ***Loargys*** • Added HCPCS codes C9399, J3490, and J3590 • Added ICD-10 diagnosis code E27.21 **Supporting Information** • Updated *Background*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Oncology Medication Clinical Coverage	Sep. 1, 2026	**Coverage Rationale** ***Oncology Products*** • Revised list of UnitedHealthcare non-preferred products for all oncology indications; added Vykoura (leucovorin)	**Description** This policy provides parameters for coverage of injectable oncology medications (including, but not limited to, octreotide acetate, leuprolide acetate, leucovorin, and levoleucovorin), including therapeutic radiopharmaceuticals, covered under the medical benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®). The Compendium lists the appropriate drugs and biologics for specific cancers using U.S. Food and Drug Administration (FDA)–approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category. Refer to the Medical Benefit Drug Policy titled White Blood Cell Colony Stimulating Factors or Erythropoiesis-Stimulating Agents, for information on those agents. This policy does not provide coverage criteria for chimeric antigen receptor (CAR) T-cell or tumor-infiltration lymphocyte (TIL) cell products. Coverage determinations are based on the member's benefits and the OptumHealth Transplant Solutions criteria for covered transplants in the Clinical Guideline titled Chimeric Antigen Receptor T-Cell (CAR T) Therapy or Tumor-Infiltrating Lymphocyte (TIL) Cell Therapy.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Oncology Medication Clinical Coverage (continued)	Sep. 1, 2026		**Coverage Rationale** The Oncology Products table in the policy lists the UnitedHealthcare preferred oncology products and respective non-preferred products. Coverage will be provided for the UnitedHealthcare preferred oncology product contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section. Coverage for any respective non-preferred oncology product will be provided contingent on the criteria in the *Preferred Product Criteria* and the *Diagnosis-Specific Criteria* sections. ***Preferred Product Criteria*** **Treatment with the respective non-preferred product specified in the Oncology Products table in the policy is medically necessary for oncology indications when both of the following are met:** • History of intolerance or contraindication to one of UnitedHealthcare's preferred oncology products; and • Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with the respective non-preferred product. **Oncology Products** Refer to the policy for a list of UnitedHealthcare preferred and non-preferred oncology products and corresponding indications. Any U.S. Food and Drug Administration (FDA)–approved product that may belong to the UnitedHealthcare Preferred or Non-Preferred Oncology Product categories and/or are approved via FDA 505(b)(2) approval process, but not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare P&T committee. ***Diagnosis-Specific Criteria*** **Injectable Oncology Medications** UnitedHealthcare recognizes indications and uses of injectable oncology medications, including therapeutic radiopharmaceuticals, in the NCCN Drugs

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Oncology Medication Clinical Coverage (continued)	Sep. 1, 2026		and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and Categories of Evidence and Consensus of 3 as unproven and not medically necessary. (However, refer to the *Benefit Considerations* section in the policy.) When there is no NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus, coverage determinations shall be based upon FDA labelling. UnitedHealthcare will cover all chemotherapy agents for individuals under the age of 19 years for oncology indications. The majority of pediatric patients receive treatments on national pediatric protocols that are quite similar in concept to the NCCN patient care guidelines. Refer to *Preferred Product Criteria* for the UnitedHealthcare preferred oncology products and indications.
Respiratory Interleukins	Oct. 1, 2026	**Title Change** • Previously titled *Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®)* **Application** ***Florida*** • Added language to clarify instruction to refer to the state's Medicaid clinical policy, *if available for the specific product, otherwise this Medical Benefit Drug Policy applies* ***Texas*** • Added language to clarify instruction to refer to the drug-specific criteria found within the *Texas Medicaid Provider Procedures Manual*, *if available for the specific product, otherwise this Medical Benefit Drug Policy applies*	This policy refers to the following drug products for administration by a healthcare professional: • Cinqair® (reslizumab) for intravenous (IV) route • Exdensur™ (depemokimab-ulaa) for subcutaneous (SC) route • Fasenra® (benralizumab) for subcutaneous (SC) route • Nucala® (mepolizumab) for subcutaneous (SC) route Refer to the policy for complete details.

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

Respiratory Interleukins (continued)	Oct. 1, 2026	**Coverage Rationale**
		• Revised list of applicable drug products for administration by a healthcare professional; added Exdensur™ (depemokimab-ulaa) for subcutaneous (SC) route
		• Added language to indicate:
		  ○ Exdensur unproven and not medically necessary for:
		  ▪ Acute bronchospasm
		  ▪ Chronic obstructive pulmonary disease (COPD)
		  ▪ Granulomatosis with polyangiitis (Wegener's)
		  ▪ Microscopic polyangiitis
		  ▪ Organ or life-threatening EGPA
		  ▪ Other eosinophilic conditions
		  ▪ Status asthmaticus
		  ○ Exdensur is proven and medically necessary for add-on therapy for the maintenance treatment of severe asthma in patients with an eosinophilic phenotype when the criteria [listed in the policy] are met
		  ○ Fasenra, for provider administration, is proven and medically necessary for patients with hypereosinophilic syndrome (HES) for greater than or equal to 6 months without an identifiable non-hematologic	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (continued)	Oct. 1, 2026	secondary cause when the criteria [listed in the policy] are met • Replaced language indicating: ○ "Cinqair/Fasenra is proven and medically necessary [for patients with severe asthma]" with "Cinqair/Fasenra is proven and medically necessary *for add-on maintenance therapy* for patients with severe asthma *with an eosinophilic phenotype*" ○ "Nucala, for provider administration, is proven and medically necessary [for patients with hypereosinophilic syndrome (HES)]" with "Nucala, for provider administration, is proven and medically necessary for patients with hypereosinophilic syndrome (HES) *for greater than or equal to 6 months without an identifiable non-hematologic secondary cause*" ○ "Nucala, for provider administration, is proven and medically necessary for patients with COPD" with "Nucala, for provider administration, is proven and medically necessary for patients with *inadequately controlled* COPD *and an*	

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Respiratory Interleukins (continued)	Oct. 1, 2026	*eosinophilic phenotype*” • Revised coverage criteria: ○ Updated list of examples of anti-interleukin 5 therapies the patient must not be receiving in combination with Cinqair/Fasenra/Nucala; added Exdensur (depemokimab) ○ Replaced criterion for Cinqair for patients with severe asthma requiring: ▪ “Asthma is an eosinophilic phenotype as defined by a baseline (pre-*reslizumab*) peripheral blood eosinophil level of ≥ 150 cells/µL” with “asthma is an eosinophilic phenotype as defined by a baseline (pre-*treatment*) peripheral blood eosinophil level of ≥ 150 cells/µL” ▪ “Contraindication or intolerance to Fasenra *or* Nucala” with “contraindication or intolerance to Fasenra *and* Nucala” ○ Removed criterion for continuation of therapy with Fasenra and Nucala requiring: ▪ Physician attestation that the patient or caregiver is	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (continued)	Oct. 1, 2026	not competent or is physically unable to administer the Fasenra or Nucala product U.S. FDA-labeled for self-administration ▪ Patient has documented history of severe hypersensitivity reactions (e.g., anaphylaxis, angioedema, bronchospasm, or hypotension) to Fasenra or Nucala within the past 6 months and requires administration and direct monitoring by a healthcare professional ○ Removed criterion for for continuation of therapy with Nucala for patients with severe asthma or CRSwNP requiring the patient is ≤ 11 years of age **Applicable Codes** • Added HCPCS code J2361 **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Spinraza® (Nusinersen)	Sep. 1, 2026	**Coverage Rationale** • Revised coverage criteria: ***Initial Therapy*** ○ Updated list of examples of other gene therapies for the	**Spinraza® (nusinersen) is proven and medically necessary for the treatment of spinal muscular atrophy (SMA) in patients who meet all of the following criteria:** • For **initial therapy**, **all** of the following: ○ Diagnosis of spinal muscular atrophy by, or in consultation with, a neurologist with expertise in the diagnosis of SMA; **and**

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Spinraza® (Nusinersen) (continued)	Sep. 1, 2026	treatment of spinal muscular atrophy (SMA); added Itvisma (onasemnogene abeparvovec-brve) ○ Replaced criterion requiring "initial authorization will be for *no more than 4 loading doses*" with "initial authorization will be for *the loading dose period of the prescribed FDA-approved regimen (up to 4 loading doses for the low dose regimen or up to 2 loading doses for the high dose regimen)*" ***Continuation of Therapy*** ○ Replaced criterion requiring "reauthorization will be for no more than 3 *maintenance* doses (12 months)" with "reauthorization will be for no more than 3 doses (12 months); *patients transitioning from the Spinraza low dose regimen to high dose regimen may receive a one-time 50 mg bolus dose administered at least 4 months (±14 days) after the last 12 mg maintenance dose, followed by 28 mg maintenance dosing every 4 months thereafter, and the one-time 50 mg bolus dose is included in the limit of no more than 3*	○ Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation or deletion of genes in chromosome 5q resulting in **one** of the following: ▪ Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13); **or** ▪ Compound heterozygous mutation [e.g., deletion of *SMN1* exon 7 (allele 1) and mutation of *SMN1* (allele 2)] **and** ○ Patient is not dependent on either of the following: ▪ Invasive ventilation; **or** ▪ Use of non-invasive ventilation beyond use for naps and nighttime sleep **and** ○ Submission of medical records (e.g., chart notes, laboratory values) of the baseline exam of at least **one** of the following exams (based on patient age and motor ability) to establish baseline motor ability:* *Baseline assessments for patients less than 2 months of age are not necessary in order to not delay access to initial therapy in recently diagnosed infants. Initial assessments shortly post-therapy can serve as baseline with respect to efficacy reauthorization assessment. ▪ Hammersmith Infant Neurological Exam Part 2 (HINE-2) (infant to early childhood); **or** ▪ Hammersmith Functional Motor Scale Expanded (HFMSE); **or** ▪ Revised Upper Limb Module (RULM) Test; **or** ▪ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) **and** ○ Spinraza is prescribed by, or in consultation with, a neurologist with expertise in the treatment of SMA; **and** ○ **One** of the following: ▪ Patient has not previously received gene replacement therapy for the treatment of SMA [e.g., Itvisma (onasemnogene abeparvovec-brve), Zolgensma (onasemnogene abeparvovec-xioi)]; **or** ▪ **Both** of the following: – Patient has previously received gene replacement therapy

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Spinraza® (Nusinersen) (continued)	Sep. 1, 2026	*doses per 12-month reauthorization period*" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	[e.g., Itvisma (onasemnogene abeparvovec-brve), Zolgensma (onasemnogene abeparvovec-xioi)] for the treatment of SMA; **and** – Submission of medical records (e.g., chart notes, laboratory values) documenting a clinically meaningful functional decline (e.g., loss of motor milestone) since receiving gene replacement therapy [e.g., Itvisma (onasemnogene abeparvovec-brve), Zolgensma (onasemnogene abeparvovec-xioi)] **and** ○ Patient is not receiving concomitant chronic survival motor neuron (SMN) modifying therapy [e.g., Evrysdi (risdiplam)]; **and** ○ Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures; **and** ○ Spinraza dosing for SMA is within accordance with the U.S. Food and Drug Administration (FDA)–approved labeling; **and** ○ Provider does not request a planned inpatient admission for the sole purpose of administering Spinraza; **and** ○ Initial authorization will be for the loading dose period of the prescribed FDA-approved regimen (up to 4 loading doses for the low dose regimen or up to 2 loading doses for the high dose regimen) • For **continuation of therapy**, **all** of the following: ○ Diagnosis of spinal muscular atrophy by, or in consultation with, a neurologist with expertise in the diagnosis of SMA; **and** ○ Patient has previously received Spinraza therapy; **and** ○ Patient is not dependent on either of the following: ▪ Invasive ventilation; **or** ▪ Use of non-invasive ventilation beyond use for naps and nighttime sleep **and** ○ Patient is not receiving concomitant chronic survival motor neuron (SMN) modifying therapy [e.g., Evrysdi (risdiplam)]; **and** ○ Submission of medical records (e.g., chart notes, laboratory values) with the most recent results documenting a positive clinical response from pretreatment baseline status to Spinraza therapy as demonstrated by at least **one** of the following exams:

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Spinraza® (Nusinersen) (continued)	Sep. 1, 2026		▪ HINE-2 milestones: **One** of the following: – Improvement or maintenance of previous improvement of at least two point (or maximal score) increase in ability to kick; **or** – Improvement or maintenance of previous improvement of at least one point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp; **or** – The patient exhibited improvement or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement); **or** – Achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk) **or** ▪ HFMSE: **One** of the following: – Improvement or maintenance of previous improvement of at least a 3-point increase in score from pretreatment baseline; **or** – Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so **or** ▪ RULM: **One** of the following: – Improvement or maintenance of previous improvement of at least a 2-point increase in score from pretreatment baseline; **or** – Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so **or** ▪ CHOP INTEND: **One** of the following: – Improvement or maintenance of previous improvement of at least a 4-point increase in score from pretreatment baseline; **or** – Patient has achieved and maintained any new motor

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Spinraza® (Nusinersen) (continued)	Sep. 1, 2026		milestone from pretreatment baseline when they would otherwise be unexpected to do so **and** ○ Spinraza is prescribed by, or in consultation with, a neurologist with expertise in the treatment of SMA; **and** ○ Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures; **and** ○ Spinraza dosing for SMA is within accordance with the FDA-approved labeling; **and** ○ Provider does not request a planned inpatient admission for the sole purpose of administering Spinraza; **and** ○ Reauthorization will be for no more than three doses** (12 months). **Patients transitioning from the Spinraza low dose regimen to high dose regimen may receive a one-time 50 mg bolus dose administered at least 4 months (±14 days) after the last 12 mg maintenance dose, followed by 28 mg maintenance dosing every 4 months thereafter. The one-time 50 mg bolus dose is included in the limit of no more than 3 doses per 12-month reauthorization period. **Unproven** **Spinraza is not proven or medically necessary for:** • Spinal muscular atrophy without chromosome 5q mutations or deletions • Concomitant treatment of SMA in patients receiving survival motor neuron (SMN) modifying therapy [e.g., Evrysdi (risdiplam)]
Tocilizumab	Sep. 1, 2026	**Coverage Rationale** • Added language to indicate: ○ Avtozma® (tocilizumab-anoh) is a preferred tocilizumab product; coverage will be provided for Avtozma contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ In order to continue coverage, members already on	This policy refers to tocilizumab products administered by intravenous infusion only. Tocilizumab for self-administered subcutaneous injection is obtained under the pharmacy benefit. This policy refers to the following tocilizumab products: • Actemra® (tocilizumab) • Avtozma® (tocilizumab-anoh) • Tofidence® (tocilizumab-bavi) • Tyenne® (tocilizumab-aazg) • Any U.S. Food and Drug Administration (FDA)–approved tocilizumab biosimilar not listed here

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Tocilizumab (continued)	Sep. 1, 2026	Actemra® (tocilizumab) or other non-preferred tocilizumab products may be required to change therapy to Avtozma® (tocilizumab-anoh) unless they meet the criteria in the *Preferred Product Criteria* section [of the policy] • Removed language indicating coverage for Avtozma® (tocilizumab-anoh) is contingent on criteria in the *Preferred Product Criteria* section [of the policy] • Revised preferred product criteria to indicate treatment with Actemra or other non-preferred tocilizumab biosimilar products is medically necessary for the indications outlined in this policy when one of the following criteria is met: ○ Both of the following: ▪ History of a trial of adequate dose and duration of two of the following resulting in minimal clinical response to therapy and residual disease activity: – Tofidence – Tyenne – Avtozma ▪ Physician attests that, in their clinical opinion, the clinical response would be expected to be	Refer to the Medical Benefit Drug Policy titled Oncology Medication Clinical Coverage for updated information based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®) for oncology indications. Refer to the policy for complete details.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Tocilizumab (continued)	Sep. 1, 2026	superior with Actemra or other tocilizumab biosimilar product than experienced with Tofidence, Tyenne, and Avtozma ○ Both of the following: ▪ History of intolerance, contraindication, or adverse event to Tofidence Tyenne, and Avtozma ▪ Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with Actemra or other tocilizumab biosimilar product	

General Information

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

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

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

Policy Update Classifications

New

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

Updated

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

Revised

An existing policy has been reviewed and revisions have been made to the clinical coverage criteria

Replaced

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

Retired

The health service(s) addressed in the policy are no longer being managed or are considered to be proven/medically necessary and are therefore not excluded as unproven/not medically necessary services, unless coverage guidelines or criteria are otherwise documented in another policy

The complete library of UnitedHealthcare Community Plan Medical Policies and Medical Benefit Drug Policies is available at **UHCprovider.com** > Policies and Protocols > Community Plan Policies > Medical & Drug Policies.