United Healthcare | UMR

UMR
Medical Policy Update Bulletin: December 2025

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Take Note

Annual CPT/HCPCS Code Updates

Beginning **Jan. 1, 2026**, all applicable Medical Policies and Medical Benefit Drug Policies will be updated to reflect the 2026 Current Procedural Terminology (CPT®) and Healthcare Common Procedure Coding System (HCPCS) code additions, revisions, and deletions. Refer to the following sources for information on the code updates:

- American Medical Association: Current Procedural Terminology: CPT®
- Centers for Medicare & Medicaid Services: Healthcare Common Procedure Coding System (HCPCS) Quarterly Update

Complete details on impacted policies and corresponding code edits will be provided in the January 2026 edition of the Medical Policy Update Bulletin.

Medical Policy Updates

New

Policy Title	Effective Date	Coverage Rationale
Remote Physiologic Monitoring (RPM)	Jan. 1, 2026	**Remote Physiologic Monitoring (RPM) is proven and medically necessary when the individual has one or more of the following conditions:** • Heart failure (HF) • Hypertensive disorders of pregnancy (HDP) **Remote Physiologic Monitoring (RPM) is unproven and not medically necessary due to insufficient evidence of efficacy for all other indications not listed as proven, including but not limited to:** • Anxiety • Bipolar disorder • Chronic obstructive pulmonary disease (COPD) • Depression • Diabetes mellitus (DM) • Gestational diabetes • Hypertension (HTN) other than hypertensive disorders of pregnancy (HDP) • Obstructive sleep apnea (OSA) • Schizoaffective disorder **Notes**: • For information on cardiac remote devices used for diagnostic and/or screening purposes, refer to the Medical Policy titled Implantable Loop Recorders and Wearable Heart Rhythm Monitors. • For information on continuous glucose monitoring devices, refer to the medical policy titled Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes.

Updated

Policy Title	Effective Date	Summary of Changes
Apheresis	Dec. 1, 2025	**Coverage Rationale** • Replaced language indicating "therapeutic apheresis including plasma exchange (plasmapheresis) or photopheresis is unproven and not medically necessary for treating or managing *the [listed]* conditions/diagnoses" with "therapeutic apheresis including plasma exchange (plasmapheresis) or photopheresis is unproven and not medically necessary for treating or managing *any other* conditions/diagnoses *[not listed in the policy as proven and medically necessary]*" **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
Catheter Ablation for Atrial Fibrillation	Jan. 1, 2026	**Template Update** • Created shared policy version to support application to Oxford plan membership

Medical Policy Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Catheter Ablation for Atrial Fibrillation (continued)	Jan. 1, 2026	**Related Policies** • Added reference link to the Medicare Advantage Medical Policy titled *Cardiovascular Diagnostic and Therapeutic Procedures* **Coverage Rationale** • Replaced reference to "InterQual® CP: Procedures, Electrophysiology (EP) Testing +/- *Radiofrequency Ablation (RFA) or Cryothermal* Ablation, Cardiac" with "InterQual® CP: Procedures, Electrophysiology (EP) Testing +/- *Catheter* Ablation, Cardiac" **Medical Records Documentation Used for Reviews** • Updated list of Medical Records Documentation Used for Reviews; replaced: ○ "Diagnosis" with "diagnosis *as documented by electrocardiogram (ECG), Holter, or rhythm strip*" ○ "Recent physical exam" with "recent physical exam *within the last 3 months*" ○ "Signs and symptoms including date of onset, duration, and frequency" with "signs and symptoms including date of onset, duration, frequency, and *whether the arrhythmia is symptomatic, paroxysmal, and/or persistent*" ○ "Reports of all recent imaging studies and applicable diagnostics" with "reports of all recent imaging studies and applicable diagnostics, *including electrolytes within the last 6 months; thyroid stimulating hormone (TSH) within the last 12 months, assessment for myocardial ischemia, e.g., stress test, within the last 12 months, and/or left ventricular ejection fraction by echocardiography or multigated acquisition (MUGA)*" **Applicable Codes** • Revised description for CPT code 93656
Interspinous Fusion and Decompression Devices	Dec. 1, 2025	**Medical Records Documentation Used for Reviews** • Updated list of Medical Records Documentation Used for Reviews: ○ Added "physician treatment plan, including device type and level" ○ Removed "describe the surgical technique(s) planned, including name of interspinous bony fusion device requested and use of an interbody cage" **Definitions** • Updated definition of: ○ Arthrodesis ○ Interlaminar Lumbar Instrumented Fusion (ILIF) ○ Interlaminar Stabilization Device ○ Neurogenic Claudication **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information
Liposuction for Lipedema	Dec. 1, 2025	**Medical Records Documentation Used for Reviews** • Updated list of Medical Records Documentation Used for Reviews; replaced "upon request we may require high-quality color photographs" with "upon request we may require high-quality color photographs *that include the transition points*"

Medical Policy Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Liposuction for Lipedema (continued)	Dec. 1, 2025	**Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information
Neurophysiologic Testing and Monitoring	Jan. 1, 2026	**Template Update** • Created shared policy version to support application to Oxford plan membership **Applicable Codes** • Removed CPT/HCPCs codes 95999 and A9279 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
Pharmacogenetic Panel Testing	Dec. 1, 2025	**Definitions** • Updated definition of "Multi-Gene Panel" **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information

Surgery of the Hip	Jan. 1, 2026	**Template Update**
		• Created shared policy version to support application to Oxford plan membership
		Applicable Codes
		• Added notation to indicate:
		  ○ Iliopsoas tendon release surgery, capsular repair, and capsular release surgery are considered integral to the primary hip procedure and not separately reimbursable
		  ○ Debridement during hip arthroscopy is considered integral to the FAI surgery (CPT codes 29914, 29915, and 29916) and would therefore not be separately reimbursable
		Supporting Information
		• Updated *Clinical Evidence* and *References* sections to reflect the most current information

Vagus and External Trigeminal Nerve Stimulation	Dec. 1, 2025	**Medical Records Documentation Used for Reviews** • Updated list of Medical Records Documentation Used for Reviews; removed "quality of life assessment with quantifiable measures of date-to-life besides the occurrence of seizures" **Definitions** • Updated definition of "Shared Decision Making" **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

Electrical and Ultrasonic Bone Growth Stimulators	Feb. 1, 2026	**Title Change**
		• Previously titled *Electrical and Ultrasound Bone Growth Stimulators*
		Related Policies
		• Removed reference link to the Medicare Advantage Medical Policy titled *Electrical Stimulators*
		Coverage Rationale
		Electrical Bone Growth Stimulators
		• Added language to clarify the use of an Invasive or Non-Invasive Electrical Bone Growth Stimulator is unproven and not medically necessary for the treatment of all other indications [not listed in the policy as proven and medically necessary] *(including stress fractures)*
		Ultrasonic Bone Growth Stimulators
		• Revised coverage criteria for Ultrasonic Bone Growth Stimulators; replaced criterion requiring "less than 6 months have passed since the date of most recent surgical *operation*" with "less than 6 months have passed since the date of most recent surgical *procedure*"
		• Added language to clarify the use of Ultrasonic Bone Growth Stimulators is unproven and not medically necessary for the treatment of all other indications
			Electrical Bone Growth Stimulators
			The use of an Invasive or Non-Invasive spinal Electrical Bone Growth Stimulator is proven and medically necessary as an adjunct to lumbar spinal fusion surgery when the following two criteria are met:
			• Radiographic evidence of skeletal maturity; and
			• Increased risk for fusion failure demonstrated by any of the following:
			  ○ Previously failed fusion at the same site, when minimum of six months has elapsed since the last surgical procedure
			  ○ Spinal fusion performed or to be performed at more than one level as part of a single surgery
			  ○ Comorbid conditions associated with compromised bone healing (e.g., diabetes, obesity, osteoporosis, current tobacco use)
			  ○ Spondylolisthesis grade II or greater
			The use of an Invasive or Non-Invasive Electrical Bone Growth Stimulator is unproven and not medically necessary for the treatment of all other indications (including stress fractures) due to insufficient evidence of efficacy and/or safety.
			Ultrasonic Bone Growth Stimulators
			The use of Ultrasonic Bone Growth Stimulators is proven and medically necessary for the treatment of Nonunion of long bone fractures when all of the following criteria are met:
			• Fracture gap is less than or equal to 1 cm
			• Radiographic evidence of a persistent fracture line without bridging callus is present for 3 months or more
			• Fracture reduced and immobilized
			• Less than 6 months have passed since the date of most recent surgical procedure
			• Fracture that is not pathological or associated with malignancy
			• Radiographic evidence of skeletal maturity
			The use of Ultrasonic Bone Growth Stimulators is unproven and not medically necessary for the treatment of all other indications (including stress fractures) due to insufficient evidence of efficacy and/or safety.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Electrical and Ultrasonic Bone Growth Stimulators (continued)	Feb. 1, 2026	[not listed in the policy as proven and medically necessary] *(including stress fractures)* **Medical Records Documentation Used for Reviews** • Updated list of Medical Records Documentation Used for Reviews: ***Electrical Bone Growth Stimulators*** ○ Added: ▪ Condition requiring procedure ▪ Detailed relevant imaging report, including: – Evidence of skeletal maturity – Presence or absence of spondylolisthesis, if present include grade ▪ Physician's treatment plan ○ Removed: ▪ List of applicable procedure codes ▪ Current physician prescription or order ▪ Spondylolisthesis (including grade) ○ Replaced: ▪ "*Member with* comorbid conditions *such as diabetes, obesity, osteoporosis, or current tobacco use* that could compromise bone healing" with "comorbid	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Electrical and Ultrasonic Bone Growth Stimulators (continued)	Feb. 1, 2026	conditions that could compromise bone healing" ▪ "*If the member has had or will be having a* spinal fusion, include t*he following*: date of surgery, *either past or future and number* of vertebral levels fused; *or documentation of failed spinal fusion and date of reoperation of same site*" with "*history of previous* spinal fusion surgery(ies); include date(s) of *previous* surgery and *site and* number of *previous* vertebral levels fused" ***Ultrasonic Bone Growth Stimulators*** ○ Added: ▪ Condition requiring treatment ▪ Relevant surgical history, including dates ▪ Physician's treatment plan ○ Removed: ▪ List of applicable procedure codes ▪ Current physician prescription or order ○ Replaced: ▪ "Diagnostic imaging reports" with "*relevant* diagnostic imaging	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Electrical and Ultrasonic Bone Growth Stimulators (continued)	Feb. 1, 2026	reports, *including size of fracture gap, if applicable, and evidence of skeletal maturity*" ▪ "Treatment of the fracture, *including treatment already completed* [date *of surgery(ies) if applicable*] and treatment *planned*" with "*previous* treatments of the fracture *tried, failed, or contraindicated*; include the dates, *duration of* treatment, *and reason for discontinuation*" **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	
Enteral Nutrition (Oral and Tube Feeding)	Jan. 1, 2026	**Template Update** • Created shared policy version to support application to Oxford plan membership **Coverage Rationale** ***Enteral Nutrition by Tube Feeding*** • Replaced language indicating "enteral nutrition administered by tube feeding (e.g., nasogastric, gastrostomy, or jejunostomy tube) is medically necessary in certain circumstances" with "enteral nutrition *(standard or Specialized*	**Enteral Nutrition by Tube Feeding** **Enteral nutrition (standard or Specialized Nutrient Formula) administered by tube feeding (e.g., nasogastric, gastrostomy, or jejunostomy tube) is medically necessary in certain circumstances.** For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Enteral and Parenteral Nutrition Therapy. Click here to view the InterQual® criteria. **Note**: When used for tube feeding, standard formula may be considered medically necessary because standard foods cannot be administered through a tube.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Enteral Nutrition (Oral and Tube Feeding) (continued)	Jan. 1, 2026	*Nutrient Formula)* administered by tube feeding (e.g., nasogastric, gastrostomy, or jejunostomy tube) is medically necessary in certain circumstances" • Added notation to indicate standard formula may be considered medically necessary when used for tube feeding because standard foods cannot be administered through a tube	**Oral Nutrition** **Specialized Nutrient Formula administered orally, as a primary or supplementary source of nutrition, is considered medically necessary when all of the following criteria are met:** • A physician, advanced practitioner (NP, CNS, or PA), or registered dietician prescribes the therapy; and • The condition is chronic and is expected to last for an undetermined or prolonged period of time; and • Adequate nutrition is not possible by dietary adjustment; and • The formula used is a Medical Food that is specially formulated for a specific condition; and • The individual has one of the following conditions: ○ Inborn Errors of Metabolism such as phenylketonuria (PKU), maple syrup urine disease, homocystinuria, methylmalonic acidemia, propionic acidemia, isovaleric acidemia, and other disorders of leucine metabolism; glutaric aciduria type I and tyrosinemia types I and II; or urea cycle disorders; or ○ Chronic kidney disease (CKD) stages 2 to 5 (or on dialysis) for individuals ages less than 24 months; or ○ Crohn's disease; or ○ Severe malabsorption syndrome (such as cystic fibrosis, short bowel syndrome, or intestinal failure); or ○ Malnutrition or individual will become malnourished or suffer from severe disorders such as physical disability, Intellectual Disability, or death if the nutritional therapy is not instituted; or ○ Severe food allergies, including eosinophilic esophagitis, other forms of eosinophilic gastrointestinal diseases, food protein-induced allergic proctocolitis (FPIAP) and food protein-induced enterocolitis syndrome (FPIES) which, if left untreated, will cause life-threatening allergic reactions, malnourishment, or death (mild and moderate food allergies or food intolerance can usually be treated with formula that is readily available in food stores and pharmacies, or by careful food selection; formulas for the treatment of such conditions are not considered medically necessary); or ○ Gastroesophageal reflux with failure to thrive (in children) **Note**: Refer to the *Benefit Considerations* section of the policy for additional information on coverage limitations and exclusions.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

FDA Cleared or Approved Companion Diagnostic Testing	Jan. 1, 2026	**Template Update**
		• Created shared policy version to support application to Oxford plan membership
		Related Policies
		• Added reference link to the Medical Policy titled *Oncology Medication Clinical Coverage*
		Coverage Rationale
		• Revised language to indicate:
		  ○ This policy applies to tests that have been granted approval as FDA cleared or approved Companion Diagnostic (CDx) tests
		  ○ FoundationOne® CDx is proven and medically necessary when used to inform management of any of the following indication/drug pairings:
		  ▪ Breast cancer
		  – Herceptin® (trastuzumab)
		  – Kadcyla® (ado-trastuzumab emtansine)
		  – Perjeta® (pertuzumab)
		  – Piqray® (alpelisib)
		  – Truqap® (capivasertib) in combination with Faslodex® (fulvestrant)
		  ▪ Cholangiocarcinoma
		  – Pemazyre® (pemigatinib)
			This policy applies to tests that have been granted approval as FDA cleared or approved Companion Diagnostic (CDx) tests.
			
			FoundationOne®CDx is proven and medically necessary when used to inform management of any of the following indication/drug pairings:
			• Breast cancer
			  ○ Herceptin® (trastuzumab)
			  ○ Kadcyla® (ado-trastuzumab emtansine)
			  ○ Perjeta® (pertuzumab)
			  ○ Piqray® (alpelisib)
			  ○ Truqap® (capivasertib) in combination with Faslodex® (fulvestrant)
			• Cholangiocarcinoma
			  ○ Pemazyre® (pemigatinib)
			• Colorectal cancer
			  ○ Erbitux® (cetuximab)
			  ○ Vectibix® (panitumumab)
			• Glioma (low-grade)
			  ○ Ojmeda® (tovorafenib)
			• Melanoma
			  ○ Mekinist® (trametinib)
			  ○ Tafinlar® (dabrafenib)
			  ○ Tecentriq® (atezolizumab) in combination with Cotellic® (cobimetinib) and Zelboraf® (vemurafenib)
			  ○ Zelboraf® (vemurafenib)
			• Non-small cell lung cancer (NSCLC)
			  ○ Alecensa® (alectinib)
			  ○ Braftovi® (encorafenib) in combination with Mektovi® (binimetinib)
			  ○ Gilotrif® (afatinib)
			  ○ Iressa® (gefitinib)
			  ○ Lazcluze® (lazertinib) in combination with Rybrevant® (amivantamab)
			  ○ Tabrecta® (capmatinib)
			  ○ Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib)
			  ○ Tagrisso® (osimertinib)
			  ○ Tarceva® (erlotinib)
			  ○ Vizimpro® (dacomitinib)
			  ○ Xalkori® (crizotinib)
			  ○ Zykadia® (ceritinib)

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
FDA Cleared or Approved Companion Diagnostic Testing (continued)	Jan. 1, 2026	▪ Colorectal cancer – Erbitux® (cetuximab) – Vectibix® (panitumumab) ▪ Glioma (low-grade) – Ojmeda® (tovorafenib) ▪ Melanoma – Mekinist® (trametinib) – Tafinlar® (dabrafenib) – Tecentriq® (atezolizumab) in combination with Cotellic® (cobimetinib) and Zelboraf® (vemurafenib) – Zelboraf® (vemurafenib) ▪ Non-small cell lung cancer (NSCLC) – Alecensa® (alectinib) – Braftovi® (encorafenib) in combination with Mektovi® (binimetinib) – Gilotrif® (afatinib) – Iressa® (gefitinib) – Lazcluze® (lazertinib) in combination with Rybrevant® (amivantamab) – Tabrecta® (capmatinib) – Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib)	• Ovarian cancer ○ Lynparza® (olaparib) • Prostate cancer (metastatic castration-resistant) ○ Akeega® (niraparib and abiraterone acetate) ○ Lynparza® (olaparib) • Solid tumors ○ Keytruda® (pembrolizumab) ○ Retevmo® (selpercatinib) ○ Rozlytrek® (entrectinib) ○ Vitrakvi® (larotrectinib) **FoundationOne® Liquid CDx is proven and medically necessary when used to inform management of any of the following indication/drug pairings:** • Breast cancer ○ Itovebi® in combination with Ibrance® (palbociclib) and Faslodex® (fulvestrant) ○ Piqray® (alpelisib) • Colorectal cancer (metastatic) ○ Braftovi® (encorafenib) in combination with Erbitux® (cetuximab) • Non-small cell lung cancer (NSCLC) ○ Alecensa® (alectinib) ○ Braftovi® (encorafenib) in combination with Mektovi® (binimetinib) ○ Iressa® (gefitinib) ○ Lazcluze® (lazertinib) in combination with Rybrevant® (amivantamab) ○ Tabrecta® (capmatinib) ○ Tagrisso® (osimertinib) ○ Tarceva® (erlotinib) ○ Tepmetko® (tepotinib) • Prostate cancer (metastatic castration-resistant) ○ Akeega® (niraparib and abiraterone acetate) ○ Lynparza® (olaparib) ○ Rubraca® (rucaparib) • Solid tumors ○ Rozlytrek® (entrectinib)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
FDA Cleared or Approved Companion Diagnostic Testing (continued)	Jan. 1, 2026	– Tagrisso® (osimertinib) – Tarceva® (erlotinib) – Vizimpro® (dacomitinib) – Xalkori® (crizotinib) – Zykadia® (ceritinib) ▪ Ovarian cancer – Lynparza® (olaparib) ▪ Prostate cancer (metastatic castration-resistant) – Akeega® (niraparib and abiraterone acetate) – Lynparza® (olaparib) ▪ Solid tumors – Keytruda® (pembrolizumab) – Retevmo® (selpercatinib) – Rozlytrek® (entrectinib) – Vitrakvi® (larotrectinib) ○ FoundationOne® Liquid CDx is proven and medically necessary when used to inform management of any of the following indication/drug pairings: ▪ Breast cancer – Itovebi® in combination with Ibrance® (palbociclib) and Faslodex® (fulvestrant) – Piqray® (alpelisib)	**Guardant360® CDx is proven and medically necessary when used to inform management of any of the following indication/drug pairings:** • Breast cancer ○ Orserdu® (elacestrant) • Non-small cell lung cancer (NSCLC) ○ Enhertu® (fam-trastuzumab deruxtecan-nxki) ○ Lumakras® (sotorasib) ○ Rybrevant® (amivantamb) ○ Tagrisso® (osimertinib) **MI Cancer Seek™ is proven and medically necessary when used to inform management of any of the following indication/drug pairings:** • Breast cancer ○ Piqray® (alpelisib) • Colorectal cancer ○ Braftovi® (encorafenib) in combination with Erbitux® (cetuximab) ○ Vectibix® (panitumumab) • Melanoma ○ Braftovi® (encorafenib) in combination with Mektovi® (binimetinib) ○ Cotellic® (cobimetinib) in combination with Zelboraf® (vemurafenib) ○ Mekinist® (trametinib) ○ Tafinlar® (dabrafenib) ○ Zelboraf® (vemurafenib) • Non-small cell lung cancer (NSCLC) ○ Gilotrif® (afatinib) ○ Iressa® (gefitinib) ○ Lazcluze® (lazertinib) in combination with Rybrevant® (amivantamab) ○ Tagrisso® (osimertinib) ○ Tarceva® (erlotinib) ○ Vizimpro® (dacomitinib) • Solid tumors ○ Jemperli® (dostarlimab-gxly) ○ Keytruda® (pembrolizumab) **Oncomine™ Dx Express Test is proven and medically necessary when used to inform management of NSCLC with Zegfrovy® (sunvozertinib).**

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
FDA Cleared or Approved Companion Diagnostic Testing (continued)	Jan. 1, 2026	▪ Colorectal cancer (metastatic) – Braftovi® (encorafenib) in combination with Erbitux® (cetuximab) ▪ Non-small cell lung cancer (NSCLC) – Alecensa® (alectinib) – Braftovi® (encorafenib) in combination with Mektovi® (binimetinib) – Iressa® (gefitinib) – Lazcluze® (lazertinib) in combination with Rybrevant® (amivantamab) – Tabrecta® (capmatinib) – Tagrisso® (osimertinib) – Tarceva® (erlotinib) – Tepmetko® (tepotinib) ▪ Prostate cancer (metastatic castration-resistant) – Akeega® (niraparib and abiraterone acetate) – Lynparza® (olaparib) – Rubraca® (rucaparib) ▪ Solid tumors – Rozlytrek® (entrectinib) ○ Guardant360® CDx is proven and medically necessary	**Oncomine™ Dx Target Test is proven and medically necessary when used to inform management of any of the following indication/drug pairings:** • Astrocytoma ○ Voranigo® (vorasidenib) • Cholangiocarcinoma ○ Tibsovo® (ivosidenib) • Non-small cell lung cancer (NSCLC) ○ Enhertu® (fam-trastuzumab deruxtecan-nxki) ○ Gavreto® (pralsetinib) ○ Hernexeos® (zongertinib) ○ Iressa® (gefitinib) ○ Retevmo® (selpercatinib) ○ Rybrevant® (amivantamb) ○ Tafinlar® (dabrafenib) ○ Xalkori® (crizotinib) • Oligodendroglioma ○ Voranigo® (vorasidenib) • Thyroid cancer, anaplastic ○ Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib) • Thyroid cancer, medullary ○ Retevmo® (selpercatinib) **oncoReveal™ CDx is proven and medically necessary when used to inform management of any of the following indication/drug pairings:** • Colorectal cancer ○ Erbitux® (cetuximab) ○ Vectibix® (panitumumab) • Non-small cell lung cancer (NSCLC) ○ Gilotrif® (afatinib) ○ Iressa® (gefitinib) ○ Lazcluze® (lazertinib) in combination with Rybrevant® (amivantamab) ○ Tagrisso® (osimertinib) ○ Tarceva® (erlotinib) ○ Vizimpro® (dacomitinib)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
FDA Cleared or Approved Companion Diagnostic Testing (continued)	Jan. 1, 2026	when used to inform management of any of the following indication/drug pairings: ▪ Breast cancer – Orserdu® (elacestrant) ▪ Non-small cell lung cancer (NSCLC) – Enhertu® (fam-trastuzumab deruxtecan-nxki) – Lumakras® (sotorasib) – Rybrevant® (amivantamb) – Tagrisso® (osimertinib) ○ MI Cancer Seek™ is proven and medically necessary when used to inform management of any of the following indication/drug pairings: ▪ Breast cancer – Piqray® (alpelisib) ▪ Colorectal cancer – Braftovi® (encorafenib) in combination with Erbitux® (cetuximab) – Vectibix® (panitumumab) ▪ Melanoma – Braftovi® (encorafenib) in combination with Mektovi® (binimetinib) – Cotellic® (cobimetinib) in combination with	**TruSight™ Oncology Comprehensive is proven and medically necessary when used to inform management of any of the following indication/drug pairings:** ● Non-small cell lung cancer (NSCLC) ○ Retevmo® (selpercatinib) ● Solid tumors ○ Vitrakvi® (larotrectinib) **xT CDx is proven and medically necessary when used to inform management of any of the following indication/drug pairings:** ● Colorectal cancer ○ Erbitux® (cetuximab) ○ Vectibix® (panitumumab) **FDA cleared or approved CDx tests not listed above or used for indication/drug pairings not listed above are proven and medically necessary when both of the following criteria are met:** ● The test results will be used to inform the use of a targeted oncology therapeutic product or group of products in an individual with the corresponding clinical indication; and ● One of the following: ○ The test appears in the U.S. Food and Drug Administration (FDA)'s Cleared or Approved Companion Diagnostic Devices Table for use with the intended targeted therapeutic product and clinical indication; or ○ The test has an approval order designating it as an FDA cleared or approved CDx test for use with the intended targeted therapeutic product and clinical indication in the FDA Premarket Approval Database, but the approval does not yet appear in the U.S. Food and Drug Administration (FDA)'s Cleared or Approved Companion Diagnostic Devices Table **Subsequent use of an FDA cleared or approved CDx test on a new specimen for the purpose of assisting with therapy selection is considered proven and medically necessary when both of the following criteria are met:** ● The criteria above for the CDx test are met; and

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
FDA Cleared or Approved Companion Diagnostic Testing (continued)	Jan. 1, 2026	Zelboraf® (vemurafenib) – Mekinist® (trametinib) – Tafinlar® (dabrafenib) – Zelboraf® (vemurafenib) ▪ Non-small cell lung cancer (NSCLC) – Gilotrif® (afatinib) – Iressa® (gefitinib) – Lazcluze® (lazertinib) in combination with Rybrevant® (amivantamab) – Tagrisso® (osimertinib) – Tarceva® (erlotinib) – Vizimpro® (dacomitinib) ▪ Solid tumors – Jemperli® (dostarlimab-gxly) – Keytruda® (pembrolizumab) ○ Oncomine™ Dx Express Test is proven and medically necessary when used to inform management of NSCLC with Zegfrovy® (sunvozertinib) ○ Oncomine™ Dx Target Test is proven and medically necessary when used to inform management of any of the following indication/drug pairings: ▪ Astrocytoma	• One of the following: ○ The individual is experiencing disease recurrence; or ○ The individual's cancer has progressed or did not respond to the most recent systemic therapy **Concurrent Testing using an FDA Cleared or Approved tissue-based CDx test and a Liquid Biopsy-based CDx test is considered proven and medically necessary for the following cancer types when the criteria above for the CDx test are met:** • Advanced or metastatic (stage IV) breast cancer • Advanced or metastatic (stage IV) NSCLC **Due to insufficient evidence of efficacy, all other uses of the above FDA cleared or approved CDx tests are unproven and not medically necessary.** **Note**: For molecular oncology tests that have not been cleared or approved by the FDA as CDx tests, refer to the Medical Policy titled Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions or Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and Treatment Decisions.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
FDA Cleared or Approved Companion Diagnostic Testing (continued)	Jan. 1, 2026	– Voranigo® (vorasidenib) ▪ Cholangiocarcinoma – Tibsovo® (ivosidenib) ▪ Non-small cell lung cancer (NSCLC) – Enhertu® (fam-trastuzumab deruxtecan-nxki) – Gavreto® (pralsetinib) – Hernexeos® (zongertinib) – Iressa® (gefitinib) – Retevmo® (selpercatinib) – Rybrevant® (amivantamb) – Tafinlar® (dabrafenib) – Xalkori® (crizotinib) ▪ Oligodendroglioma – Voranigo® (vorasidenib) ▪ Thyroid cancer, anaplastic – Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib) ▪ Thyroid cancer, medullary – Retevmo® (selpercatinib) ○ oncoReveal™ CDx is proven and medically necessary when used to inform management of any of the following indication/drug pairings: ▪ Colorectal cancer	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
FDA Cleared or Approved Companion Diagnostic Testing (continued)	Jan. 1, 2026	– Erbitux® (cetuximab) – Vectibix® (panitumumab) ▪ Non-small cell lung cancer (NSCLC) – Gilotrif® (afatinib) – Iressa® (gefitinib) – Lazcluze® (lazertinib) in combination with Rybrevant® (amivantamab) – Tagrisso® (osimertinib) – Tarceva® (erlotinib) – Vizimpro® (dacomitinib) ○ TruSight™ Oncology Comprehensive is proven and medically necessary when used to inform management of any of the following indication/drug pairings: ▪ Non-small cell lung cancer (NSCLC) – Retevmo® (selpercatinib) ▪ Solid tumors – Vitrakvi® (larotrectinib) ○ xT CDx is proven and medically necessary when used to inform management of any of the following indication/drug pairings: ▪ Colorectal cancer – Erbitux® (cetuximab) – Vectibix® (panitumumab)	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
FDA Cleared or Approved Companion Diagnostic Testing (continued)	Jan. 1, 2026	○ FDA cleared or approved CDx tests not listed above or used for indication/drug pairings not listed above are proven and medically necessary when both of the following criteria are met: ▪ The test results will be used to inform the use of a targeted oncology therapeutic product or group of products in an individual with the corresponding clinical indication ▪ One of the following: – The test appears in the *U.S. Food and Drug Administration (FDA)'s Cleared or Approved Companion Diagnostic Devices Table* for use with the intended targeted therapeutic product and clinical indication – The test has an approval order designating it as an FDA cleared or approved CDx test for use with the intended targeted therapeutic product and clinical indication in the FDA Premarket Approval Database, but the	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
FDA Cleared or Approved Companion Diagnostic Testing (continued)	Jan. 1, 2026	approval does not yet appear in the *U.S. Food and Drug Administration (FDA)'s Cleared or Approved Companion Diagnostic Devices Table* ○ Subsequent use of an FDA cleared or approved CDx test on a new specimen for the purpose of assisting with therapy selection is considered proven and medically necessary when both of the following criteria are met: ▪ The criteria above for the CDx test are met ▪ One of the following: – The individual is experiencing disease recurrence; or – The individual's cancer has progressed or did not respond to the most recent systemic therapy ○ Concurrent Testing using an FDA Cleared or Approved tissue-based CDx test and a Liquid Biopsy-based CDx test is considered proven and medically necessary for the following cancer types when the criteria above for the CDx	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
FDA Cleared or Approved Companion Diagnostic Testing (continued)	Jan. 1, 2026	test are met: ▪ Advanced or metastatic (stage IV) breast cancer ▪ Advanced or metastatic (stage IV) NSCLC ○ Due to insufficient evidence of efficacy, all other uses of the above FDA cleared or approved CDx tests are unproven and not medically necessary ○ For molecular oncology tests that have not been cleared or approved by the FDA as CDx tests, refer to the Medical Policy titled *Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions* or *Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and Treatment Decisions* **Medical Records Documentation Used for Reviews** • Updated list of Medical Records Documentation Used for Reviews: ○ Added “disease response to most recent systemic therapy and/or disease recurrence or progression, if applicable” ○ Removed “line of therapy being considered” ○ Replaced “results of prior companion diagnostic testing comprehensive genomic	

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

FDA Cleared or Approved Companion Diagnostic Testing (continued)	Jan. 1, 2026	profiling, if applicable" with "results *and dates* of prior companion diagnostic testing *and/or* comprehensive genomic profiling, if applicable"
		Definitions
		• Added definition of "Concurrent Testing"
		• Removed definition of:
		  ○ Comprehensive Genomic Profiling (CGP)
		  ○ Next Generation Sequencing (NGS)
		• Updated definition of:
		  ○ Advanced Cancer
		  ○ Companion Diagnostic
		  ○ Liquid Biopsy
		Applicable Codes
		• Added CPT codes 0211U and 0523U
		• Removed CPT codes 0179U, 81445, 81449, 81450, 81451, 81455, 81456, and 81599
		Supporting Information
		• Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	

Gastrointestinal Disorders Diagnostic Procedures	Feb. 1, 2026	**Title Change** • Previously titled *Gastrointestinal Motility Disorders, Diagnosis and Treatment* **Coverage Rationale** • Removed and relocated language pertaining to gastric electrical	**The following procedures are unproven and not medically necessary due to insufficient evidence of efficacy:** • Magnetic Resonance Imaging (MRI) Defecography for evaluating Constipation and Anorectal or pelvic floor disorders • Cutaneous, mucous, or serosal Electrogastrography, electroenterography, or body surface gastric mapping for diagnosing intestinal or gastric disorders including Gastroparesis

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

Gastrointestinal Disorders Diagnostic Procedures (continued)	Feb. 1, 2026	stimulation (GES) therapy; refer to the Medical Policy titled *Minimally Invasive Procedures for the Treatment of Upper Gastrointestinal Diseases*
		• Revised list of unproven and not medically necessary procedures:
		  ○ Added "functional lumen imaging probe (FLIP) technology for diagnosing Achalasia"
		  ○ Removed list of examples of:
		  ▪ Cutaneous, mucous, or serosal Electrogastrography, electroenterography, or body surface gastric mapping: Gastric Alimetry System, G-Tech Gut Tracker wireless patch system
		  ▪ Esophageal Mucosal Integrity Testing by electrical impedance: MiVu™ Mucosal Integrity Testing System
		Definitions
		• Added definition of:
		  ○ Achalasia
		  ○ Functional Lumen Imaging Probe (FLIP)
		Applicable Codes
		• Removed CPT codes 43647, 43648, 43881, 43882, 64590, and 64595
			• Esophageal Mucosal Integrity Testing by electrical impedance for the diagnosis of gastroesophageal reflux disease (GERD), eosinophilic esophagitis (EoE), and nonacid reflux disease (non-GERD), or for the monitoring of treatment response in GERD and EoE
			• Functional Lumen Imaging Probe (FLIP) technology for diagnosing Achalasia

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Gastrointestinal Disorders Diagnostic Procedures (continued)	Feb. 1, 2026	**Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Removed *Medical Records Documentation Used for Reviews* section	
Minimally Invasive Procedures for the Treatment of Upper Gastrointestinal Diseases	Feb. 1, 2026	**Title Change** • Previously titled *Minimally Invasive Procedures for Gastric and Esophageal Diseases* **Coverage Rationale** • Added language to indicate: ○ Gastric electrical stimulation (GES) therapy is proven and medically necessary for treating refractory Gastroparesis that has failed other therapies, or chronic intractable (drug-refractory) nausea and vomiting secondary to Gastroparesis of diabetic or idiopathic etiology; refer to the *U.S. Food and Drug Administration (FDA)* section for information regarding FDA labeling and Humanitarian Device Exemption (HDE) for GES (relocated from the Medical Policy titled *Gastrointestinal Disorders Diagnostic Procedures*) ○ Surgical pyloroplasty (open or laparoscopic) is proven and medically necessary for	**Gastric electrical stimulation (GES) therapy is proven and medically necessary for treating refractory Gastroparesis that has failed other therapies, or chronic intractable (drug-refractory) nausea and vomiting secondary to Gastroparesis of diabetic or idiopathic etiology.** Refer to the *U.S. Food and Drug Administration (FDA)* section of the policy for information regarding FDA labeling and Humanitarian Device Exemption (HDE) for GES. **Surgical pyloroplasty (open or laparoscopic) is proven and medically necessary for treating refractory Gastroparesis that has failed other therapies, or chronic-intractable (drug-refractory) nausea and vomiting secondary to Gastroparesis of diabetic or idiopathic etiology.** **The per oral endoscopic myotomy (POEM) procedure is proven and medically necessary for treating individuals with Achalasia or Diffuse Esophageal Spasm.** **Per oral endoscopic myotomy (POEM) is unproven and not medically necessary for all other indications (e.g., Zenker's diverticula) due to insufficient evidence of efficacy.** **Gastric per oral endoscopic myotomy (G-POEM) is unproven and not medically necessary for the treatment of Gastroparesis.** **The following are unproven and not medically necessary for treating Gastroesophageal Reflux Disease (GERD) due to insufficient evidence of efficacy:** • Endoscopic therapies

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Minimally Invasive Procedures for the Treatment of Upper Gastrointestinal Diseases (continued)	Feb. 1, 2026	treating refractory Gastroparesis that has failed other therapies, or chronic-intractable (drug-refractory) nausea and vomiting secondary to Gastroparesis of diabetic or idiopathic etiology • Removed language indicating functional lumen imaging probe technology is unproven and not medically necessary for diagnosing Achalasia **Medical Records Documentation Used for Reviews** • Added language to indicate: ○ Benefit coverage for health services is determined by the member specific benefit plan document 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; refer to the guidelines titled Medical Records Documentation Used for Reviews **Definitions** • Updated definition of "Gastroparesis"	• Injection or implantation techniques • LINX Reflux Management System **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.** Refer to the Medical Policy titled Bariatric Surgery for information regarding endoscopic therapies for the treatment of obesity.

Medical Policy Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Minimally Invasive Procedures for the Treatment of Upper Gastrointestinal Diseases (continued)	Feb. 1, 2026	**Applicable Codes** • Added CPT codes 43647, 43648, 43659, 43881, 43882, 64590, and 64595 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Preventive Care Services	Jan. 1, 2026	**Template Update** • Created shared policy version to support application to Oxford plan membership **Frequently Asked Questions (FAQ)** • Added Q&A #6 pertaining to listing required diagnosis codes on claims **Applicable Codes** ***Preventive Care Services*** Chlamydia Infection Screening ***and*** Gonorrhea Screening • Updated list of applicable CPT codes; added 87494 Syphilis Screening: Asymptomatic Pregnant Women • Revised service description: ○ Removed Sep. 2018 USPSTF “A” rating ○ Added May 2025 USPSTF “A” rating to indicate the USPSTF recommends early, universal screening for syphilis infection during pregnancy; if an individual is not screened early in pregnancy, the USPSTF recommends screening at the first available opportunity Wellness Examinations • Revised list of services with HRSA requirements for wellness examinations: ○ Added “patient navigation services for breast and cervical cancer screening” ○ Replaced “screening and counseling for *interpersonal* domestic violence” with “screening and counseling for *intimate partner and* domestic violence” Screening for Intimate Partner Violence • Revised service description: ○ Removed Oct. 2018 USPSTF “B” rating ○ Added Jun. 2025 USPSTF “B” rating to indicate the USPSTF recommends that clinicians screen for intimate partner violence (IPV) in women of reproductive age, including those who are pregnant and postpartum	

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

Preventive Care Services (continued)	Jan. 1, 2026	***Expanded Women's Preventive Health***
		Contraceptive Methods (Including Sterilizations): Code Group 6
		• Updated list of applicable CPT codes; revised description for 58562
		• Removed list of applicable ICD-10 diagnosis codes: Z30.432 and Z30.433
		• Revised preventive benefit instructions to indicate the listed CPT code does not have diagnosis code requirements for preventive benefits to apply
		Screening and Counseling for Intimate Partner and Domestic Violence
		• Revised service description:
		  ○ Removed Dec. 2016 HRSA requirement
		  ○ Added Dec. 2024 HRSA requirement to indicate:
		  ▪ The Women's Preventive Services Initiative recommends screening adolescent and adult women for intimate partner and domestic violence, at least annually, and, when needed, providing or referring to intervention services
		  ▪ Intimate partner and domestic violence includes physical violence, sexual violence, stalking and psychological aggression (including coercion), reproductive coercion, neglect, and the threat of violence, abuse, or both
		  ▪ Intervention services include, but are not limited to, counseling, education, harm reduction strategies, and appropriate supportive services
		Breast Cancer Screening for Women at Average Risk
		• Revised service description:
		  ○ Removed Dec. 2016 HRSA requirement
		  ○ Added Dec. 2024 HRSA requirement to indicate:
		  ▪ The Women's Preventive Services Initiative recommends that women at average risk of breast cancer initiate mammography screening no earlier than age 40 years and no later than age 50 years; screening mammography should occur at least biennially and as frequently as annually
		  ▪ Women may require additional imaging to complete the screening process or to address findings on the initial screening mammography; if additional imaging [e.g., magnetic resonance imaging (MRI), ultrasound, mammography] and pathology evaluation are indicated, these services also are recommended to complete the screening process for malignancies
		  ▪ Screening should continue through at least age 74 years, and age alone should not be the basis for discontinuing screening
		  ▪ Women at increased risk also should undergo periodic mammography screening; however, recommendations for additional services are beyond the scope of this recommendation
		• Removed instruction to refer to the *Screening Mammography* section of this policy for applicable codes and preventive benefit instructions
		• Added lists of applicable codes and preventive benefit instructions for:	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Care Services (continued)	Jan. 1, 2026	*Mammography Screening* ○ Added CPT codes 77063 and 77067 ○ Added revenue code 0403 ○ Added language to indicate: ▪ The listed CPT codes do not have diagnosis code requirements for the preventive benefit to apply ▪ There is no age limit for mammography screening *Mammography Diagnostic – To Complete the Screening Process* ○ Added CPT/HCPCS codes 77061, 77062, 77065, 77066, and G0279 ○ Added revenue code 0401 ○ Added language to indicate: ▪ The listed CPT/HCPCS codes require one of the listed *Average Risk Diagnosis Codes* ▪ There is no age limit for mammography diagnostics to complete the screening process *Breast Ultrasound – To Complete the Screening Process* ○ Added CPT codes 0857T, 76641, and 76642 ○ Added language to indicate: ▪ The listed CPT codes require one of the listed *Average Risk Diagnosis Codes* ▪ There is no age limit for breast ultrasound to complete the screening process *Breast MPI – To Complete the Screening Process* ○ Added CPT/HCPCS codes 77046, 77047, 77048, 77049, A9575, A9576, A9577, A9578, A9579, A9581, and A9585 ○ Added language to indicate: ▪ The listed CPT/HCPCS codes require one of the listed *Average Risk Diagnosis Codes* ▪ There is no age limit for breast MRI to complete the screening process *Pathology Evaluation – To Complete the Screening Process* ○ Added CPT/HCPCS codes 19081, 19082, 19083, 19084, 19085, 19086, 19100, 19101, 19281, 19282, 19283, 19284, 19285, 19286, 19287, 19288, 76942, 77002, 88172, 88173, 88177, 88305, 96374, 99152, 99153, 99156, 99157, and Q9967 ○ Added language to indicate: ▪ The listed CPT/HCPCS codes require one of the listed *Average Risk Diagnosis Codes* ▪ There is no age limit for breast pathology evaluation to complete the screening process *Average Risk Diagnosis Codes* ○ Added ICD-10 diagnosis codes for: ▪ **Cysts**: N60.01, N60.02, N60.09, N60.11, N60.12, N60.19, N60.41, N60.42, and N60.49 ▪ **Hypertrophy**: N62 ▪ **Mammographic calcification or inconclusive findings**: R92.0, R92.1, R92.2, R92.8 ▪ **Dense breast(s)**: R92.30, R92.311, R92.312, R92.313, R92.321, R92.322, R92.323, R92.331, R92.332,	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Preventive Care Services (continued)	Jan. 1, 2026	R92.333, R92.341, R92.342, and R92.343 ▪ **Screening**: Z12.31, Z12.39, Z13.71, and Z13.79 ▪ **Personal history, genetic susceptibility, or family history**: Z14.8, Z15.01, Z15.02, Z15.09, Z15.89, Z71.83, Z80.3, Z85.3, and Z86.000 ▪ **Prophylactic or acquired absence of breast/nipple**: Z40.01, Z90.10, Z90.11, Z90.12, and Z90.13 ○ Added language to indicate one of these average risk diagnosis codes are required for: ▪ Mammography diagnostic to complete the screening process ▪ Breast ultrasound to complete the screening process ▪ Breast MRI to complete the screening process ▪ Pathology evaluation to complete the screening process Patient Navigation Services for Breast and Cervical Cancer Screening • Added Dec. 2024 HRSA requirement to indicate: ○ The Women's Preventive Services Initiative recommends patient navigation services for breast and cervical cancer screening and follow-up, as relevant, to increase utilization of screening recommendations based on an assessment of the patient's needs for navigation services ○ Patient navigation services involve person-to-person (e.g., in-person, virtual, hybrid models) contact with the patient; components of patient navigation services should be individualized ○ Services include, but are not limited to, person-centered assessment and planning, health care access and health system navigation, referrals to appropriate support services (e.g., language translation, transportation, and social services), and patient education • Added instruction to refer to the *Wellness Examinations* section of the policy for applicable codes and preventive benefit instructions Refer to the policy for complete details.	
Sleep Studies	Jan. 1, 2026	**Template Update** • Created shared policy version to support application to Oxford plan membership **Coverage Rationale** ***Home Sleep Apnea Testing (HSAT)*** • Added notation to indicate performing a repeat HSAT is not recommended when an initial test is negative, inconclusive, or technically inadequate, due to the	**Home Sleep Apnea Testing** **Home Sleep Apnea Testing (HSAT), using a portable monitor, is medically necessary for evaluating adults with suspected Obstructive Sleep Apnea (OSA).** Where HSAT is indicated, an autotitrating Positive Airway Pressure (APAP) device is an option to determine a fixed PAP pressure. **Note**: Performing a repeat HSAT is not recommended when an initial test is negative, inconclusive or technically inadequate, due to the higher likelihood that a second test will also be negative, inconclusive or technically inadequate. Therefore, after a single negative, inconclusive or technically

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Sleep Studies (continued)	Jan. 1, 2026	higher likelihood that a second test will also be negative, inconclusive, or technically inadequate; therefore, after a single negative, inconclusive, or technically inadequate HSAT result, performance of attended full-channel polysomnography is strongly recommended ***Attended Full-Channel Polysomnography, Performed in a Healthcare Facility or Laboratory Setting*** Suspected Obstructive Sleep Apnea (OSA) • Revised coverage criteria for attended full-channel Polysomnography for evaluating individuals with suspected OSA; replaced criterion requiring "results of previous HSAT are negative, indeterminate, or technically inadequate to make a diagnosis of OSA" with "results of previous *(within the past 12 months)* HSAT are negative, indeterminate, or technically inadequate to make a diagnosis of OSA" ***Daytime Sleep Studies*** • Replaced language indicating "Multiple Sleep Latency Testing (MSLT) is medically necessary *when it is indicated by* suspected Narcolepsy or idiopathic Hypersomnia and other cause of	inadequate HSAT result, performance of attended full-channel Polysomnography is strongly recommended (Kapur et al., 2017). **Attended Full-Channel Polysomnography, Performed in a Healthcare Facility or Laboratory Setting** ***Suspected Obstructive Sleep Apnea*** **Attended full-channel Polysomnography is medically necessary for evaluating individuals with suspected OSA when:** • Results of previous (within the past 12 months) HSAT are negative, indeterminate, or technically inadequate to make a diagnosis of OSA (Kapur et al., 2017; Centers for Medicare and Medicaid Services); or • Individual is a child or adolescent (i.e., less than 18 years of age); or • Individual is known to have one or more of the following comorbid medical conditions that prohibits the use of a HSAT: ○ Significant Chronic Pulmonary Disease as defined by a forced expiratory volume (FEV_1) % predicted of < 60 (Pellegrino et al., 2005) ○ Progressive neuromuscular disease/neurodegenerative disorder (examples include but are not limited to Parkinson's disease, myotonic dystrophy, amyotrophic lateral sclerosis, multiple sclerosis with associated pulmonary disease, and history of stroke with persistent neurological sequelae) ○ Moderate to severe heart failure [New York Heart Association class III or IV (NYHA, 1994) or left ventricular ejection fraction ≤ 40 (Yancy et al., 2013; Yancy et al., 2017)] ○ Body mass index (BMI) > 50 (DeMaria et al., 2007; Blackstone and Cortés, 2010) ○ Obesity Hypoventilation Syndrome ○ Documented ongoing epileptic seizures in the presence of symptoms of sleep disorder ○ Chronic opiate medication use (> 3 months) (Dowell et al., 2022) Also, refer to the Repeat Testing section below.

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

Sleep Studies (continued)	Jan. 1, 2026	Excessive Sleepiness have been excluded by appropriate clinical assessment" with "Multiple Sleep Latency Testing (MSLT) is medically necessary *for evaluating* suspected Narcolepsy *when* other causes of Excessive Sleepiness have been excluded by appropriate clinical assessment"
		• Revised language pertaining to medical necessity clinical coverage criteria; removed reference to the InterQual® CP: Procedures, Sleep Studies for Maintenance of Wakefulness Testing (MWT)
		Attended Repeat Testing
		• Replaced language indicating "repeat attended full-channel polysomnography and repeat Positive Airway Pressure (PAP) titration are medically necessary for *certain* individuals who have persistent or new symptoms, despite documented appropriate current treatment or PAP therapy" with "repeat attended full-channel polysomnography and repeat Positive Airway Pressure (PAP) titration are medically necessary for individuals who have persistent, *recurrent,* or new symptoms, despite documented appropriate current treatment or PAP therapy"
			Other Conditions
			Attended full-channel Polysomnography is medically necessary following an appropriate clinical assessment either because OSA has been excluded, OSA has been adequately treated, or documented symptoms suggest one of the following conditions:
			• Periodic Limb Movement Disorder (PLMD) (not leg movements associated with another disorder such as sleep disordered breathing)
			• Restless Legs Syndrome (RLS)/Willis-Ekbom Disease that has not responded to treatment
			• Parasomnia with documented disruptive, violent, or potentially injurious sleep behavior suspicious of Rapid Eye Movement Sleep Behavior Disorder (RBD)
			• Narcolepsy, once other causes of Excessive Sleepiness have been ruled out by appropriate clinical assessment (also refer to the Daytime Sleep Studies section below)
			• Central Sleep Apnea
			Implantable Hypoglossal Nerve Stimulator
			Attended full-channel Polysomnography is medically necessary to rule out Central Sleep Apnea prior to implantation and/or calibration of an implantable hypoglossal nerve stimulator when the device is indicated. Refer to the Medical Policy titled Obstructive and Central Sleep Apnea Treatment for implantable hypoglossal nerve stimulator indications.
			Other Studies
			The following studies are not medically necessary due to insufficient evidence of efficacy:
			• Attended full-channel Polysomnography for evaluating any of the following conditions:
			  ○ Circadian Rhythm Disorders
			  ○ Depression
			  ○ Insomnia
			• Actigraphy for any sleep disorders

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Sleep Studies (continued)	Jan. 1, 2026	• Added language to indicate repeat attended full-channel polysomnography and repeat PAP titration are medically necessary for individuals who have experienced a clinically significant weight loss or gain (≥ 10%) or changes in cardiovascular disease since the last study **Medical Records Documentation Used for Reviews** • Updated list of Medical Records Documentation Used for Reviews; added "for Attended Repeat Testing and/or appliance adjustment, in addition to the [listed documentation requirements], also include reason why repeat study should be performed" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	**Daytime Sleep Studies** **Note**: The following sleep studies may be performed during the night if necessary to match an individual's normal sleep pattern. **Multiple Sleep Latency Testing (MSLT) is medically necessary for evaluating suspected Narcolepsy or idiopathic Hypersomnia when other causes of Excessive Sleepiness have been excluded by appropriate clinical assessment.** For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures: • Sleep Studies • Sleep Studies (Pediatric) Click here to view the InterQual® criteria. **Maintenance of Wakefulness Testing (MWT) is medically necessary for evaluating the following:** • An adult who is unable to stay awake, resulting in a safety issue; or • Assessing response to treatment in adults with sleep disorders **MWT is unproven and not medically necessary in children and adolescents less than 18 years of age.** **Abbreviated daytime sleep studies (e.g., PAP-Nap) are not medically necessary due to insufficient evidence of efficacy.** **Attended PAP Titration** **When an individual meets the above criteria for an attended full-channel Polysomnography sleep study, the following are medically necessary:** • A split-night sleep study, performed in a healthcare facility or laboratory setting, for diagnosis and PAP titration; or • A full night study for PAP titration, when a split-night sleep study is inadequate or not feasible and the individual has a confirmed diagnosis of OSA Also, refer to the Repeat Testing section below.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Sleep Studies (continued)	Jan. 1, 2026		**Attended Repeat Testing** **Repeat attended full-channel Polysomnography and repeat PAP titration are medically necessary in the following circumstances:** • Individuals who have persistent, recurrent or new symptoms, despite documented appropriate current treatment or PAP therapy (e.g., equipment failure, improper mask fit, pressure leaks, unsuccessful titration, inadequate pressure, and medical problems including nasal congestion have been addressed and appropriately managed); or • Individuals who have experienced a clinically significant weight loss or gain (≥ 10%) or changes in cardiovascular disease since the last study (Caples et al., 2021; Peppard et al., 2000). **Repeat Testing for Oral Appliance Adjustments** Repeat testing and repositioning/adjustments for oral sleep appliances can be done in the home unless the individual meets criteria for an attended sleep study.
Total Artificial Disc Replacement for the Spine	Feb. 1, 2026	**Coverage Rationale** • Revised language to indicate: ***Cervical*** ○ Cervical total artificial disc replacement (TADR) is proven and medically necessary when all of the following are present and InterQual® criteria are met: ▪ An FDA-approved prosthetic intervertebral disc is utilized ▪ Individual diagnosed with only one or two Contiguous Levels of cervical degenerative disc disease (C3-C7) ▪ Skeletally Mature individual with radiculopathy and/or	**Cervical** **Cervical total artificial disc replacement (TADR) is proven and medically necessary when all of the following are present AND InterQual criteria are met:** • An FDA-approved prosthetic intervertebral disc is utilized • Individual diagnosed with only one or two Contiguous Levels of cervical degenerative disc disease (C3-C7) • Skeletally Mature individual with radiculopathy and/or myelopathy • The arthroplasty will be performed at all symptomatic Contiguous Levels (up to two levels between C3-C7) **Note**: For two-level contiguous cervical total artificial disc replacement, the device being utilized must be FDA-approved for two levels. When a cervical total artificial disc replacement was previously performed, the second Contiguous Level artificial disc must be FDA approved for two levels. **Cervical total artificial disc replacement in an individual with a history of prior cervical spinal fusion is proven and medically necessary when all of the following are present and InterQual criteria are met:** • An FDA-approved prosthetic intervertebral disc is utilized

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Total Artificial Disc Replacement for the Spine (continued)	Feb. 1, 2026	myelopathy ▪ The arthroplasty will be performed at all symptomatic Contiguous Levels (up to two levels between C3-C7) ○ For two-level contiguous cervical total artificial disc replacement, the device being utilized must be FDA-approved for two levels; when a cervical total artificial disc replacement was previously performed, the second contiguous level artificial disc must be FDA approved for two levels ○ Cervical total artificial disc replacement in an individual with a history of prior cervical spinal fusion is proven and medically necessary when all of the following are present and InterQual® criteria are met: ▪ An FDA-approved prosthetic intervertebral disc is utilized ▪ Treating individuals with only one level or two Contiguous Levels of cervical degenerative disc disease (C3-C7) ▪ Skeletally Mature individual with radiculopathy and/or myelopathy	• Treating individuals with only one level or two Contiguous Levels of cervical degenerative disc disease (C3-C7) • Skeletally Mature individual with radiculopathy and/or myelopathy • The arthroplasty will be performed at all symptomatic Contiguous Levels (up to two levels between C3-C7) • Radiographically Confirmed Complete Arthrodesis of a previous cervical spinal fusion at another level (adjacent or non-adjacent) For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Artificial Disc Replacement, Cervical. Click here to view the InterQual® criteria. **Cervical artificial disc removal or replacement with an FDA-approved (one or two-level) prosthetic intervertebral disc is proven and medically necessary in individuals with implant failure after prior disc replacement.** **Cervical total artificial disc replacement is unproven and not medically necessary when performed at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent), as part of the same surgical plan (Hybrid Cervical Surgery).** **Lumbar** **Lumbar total artificial disc replacement is proven and medically necessary when all of the following are present and InterQual criteria are met:** • An FDA-approved prosthetic intervertebral disc is utilized • Treating individuals with only single level of lumbar degenerative disc disease • Skeletally Mature individual • Symptomatic intractable discogenic low back pain attributable to that level For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined, CP: Procedures, Artificial Disc Replacement, Lumbar (Custom) - UHG.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Total Artificial Disc Replacement for the Spine (continued)	Feb. 1, 2026	▪ The arthroplasty will be performed at all symptomatic Contiguous Levels (up to two levels between C3-C7) ▪ Radiographically Confirmed Complete Arthrodesis of a previous cervical spinal fusion at another level (adjacent or non-adjacent) ○ For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Artificial Disc Replacement, Cervical ○ Cervical artificial disc removal or replacement with an FDA-approved (one or two-level) prosthetic intervertebral disc is proven and medically necessary in individuals with implant failure after prior disc replacement ○ Cervical total artificial disc replacement is unproven and not medically necessary when performed at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent), as part of the same surgical plan (Hybrid Cervical Surgery) ***Lumbar*** ○ Lumbar total artificial disc replacement is proven and	Click here to view the InterQual® criteria. **Lumbar total artificial disc replacement is unproven and not medically necessary due to insufficient evidence of efficacy when:** ● Performed at one level combined with an existing lumbar spinal fusion surgery at another level (adjacent or non-adjacent); or ● Performed with lumbar spinal fusion surgery as part of the same surgical plan (Hybrid Lumbar Surgery); or ● Performed at more than one spinal level

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Total Artificial Disc Replacement for the Spine (continued)	Feb. 1, 2026	medically necessary when all of the following are present and InterQual® criteria are met: ▪ An FDA-approved prosthetic intervertebral disc is utilized ▪ Treating individuals with only single level of lumbar degenerative disc disease ▪ Skeletally Mature individual ▪ Symptomatic intractable discogenic low back pain attributable to that level ○ For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined, CP: Procedures, Artificial Disc Replacement, Lumbar (Custom) - UHG ○ Lumbar total artificial disc replacement is unproven and not medically necessary due to insufficient evidence of efficacy when: ▪ Performed at one level combined with an existing lumbar spinal fusion surgery at another level (adjacent or non-adjacent) ▪ Performed with lumbar spinal fusion surgery as part of the same surgical plan (Hybrid Lumbar	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Total Artificial Disc Replacement for the Spine (continued)	Feb. 1, 2026	Surgery) ▪ Performed at more than one spinal level **Medical Records Documentation Used for Reviews** ● Updated list of Medical Records Documentation Used for Reviews: ○ Added: ▪ Relevant imaging and diagnostic testing, including documentation of instability ▪ For total artificial disc removal or replacement, also include: – Details of complication – Surgical plan ○ Replaced: ▪ "Physical exam, including *spasticity, including investigation for other etiologies*" with "physical exam, including *detailed neurological findings*" ▪ "Treatments tried, failed, or contraindicated; include the dates and reason for discontinuation" with "treatments tried, failed, or contraindicated; include the dates, *duration*, and reason for discontinuation" ▪ "Physician treatment plan" with "physician treatment plan, *including surgical technique to be used and the number of*	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Total Artificial Disc Replacement for the Spine (continued)	Feb. 1, 2026	*levels involved and their location*" ▪ "For lumbar surgery, in addition to the [listed documentation requirements], *provide medical notes documenting the following, when applicable: provide* psychosocial-behavioral, *documentation of instability (listhesis-, spondylolisthesis and grade), and provide the surgical technique to be used and the number of levels involved and their location*" with "for lumbar surgery, in addition to the [listed documentation requirements], *also include* psychosocial-behavioral *evaluation*" **Definitions** • Added definition of: ○ Contiguous Levels ○ Hybrid Cervical Surgery ○ Hybrid Lumbar Surgery ○ Radiographically Confirmed Complete Arthrodesis • Updated definition of "Skeletally Mature" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	

Medical Policy Updates

Retired		
Policy Title	**Effective Date**	**Summary of Changes**
Electrical Stimulation for Wounds	Dec. 1, 2025	• Retired policy; electrical stimulation for wounds no longer requires clinical review

Medical Benefit Drug Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®)	Dec. 1, 2025	**Coverage Rationale** • Replaced reference to "Rystiggo (rozanolixizumab-noli) for *intravenous (IV)* route" with "Rystiggo (rozanolixizumab-noli) for *subcutaneous (SC)* route"
Rebyota® (Fecal Microbiota, Live-Jslm)	Dec. 1, 2025	**Coverage Rationale** • Replaced reference to "*Dificid* (fidaxomicin)" with "fidaxomicin" **Supporting Information** • Updated *References* section to reflect the most current information

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Botulinum Toxins A and B	Jan. 1, 2026	**Related Policies** • Added reference link to the Medical Benefit Drug Policy titled *Medical Benefit Therapeutic Equivalent Medications – Excluded Drugs* **Coverage Rationale** • Added language to indicate: ○ Daxxify® is typically excluded from coverage and coverage reviews may be in place if required by law or the benefit plan; refer to the Medical Benefit Drug Policy titled *Medical Benefit Therapeutic Equivalent Medications – Excluded Drugs* and the corresponding excluded drug list with preferred alternatives ○ For requests that require medical necessity review, also refer to the *General Requirements* and *Diagnosis-Specific Requirements* sections [of the policy] ○ Coverage for Dysport®, Xeomin®, Botox®, Myobloc® is	**This policy refers to the following botulinum toxin types A and B:** • Dysport® (abobotulinumtoxinA) • Daxxify® (daxibotulinumtoxinA-lanm) • Xeomin® (incobotulinumtoxinA) • Botox® (onabotulinumtoxinA) • Myobloc® (rimabotulinumtoxinB) Refer to the policy for complete details.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Botulinum Toxins A and B (continued)	Jan. 1, 2026	contingent on criteria in the *General Requirements* and *Diagnosis-Specific Requirements* sections [of the policy] ***Myobloc*** ○ Myobloc is medically necessary for the treatment of cervical dystonia when all of the following criteria are met: Initial Therapy ▪ Diagnosis of cervical dystonia ▪ History of failure, contraindication, or intolerance to one of the following: – Botox – Dysport – Xeomin ▪ Initial authorization will be for no more than 12 months Continuation of Therapy ▪ Reauthorization will be for no more than 12 months ○ Myobloc is medically necessary for the treatment of detrusor overactivity when all of the following criteria are met: Initial Therapy ▪ Diagnosis of detrusor overactivity ▪ History of failure, contraindication, or	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Botulinum Toxins A and B (continued)	Jan. 1, 2026	intolerance to one of the following: – Botox – Dysport ▪ Initial authorization will be for no more than 12 months Continuation of Therapy ▪ Reauthorization will be for no more than 12 months ○ Myobloc is medically necessary for the treatment of sialorrhea when all of the following criteria are met: Initial Therapy ▪ Diagnosis of sialorrhea ▪ History of failure, contraindication, or intolerance to one of the following: – Botox – Dysport – Xeomin ▪ Initial authorization will be for no more than 12 months Continuation of Therapy ▪ Reauthorization will be for no more than 12 months ○ Myobloc is medically necessary for the treatment of spasticity when all of the following criteria are met: Initial Therapy ▪ Diagnosis of spasticity	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Botulinum Toxins A and B (continued)	Jan. 1, 2026	▪ History of failure, contraindication, or intolerance to one of the following: – Botox – Dysport – Xeomin ▪ Initial authorization will be for no more than 12 months Continuation of Therapy ▪ Reauthorization will be for no more than 12 months • Revised list of proven indications for treatment with Botox (onabotulinumtoxinA), Dysport (abobotulinumtoxinA), Myobloc (rimabotulinumtoxinB), or Xeomin (incobotulinumtoxinA); replaced "spasticity *associated with cerebral palsy, multiple sclerosis, neuromyelitis optica spectrum disorder (NMOSD), stroke, or other injury, disease, or tumor of the brain or spinal cord*" with "spasticity" • Revised list of unproven and not medically necessary indications for Botox, Daxxify, Dysport, Myobloc, and Xeomin; removed: ○ Pelvic floor spasticity (and associated pain conditions) ○ Stiff-person syndrome **Supporting Information** • Added *CMS* section	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Clotting Factors, Coagulant Blood Products, & Other Hemostatics	Jan. 1, 2026	**Coverage Rationale** • Removed reference link to the Medical Benefit Drug Policy titled *Review at Launch for New to Market Medications* for Alhemo (concizumab-mtci) ***Concizumab-Mtci (Alhemo)*** • Revised medical necessity criteria for initial therapy; added criterion requiring one of the following: ○ Based on clinical patient assessment, the provider has determined that the patient is not an appropriate candidate for Hympavzi (document reason) ○ Patient is currently on Alhemo therapy **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information	Refer to the policy for complete details.
Complement Inhibitors	Jan. 1, 2026	**Coverage Rationale** • Removed reference link to the Medical Benefit Drug Policy titled *Review at Launch for New to Market Medications* for Bkemv (eculizumab-aeeb) and Epysqli (eculizumab-aagh) • Added language to indicate: ***Medical Necessity Plans*** ○ Bkemv (eculizumab-aeeb) and Epysqli (eculizumab-aagh) are the preferred eculizumab products; coverage will be provided for	This policy refers only to the following complement inhibitor drug products: • Bkemv (eculizumab-aeeb) • Epysqli (eculizumab-aagh) • PiaSky (crovalimab-akkz) • Soliris (eculizumab) • Ultomiris (ravulizumab-cwvz) Refer to the policy for complete details.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Complement Inhibitors (continued)	Jan. 1, 2026	Bkemv (eculizumab-aeeb) and Epysqli (eculizumab-aagh) contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ Coverage for Soliris (eculizumab) will be provided contingent on the criteria in the *Preferred Product Criteria* section [of the policy] and the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ In order to continue coverage, members already on Soliris will be required to change therapy to Bkemv (eculizumab-aeeb) or Epysqli (eculizumab-aagh) unless they meet the criteria in the *Preferred Product Criteria* section [of the policy] Preferred Product Criteria ○ Treatment with Soliris is medically necessary for the indications specified in this policy when both of the following criteria are met: ▪ One of the following: – Documentation of a trial of at least 14 weeks of Bkemv and Epysqli resulting in minimal clinical response to therapy and residual disease	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Complement Inhibitors (continued)	Jan. 1, 2026	activity and the physician attests that in their clinical opinion, the clinical response would be expected to be superior with Soliris than experienced with Bkemv and Eqpysqli – Documentation of intolerance, contraindication, or adverse event to Bkemv and Epysqli and the physician attests that in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with Soliris ▪ Patient has not had a loss of a favorable response after established maintenance therapy with an eculizumab product ***Non-Medical Necessity Plans*** ○ Any complement inhibitor is to be approved contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ● Removed language indicating	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Complement Inhibitors (continued)	Jan. 1, 2026	Zilbrysq (zilucoplan) is a self-administered injection obtained under the member's pharmacy benefit **Supporting Information** • Updated *CMS* section to reflect the most current information	
Denosumab	Jan. 1, 2026	**Related Policies** • Added reference link to the Medical Benefit Drug Policy titled: ○ *Maximum Dosage and Frequency* ○ *Medical Benefit Therapeutic Equivalent Medications – Excluded Drugs* ○ *Oncology Medication Clinical Coverage* ○ *Provider Administered Drugs – Site of Care* **Coverage Rationale** • Removed reference link to the Medical Benefit Drug Policy titled *Review at Launch for New to Market Medications* for Jubbonti® (denosumab-bbdz) and Stoboclo® (denosumab-bmwo) • Revised list of applicable denosumab products for non-oncology conditions: ○ Added "any FDA-approved denosumab product not listed [in the policy]" ○ Removed: ▪ Osenvelt® (denosumab-bmwo) ▪ Xgeva® (denosumab)	**Bildyos® (denosumab-nxxp), Bosaya™ (denosumab-kyqq), Conexxence® (denosumab-bnht), Enoby™ (denosumab-qbde), and Ospomyv™ (denosumab-dssb) have been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Refer to the Medical Benefit Drug Policy titled Review at Launch for New to Market Medications for additional details.** This policy refers to the following denosumab products for non-oncology conditions: • Jubbonti® (denosumab-bbdz) • Prolia® (denosumab) • Stoboclo® (denosumab-bmwo) • Any FDA-approved denosumab product not listed here* *Any U.S. Food and Drug Administration approved denosumab product not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare. For oncology indications, 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®). **Jubbonti® is typically excluded from coverage. Coverage reviews may be in place if required by law or the benefit plan.** Refer to the Medical Benefit Drug Policy titled Medical Benefit Therapeutic Equivalent Medications – Excluded Drugs and the corresponding excluded drug list with preferred alternatives.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Denosumab (continued)	Jan. 1, 2026	▪ Wyost® (denosumab-bbdz) • Added language to indicate: ○ Bildyos® (denosumab-nxxp), Bosaya™ (denosumab-kyqq), Conexxence® (denosumab-bnht), Enoby™ (denosumab-qbde), and Ospomyv™ (denosumab-dssb) have been added to the Review at Launch program and some members may not be eligible for coverage of this medication at this time; refer to the Medical Benefit Drug Policy titled *Review at Launch for New to Market Medications* for additional details ○ Any U.S. Food and Drug Administration approved denosumab product not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare ○ For oncology indications, 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®) ○ Jubbonti® is typically	**Preferred Product** ***Medical Necessity Plans*** Prolia and Stoboclo are the preferred denosumab products. Coverage will be provided for Prolia and Stoboclo contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Coverage for Jubbonti or other non-preferred denosumab products will be provided contingent on the criteria in this Preferred Product Criteria section and the coverage criteria in the Diagnosis-Specific Criteria section. In order to continue coverage, members already on Jubbonti or other non-preferred denosumab products will be required to change therapy to Prolia or Stoboclo unless they meet the criteria in this section. **Preferred Product Criteria** (*For Medicare reviews, refer to the CMS section of the policy.)* **Treatment with Jubbonti or other non-preferred denosumab products is medically necessary for the indications specified in the policy when one of the following is met:** • **Both** of the following: ○ History of a trial of adequate dose and duration of Prolia or Stoboclo, resulting in minimal clinical response; **and** ○ Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Jubbonti or other non-preferred denosumab product, than experienced with Prolia or Stoboclo. **or** • **Both** of the following: ○ History of intolerance, contraindication, or adverse event to Prolia or Stoboclo; **and** ○ Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with Jubbonti or other non-preferred denosumab product **Non-Medical Necessity Plans** Any denosumab product is to be approved contingent on the coverage criteria in the Diagnosis-Specific Criteria section.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab (continued)	Jan. 1, 2026	excluded from coverage and coverage reviews may be in place if required by law or the benefit plan; refer to the Medical Benefit Drug Policy titled *Medical Benefit Therapeutic Equivalent Medications – Excluded Drugs* and the corresponding excluded drug list with preferred alternatives ***Medical Necessity Plans*** ○ Prolia and Stoboclo are the preferred denosumab products; coverage will be provided for Prolia and Stoboclo contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ Coverage for Jubbonti or other non-preferred denosumab products will be provided contingent on the criteria in the *Preferred Product Criteria* section [of the policy] and the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ In order to continue coverage, members already on Jubbonti or other non-preferred denosumab products will be required to change therapy to Prolia or Stoboclo unless they meet the criteria in the	**Diagnosis-Specific Criteria** "Denosumab" will be used to refer to all denosumab products. **Denosumab is proven for the treatment of postmenopausal patients with osteoporosis or to increase bone mass in patients with osteoporosis at high risk for fracture when all of the following criteria are met:** • **Initial Therapy** ○ Diagnosis of osteoporosis; **and** ○ Patient is at high risk for fracture (e.g., history of osteoporotic fracture, multiple risk factors for fracture, patients who have failed or are intolerant to other available osteoporosis therapy); **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Authorization is for no more than 12 months • **Reauthorization/Continuation of Care Criteria** ○ Documentation of positive clinical response to therapy; **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Authorization is for no more than 12 months **Denosumab is proven to treat glucocorticoid-induced osteoporosis in patients at high risk for fracture when all of the following criteria are met:** • **Initial Therapy** ○ Diagnosis of glucocorticoid-induced osteoporosis; **and** ○ Patient is at high risk for fracture (e.g., history of osteoporotic fracture, multiple risk factors for fracture, patients who have failed or are intolerant to other available osteoporosis therapy); **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Authorization is for no more than 12 months • **Reauthorization/Continuation of Care Criteria** ○ Documentation of positive clinical response to therapy; **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Authorization is for no more than 12 months

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab (continued)	Jan. 1, 2026	*Preferred Product Criteria* section [of the policy] Preferred Product Criteria ○ Treatment with Jubbonti or other non-preferred denosumab products is medically necessary for the indications specified in the policy when one of the following is met: ▪ Both of the following: – History of a trial of adequate dose and duration of Prolia or Stoboclo, resulting in minimal clinical response – Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Jubbonti or other non-preferred denosumab product, than experienced with Prolia or Stoboclo ▪ Both of the following: – History of intolerance, contraindication, or adverse event to Prolia or Stoboclo – Physician attests that, in their clinical opinion, the same	**Unproven** **Denosumab is unproven for the following indications:** • Combination therapy with intravenous bisphosphonates • Hyperparathyroidism • Immobilization hypercalcemia • Osteogenesis imperfecta • Osteopenia

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Denosumab (continued)	Jan. 1, 2026	intolerance, contraindication, or adverse event would not be expected to occur with Jubbonti or other non-preferred denosumab product ***Non-Medical Necessity Plans*** ○ Any denosumab product is to be approved contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ***Diagnosis-Specific Criteria*** ○ "Denosumab" will be used to refer to all denosumab products • Replaced references to "Jubbonti, Prolia, and Stoboclo" with "denosumab" • Replaced language indicating "Denosumab is unproven *and not medically necessary* for the [listed] indications" with "denosumab is unproven for the [listed] indications" • Removed language indicating: ○ Jubbonti, Prolia, and Stoboclo are proven and medically necessary: ▪ To increase bone mass in patients at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Denosumab (continued)	Jan. 1, 2026	▪ To treat patients at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer ○ Osenvelt, Wyost, and Xgeva are proven and medically necessary for: ▪ The prevention of skeletal-related events in patients with multiple myeloma and with bone metastases from solid tumors ▪ The treatment of giant cell tumor of the bone ▪ The treatment of hypercalcemia of malignancy ▪ The prevention of skeletal-related events in men with castration-resistant prostate cancer who have bone metastases ▪ The treatment of osteopenia/osteoporosis in patients with systemic mastocytosis with bone pain not responding to bisphosphonates ○ Denosumab-bbdz and denosumab-bmwo are unproven and not medically necessary for the following indications:	

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Denosumab (continued)	Jan. 1, 2026	▪ Combination therapy with intravenous bisphosphonates ▪ Bone loss associated with hormone-ablation therapy (other than aromatase inhibitors) in breast/prostate cancer ▪ Cancer pain ▪ Central giant cell granuloma ▪ Hyper-parathyroidism ▪ Immobilization hypercalcemia ▪ Osteogenesis imperfecta ▪ Osteopenia ○ Denosumab is unproven for the following indications: ▪ Bone loss associated with hormone-ablation therapy (other than aromatase inhibitors) in breast/prostate cancer ▪ Cancer pain ▪ Central giant cell granuloma **Applicable Codes** • Removed ICD-10 diagnosis codes C61 and C79.81 • Removed list of applicable ICD-10 diagnosis codes for Osenvelt, Wyost, and Xgeva **Supporting Information** • Updated *Clinical Evidence*, *FDA*, *CMS*, and *References* sections to reflect the most current information	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Elevidys® (Delandistrogene Moxparvovec-Rokl)	Jan. 1, 2026	**Coverage Rationale** • Revised coverage criteria; added criterion requiring the provider does not request a planned inpatient admission for the sole purpose of administering Elevidys	**Elevidys is proven and medically necessary for the treatment of Duchenne muscular dystrophy (DMD) in patients who meet all of the following criteria:** • Diagnosis of Duchenne muscular dystrophy by, or in consultation with, a pediatric neuromuscular specialist with expertise in the diagnosis of DMD; **and** • Submission of medical records (e.g., chart notes, laboratory values) confirming **both** of the following: ○ A mutation in the DMD gene; **and** ○ The mutation is not a deletion in exon 8 or exon 9 **and** • Patient is aged 4 or 5 years of age; **and** • Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.); **and** • **Both** of the following: ○ Patient does not have preexisting hepatic impairment, acute liver disease (e.g., acute hepatic viral infection), chronic hepatic condition or elevated GGT; **and** ○ Prescriber attests that liver function (clinical exam, GGT, and total bilirubin) will be monitored weekly for the first 3 months following Elevidys administration and thereafter in accordance with the FDA approved labeling **and** • **Both** of the following: ○ Patient does not have a left ventricle ejection fraction (LVEF) < 40%; **and** ○ Prescriber attests that troponin-I will be monitored weekly for the first month following Elevidys administration and thereafter per recommendations in the prescribing information **and** • Patient does not have an elevated anti-AAVrh74 total binding antibody titer ≥ 1:400; **and** • Patient will receive a corticosteroid regimen prior to and following receipt of Elevidys in accordance with the United States Food and Drug Administration (FDA) approved Elevidys labeling; **and** • Elevidys is prescribed by, or in consultation with, a pediatric

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Elevidys® (Delandistrogene Moxparvovec-Rokl) (continued)	Jan. 1, 2026		neuromuscular specialist with expertise in the treatment of DMD; **and** • Patient will not receive exon-skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)] concomitantly or following Elevidys treatment; **and** • Patient has not previously received gene therapy for the treatment of DMD; **and** • Provider does not request a planned inpatient admission for the sole purpose of administering Elevidys; **and** • Elevidys dosing is in accordance with FDA approved labeling; **and** • Authorization will be issued for no more than one treatment per lifetime and for no longer than 45 days from approval or until 6 years of age, whichever is first **Elevidys is unproven and not medically necessary for the treatment of:** • Becker muscular dystrophy (BMD) • Duchenne muscular dystrophy (DMD) in ambulatory patients < 4 years of age and ≥ 6 years of age • Duchenne muscular dystrophy (DMD) in patients at any age who are non-ambulatory
Gamifant® (Emapalumab-Lzsg)	Jan. 1, 2026	**Coverage Rationale** • Revised medical necessity criteria; added criterion requiring the provider does not request a planned inpatient admission for the sole purpose of administering Gamifant	**Gamifant is proven for the treatment of primary hemophagocytic lymphohistiocytosis (HLH) in patients who meet all of the following criteria:** • Diagnosis of primary hemophagocytic lymphohistocytosis; **and** • Patient has refractory, recurrent or progressive disease, or intolerance with conventional HLH therapy (e.g., etoposide, corticosteroids, cyclosporine, anti-thymocyte globulin, methotrexate); **and** • Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** • Authorization will be for no more than 6 months **Gamifant is medically necessary for the treatment of primary hemophagocytic lymphohistiocytosis (HLH) in patients who meet all of the following criteria:** • Submission of medical records (e.g., chart notes, laboratory values) confirming **one** the following: ○ Confirmation of a gene mutation known to cause primary HLH (e.g., PRF1, UNC13D, RAB27A, STX11, STXBP2); **or**

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Gamifant® (Emapalumab-Lzsg) (continued)	Jan. 1, 2026		○ Confirmation that **five** of the following clinical characteristics are present: ▪ Fever ▪ Splenomegaly ▪ **Two** of the following cytopenias in the peripheral blood: – Hemoglobin < 9 g/dL; **or** – Platelet count < 100 x 109/L; **or** – Neutrophils < 1 x 109/L ▪ **One** of the following: – Hypertriglyceridemia defined as fasting triglycerides ≥ 3 mmol/L or ≥ 265 mg/dL; **or** – Hypofibrinogenemia defined as fibrinogen ≤ 1.5 g/L ▪ Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy ▪ Low or absent natural killer cell activity ▪ Ferritin ≥ 500 mcg/L ▪ Soluble CD25 (i.e., soluble IL-2 receptor) ≥ 2,400 U/mL **and** • Patient has refractory, recurrent or progressive disease, or intolerance with conventional HLH therapy (e.g., etoposide, corticosteroids, cyclosporine, anti-thymocyte globulin, methotrexate); **and** • Gamifant will be administered with dexamethasone; **and** • Patient is a candidate for hematopoietic stem cell transplant; **and** • Gamifant is being used as part of the induction or maintenance phase of hematopoietic stem cell transplant, which is to be discontinued at the initiation of conditioning for stem cell transplant; **and** • Provider does not request a planned inpatient admission for the sole purpose of administering Gamifant; **and** • Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** • Authorization will be for no more than 6 months **Gamifant is proven for the treatment of hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) in patients who meet all of the following criteria:** • **Initial Therapy** ○ Diagnosis of hemophagocytic lymphohistiocytosis (HLH)/

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Gamifant® (Emapalumab-Lzsg) (continued)	Jan. 1, 2026		macrophage activation syndrome (MAS); **and** ○ Known or suspected diagnosis of Still's disease, including systemic juvenile idiopathic arthritis (sJIA); **and** ○ Inadequate response or intolerance to glucocorticoids; **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Approval is for no more than 12 months • **Continuation of Therapy** ○ Documentation of a positive clinical response to Gamifant; **and** ○ Dosing is in accordance with the FDA approved labeling; **and** ○ Reauthorization will be for no more than 12 months **Gamifant is medically necessary for the treatment of hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) in patients who meet all of the following criteria:** • **Initial Therapy** ○ Submission of medical records (e.g., chart notes, laboratory values) confirming the following: ▪ Confirmed or suspected diagnosis of systemic juvenile idiopathic arthritis (sJIA) or adult-onset Still's disease (AOSD); **and** ▪ Diagnosis of active MAS with **both** of the following: – Ferritin > 684 ng/mL – **Two** of the following laboratory criteria: • Platelet count ≤ 181 x 10^9/L • AST > 48 U/L • Triglycerides > 156 mg/dL • Fibrinogen level ≤ 360 mg/dL **and** ○ Patient has had an inadequate response to high-dose intravenous glucorticoids; **and** ○ Provider does not request a planned inpatient admission for the sole purpose of administering Gamifant; **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Initial authorization will be for no more than 12 months • **Continuation of Therapy** ○ Documentation of a positive clinical response to Gamifant; **and**

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Gamifant® (Emapalumab-Lzsg) (continued)	Jan. 1, 2026		○ Provider does not request a planned inpatient admission for the sole purpose of administering Gamifant; **and** ○ Dosing is in accordance with the FDA approved labeling; **and** ○ Reauthorization will be for no more than 12 months **Gamifant is not proven or medically necessary for the treatment of secondary HLH.**
Gene Therapies for Hemophilia B	Jan. 1, 2026	**Coverage Rationale** • Revised coverage criteria: ○ Added criterion requiring the provider does not request a planned inpatient admission for the sole purpose of administering Beqvez/Hemgenix ○ Replaced criterion requiring "the patient is currently receiving *chronic prophylactic* Hympavzi (marstacimab-hncq) therapy" with "the patient is currently receiving *routine prophylaxis for hemophilia B with a non-factor replacement therapy [i.e., Alhemo (concizumab-mtci),* Hympavzi (marstacimab-hncq), *Qfitlia (fitusiran)]*" **Supporting Information** • Updated *References* section to reflect the most current information	**Hemophilia B (i.e., Congenital Factor IX Deficiency, Christmas Disease)** **Beqvez is proven and medically necessary for the treatment of Hemophilia B (congenital factor IX deficiency) when all of the following criteria are met:** • Patient is 18 years of age or older; **and** • **One** of the following: ○ **Both** of the following: ▪ Diagnosis of severe hemophilia B; **and** ▪ Documentation of endogenous factor IX levels less than 1% of normal factor IX (< 0.01 IU/mL) **or** ○ **All** of the following: ▪ Diagnosis of moderately severe hemophilia B; **and** ▪ Documentation of endogenous factor IX levels ≥ 1% ≤ 2% (greater than or equal to 0.01 IU/mL to less than or equal to 0.02 IU/mL); **and** ▪ **One** of the following: – Patient has current or historical life-threatening hemorrhage; **or** – Patient has repeated, serious spontaneous bleeding episodes **and** • **One** of the following: ○ Patient is currently receiving routine prophylaxis for hemophilia B with a non-factor replacement therapy [i.e., Alhemo (concizumab-mtci), Hympavzi (marstacimab-hncq), Qfitlia (fitusiran)]; **or** ○ **Both** of the following: ▪ Patient currently uses factor IX prophylaxis therapy; **and**

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Gene Therapies for Hemophilia B (continued)	Jan. 1, 2026		▪ Patient has had a minimum of 50 exposure days to a factor IX agent **or** ○ Patient has been determined to be an appropriate candidate for Beqvez by the Hemophilia Treatment Center based on willingness to adhere to initial and long-term monitoring and management **and** • Patient does not have a history of inhibitors to factor IX greater than or equal to 0.6 Bethesda units (BU); **and** • Patient does not screen positive for active factor IX inhibitors as defined as greater than or equal to 0.6 Bethesda units (BU) prior to administration of Beqvez; **and** • Patient does **not** have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test; **and** • Patient has not gone through Immune Tolerance Induction (ITI); **and** • Liver health assessments including enzyme testing [e.g., alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin] and hepatic ultrasound and/or elastography are performed to rule out radiological liver abnormalities and/or sustained liver enzyme elevations; **and** • One of the following: ○ Patient is not HIV positive; **or** ○ Patient is HIV positive and is virally suppressed with anti-viral therapy (i.e., < 200 copies of HIV per mL) **and** • The patient's hepatitis B surface antigen is negative; **and** • One of the following: ○ Patient's hepatitis C virus (HCV) antibody is negative; or ○ Patient's HCV antibody is positive, and the patient's HCV RNA is negative **and** • The patient is not currently using antiviral therapy for hepatitis B or C; **and** • Patient has not previously received treatment with Beqvez (fidanacogene elaparvovec-dzkt) or another gene therapy [e.g., Hemgenix (etranacogene dezaparvovec-drlb)] for the treatment of hemophilia B; **and**

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Gene Therapies for Hemophilia B (continued)	Jan. 1, 2026		• Beqvez is prescribed and managed by a bleeding disorder specialist on staff at a Hemophilia Treatment Center (HTC) that holds Federal designation as evidenced by being listed within the CDC's HTC directory; **and** • Prescriber attests that the patient's ALT and AST as well as factor IX activity will be monitored at least weekly for at least 4 months following administration of Beqvez and regularly thereafter per the monitoring schedule recommended in the prescribing information; **and** • Prescriber attests that counseling has been provided to the patient around the risks of alcohol consumption following administration of Beqvez; **and** • Beqvez dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** • Provider does not request a planned inpatient admission for the sole purpose of administering Beqvez; **and** • Authorization will be issued for no more than one treatment per lifetime and for no longer than 45 days from approval **Hemgenix is proven and medically necessary for the treatment of Hemophilia B (congenital factor IX deficiency) when all of the following criteria are met:** • Patient is 18 years of age or older; **and** • **One** of the following: ○ **Both** of the following: ▪ Diagnosis of severe hemophilia B; **and** ▪ Documentation of endogenous factor IX levels less than 1% of normal factor IX (< 0.01 IU/mL) **or** ○ **All** of the following: ▪ Diagnosis of moderately severe hemophilia B; **and** ▪ Documentation of endogenous factor IX levels ≥ 1% ≤ 2% (greater than or equal to 0.01 IU/mL to less than or equal to 0.02 IU/mL); **and** ▪ **One** of the following: – Patient has current or historical life-threatening hemorrhage; **or** – Patient has repeated, serious spontaneous bleeding episodes

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Gene Therapies for Hemophilia B (continued)	Jan. 1, 2026		**and**
			• **One** of the following:
			  ○ Patient is currently receiving routine prophylaxis for hemophilia B with a non-factor replacement therapy [i.e., Alhemo (concizumab-mtci), Hympavzi (marstacimab-hncq), Qfitlia (fitusiran)]; **or**
			  ○ **Both** of the following:
			  ▪ Patient currently uses factor IX prophylaxis therapy; **and**
			  ▪ Patient has had a minimum of 50 exposure days to a factor IX agent
			  or
			  ○ Patient has been determined to be an appropriate candidate for Hemgenix by the Hemophilia Treatment Center based on willingness to adhere to initial and long-term monitoring and management
			and
			• Patient does not have a history of inhibitors to factor IX greater than or equal to 0.6 Bethesda units (BU); **and**
			• Patient does not screen positive for active factor IX inhibitors as defined as greater than or equal to 0.6 Bethesda units (BU) prior to administration of Hemgenix; **and**
			• Patient has not gone through Immune Tolerance Induction (ITI); **and**
			• Liver health assessments including enzyme testing [e.g., alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin] and hepatic ultrasound and/or elastography are performed to rule out radiological liver abnormalities and/or sustained liver enzyme elevations; **and**
			• **All** of the following:
			  ○ Documentation that the patient has been evaluated for the presence of preexisting neutralizing antibodies to the adenovirus vector (e.g., AAV-5) used to deliver the therapy; **and**
			  ○ Patient has had pre-existing anti-AAV5 neutralizing antibodies measured through the laboratory developed, CLIA-validated AAV5 Neutralizing Antibody Test made available through CSL Behring; **and**
			  ○ The patient does not have high anti-AAV antibody (e.g., AAV-5) titers that may be associated with a lack of response to treatment based on published clinical evidence
			and

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Gene Therapies for Hemophilia B (continued)	Jan. 1, 2026		• One of the following:
			  ○ Patient is not HIV positive; **or**
			  ○ Patient is HIV positive and is virally suppressed with anti-viral therapy (i.e., < 200 copies of HIV per mL)
			and
			• The patient's hepatitis B surface antigen is negative; **and**
			• One of the following:
			  ○ Patient's hepatitis C virus (HCV) antibody is negative; or
			  ○ Patient's HCV antibody is positive, and the patient's HCV RNA is negative
			and
			• The patient is not currently using antiviral therapy for hepatitis B or C; **and**
			• Patient has not previously received treatment with Hemgenix (etranacogene dezaparvovec-drlb) or another gene therapy [e.g., Beqvez (fidanacogene elaparvovec-dzkt)] for the treatment of hemophilia B; **and**
			• Hemgenix is prescribed and managed by a bleeding disorder specialist on staff at a Hemophilia Treatment Center (HTC) that holds Federal designation as evidenced by being listed within the CDC's HTC directory; **and**
			• Prescriber attests that the patient's ALT and AST as well as factor IX activity will be monitored weekly for at least 3 months following administration of Hemgenix and regularly thereafter per the monitoring schedule recommended in the prescribing information; **and**
			• Prescriber attests that counseling has been provided to the patient around the risks of alcohol consumption following administration of Hemgenix; **and**
			• Hemgenix dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
			• Provider does not request a planned inpatient admission for the sole purpose of administering Hemgenix; **and**
			• Authorization will be issued for no more than one treatment per lifetime and for no longer than 45 days from approval
			
			Additional information relevant to the review process for Beqvez and Hemgenix but not impacting the determination of medical necessity:

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Gene Therapies for Hemophilia B (continued)	Jan. 1, 2026		• Prescriber attests that the patient, while under the care of the prescriber, will be assessed for treatment efficacy including, but not limited to evaluation of factor IX expression, breakthrough bleeding episodes, factor IX product utilization, inhibitor development;* **and** • Prescriber acknowledges that UnitedHealthcare may request documentation, not more frequently than biannually, and not for a period to exceed 5 years of follow-up patient assessment(s) including, but not necessarily limited to, evaluation of factor IX expression, breakthrough bleeding episodes, factor IX product utilization, inhibitor development while the patient is under the care of the prescriber* *For quality purposes only, this information will not be considered as part of the individual coverage decision. **Beqvez and Hemgenix are unproven and not medically necessary in the following:** • The treatment of hemophilia A • The repeat administration of Hemgenix or Beqvez for the treatment of hemophilia B • The treatment of hemophilia B after previously receiving another factor IX gene therapy product • The routine combination treatment with chronically administered prophylactic therapy for hemophilia B • The treatment of hemophilia B in patients less than 18 years of age
Immune Globulin (IVIG and SCIG)	Jan. 1, 2026	**Coverage Rationale** • Removed reference link to the Medical Benefit Drug Policy titled *Review at Launch for New to Market Medications* for Yimmugo® (immune globulin intravenous, human - dira) • Added language to indicate: ○ Qivigy (immune globulin intravenous, human-kthm) has been added to the Review at Launch program and some members may not	Refer to the policy for complete details.

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Immune Globulin (IVIG and SCIG) (continued)	Jan. 1, 2026	be eligible for coverage of this medication at this time; refer to the Medical Benefit Drug Policy titled *Review at Launch for New to Market Medications* for additional details ○ Any U.S. Food and Drug Administration approved immune globulin product not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare ***Medical Necessity Plans*** ○ Coverage will be provided for preferred products contingent on the coverage criteria in the *General Requirements* and *Diagnosis-Specific Criteria* sections [of the policy] ○ Coverage for any non-preferred immune globulin product, or any immune globulin not listed by name in this policy, will be provided contingent on the criteria in the *Preferred Product* section [of the policy], in addition to the coverage criteria in the *General Requirements* and *Diagnosis-Specific Criteria* sections [of the policy] ○ In order to continue coverage, members already on a non-preferred immune globulin product will be required to	

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Immune Globulin (IVIG and SCIG) (continued)	Jan. 1, 2026	change therapy to a preferred immune globulin product unless they meet the criteria in the *Preferred Product* section [of the policy] Preferred Product Criteria ○ Treatment with a non-preferred immune globulin is medically necessary for the indications specified in this policy when one of the following criteria is met: ▪ Both of the following: – Documentation of a trial of all of the preferred immune globulin products resulting in minimal clinical response to therapy and residual disease activity – Physician attests that in their clinical opinion, the clinical response would be expected to be superior with the requested non-preferred product, than experienced with all of the preferred immune globulin products ▪ Both of the following: – Documentation of intolerance, contraindication, or	

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Immune Globulin (IVIG and SCIG) (continued)	Jan. 1, 2026	adverse event to all of the preferred immune globulin products – Physician attests that in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with the requested non-preferred product ***Non-Medical Necessity Plans*** ○ Any immune globulin product is to be approved contingent on the coverage criteria in the *General Requirements* and *Diagnosis-Specific Criteria* sections [of the policy] • Removed language indicating prescribing and dosing information from the package insert is the clinical information used to determine benefit coverage in absence of a product listed and in addition to applicable criteria outlined within the drug policy • Revised coverage criteria for **measles (rubeola) post-exposure prophylaxis**; replaced criterion requiring "the patient has received hematopoietic stem cell transplant (HSCT) and *has*	

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Immune Globulin (IVIG and SCIG) (continued)	Jan. 1, 2026	*finished all* immunosuppressive treatment within 12 months" with "the patient has received hematopoietic stem cell transplant (HSCT) and *is currently receiving* immunosuppressive treatment *or has finished immunosuppressive treatment regimen* within *the past* 12 months" **Supporting Information** • Updated *CMS* section to reflect the most current information	
Luxturna® (Voretigene Neparvovec-Rzyl)	Jan. 1, 2026	**Coverage Rationale** • Revised coverage criteria; added criterion requiring the provider does not request a planned inpatient admission for the sole purpose of administering Luxturna	**Luxturna is proven and/or medically necessary for the treatment of inherited retinal dystrophies (IRD) caused by mutations in the retinal pigment epithelium-specific protein 65kDa (RPE65) gene in patients who meet all of the following criteria:** • Patient is greater than 12 months of age; **and** • Diagnosis of a confirmed biallelic RPE65 mutation-associated retinal dystrophy [e.g., Leber's congenital amaurosis (LCA), Retinitis pigmentosa (RP), Early Onset Severe Retinal Dystrophy (EOSRD), etc.]; **and** • Genetic testing documenting biallelic mutations of the RPE65 gene; **and** • Sufficient viable retinal cells as determined by optical coherence tomography (OCT) confirming an area of retina within the posterior pole of > 100 µm thickness; **and** • Prescribed and administered by ophthalmologist or retinal surgeon with experience providing sub-retinal injections; **and** • Patient has not previously received Luxturna treatment in intended eye; **and** • Provider does not request a planned inpatient admission for the sole purpose of administering Luxturna; **and** • Authorization will be issued for no more than one treatment per lifetime per eye and for no longer than 45 days from approval

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Maximum Dosage and Frequency	Jan. 1, 2026	**Coverage Rationale** • Revised list of applicable drug products; added: ○ denosumab-bmwo (Stoboclo® & Osenvelt®) ○ eculizumab-aagh (Epysqli®) ○ eculizumab-aeeb (Bkemv™) ○ ustekinumab-srlf (Imuldosa) ***Maximum Allowed Quantities by HCPCS Units*** • Added maximum allowed quantities for: ○ Bkemv (eculizumab-aeeb) (HCPCS code Q5152) ○ Epysqli (eculizumab-aagh) (HCPCS code Q5151) ○ Imuldosa (ustekinumab-srlf) (HCPCS code Q5098) ○ Osenvelt (denosumab-bmwo) (HCPCS code Q5157) ○ Stoboclo (denosumab-bmwo) (HCPCS code Q5157) ***Maximum Allowed Quantities for National Drug Code (NDC) Billing*** • Added maximum allowed quantities for: ○ Bkemv (eculizumab-aeeb) (NDC 55513-0180-01) ○ Epysqli (eculizumab-aagh) (NDC 51759-0208-13) ○ Imuldosa (ustekinumab-srlf) (NDCs 51407-0929-11, 51407-0930-11, 51407-0931-11, 69448-0017-63, 69448-0018-63, and 69448-0019-26)	This policy provides information about the maximum dosage per administration and dosing frequency for certain medications administered by a medical professional. Most medications have a maximum dosage and frequency based upon body surface area or patient weight or a set maximal dosage and frequency independent of patient body size. **Drug Products** • abatacept (Orencia®) • abobotulinumtoxinA (Dysport®) • aflibercept (Eylea®) • aflibercept (Eylea® HD) • aflibercept-ayyh (Pavblu™) • atezolizumab (Tecentriq®) • avelumab (Bavencio®) • axatilimab-csfr (Niktimvo™) • benralizumab (Fasenra®) • bevacizumab (Avastin®) • bevacizumab-adcd (Vegzelma®) • bevacizumab-awwb (Mvasi™) • bevacizumab-bvzr (Zirabev®) • bevacizumab-maly (Alymsys®) • brolucizumab-dbll (Beovu®) • canakinumab (Ilaris®) • cemiplimab-rwlc (Libtayo®) • certolizumab pegol (Cimzia®) • crovalimab-akkz (PiaSky™) • daxibotulinumtoxina-lanm (Daxxify®) • denosumab (Prolia® & Xgeva®) • denosumab-bbdz (Jubbonti® & Wyost®) • denosumab-bmwo (Stoboclo® & Osenvelt®) • durvalumab (Imfinzi®) • eculizumab (Soliris®) • pegfilgrastim (Neulasta®) • pegfilgrastim-apgf (Nyvepria™) • pegfilgrastim-cbqv (Udenyca®) • pegfilgrastim-fpgk (Stimufend®) • pegfilgrastim-jmdb (Fulphila™) • pegfilgrastim-pbbk (Fylnetra®) • pegfilgrastim-bmez (Ziextenzo®) • pegloticase (Krystexxa®) • pembrolizumab (Keytruda®) • ranibizumab (Lucentis®) • ranibizumab-nuna (Byooviz™) • ranibizumab-eqrn (Cimerli™) • ravulizumab-cwvz (Ultomiris®) • reslizumab (Cinqair®) • rimabotulinumtoxinB (Myobloc®) • risankizumab-rzaa (Skyrizi®) • rituximab (Rituxan®) • rituximab-pvvr (Ruxience™) • rituximab-abbs (Truxima®) • rituximab-arrx (Riabni™) • rituximab and hyaluronidase (Rituxan Hycela®) • rozanolixizumab-noli (Rystiggo®) • spesolimab-sbzo (Spevigo®) • testosterone cypionate (Depo-Testosterone®) • testosterone enanthate • testosterone pellets (Testopel®)

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Maximum Dosage and Frequency (continued)	Jan. 1, 2026	○ Osenvelt (denosumab-bmwo) (NDC 72606-0038-01) ○ Stoboclo (denosumab-bmwo) (NDC 72606-0037-01) ***Maximum Allowed Frequencies*** • Added maximum allowed frequencies for: ○ Bkemv (eculizumab-aeeb) ○ Epysqli (eculizumab-aagh) ○ Imuldosa (ustekinumab-srlf) ○ Osenvelt (denosumab-bmwo) ○ Stoboclo (denosumab-bmwo) **Applicable Codes** • Added HCPCS codes Q5098, Q5151, Q5152, and Q5157 • Added NDCs 51407-0929-11, 51407-0930-11, 51407-0931-11, 51759-0208-13, 55513-0180-01, 61314-0228-94, 61314-0240-63, 69448-0017-63, 69448-0018-63, 69448-0019-26, 72606-0037-01, and 72606-0038-01 **Supporting Information** • Updated *References* section to reflect the most current information	• eculizumab-aagh (Epysqli®) • eculizumab-aeeb (Bkemv™) • edaravone (Radicava®) • efgartigimod alfa-fcab (Vyvgart®) • efgartigimod alfa and hyaluronidase-qvfc (Vyvgart® Hytrulo) • eflapegrastim-xnst (Rolvedon™) • emicizumab-kxwh (Hemlibra®) • eptinezumab-jjmr (Vyepti®) • faricimab-svoa (Vabysmo™) • golimumab (Simponi Aria®) • guselkumab (Tremfya®) • inclisiran (Leqvio®) • incobotulinumtoxinA (Xeomin®) • infliximab (Remicade®) • infliximab-axxq (Avsola™) • infliximab-dyyb (Inflectra®) • infliximab-abda (Renflexis®) • ipilimumab (Yervoy®) • mepolizumab (Nucala®) • mirikizumab-mrkz (Omvoh®) • nivolumab (Opdivo®) • ocrelizumab (Ocrevus®) • omalizumab (Xolair®) • onabotulinumtoxinA (Botox®) • patisiran (Onpattro®) • pegcetacoplan (Syfovre™) • testosterone undecanoate (Aveed®) • tezepelumab-ekko (Tezspire®) • tildrakizumab-asmn (Ilumya™) • tocilizumab (Actemra®) • tocilizumab-aazg (Tyenne®) • tocilizumab-bavi (Tofidence™) • tofersen (Qalsody™) • trastuzumab (Herceptin®) • trastuzumab-anns (Kanjinti™) • trastuzumab-dkst (Ogivri™) • trastuzumab-dttb (Ontruzant®) • trastuzumab-pkrb (Herzuma®) • trastuzumab-qyyp (Trazimera™) • ustekinumab (Stelara®) • ustekinumab-aauz (Otulfi™) • ustekinumab-aekn (Selarsdi™)ustekinumab-stba (Steqeyma®) • ustekinumab-auub (Wezlana™) • ustekinumab-kfce (Yesintek) • ustekinumab-srlf (Imuldosa) • ustekinumab-ttwe (Pyzchiva®) • vedolizumab (Entyvio®) • vutrisiran (Amvuttra™) • zoledronic acid (zoledronic acid, Reclast®) **The use of medications included in this policy when given within the maximum dosage and/or frequency based upon body surface area or patient weight or a set of maximal dosage and/or frequency independent of patient body size are proven when used according to labeled indications or when otherwise supported by published clinical evidence [e.g., well-designed systematic reviews (with or without meta-**

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Maximum Dosage and Frequency (continued)	Jan. 1, 2026		**analyses) of multiple well-designed randomized controlled trials, the National Comprehensive Cancer Network (NCCN) guidelines].** **The use of medications included in this policy when given beyond maximum dosages and/or frequency based upon body surface area or patient weight or a set maximal dosage independent of patient body size are not supported by package labeling or published clinical evidence and are unproven.** **Continued use of a medication or dosages used beyond labeled indication or other published clinical evidence [e.g., well-designed systematic reviews (with or without meta-analyses) of multiple well-designed randomized controlled trials, NCCN guidelines] is considered not medically necessary.** This policy creates an upper dose limit based on the clinical evidence and the 95th percentile for adult body weight (140 kg) and body surface area (2.71 meters^2) in the U.S. (adult male, 30 to 39 years, Fryar, 2021). In some cases, the maximum allowed units and/or vials may exceed the upper level limit as defined within this policy due to an individual patient body weight > 140 kg or body surface area > 2.71 meters^2. Refer to the policy for complete details.
Natalizumab (Tyruko® & Tysabri®)	Jan. 1, 2026	**Title Change** • Previously titled *Tysabri® (Natalizumab)* **Coverage Rationale** • Added language to indicate: ○ This policy refers to the following natalizumab products for injection: ▪ Tyruko (natalizumab-sztn) ▪ Tysabri (natalizumab) ▪ Any FDA-approved natalizumab biosimilar product not listed here ○ Coverage criteria for Tyruko contained in this drug policy	This policy refers to the following natalizumab products for injection: • Tyruko (natalizumab-sztn)* • Tysabri (natalizumab) • Any FDA-approved natalizumab biosimilar product not listed here** *Coverage criteria for Tyruko contained in this drug policy will be applicable immediately upon product launch. **Any U.S. Food and Drug Administration approved and launched natalizumab biosimilar product not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare. **Preferred Product** ***Medical Necessity Plans*** **Tysabri** is the preferred natalizumab products. Coverage will be provided for Tysabri is contingent on the coverage criteria in the Diagnosis-Specific Criteria section.

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Natalizumab (Tyruko® & Tysabri®) (continued)	Jan. 1, 2026	will be applicable immediately upon product launch ○ Any U.S. Food and Drug Administration approved and launched natalizumab biosimilar product not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare ***Medical Necessity Plans*** ○ Tysabri is the preferred natalizumab products; coverage will be provided for Tysabri is contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ Coverage for Tyruko or other non-preferred natalizumab product will be provided contingent on the criteria in the *Preferred Product Criteria* section [of the policy] and the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ In order to continue coverage, members already on Tyruko or other non-preferred natalizumab product will be required to change therapy to Tysabri unless they meet the criteria in the *Preferred Product Criteria* section [of the policy] Preferred Product Criteria	Coverage for Tyruko or other non-preferred natalizumab product will be provided contingent on the criteria in this Preferred Product Criteria section and the coverage criteria in the Diagnosis-Specific Criteria section. In order to continue coverage, members already on Tyruko or other non-preferred natalizumab product will be required to change therapy to Tysabri unless they meet the criteria in this section. **Preferred Product Criteria** (***For Medicare reviews, refer to the CMS section of the policy.***) **Treatment with Tyruko or other non-preferred natalizumab product is medically necessary for the indications specified in this policy when both of the following criteria are met:** • **One** of the following: ○ **Both** of the following: ▪ Documentation of a trial of at least 14 weeks of Tysabri resulting in minimal clinical response to therapy and residual disease activity; **and** ▪ Provider attests that in their clinical opinion, the clinical response would be expected to be superior with Tyruko or other natalizumab biosimilar product, than experienced with Tysabri **or** ○ **Both** of the following: – Documentation of intolerance, contraindication, or adverse event to Tysabri; **and** – Provider attests that in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with Tyruko or other natalizumab biosimilar product **and** • Patient has **not** had a loss of a favorable response after established maintenance therapy with Tysabri or other natalizumab product ***Non-Medical Necessity Plans*** Any natalizumab product is to be approved contingent on the coverage criteria in the Diagnosis-Specific Criteria section.

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Natalizumab (Tyruko® & Tysabri®) (continued)	Jan. 1, 2026	○ Treatment with Tyruko or other non-preferred natalizumab product is medically necessary for the indications specified in this policy when both of the following criteria are met: ▪ One of the following: – Documentation of a trial of at least 14 weeks of Tysabri resulting in minimal clinical response to therapy and residual disease activity and the provider attests that in their clinical opinion, the clinical response would be expected to be superior with Tyruko or other natalizumab biosimilar product, than experienced with Tysabri – Documentation of intolerance, contraindication, or adverse event to Tysabri and the provider attests that in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to	**Diagnosis-Specific Criteria** "Natalizumab" will be used to refer to all natalizumab products. **Natalizumab is proven for the treatment of:** • **Relapsing Forms of Multiple Sclerosis** **Natalizumab is medically necessary for the treatment of relapsing forms of multiple sclerosis (MS) when all of the following are met:** ○ **Initial Therapy** ▪ Diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, active secondary-progressive disease); **and** ▪ Patient is **not** receiving natalizumab in combination with **any** of the following (used as monotherapy): – Disease modifying therapy (e.g., interferon beta preparations, glatiramer acetate, fingolimod, cladribine, siponimod, or teriflunomide) – B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab) – Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) **and** ▪ Natalizumab is dosed according to the U.S. FDA labeled dosing; **and** ▪ Initial authorization is for no more than 12 months ○ **Continuation of Therapy** ▪ Patient has previously received treatment with natalizumab; **and** ▪ Documentation of positive clinical response to natalizumab therapy; **and** ▪ Patient is **not** receiving natalizumab in combination with **any** of the following (used as monotherapy): – Disease modifying therapy (e.g., interferon beta preparations, glatiramer acetate, fingolimod, cladribine, siponimod, or teriflunomide) – B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab) – Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) **and**

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Natalizumab (Tyruko® & Tysabri®) (continued)	Jan. 1, 2026	occur with Tyruko or other natalizumab biosimilar product ▪ Patient has not had a loss of a favorable response after established maintenance therapy with Tysabri or other natalizumab product ***Non-Medical Necessity Plans*** ○ Any natalizumab product is to be approved contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ***Diagnosis-Specific Criteria*** ○ "Natalizumab" will be used to refer to all natalizumab products • Replaced references to "Tysabri" with "natalizumab" **Applicable Codes** • Added HCPCS code Q5134 **Supporting Information** • Added *CMS* section • Updated *Background* and *References* sections to reflect the most current information	▪ Natalizumab is dosed according to the U.S. FDA labeled dosing; **and** ▪ Authorization is for no more than 12 months • **Crohn's Disease** **Natalizumab is medically necessary for inducing and maintaining clinical response and remission in patients with moderate to severe Crohn's disease (CD) when all of the following are met:** ○ **Initial Therapy** ▪ Diagnosis of moderately to severely active Crohn's disease; **and** ▪ History of inadequate response or intolerance to conventional Crohn's disease therapies and inhibitors of TNF-α. Conventional Crohn's disease therapies may include aminosalicylates (such as mesalamine and sulfasalazine), corticosteroids, immunomodulators (such as azathioprine, 6-mercaptopurine, and methotrexate) and TNF-inhibitors [e.g., infliximab, adalimumab, certolizumab pegol (Cimzia®)]; **and** ▪ Patient is not receiving concomitant treatment with immunosuppressants (e.g., 6-MP, azathioprine, cyclosporine, or methotrexate) **or** TNF-inhibitors [e.g., Enbrel (etanercept), infliximab, adalimumab, or certolizumab pegol (Cimzia)]; **and** ▪ Natalizumab is dosed according to the U.S. FDA labeled dosing; **and** ▪ Initial authorization is for no more than 12 months ○ **Continuation of Therapy** ▪ Patient has previously received treatment with natalizumab; **and** ▪ Documentation of positive clinical response to natalizumab therapy; **and** ▪ Patient is not receiving concomitant treatment with immunosuppressants (e.g., 6-MP, azathioprine, cyclosporine, or methotrexate) or TNF-inhibitors [e.g., Enbrel (etanercept), adalimumab, certolizumab pegol (Cimzia), or infliximab]; **and** ▪ Natalizumab is dosed according to the U.S. FDA labeled dosing; **and** ▪ Authorization is for no more than 12 months **Natalizumab is unproven for the treatment of other conditions or diseases, including types of MS other than relapsing forms.** Statistically

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Natalizumab (Tyruko® & Tysabri®) (continued)	Jan. 1, 2026		robust randomized controlled trials are needed to address the issue of whether natalizumab has sufficient superiority in clinical efficacy compared to other available treatments to justify the substantial inherent clinical risk in its use.
Oncology Medication Clinical Coverage	Jan. 1, 2026	**Coverage Rationale** • Revised list of UnitedHealthcare preferred and non-preferred oncology products for all oncology indications: ○ Added: ▪ Avgemsi (non-preferred) ▪ Bomyntra (denosumab-bnht) (non-preferred) ▪ Conexxence (denosumab-bnht) (non-preferred) ▪ Gemcitabine (HCPCS codes J9201 and J9196) (preferred) ▪ Jubbonti (denosumab-bbdz) (non-preferred) ▪ Osenvelt (denosumab-bmwo) (preferred) ▪ Prolia (denosumab) (preferred) ▪ Stoboclo (denosumab-bmwo) (preferred) ▪ Wyost (denosumab-bbdz) (non-preferred) ▪ Xgeva (denosumab) (preferred) ○ Changed status of the following from “preferred” to “non-preferred”: ▪ Trazimera (trastuzumab-qyyp)	**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 US Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category. Coverage of White Blood Cell Colony Stimulating Factors and Erythropoiesis-Stimulating Agents are addressed in separate policies. This policy does not provide coverage criteria for Chimeric Antigen Receptor (CAR)-T cell or Tumor-Infiltrating Lymphocyte (TIL) cell products. Coverage determinations are based on the member’s benefits and the OptumHealth Transplant Solutions criteria for covered transplants; refer to the Clinical Guideline titled Chimeric Antigen Receptor T-cell (CAR T) Therapy, Tumor-Infiltrating Lymphocyte (TIL) Cell Therapy. **Coverage Rationale** ***Medical Necessity Plans*** 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. Members new to therapy will be required to utilize the UnitedHealthcare preferred oncology product unless they meet the criteria in this section.

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Oncology Medication Clinical Coverage (continued)	Jan. 1, 2026	▪ Trazimera (trastuzumab-qyyp) + Perjeta (pertuzumab) ○ Changed status of Riabni (rituximab-arrx) from "non-preferred" to "preferred" **Applicable Codes** ● Added HCPCS codes J0897, J9196, J9201, and Q5136	***Preferred Product Criteria*** *(For Medicare reviews, refer to the CMS section of the policy.)* **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 the 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 approved product that may belong to UnitedHealthcare Preferred or Non-preferred Oncology Product categories 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, listed in the NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and medically necessary, and Categories of Evidence and Consensus of 3 as unproven and not medically necessary. 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.

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Provider Administered Drugs – Site of Care	Jan. 1, 2026	**Related Policies**
		• Added reference link to the Medical Benefit Drug Policy titled:
		  ○ *Denosumab*
		  ○ *Testosterone Replacement or Supplementation Therapy*
		Coverage Rationale
		• Revised list of medications that require healthcare provider administration; added:
		  ○ Azmiro™ (testosterone cypionate)
		  ○ Bkemv™ (eculizumab-aeeb)
		  ○ Epysqli® (eculizumab-aagh)
		  ○ Imuldosa (ustekinumab-srlf)
		  ○ Jubbonti® (denosumab-bbdz)
		  ○ Starjemza (ustekinumab-hmny)
		  ○ Yimmugo® (IV)
		• Added language to indicate this Medical Benefit Drug Policy applies to the non-oncology use of Jubbonti® (denosumab-bbdz) only
		Documentation Requirements
		• Revised list of specialty medications with associated documentation requirements; added:
		  ○ Azmiro™ (testosterone cypionate) (HCPCS code J1072)
		  ○ Bkemv™ (eculizumab-aeeb) (HCPCS code Q5152)
		  ○ Epysqli® (eculizumab-aagh) (HCPCS code Q5151)
			This policy addresses the criteria for consideration of allowing hospital outpatient facility infusion services for specialty medications and intravenous Immune Globulin (IVIG) and subcutaneous Immune Globulin (SCIG) therapy. This includes claim submission for hospital-based services with the following CMS/AMA place of service codes:
			• 19 Off Campus-Outpatient Hospital; and
			• 22 On Campus-Outpatient Hospital
			
			Alternative Sites of Care, such as non-hospital outpatient infusion, physician office, ambulatory infusion suites, or home infusion services are well accepted places of service for medication infusion therapy. If an individual does not meet criteria for outpatient hospital facility infusion, alternative sites of care may be used.
			
			Submission of medical records documenting that outpatient hospital facility-based administration is medically necessary for individuals who meet at least one of the following criteria:
			• The patient is medically unstable and is at risk of requiring medical services and equipment available only in an outpatient hospital setting (e.g., endotracheal tube, chest tube insertion equipment, cricothyroidotomy set, mechanical ventilator) during administration of the requested drug based on **one** of the following:
			  ○ History of cardiopulmonary conditions that cause an increased risk of severe adverse reactions during or immediately following infusion; **or**
			  ○ An inability to tolerate fluid volume load (for intravenous infusions only) despite using the minimum amount of fluid required for infusion (e.g., unstable renal function)
			or
			• Treatment at an alternative Site of Care presents a health risk due to a clinically significant physical or cognitive impairment; **or**
			• Severe patent vascular access issues (for intravenous infusions only) that require specialized equipment only available in an outpatient hospital setting (e.g., ultrasound guidance) and member is not a viable candidate for long-term vascular access devices such as picc line or port-a-cath; **or**
			• Previous episode(s) of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial

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Provider Administered Drugs – Site of Care (continued)	Jan. 1, 2026	○ Imuldosa (ustekinumab-srlf) (HCPCS code Q5098) ○ Jubbonti® (denosumab-bbdz) (HCPCS code Q5136) ○ Starjemza (ustekinumab-hmny) (HCPCS code C9399 and J3590) ○ Yimmugo® (IV) (HCPCS code J1599) **Applicable Codes** • Added HCPCS codes J1072, Q5098, Q5136, Q5151, and Q5152	infarction, renal failure), not including the first or second infusion, that have occurred while receiving requested therapy that was unresponsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual while administering at alternative Sites of Care; **or** • Initial infusion or re-initiation of previous therapy after more than 6 months (excludes drugs dosed at an interval of 6 months or greater) for a short duration of time (e.g., 4 weeks); **or** • **For IVIG or SCIG only**: Individual has immunoglobulin A (IgA) deficiency with anti-IgA antibodies; **or** • **All** of the following: ○ Homecare or home infusion provider has deemed that the individual or home environment is not suitable for home infusion therapy; **and** ○ The prescriber is unable to administer in the office setting; **and** ○ There are no ambulatory infusion suite options available for this member Ongoing outpatient hospital facility-based infusion duration of therapy will be no more than 6 months to allow for reassessment of the individual's ability to receive therapy at an alternative Site of Care. **Note**: If more than one of the above criteria are met, then the greatest of the applicable approval time periods will be allowed. Refer to the policy for complete details.
Rituximab (Riabni®, Rituxan®, Ruxience®, & Truxima®)	Jan. 1, 2026	**Coverage Rationale** ***Preferred Product*** • Added language to indicate Riabni (rituximab-arrx) is a preferred rituximab product and coverage will be provided contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] • Removed language indicating Riabni (rituximab-arrx) will be provided contingent on the criteria	This policy refers only to the following drug products, rituximab injections for intravenous infusion for non-oncology conditions: • Riabni® (rituximab-arrx) • Rituxan® (rituximab) • Rituxan Hycela® (rituximab and hyaluronidase human)* • Ruxience® (rituximab-pvvr) • Truxima® (rituximab-abbs) • Any FDA-approved rituximab biosimilar product not listed here Refer to the policy for complete details.

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Rituximab (Riabni®, Rituxan®, Ruxience®, & Truxima®) (continued)	Jan. 1, 2026	in the *Preferred Product* section [of the policy] and the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy]; in order to continue coverage, members already on Riabni will be required to change therapy to Ruxience or Truxima unless they meet the criteria in the *Preferred Product* section [of the policy] • Replaced language indicating "treatment with Rituxan, *Riabni*, or other rituximab products is medically necessary for the indications specified in this policy when the patient has a history of intolerance, contraindication, or serious adverse event to *either* Truxima or Ruxience" with "treatment with Rituxan or other rituximab products is medically necessary for the indications specified in this policy when the patient has a history of intolerance, contraindication, or serious adverse event to *Riabni*, Ruxience, or Truxima" ***Diagnosis-Specific Criteria*** • Revised coverage criteria for **immune thrombocytopenic purpura (ITP)**; replaced criterion allowing coverage when "the patient has a history of failure, contraindication, or intolerance to a thrombopoietin receptor agonist (TPO-RA) [e.g., *Promacta* (eltrombopag), Nplate	

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Rituximab (Riabni®, Rituxan®, Ruxience®, & Truxima®) (continued)	Jan. 1, 2026	(romiplostim)]" with "the patient has a history of failure, contraindication, or intolerance to a thrombopoietin receptor agonist (TPO-RA) [e.g., eltrombopag, Nplate (romiplostim)]" **Supporting Information** • Added *CMS* section	
Roctavian® (Valoctocogene Roxaparvovec-Rvox)	Jan. 1, 2026	**Coverage Rationale** • Revised coverage criteria: ○ Added criterion requiring the provider does not request a planned inpatient admission for the sole purpose of administering Roctavian ○ Replaced criterion requiring "the patient is currently receiving *chronic prophylactic* Hemlibra (emicizumab-kxwh) therapy or Hympavzi (marstacimab-hncq) therapy" with "the patient is currently receiving *routine prophylaxis for hemophilia A with a non-factor replacement therapy [i.e., Alhemo (concizumab-mtci),* Hemlibra (emicizumab-kxwh), Hympavzi (marstacimab-hncq), *Qfitlia (fitusiran)]* therapy"	**Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)** **Roctavian is proven and medically necessary for the treatment of Hemophilia A (factor VIII Deficiency) when all of the following criteria are met:** • Patient is 18 years of age or older; **and** • **Both** of the following: ○ Diagnosis of severe hemophilia A; **and** ○ Documentation of endogenous factor VIII levels less than 1% of normal factor VIII (< 0.01 IU/mL, < 1 IU/dL) **and** • **One** of the following: ○ Patient is currently receiving routine prophylaxis for hemophilia A with a non-factor replacement therapy [i.e., Alhemo (concizumab-mtci), Hemlibra (emicizumab-kxwh), Hympavzi (marstacimab-hncq), Qfitlia (fitusiran)]; **or** ○ **Both** of the following: ▪ Patient currently uses factor VIII prophylaxis therapy; **and** ▪ Patient has had a minimum of 150 exposure days to a factor VIII agent **or** ○ Patient has been determined to be an appropriate candidate for Roctavian by the Hemophilia Treatment Center based on willingness to adhere to initial and long-term monitoring and management **and** • Patient does not have a history of inhibitors to factor VIII greater than or equal to 0.6 Bethesda units (BU); **and**

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Roctavian® (Valoctocogene Roxaparvovec-Rvox) (continued)	Jan. 1, 2026		• Patient does not screen positive for active factor VIII inhibitors as defined as greater than or equal to 0.6 Bethesda units (BU) prior to administration of Roctavian; **and** • Patient does **not** have pre-existing immunity to the AAV5 capsid as detected by the FDA-approved companion diagnostic test AAV5 DetectCDx®; **and** • Patient has not gone through Immune Tolerance Induction (ITI); **and** • Liver health assessments including enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin] and hepatic ultrasound and elastography are performed to rule out radiological liver abnormalities and/or sustained liver enzyme elevations; **and** • One of the following: ○ Patient is not HIV positive; **or** ○ Patient is HIV positive and is virally suppressed with anti-viral therapy (i.e., < 200 copies of HIV per mL) **and** • The patient's hepatitis B surface antigen is negative; **and** • One of the following: ○ Patient's hepatitis C virus (HCV) antibody is negative; **or** ○ Patient's HCV antibody is positive, and the patient's HCV RNA is negative **and** • The patient is not currently using antiviral therapy for hepatitis B or C; **and** • Patient has not previously received treatment with Roctavian or other gene therapy product for the treatment of hemophilia A in the patient's lifetime; **and** • Roctavian is prescribed and managed by a bleeding disorder specialist on staff at a Hemophilia Treatment Center (HTC) that holds Federal designation as evidenced by being listed within the CDC's HTC directory; **and** • Prescriber attests that the patient's ALT and factor VIII activity will be monitored weekly for at least 26 weeks following administration of Roctavian and regularly thereafter per the monitoring schedule recommended in the prescribing information; **and**

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Roctavian® (Valoctocogene Roxaparvovec-Rvox) (continued)	Jan. 1, 2026		• Prescriber attests that counseling has been provided to the patient to abstain from consuming alcohol for at least one year following administration of Roctavian and regarding how much alcohol may be acceptable for the patient in the longer term; **and** • Roctavian dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** • Provider does not request a planned inpatient admission for the sole purpose of administering Roctavian; **and** • Authorization will be issued for no more than one treatment per lifetime and for no longer than 45 days from approval **Additional information relevant to the review process but not impacting the determination of medical necessity:** • Prescriber attests that the patient, while under the care of the prescriber, will be assessed for treatment efficacy including, but not limited to evaluation of factor VIII expression, breakthrough bleeding episodes, factor VIII product utilization, inhibitor development*; **and** • Prescriber acknowledges that UnitedHealthcare may request documentation, not more frequently than biannually, and not for a period to exceed 5 years of follow-up patient assessment(s) including, but not necessarily limited to, evaluation of factor VIII expression, breakthrough bleeding episodes, factor VIII product utilization, inhibitor development while the patient is under the care of the prescriber* *For quality purposes only, this information will not be considered as part of the individual coverage decision. **Roctavian is not proven or medically necessary for:** • The treatment of hemophilia B • The treatment of mild or moderate hemophilia A • The repeat administration of Roctavian for the treatment of hemophilia A • The treatment of hemophilia A after previously receiving another factor VIII gene therapy product • The routine combination treatment with chronically administered prophylactic therapy for hemophilia A • The treatment of hemophilia A in patients less than 18 years of age • The treatment of hemophilia A in patients with elevated AAV5 antibodies

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Spinraza® (Nusinersen)	Jan. 1, 2026	**Coverage Rationale** • Revised coverage criteria; added criterion requiring the provider does not request a planned inpatient admission for the sole purpose of administering Spinraza **Supporting Information** • Updated *Background*, *Clinical Evidence*, and *References* sections to reflect the most current information	**Spinraza® (nusinersen) is proven and medically necessary for the treatment of spinal muscular atrophy (SMA) in patients who meet all of the following criteria:** **Initial Therapy** • Diagnosis of spinal muscular atrophy by, or in consultation with, a neurologist with expertise in the diagnosis of SMA; **and** • 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) ○ Hammersmith Functional Motor Scale Expanded (HFMSE) ○ Revised Upper Limb Module (RULM) Test ○ 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:

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Spinraza® (Nusinersen) (continued)	Jan. 1, 2026		○ Patient has not previously received gene replacement therapy [e.g., Zolgensma (onasemnogene abeparvovec-xioi)] for the treatment of SMA; **or** ○ **Both** of the following: ▪ Patient has previously received gene replacement therapy [e.g., 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., 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 United States Food and Drug Administration approved labeling; **and** • Provider does not request a planned inpatient admission for the sole purpose of administering Spinraza; **and** • Initial authorization will be for no more than 4 loading doses **Continuation Therapy** • 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**

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Spinraza® (Nusinersen) (continued)	Jan. 1, 2026		**pretreatment baseline status** to Spinraza therapy as demonstrated by at least **one** of the following exams: ○ HINE-2 milestones: ▪ **One** of the following: – Improvement or maintenance of previous improvement of at least 2 point (or maximal score) increase in ability to kick; **or** – Improvement or maintenance of previous improvement of at least 1 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 milestone from pretreatment baseline when they would otherwise be

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Spinraza® (Nusinersen) (continued)	Jan. 1, 2026		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 United States Food and Drug Administration 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 3 maintenance doses (12 months) **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)]
Testosterone Replacement or Supplementation Therapy	Jan. 1, 2026	**Coverage Rationale** • Removed reference link to the Medical Benefit Drug Policy titled *Review at Launch for New to Market Medications* for Azmiro™ (testosterone cypionate) • Added language to indicate: ○ Azmiro™ is typically excluded from coverage and coverage reviews may be in place if required by law or the benefit plan; refer to the Medical Benefit Drug Policy titled *Medical Benefit Therapeutic Equivalent Medications – Excluded Drugs* and the	This policy refers to the following testosterone products: • Testosterone cypionate (Azmiro™, Depo-Testosterone®) • Testosterone enanthate • Testosterone pellets (Testopel®) • Testosterone undecanoate (Aveed®) **Azmiro™ is typically excluded from coverage. Coverage reviews may be in place if required by law or the benefit plan.** Refer to the Medical Benefit Drug Policy titled Medical Benefit Therapeutic Equivalent Medications - Excluded Drugs and the corresponding excluded drug list with preferred alternatives. **Note**: For requests that require medical necessity review, also refer to the Diagnosis-Specific Requirements section below. (For Medicare reviews, refer to the *CMS* section of the policy.)

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Testosterone Replacement or Supplementation Therapy (continued)	Jan. 1, 2026	corresponding excluded drug list with preferred alternatives ○ For requests that require medical necessity review, also refer to the *Diagnosis-Specific Requirements* section [of the policy] ○ Coverage for testosterone cypionate (Depo-Testosterone®), testosterone enanthate, testosterone pellets (Testopel®), and testosterone undecanoate (Aveed®) is contingent on criteria in the *Diagnosis-Specific Requirements* section [of the policy] **Supporting Information** • Added *CMS* section • Updated *References* section to reflect the most current information	**Coverage for testosterone cypionate (Depo-Testosterone®), testosterone enanthate, testosterone pellets (Testopel®), and testosterone undecanoate (Aveed®) is contingent on criteria in the Diagnosis-Specific Requirements sections.** **Diagnosis-Specific Requirements** The information below indicates the list of proven and medically necessary indications. **Injectable testosterone and Testopel (testosterone pellets) are proven for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone, including primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired).** **Injectable testosterone and Testopel (testosterone pellets) are medically necessary for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone, including primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired), when the following criteria are met:** • **One** of the following: ○ Patient has history of **one** of the following: ▪ Bilateral orchiectomy; **or** ▪ Panhypopituitarism; **or** ▪ A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome) **or** ○ **All** of the following: ▪ **One** of the following: – Two pre-treatment early morning serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab, taken at separate times; **or** – **Both** of the following: • Patient has condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity); **and**

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Testosterone Replacement or Supplementation Therapy (continued)	Jan. 1, 2026		• **One** pre-treatment calculated free or bioavailable testosterone level less than 50 pg/mL (< 5 ng/dL or < 0.17 nmol/L) or less than the reference range for the lab **or** – **Both** of the following: • Patient is currently on testosterone therapy; **and** • **One** of the following: ○ Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy (i.e., on therapy for less than one year), or 12 months for patients continuing testosterone therapy (i.e., on therapy for one year or longer), is within or below the normal male limits of the reporting lab; **or** ○ Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy (i.e., on therapy for less than one year), or 12 months for patients continuing testosterone therapy (i.e., on therapy for one year or longer), is outside of upper male limits of normal for the reporting lab and the dose is adjusted **and** ▪ Patient was male at birth; **and** ▪ Diagnosis of hypogonadism **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Authorization will be for no more than 12 months **Injectable testosterone and Testopel (testosterone pellets) may be covered for gender-affirming hormonal therapy for transgender adults when the following criteria are met:** • **All** of the following: ○ Diagnosis of gender dysphoria, according to the current DSM (i.e., DSM-5-TR) criteria, by a mental health professional; **and** ○ Medication is prescribed by or in consultation with an endocrinologist or a medical provider knowledgeable in transgender hormone

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Testosterone Replacement or Supplementation Therapy (continued)	Jan. 1, 2026		therapy; **and** ○ Authorization will be for no more than 12 months **Compounded hormone products (e.g., pellets), including but not limited to compounded testosterone, estrogen, and progesterone pellets are not proven or medically necessary for any indication.** Compounded drugs, including compounded testosterone, estrogen, or progesterone pellets are not FDA approved.
Ustekinumab	Jan. 1, 2026	**Coverage Rationale** • Revised list of applicable ustekinumab products for injection by a healthcare professional; added: ○ Imuldosa (ustekinumab-srlf) ○ Starjemza (ustekinumab-hmny) • Added language to indicate: ○ Coverage for Imuldosa or Starjemza will be provided contingent on the criteria in the *Preferred Product Criteria* section [of the policy] and the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ In order to continue coverage, members already on Imuldosa or Starjemza will be required to change therapy to Steqeyma, Wezlana, or Yesintek unless they meet the criteria in the *Preferred Product Criteria* section [of the policy] ○ Treatment with Imuldosa or Starjemza is medically necessary for the indications specified in this policy when	This policy refers to the following ustekinumab products for injection by a healthcare professional. Ustekinumab products for self-administered subcutaneous injection are obtained under the pharmacy benefit, unless otherwise specified in the member's benefit plan documents. Exception: For members enrolled in UnitedHealthcare of California plans with a delegated provider group conducting the prior authorization review, the self-administered ustekinumab may be obtained under the medical benefit. • Imuldosa (ustekinumab-srlf) • Otulfi (ustekinumab-aauz) • Pyzchiva (ustekinumab-ttwe) • Selarsdi (ustekinumab-aekn) • Stelara (ustekinumab) • Starjemza (ustekinumab-hmny) • Steqeyma (ustekinumab-stba) • Wezlana (ustekinumab-auub) • Yesintek (ustekinumab-kfce) • Any FDA-approved ustekinumab biosimilar product not listed here Refer to the policy for complete details.

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Ustekinumab (continued)	Jan. 1, 2026	both of the following criteria are met: ▪ One of the following: – Documentation of a trial of at least 14 weeks of Steqeyma, Wezlana, or Yesintek resulting in minimal clinical response to therapy and residual disease activity and the provider attests that in their clinical opinion, the clinical response would be expected to be superior with Imuldosa or Starjemza than experienced with Steqeyma, Wezlana, or Yesintek – Documentation of intolerance, contraindication, or adverse event to Steqeyma, Wezlana, or Yesintek and the provider attests that in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with Imuldosa or Starjemza	

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Ustekinumab (continued)	Jan. 1, 2026	▪ The patient has not had a loss of a favorable response after established maintenance therapy with Steqeyma, Wezlana, Yesintek, or other ustekinumab product **Applicable Codes** • Added HCPCS codes C9399, J3490, J3590, and Q5098 **Supporting Information** • Updated *CMS* and *References* sections to reflect the most current information	
Vyjuvek® (Beramagene Geperpavec-Svdt)	Jan. 1, 2026	**Coverage Rationale** • Revised coverage criteria: ○ Added criterion requiring the provider does not request a planned inpatient admission for the sole purpose of administering Vyjuvek ○ Removed criterion requiring the patient is aged at least 6 months or older for initial therapy **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information	**Vyjuvek is proven and medically necessary for the treatment of wounds in patients with dystrophic epidermolysis bullosa (DEB) who meet all of the following criteria:** • For **initial therapy**, **all** of the following: ○ Diagnosis of dystrophic epidermolysis bullosa (DEB); **and** ○ Submission of medical records (e.g., chart notes, laboratory values) confirming a mutation in the collagen type VII alpha 1 chain (*COL7A1*) gene; **and** ○ Patient has at least **one** recurrent or chronic open wound that meets **all** of the following criteria: ▪ Adequate granulation tissue ▪ Excellent vascularization ▪ No evidence of active wound infection ▪ No evidence or history of squamous cell carcinoma ○ Vyjuvek is prescribed by, or in consultation with, a dermatologist with expertise in the treatment of DEB; **and** ○ Vyjuvek is not being used in combination with Filsuvez (birch triterpenes) on the same wound(s); **and** ○ Provider does not request a planned inpatient admission for the sole purpose of administering Vyjuvek; **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**

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Vyjuvek® (Beramagene Geperpavec-Svdt) (continued)	Jan. 1, 2026		○ Initial authorization will be issued for no more than 12 months and no more than 52 doses • For **continuation of therapy**, **all** of the following: ○ Patient has previously been treated with Vyjuvek therapy; **and** ○ Patient had a positive clinical response to Vyjuvek therapy (e.g., decrease in wound size, increase in granulation tissue, complete wound closure); **and** ○ Wound(s) being treated to meet **all** of the following criteria: ▪ Adequate granulation tissue ▪ Excellent vascularization ▪ No evidence of active wound infection ▪ No evidence or history of squamous cell carcinoma **and** ○ Vyjuvek is prescribed by, or in consultation with, a dermatologist with expertise in the treatment of DEB; **and** ○ Vyjuvek is not being used in combination with Filsuvez (birch triterpenes) on the same wound(s); **and** ○ Provider does not request a planned inpatient admission for the sole purpose of administering Vyjuvek; **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Reauthorization will be issued for no more than 12 months and no more than 52 doses
Xiaflex® (Collagenase Clostridium Histolyticum)	Jan. 1, 2026	**Coverage Rationale** • Replaced language indicating: ○ "Xiaflex is proven *and* medically necessary for the treatment of Dupuytren's contracture when all of the [listed] criteria are met" with "Xiaflex is proven for the treatment of Dupuytren's contracture *with a palpable cord*; Xiaflex is medically necessary for the treatment of Dupuytren's contracture when all of the [listed] criteria are	**Dupuytren's Contracture** **Xiaflex is proven for the treatment of Dupuytren's contracture with a palpable cord. Xiaflex is medically necessary for the treatment of Dupuytren's contracture when all of the following criteria are met:** • For **initial therapy**, **all** of the following: ○ Patient has diagnosis of Dupuytren's contracture with a palpable cord; **and** ○ Patient is 18 years of age or older; **and** ○ Xiaflex is prescribed and administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's contracture; **and** ○ Documented contracture of at least 20 degrees flexion for a metacarpophalangeal (MP) joint contracture or proximal interphalangeal (PIP) joint contracture; **and**

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Xiaflex® (Collagenase Clostridium Histolyticum) (continued)	Jan. 1, 2026	met" ○ "Xiaflex is proven *and* medically necessary for the treatment of Peyronie's disease when all of the [listed] criteria are met" with "Xiaflex is proven for the treatment of for the treatment of *adult men with* Peyronie's disease *with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy*; Xiaflex is medically necessary for the treatment of Peyronie's disease when all of the [listed] criteria are met"	○ Documentation that the flexion deformity results in functional limitations; **and** ○ Patient has not received surgical treatment on the selected primary joint within the last 90 days; **and** ○ If two injections (two vials) are requested, they are for **one** of the following: ▪ One cord affecting two joints in the same finger; **or** ▪ Two cords affecting two joints in the same hand **and** ○ Xiaflex dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling: 0.58 mg per injection into a palpable cord; **and** ○ The total number of injections does not exceed 3 injections per cord at approximately 4-week intervals; **and** ○ Authorization is for no more than 2 injections in the same hand • For **continuation of therapy**, **all** of the following: ○ Patient has previously received Xiaflex; **and** ○ Documentation of positive clinical response to Xiaflex; **and** ○ Treatment request is for at least **one** of the following: ▪ Metacarpophalangeal (MP) or proximal interphalangeal (PIP) contracture remains in affected cord since previous injection and the contracture is > 5 degrees ▪ A different MP or PIP contracture will be injected **and** ○ If two injections (two vials) are requested, use is for **one** of the following: ▪ One cord affecting two joints in the same finger; **or** ▪ Two cords affecting two joints in the same hand **and** ○ Patient has not received surgical treatment (e.g., fasciectomy, fasciotomy) on the selected primary joint within the last 90 days; **and** ○ The previous treatment was at least 4 weeks ago; **and** ○ Xiaflex dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling: 0.58 mg per injection into a palpable cord; **and** ○ The total number of injections does not exceed 3 injections per cord at approximately 4-week intervals; **and**

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Xiaflex® (Collagenase Clostridium Histolyticum) (continued)	Jan. 1, 2026		○ Authorization is for no more than 2 injections in the same hand **Peyronie's Disease** **Xiaflex is proven for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.** **Xiaflex is medically necessary for the treatment of Peyronie's disease when all of the following criteria are met:** • For **initial therapy**, **all** of the following: ○ Patient has diagnosis of Peyronie's disease with **both** of the following: ▪ Palpable plaque; **and** ▪ Curvature deformity of greater than or equal to 30 degrees at the start of therapy **and** ○ Patient is 18 years of age or older; **and** ○ Xiaflex is prescribed and administered by a healthcare provider experienced in the treatment of male urological diseases; **and** ○ Xiaflex dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling: 0.58 mg per injection into a Peyronie's plaque; **and** ○ Authorization is for no more than two injections and 6 weeks duration • For **continuation of therapy**, **all** of the following: ○ Patient has previously received Xiaflex; **and** ○ Documentation of positive clinical response to Xiaflex; **and** ○ Last treatment was at least 6 weeks ago; **and** ○ Documented curvature deformity of ≥ 15 degrees remaining since last treatment cycle; **and** ○ Patient has received less than 4 treatment cycles [i.e., less than 8 injections (2 injections per cycle)]; **and** ○ Xiaflex dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling: 0.58 mg per injection into a Peyronie's plaque; **and** ○ Authorization is for no more than two injections and 6 weeks duration **Xiaflex is considered unproven and not medically necessary for any other uses.**

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 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.

UMR is a wholly owned subsidiary of UnitedHealthcare, a part of UnitedHealth Group. UMR is a third-party administrator (TPA) for self-funded plans.

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 UMR Medical Policies and Medical Benefit Drug Policies is available at **UHCprovider.com/policies** > For Commercial Plans > UnitedHealthcare | UMR Medical & Drug Policies.