UMR
Medical Policy Update Bulletin: November 2026

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Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Bariatric Surgery	Dec. 1, 2026	**Applicable Codes** • Removed CPT code 43882
Category III Codes	Jan. 1, 2027	**Applicable Codes** • Removed CPT codes 0908T*, 0909T*, 0910T*, 0911T*, 0912T*, 0913T, 0914T, and 0936T** *Refer to the Medical Policy titled *Vagus and External Trigeminal Nerve Stimulation* **Refer to the Medical Policy titled *Omnibus Codes*
Mechanical Stretching Devices	Dec. 1, 2026	**Applicable Codes** • Removed HCPCS code E1830 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information
Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache)	Dec. 1, 2026	**Applicable Codes** • Removed CPT code 64570
Percutaneous Neuroablation for Pancreatic Cancer Pain, Severe Cancer Pain, and Trigeminal Neuralgia	Dec. 1, 2026	**Coverage Rationale** • Updated language pertaining to medical necessity clinical coverage criteria; replaced reference to the "InterQual® CP: Procedures, Neuroablation, Percutaneous" with "InterQual® *Client Defined* CP: Procedures, Neuroablation, Percutaneous *(AQS) (Custom) - UHG*"

Sacroiliac Joint Interventions	Nov. 1, 2026	**Coverage Rationale**
		• Replaced reference to "Sacroiliac Joint Fusion" with "Sacroiliac Joint Fusion *(Arthrodesis)*"
		Definitions
		• Updated definition of:
		  ○ Provocative Tests
		  ○ Titanium Triangular Implant
		Supporting Information
		• Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information

Spinal Fusion and Decompression	Dec. 1, 2026	**Applicable Codes** • Removed CPT codes 22850, 22855, and 63286

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Policy Title	Effective Date	Summary of Changes
Surgery for the Prevention and Treatment of Lymphedema	Nov. 1, 2026	**Coverage Rationale** • Replaced reference to "Lymphaticovenous Anastomosis" with "*Lymphaticovenular*/Lymphaticovenous Anastomosis" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information
Vagus and External Trigeminal Nerve Stimulation	Jan. 1, 2027	**Coverage Rationale** • Removed list of examples of unproven and not medically necessary conditions for implantable vagus nerve stimulators **Applicable Codes** • Added CPT codes 0908T, 0909T, 0910T, 0911T, and 0912T • Removed CPT code 64570 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Implanted Electrical Stimulator for the Spinal Cord	Jan. 1, 2027	***Replacement of a Previously Implanted Device*** • Replaced language indicating "coverage of a replacement battery/generator for a previously implanted electrical stimulator is appropriate when the individual's existing battery/generator is malfunctioning, cannot be repaired, and *is no longer under warranty*" with "coverage of a replacement battery/generator for a previously implanted electrical stimulator is appropriate when the individual's existing battery/generator is malfunctioning and cannot be repaired *or normal battery depletion/end of service life has been reached*"	**Implanted electrical spinal cord stimulators are proven and medically necessary for treating the following conditions in certain circumstances when performed according to FDA-labeled indications, contraindications, warnings, and precautions:** • Complex regional pain syndrome (CRPS) • Painful diabetic neuropathy • Failed back surgery syndrome For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Spinal Cord Stimulator (SCS) Insertion. Click here to view the InterQual® criteria. **Implanted electrical spinal cord stimulators are unproven and not medically necessary for treating the following conditions due to insufficient evidence of efficacy:** • Chronic intractable back pain without prior spine surgery • Refractory angina pectoris

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Implanted Electrical Stimulator for the Spinal Cord (continued)	Jan. 1, 2027	• Added language to indicate replacement of a functioning non–high-frequency spinal cord stimulator with a high-frequency spinal cord stimulator is not medically necessary **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	**Dorsal root ganglion stimulation is proven and medically necessary for treating complex regional pain syndrome (CRPS I, CRPS II) in certain circumstances when performed according to FDA-labeled indications, contraindications, warnings, and precautions.** For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Spinal Cord Stimulator (SCS) Insertion. Click here to view the InterQual® criteria. **Dorsal root ganglion stimulation is unproven and not medically necessary for treating all other conditions due to insufficient evidence of efficacy.** **Replacement of a Previously Implanted Device** **Coverage of a replacement battery/generator for a previously implanted electrical stimulator is appropriate when the individual's existing battery/generator is malfunctioning and cannot be repaired or normal battery depletion/end of service life has been reached.** **Replacement of a functioning non–high-frequency spinal cord stimulator with a high-frequency spinal cord stimulator is not medically necessary.**
Implanted Spinal Drug Delivery Systems	Dec. 1, 2026	**Coverage Rationale** ***Chronic Nonmalignant Pain*** • Revised coverage criteria; replaced criterion requiring "age **>** 18" with "age **≥** 18"	**Cancer-Related Pain** **Epidural or intrathecal drug infusion trial or catheter pump placement for cancer-related pain is proven and medically necessary in certain circumstances.** For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined CP: Procedures, Epidural or Intrathecal Catheter Placement (AQS) (Custom) - UHG. Click here to view the InterQual® criteria. **Spasticity** **Epidural or intrathecal drug infusion trial or catheter pump placement for severe spasticity is proven and medically necessary in certain circumstances.** For medical necessity clinical coverage criteria, refer to the

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Implanted Spinal Drug Delivery Systems (continued)	Dec. 1, 2026		InterQual® Client Defined CP: Procedures, Epidural or Intrathecal Catheter Placement (AQS) (Custom) - UHG.
			
			Click here to view the InterQual® criteria.
			
			Chronic Nonmalignant Pain
			Epidural or intrathecal catheter drug infusion trial for nonmalignant pain is proven and medically necessary for the following:
			• Chronic, intractable pain of a nonmalignant origin (e.g., failed back surgery syndrome, complex regional pain syndrome, neuropathic pain) when all the following criteria are met:
			  ○ Age ≥ 18 years*; and
			  ○ Etiology of pain is known and clearly documented; and
			  ○ Further treatment or surgical intervention for underlying condition is not indicated or refused; and
			  ○ Documentation of treatment failure due to intolerable side effects or failure to provide analgesia safely after a minimum of a 6-month trial of conservative methods of pain management (e.g., pharmacological, physical therapy, behavioral health treatment); and
			  ○ Documentation of the absence of underlying, untreated psychological or psychosocial issues that will interfere with successful pain treatment
			
			Epidural or intrathecal catheter pump placement for nonmalignant pain is proven and medically necessary when all the following criteria are met:
			• Completion of drug infusion trial that met the above criteria; and
			• Documentation of a ≥ 50% reduction in pain during the trial
			
			Replacement of Device
			Replacement of the device is considered medically necessary when the individual has met all the criteria for initial placement and the existing device is nonfunctional and either cannot be repaired or is no longer under warranty.
			
			***Note**: This policy does not address individuals who are younger than 18 years of age.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Omnibus Codes	Jan. 1, 2027	**Coverage Rationale** • Added coverage guidelines for: ***Creation of a Digital Three-Dimensional Model From Surface Mesh Files of Patient-Specific Anatomy (e.g., Final Anatomical Representation) (CPT codes 1030T, 1031T, 1032T, 1033T, 1034T, and 1035T)*** ○ Added language to indicate creation of a digital three-dimensional model from surface mesh files of patient-specific anatomy (e.g., final anatomical representation), when performed, is considered unproven and not medically necessary due to insufficient evidence of safety and/or efficacy ***CRISPR (Clustered Regularly Interspaced Short Palindromic Repeat)–Based Analysis of Plasma or Serum (CPT code 0629U)*** ○ Added language to indicate CRISPR (clustered regularly interspaced short palindromic repeat)–based analysis of plasma or serum for the detection of tuberculosis DNA is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy ***Laboratory Tests Using Proprietary, Algorithmic, Genetic, Cellular, or Multianalyte Biomarker Approaches for Alzheimer Disease (AD) or Other Dementias (CPT codes 0206U, 0207U, 0289U, 0393U, 0412U, 0443U, 0479U, 0503U, 0547U, 0568U, 0596U, 0616U, and 83884)*** ○ Added language to indicate laboratory tests using proprietary, algorithmic, genetic, cellular, or multianalyte biomarker approaches for Alzheimer disease (AD) or other dementias are unproven and not medically necessary due to insufficient evidence of efficacy; these include but are not limited to blood- or tissue-based assays, cell-based tests, genetic susceptibility testing (e.g., *APOE*), and biomarker panels (e.g., amyloid, tau, or neurodegeneration markers) ***Photobiomodulation Therapy (PBM) (CPT code 0936T)*** ○ Added language to indicate photobiomodulation therapy (PBM) is unproven and not medically necessary for the treatment of age-related macular degeneration (AMD) due to insufficient evidence of efficacy • Revised coverage guidelines for: ***Ablation, Irreversible Electroporation (IRE) (CPT codes 0600T, 0601T, and 47384)*** ○ Replaced language indicating "ablation, irreversible electroporation (IRE), is unproven and not medically necessary due to insufficient *studies that demonstrate* improvement in health outcomes compared *to* other standard treatments" with "ablation, irreversible electroporation (IRE) is unproven and not medically necessary due to insufficient *clinical evidence supporting safety and efficacy or* improvement in health outcomes compared *with* other standard treatments" ***BeScreened-CRC (Beacon Biomedical) (CPT code 0163U)*** ○ Replaced language indicating "the use of *a biomarker panel based algorithmic analysis test* [e.g., BeScreened™-CRC *using three tumor proteins teratocarcinoma derived growth factor-1 (TDGF-1, Cripto-1), carcinoembryonic antigen (CEA), extracellular matrix protein (ECM)]* to screen for colorectal cancer or

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Policy Title	Effective Date	Summary of Changes / Coverage Rationale
Omnibus Codes (continued)	Jan. 1, 2027	advanced adenomas is unproven and not medically necessary" with "the use of BeScreened-CRC *(Beacon Biomedical)* to screen for colorectal cancer (CRC) or advanced adenomas is unproven and not medically necessary" ***BIOTIA-ID Urine NGS Assay (CPT code 0590U)*** ○ Revised description for CPT code 0590U ○ Replaced language indicating "next-generation sequencing of 44 organisms (bacterial and fungi) is unproven and not medically necessary" with "*BIOTIA-ID Urine NGS Assay* next-generation sequencing of 44 organisms (bacterial and fungi) is unproven and not medically necessary" ***Evaluation or Evacuation of Meibomian Glands (CPT codes 0207T, 0563T, and 17999)*** ○ Added CPT code 17999 ○ Revised list of unproven and not medically necessary services; added "intense pulsed light treatment" ***External Urine Management Systems (HCPCS code E2001)*** ○ Replaced language indicating: ▪ "*Female* external urine management systems *(including but not limited to QiVi™ Female External Urine Management System, CareDry® System, PrimaFit External Urine Management Device, PureWick™ System, and Versette® external catheter)* are unproven and not medically necessary for managing urinary incontinence" with "external urine management systems are unproven and not medically necessary for managing urinary incontinence" ▪ "*Male* external urine management systems *(including but not limited to PureWick™ Urine Collection system and the PrimoFit™ External Male Urine Management System)* are unproven and not medically necessary for managing urinary incontinence" with "external urine management systems are unproven and not medically necessary for managing urinary incontinence" ***Histotripsy (CPT codes 0686T, 0888T, and 1037T)*** ○ Added CPT code 1037T ○ Replaced language indicating "histotripsy is unproven and not medically necessary for treating malignant liver and renal tumors" with "histotripsy is unproven and not medically necessary for treating malignant liver, renal, *and pancreatic* tumors" ***IVD CAPSULE PSP–Rapid Sepsis Test (CPT code 0594U)*** ○ Revised description for CPT code 0594U ○ Replaced language indicating "semiquantitative measurement of pancreatic stone protein concentration in whole blood to assess sepsis is unproven and not medically necessary" with "*IVD CAPSULE PSP–rapid sepsis test for* semiquantitative measurement of pancreatic stone protein concentration in whole blood to assess sepsis is unproven and not medically necessary" ***Noninvasive Bimodal Neuromodulation (HCPCS code E1399)*** ○ Updated list of examples of noninvasive bimodal neuromodulation; removed "Neosensory"

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Omnibus Codes (continued)	Jan. 1, 2027	***Percutaneous Gastrostomy Tube Insertion (CPT code 0647T)*** ○ Added language to clarify percutaneous gastrostomy tube insertion *with magnetic gastropexy* by ultrasound guidance is unproven and not medically necessary ***Surgical Treatment (e.g., Laminectomy and Sacral Reconstruction) of a Sacral Perineural Tarlov Cyst (CPT code 63268)*** ○ Revised coverage criteria; replaced criterion requiring "failure of individual to improve with *non-surgical treatment for at least 12 weeks*" with "failure of individual to improve with *conservative multidisciplinary management*" ***Tests to Evaluate Response/No Response to Therapy and/or Disease Progression/Regression (CPT codes 0558U and 0559U)*** ○ Revised language to indicate the use of either of the following tests to evaluate response/no response to therapy and/or disease progression/regression is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy: ▪ IGoCheck (Blood-Based Colorectal Cancer Test) (Milagen, Inc.) ▪ MammoCheck (Blood-Based Breast Cancer Test) (Milagen, Inc.) ***Transcatheter Intracoronary Infusion of Supersaturated Oxygen (CPT code 0659T)*** ○ Updated language pertaining to FDA approval of the TherOx® SuperSaturated Oxygen (SSO_2) Therapy (ZOLL Medical) ● Removed coverage guidelines for: ***Insertion, Repositioning, Programming, Interrogation, and Evaluation of Implantable Cardioverter-Defibrillator System With a Substernal (Extravascular) Electrode (CPT codes 0571T, 0572T, 0573T, 0574T, 0575T, 0576T, 0577T, 0578T, 0579T, 0580T, and 0614T)*** ○ CPT codes 0571T, 0572T, 0573T, 0574T, 0575T, 0576T, 0577T, 0578T, 0579T, 0580T, and 0614T no longer require clinical review ***Magnetically Controlled Capsule Endoscopy (CPT code 0651T)*** ○ CPT code 0651T no longer requires clinical review ● Updated list of applicable CPT codes for: ***Laboratory Measurement of Antidrug Antibodies (ADAs) and Serum Levels of Biological Agents and Biosimilars (CPT codes 0514U, 0515U, 80145, 80230, 80280, and 80299)*** ○ Added 0514U and 0515U **Supporting Information** ● Updated *Clinical Evidence* and *References* sections to reflect the most current information	

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Spinal Fusion and Related Bone Healing Enhancement Products	Jan. 1, 2027	**Title Change** • Previously titled *Spinal Fusion and Bone Healing Enhancement Products* **Coverage Rationale** • Revised list of proven and medically necessary indications; replaced: ○ "Demineralized Bone Matrix (DBM) *without added* products listed as unproven and not medically necessary" with "Demineralized Bone Matrix *except when used with a* product listed as unproven and not medically necessary" ○ "Allograft-based products *not* listed as unproven and not medically necessary" with "Allograft-based products *except for those* listed as unproven and not medically necessary"	**The following are proven and medically necessary for the enhancement of spinal fusion:** • Autografts [including Bone Marrow Aspiration (BMA) used for bone grafting] • Demineralized Bone Matrix except when used with a product listed below as unproven and not medically necessary • Allograft-based products except for those listed below as unproven and not medically necessary • InFUSE® Bone Graft [recombinant human bone morphogenetic protein-2 (rhBMP-2)] of the lumbar spine when the following criteria are met: ○ The approach is anterior or oblique and used in conjunction with a FDA-approved interbody fusion device ○ Skeletally mature individual (18 years of age or older or radiographic evidence of epiphyseal closure) with degenerative disc disease ○ The fusion involves vertebral bodies L2-S1 without or with spondylolisthesis of no more than Meyerding Classification System of Spondylolisthesis grade 1 (25% displacement) at the involved level ○ The fusion is single level • The InFUSE/Mastergraft™ Posterolateral Revision Device System (or InFUSE bone morphogenetic protein used with Mastergraft), when used according to FDA indications, contraindications, warnings, and precautions, in individuals who meet all the following criteria: ○ Implanted via a posterolateral approach ○ Presence of symptomatic posterolateral lumbar spine pseudoarthrosis ○ Skeletally mature individual (older than 21 years of age or radiographic evidence of epiphyseal closure) ○ Autologous bone and/or bone marrow harvest is not feasible or is not expected to promote fusion **The following are unproven and not medically necessary for the enhancement of spinal fusion and bone healing due to insufficient evidence of efficacy and/or safety:** • Allograft-based products: ○ Cell based (e.g., mesenchymal stem cells) ○ Human Amniotic Tissue Membrane, including amniotic fluid stem cell

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Spinal Fusion and Related Bone Healing Enhancement Products (continued)	Jan. 1, 2027	○ "InFUSE® Bone Graft [recumbent human bone morphogenetic protein-2 (rhBMP-2)] of the lumbar spine when the fusion involves vertebral bodes L2-S1 without or with spondylolisthesis of no more than *grade* 1 (25% displacement) at the involved level" with "InFUSE® Bone Graft [recumbent human bone morphogenetic protein-2 (rhBMP-2)] of the lumbar spine when the fusion involves vertebral bodes L2-S1 without or with spondylolisthesis of no more than *Meyerding Classification System of Spondylolisthesis Grade* 1 (25% displacement) at the involved level" • Revised list of unproven and not medically necessary indications: ○ Added "Other Combinations of Bone Graft Substitutes (e.g., P-15 Peptide Enhanced Bone Graft, xenograft)" ○ Replaced reference to "human amniotic tissue *materials*" with "Human Amniotic Tissue *Membrane*" ○ Updated list of examples of Ceramic-Based Products; added "calcium carbonate" **Definitions** • Added definition of:	substitutes ○ Recombinant human bone morphogenetic protein-2 (e.g., rhBMP-2, InFUSE) and InFUSE/Mastergraft (or InFUSE bone morphogenetic protein used with Mastergraft or Mastergraft alone) Posterolateral Revision Device for all other indications not included above ○ Ceramic-Based Products (e.g., β-tricalcium phosphate, calcium phosphate, calcium sulfate, calcium carbonate) used alone or in combination with other grafts and/or graft components, including BMA • Bioactive Glass used alone or in combination with other grafts, including BMA • Expandable interbody fusion system • Other Combinations of Bone Graft Substitutes (e.g., P-15 Peptide Enhanced Bone Graft, xenograft)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Spinal Fusion and Related Bone Healing Enhancement Products (continued)	Jan. 1, 2027	○ Brantigan-Steffee Classification ○ Meyerding Classification System of Spondylolisthesis ○ Other Combinations of Bone Graft Substitutes • Updated definition of "Demineralized Bone Matrix" **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	
Whole Exome and Whole Genome Sequencing (Non-Oncology Conditions)	Jan. 1, 2027	**Related Policies** • Added reference link to the Medical Policy titled *Genetic Testing for Hereditary Cancer* **Coverage Rationale** • Added language to indicate the use of Whole-Exome Sequencing and Whole-Genome Sequencing in oncology is addressed in the Medical Policies titled *Genetic Testing for Hereditary Cancer* and *Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions*; for low-pass genome sequencing, refer to the Medical Policy titled *Chromosome Microarray Testing (Non-Oncology Conditions)* • Replaced language indicating: ○ "Genetic counseling is recommended *prior to Whole Exome Sequencing or Whole Genome Sequencing in order*	**Note**: The use of Whole-Exome Sequencing and Whole-Genome Sequencing in oncology is addressed in the Medical Policies titled Genetic Testing for Hereditary Cancer and Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions. For low-pass genome sequencing, refer to the Medical Policy titled Chromosome Microarray Testing (Non-Oncology Conditions). Pretest genetic counseling is recommended to inform persons being tested about the advantages and limitations of the test as applied to their unique situation. **Whole-Exome Sequencing and Whole-Genome Sequencing** **Whole-Exome Sequencing (WES) or Whole-Genome Sequencing (WGS), with or without concurrent Comparator Analysis, is proven and medically necessary when all the following criteria are met:** • The affected individual has signs or symptoms of an undiagnosed or unexplained disorder with a suspected genetic cause • Test results are intended to directly impact the individual's medical management • The clinical presentation does not fit a Well-Delineated Genetic Syndrome or disorder for which a specific test or a Targeted Panel test is available (if a specific genetic syndrome is suspected, a single-gene or

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Whole Exome and Whole Genome Sequencing (Non-Oncology Conditions) (continued)	Jan. 1, 2027	to inform persons being tested about the advantages and limitations of the test as applied to their unique situation" with "*pretest* genetic counseling is recommended to inform persons being tested about the advantages and limitations of the test as applied to their unique situation" ○ "This policy *for Whole Exome and Whole Genome Sequencing (Non-Oncology Conditions)* is applicable only to testing in an outpatient setting or upon discharge from an inpatient setting" with "this policy is applicable only to testing in an outpatient setting or on discharge from an inpatient setting" • Removed reference link to the Medical Policy titled *FDA Cleared or Approved Companion Diagnostic Testing* and *Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and Treatment Decisions* ***Whole-Exome Sequencing and Whole-Genome Sequencing*** • Revised medically necessary clinical coverage criteria for Whole-Exome Sequencing (WES) or Whole-Genome Sequencing (WGS), with or without concurrent Comparator Analysis; replaced	Targeted Panel should be performed prior to determining if WES or WGS is necessary) • The test is ordered by or in consultation with a medical geneticist, neonatologist, neurologist, immunologist, or developmental pediatrician • The clinical presentation includes: ○ One or more of the following: ▪ Multiple Congenital Anomalies that affect at least two different organ systems ▪ Intellectual Disability characterized as moderate, severe, or profound and diagnosed by 18 years of age ▪ Global Developmental Delay ▪ Epileptic Encephalopathy with onset before 3 years of age or ○ Two or more of the following: ▪ Congenital Anomaly ▪ Significant hearing or visual impairment diagnosed by 18 years of age ▪ Laboratory abnormalities that are suggestive of an inborn error of metabolism ▪ Autism Spectrum Disorder ▪ Neuropsychiatric condition (e.g., bipolar disorder, schizophrenia, obsessive-compulsive disorder) ▪ Hypotonia or hypertonia in infancy ▪ Dystonia, ataxia, hemiplegia, neuromuscular disorder, movement disorder, or other serious neurological abnormality ▪ Unexplained developmental regression unrelated to Autism Spectrum Disorder or epilepsy ▪ Growth abnormality (e.g., failure to thrive, short stature, microcephaly, macrocephaly, or overgrowth) ▪ Persistent and severe immunologic or hematologic disorder ▪ Dysmorphic features ▪ Consanguinity ▪ Other first- or second-degree family member(s) with a similar clinical diagnosis **Nonconcurrent Comparator Analysis for WES or WGS is proven and medically necessary when both of the following criteria are met:**

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Whole Exome and Whole Genome Sequencing (Non-Oncology Conditions) (continued)	Jan. 1, 2027	criterion requiring "the test is ordered by a medical geneticist, neonatologist, neurologist, immunologist, or developmental pediatrician" with "the test is ordered by *or in consultation with* a medical geneticist, neonatologist, neurologist, immunologist, or developmental pediatrician" **Definitions** • Updated definition of: ○ Well-Delineated Genetic Syndrome ○ Whole-Exome Sequencing ○ Whole-Genome Sequencing **Applicable Codes** ***Surest Only*** • Added CPT codes 0335U, 81425, and 81426 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information ***Surest Only*** • Added *Medical Records Documentation Used for Reviews* section	• The affected individual meets the above criteria for WES or WGS • WES or WGS has been previously performed on the affected individual **Exome and Genome Data Reanalysis** **Reanalysis of WES or WGS data is proven and medically necessary when all the following criteria are met:** • At least 18 months have passed since the initial WES or WGS was performed • The affected individual meets the above criteria for WES or WGS • Either of the following occurs: ○ The affected individual experiences additional symptoms after initial WES or WGS that cannot be explained by the results of the initial testing ○ New data or new family history emerges that suggests a link between the individual's symptoms and specific genes **Prenatal Whole-Exome Sequencing** **Prenatal WES is proven and medically necessary for diagnosing or evaluating a genetic disorder when all the following criteria are met:** • Chromosome microarray analysis and/or karyotyping has been performed but was uninformative • WES is ordered by or in consultation with a medical geneticist or maternal-fetal medicine specialist (perinatologist) • The specimen is obtained from amniotic fluid and/or chorionic villi, or DNA is extracted from fetal blood or tissue • The fetus has one or more of the following: ○ Multiple Congenital Anomalies that affect at least two different organ systems ○ Fetal hydrops of unknown etiology ○ A Congenital Anomaly that affects a single organ system and family history that suggests a genetic etiology **Unproven Services** **Due to insufficient evidence of efficacy, WES is unproven and not medically necessary for all other indications, including but not limited to the following:**

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Whole Exome and Whole Genome Sequencing (Non-Oncology Conditions) (continued)	Jan. 1, 2027		• Evaluation of fetal demise • Prenatal testing via cell-free fetal DNA • Preimplantation Genetic Testing (PGT) in embryos • Screening and evaluating disorders in individuals when the above criteria are not met **Due to insufficient evidence of efficacy, WGS is unproven and not medically necessary for all other indications, including but not limited to the following:** • Evaluation of fetal demise • Preimplantation Genetic Testing in embryos • Prenatal genetic diagnosis or screening • Screening and evaluating disorders in individuals when the above criteria are not met ***Epigenetic Signature Analysis*** **Epigenetic signature analysis is considered unproven and not medically necessary for any indication due to insufficient evidence of efficacy.** ***Optical Genome Mapping*** **Optical genome mapping is considered unproven and not medically necessary for any indication due to insufficient evidence of efficacy.** ***Whole-Transcriptome Sequencing*** **Whole-transcriptome sequencing is considered unproven and not medically necessary for any indication due to insufficient evidence of efficacy.** ***Rapid Whole-Exome and Whole-Genome Sequencing*** **The use of rapid Whole-Exome Sequencing, rapid Whole-Genome Sequencing, or ultrarapid Whole-Genome Sequencing is unproven and not medically necessary in outpatient settings.** This medical policy is applicable only to testing in an outpatient setting or on discharge from an inpatient setting.

Medical Policy Updates

Retired		
Policy Title	**Effective Date**	**Summary of Changes**
Surgery of the Elbow	Nov. 1, 2026	Retired policy; surgery of the elbow no longer requires clinical review
Video Electroencephalographic (vEEG) Monitoring and Recording	Nov. 1, 2026	Retired policy; video electroencephalographic (vEEG) monitoring and recording no longer requires clinical review

Medical Benefit Drug Policy Updates

New		
Policy Title	**Effective Date**	**Coverage Rationale**

Genglycos™ (Pariglasgene Brecaparvovec-Opnr)	Dec. 1, 2026	**Genglycos (pariglasgene brecaparvovec-opnr) has 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.**
		
		Genglycos (pariglasgene brecaparvovec-opnr) is proven and medically necessary for the treatment of glycogen storage disease type Ia (GSDIa) in patients who meet all of the following criteria:
		• Patient is ≥ 8 years of age; **and**
		• Diagnosis of glycogen storage disease type Ia (GSDIa); **and**
		• Submission of medical records (e.g., chart notes, laboratory values) documenting confirmation of diagnosis by **one** of the following:
		  ○ Bi-allelic pathogenic or likely pathogenic variants in the glucose-6-phosphatase (G6PC) gene; **or**
		  ○ Deficiency or absence of glucose-6-phosphatase (G6Pase) enzyme activity on liver biopsy
		and
		• Patient is currently prescribed and receiving a therapeutic regimen of cornstarch (or equivalent) for the treatment of GSDIa; **and**
		• Patient does not have detectable pre-existing antibodies to the adeno-associated virus serotype 8 (AAV8) capsid; **and**
		• Patient has not previously received gene therapy for the treatment of GSDIa; **and**
		• Prescribed by, or in consultation with, a metabolic disease specialist (e.g., pediatric endocrinologist, metabolic pediatrician, geneticist); **and**
		• Provider does not request a planned inpatient admission for the sole purpose of administering Genglycos (pariglasgene brecaparvovec-opnr); **and**
		• Dosing is in accordance with the 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

Pasatru™ (Garetosmab-Grts)	Dec. 1, 2026	**Pasatru (garetosmab) has 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.**
		
		Pasatru is proven for the treatment of fibrodysplasia ossificans progressiva (FOP). Pasatru is medically necessary when all of the following criteria are met:
		• For **initial therapy**, **all** of the following:
		  ○ Patient is greater than 18 years of age; **and**
		  ○ Diagnosis of fibrodysplasia ossificans progressiva (FOP); **and**
		  ○ Submission of medical records (e.g., chart notes, laboratory values) documenting both of the following:
		  ▪ Clinical signs and symptoms of FOP [e.g., malformation of the great toe, episodic soft tissue swelling, progressive heterotopic ossification (HO)]; **and**

New

Policy Title	Effective Date	Coverage Rationale
Pasatru™ (Garetosmab-Grts) (continued)	Dec. 1, 2026	▪ Genetic testing confirming the presence of a mutation in the activin receptor type 1 (ACVR1) gene consistent with FOP (e.g., R206H) **and** ○ Pasatru is being used to reduce formation of new heterotopic ossification (HO) lesions and clinician-assessed flare-ups; **and** ○ Pasatru will not be used in combination with Sohonos (palovarotene); **and** ○ Prescribed by or in consultation with an FOP expert (e.g., endocrinologist, geneticist, pediatric orthopedist, pediatric rheumatologist); **and** ○ Dosing is in accordance with the FDA-approved labeling; **and** ○ Initial authorization will be for no more than 12 months ● For **continuation of therapy**, **all** of the following: ○ Documentation of positive clinical response (e.g., reduction in new HO lesions, reduction in flare-ups, improved CAJIS scores, improved quality of life); **and** ○ Pasatru is not being used in combination with Sohonos (palovarotene); **and** ○ Prescribed by or in consultation with an FOP expert (e.g., endocrinologist, geneticist, pediatric orthopedist, pediatric rheumatologist); **and** ○ Dosing is in accordance with the FDA-approved labeling; **and** ○ Reauthorization will be for no more than 12 months

Updated

Policy Title	Effective Date	Summary of Changes
Alpha1-Proteinase Inhibitors	Nov. 1, 2026	**Template Update** ● Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans ● Added *Application* section to indicate this policy applies to: ○ UnitedHealthcare Commercial benefit plans ○ Individual Exchange benefit plans
Brineura® (Cerliponase Alfa)	Nov. 1, 2026	**Template Update** ● Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans ● Added *Application* section to indicate this policy applies to: ○ UnitedHealthcare Commercial benefit plans ○ Individual Exchange benefit plans
Evenity® (Romosozumab-Aqqg)	Nov. 1, 2026	**Template Update** ● Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans ● Added *Application* section to indicate this policy applies to:

Medical Benefit Drug Policy Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Evenity® (Romosozumab-Aqqg) (continued)	Nov. 1, 2026	○ UnitedHealthcare Commercial benefit plans ○ Individual Exchange benefit plans **Supporting Information** • Updated *References* section to reflect the most current information
Hereditary Angioedema (HAE), Treatment and Prophylaxis	Nov. 1, 2026	**Template Update** • Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans • Added *Application* section to indicate this policy applies to: ○ UnitedHealthcare Commercial benefit plans ○ Individual Exchange benefit plans
Ilaris® (Canakinumab)	Nov. 1, 2026	**Template Update** • Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans • Added Application section to indicate this policy applies to: ○ UnitedHealthcare Commercial benefit plans ○ Individual Exchange benefit plans **Coverage Rationale** ***Active Still's Disease Including Adult-Onset Stills's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA)*** • Added language to clarify the patient must not be receiving Ilaris in combination with *another systemic* targeted immunomodulator *for treatment of the same indication* **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information
Krystexxa® (Pegloticase)	Nov. 1, 2026	**Template Update** • Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans • Added *Application* section to indicate this policy applies to: ○ UnitedHealthcare Commercial benefit plans ○ Individual Exchange benefit plans **Supporting Information** • Updated *Clinical Evidence, CMS*, and *References* sections to reflect the most current information
Preventive Vaccines (Immunizations)	Nov. 1, 2026	**Applicable Codes** • Added reference link to the applicable codes list titled Professional Medical Society Preventive Vaccine Recommendations: Vaccine Codes (CPT codes 90616, 90657, and 90658)

Medical Benefit Drug Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
RNA-Targeted Therapies (Amvuttra® and Onpattro®)	Nov. 1, 2026	**Coverage Rationale** • Added language to indicate Wainua (eplontersen) has 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 **Applicable Codes** • Added HCPCS codes C9311, J3490, and J3590
Vyjuvek® (Beramagene Geperpavec-Svdt)	Nov. 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

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Clotting Factors, Coagulant Blood Products, & Other Hemostatics	Jan. 1, 2027	**Coverage Rationale** ***Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)*** Antihemophilic Factor (recombinant), Pegylated-aucl (Jivi) • Replaced language indicating "antihemophilic factor (recombinant), Pegylated-aucl (Jivi) is *proven when all of the [listed] criteria are met*" with "antihemophilic factor (recombinant), Pegylated-aucl (Jivi) is *not medically necessary for treatment of hemophilia A for [the listed conditions]*" • Added language to indicate the published clinical evidence does not demonstrate superiority in	Refer to the policy for complete details.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Clotting Factors, Coagulant Blood Products, & Other Hemostatics (continued)	Jan. 1, 2027	efficacy and treatment adherence of Jivi to other available recombinant factor products	
FcRn Blockers	Jan. 1, 2027	**Template Update** • Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans • Added *Application* section to indicate this policy applies to: ○ UnitedHealthcare Commercial benefit plans ○ Individual Exchange benefit plans **Coverage Rationale** ***Warm Autoimmune Hemolytic Anemia (wAIHA): Imaavy*** • Added language to indicate Imaavy is proven for the treatment of warm autoimmune hemolytic anemia (wAIHA) in adult and pediatric patients 12 years of age and older currently or previously treated with corticosteroids; Imaavy is medically necessary for the treatment of warm autoimmune hemolytic anemia (wAIHA) currently or previously treated with corticosteroids when the following criteria are met: Initial Therapy ○ Submission of medical	This policy refers to the following drug products for administration by a healthcare professional: • Imaavy™ (nipocalimab-aahu) for intravenous (IV) route • Rystiggo® (rozanolixizumab-noli) for subcutaneous (SC) route • Vyvgart® (efgartigimod alfa-fcab) for intravenous (IV) route • Vyvgart Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc) vial for subcutaneous (SC) route Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for self-administered subcutaneous injection is obtained under the pharmacy benefit, unless otherwise specified in the member specific benefit plan document. **Exception**: For members enrolled in UnitedHealthcare of California plans with a delegated provider group conducting the prior authorization review, the self-administered Vyvgart Hytrulo may be obtained under the medical benefit. Refer to the policy for complete details.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
FcRn Blockers (continued)	Jan. 1, 2027	records (e.g., chart notes, laboratory values, etc.) confirming a diagnosis of warm autoimmune hemolytic anemia (wAIHA) demonstrated by all of the following: ▪ Presence of hemolytic anemia ▪ One of the following: – Positive direct antiglobulin test (DAT; direct Coombs test) – Both of the following: negative direct antiglobulin test (DAT; direct Coombs test) and other causes of immune and nonimmune hemolysis have been eliminated [e.g., paroxysmal nocturnal hemoglobinuria (PNH), hereditary spherocytosis, cold-active antibodies (paroxysmal cold hemoglobinuria or cold agglutinin disease), hemoglobinopathies, thrombotic microangiopathies (TMAs), and other causes of	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
FcRn Blockers (continued)	Jan. 1, 2027	microangiopathic hemolysis] ▪ Signs and symptoms consistent with warm AIHA [e.g., dyspnea on exertion, jaundice, splenomegaly, deep vein thrombosis (DVT), pigment gallstones] ○ One of the following: ▪ Patient is currently receiving treatment for wAIHA with one of the following: – Corticosteroid (e.g., prednisone, methylprednisolone) – Immunosuppressant (e.g., mycophenolate mofetil, cyclophosphamide, sirolimus, azathioprine) ▪ Trial and failure (after a trial of at least two weeks), contraindication, or intolerance to corticosteroids(e.g., prednisone, methylprednisolone) ○ Trial and failure, contraindication, or intolerance to rituximab (e.g., Riabni, Rituxan, Ruxience, Truxima) ○ Patient is not receiving Imaavy in combination with	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
FcRn Blockers (continued)	Jan. 1, 2027	any of the following used for the same indication: ▪ Rituximab (e.g., Riabni, Rituxan, Ruxience, Truxima) ▪ Immune globulin (e.g., Hizentra, Privigen, Gammagard) ○ Imaavy is dosed according to the FDA-labeled dosing for wAIHA ○ Prescribed by or in consultation with a hematologist ○ Initial authorization will be for no more than 12 months Continuation of Therapy ○ Patient has previously been treated with Imaavy ○ Documentation of positive clinical response to Imaavy therapy (e.g., reduction in glucocorticoid use, stabilization or reduction in immunosuppressive therapy, reduction in episodes of hemolysis) ○ Patient is not receiving Imaavy in combination with any of the following used for the same indication: ▪ Rituximab (e.g., Riabni, Rituxan, Ruxience, Truxima) ▪ Immune globulin (e.g., Hizentra, Privigen, Gammagard)	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
FcRn Blockers (continued)	Jan. 1, 2027	○ Imaavy is dosed according to the FDA-labeled dosing for wAIHA ○ Prescribed by or in consultation with a hematologist ○ Reauthorization will be for no more than 12 months **Applicable Codes** • Added ICD-10 diagnosis code D59.11 **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Ilumya® (Tildrakizumab-Asmn)	Jan. 1, 2027	**Coverage Rationale** ***Moderate to Severe Plaque Psoriasis*** Initial Therapy • Revised list of preferred biologic products for which the patient must have a history of treatment failure, contraindication, or intolerance: ○ Added: ▪ Bimzelx (bimekizumab-bkzx) ▪ Icotyde (icotrokinra) ○ Removed Sotyktu (deucravacitinib)	Ilumya to be used as a self-administered, subcutaneous injection for the treatment of plaque psoriasis should be 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 Ilumya may be obtained under the medical benefit. **Ilumya (tildrakizumab) is proven for provider administration for the treatment of moderate to severe plaque psoriasis when the following criteria are met:** • For **initial therapy**: ○ Diagnosis of moderate to severe plaque psoriasis; **and** ○ Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug; physician must submit explanation; **and** ○ Patient is not receiving Ilumya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ilumya® (Tildrakizumab-Asmn) (continued)	Jan. 1, 2027		(ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication; **and** ○ Dosing is in accordance with the FDA-approved labeling; **and** ○ Initial authorization will be for no longer than 12 months • For **continuation of therapy**: ○ Documentation of positive clinical response to Ilumya therapy; **and** ○ Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug; physician must submit explanation; **and** ○ Patient is not receiving Ilumya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication; **and** ○ Dosing is in accordance with the FDA-approved labeling; **and** ○ Reauthorization will be for no longer than 12 months **Ilumya (tildrakizumab) is medically necessary for provider administration for the treatment of moderate to severe plaque psoriasis when the following criteria are met:** • For **initial therapy**, submission of medical records (e.g., chart notes, laboratory values) documenting all of the following: ○ Diagnosis of chronic moderate to severe plaque psoriasis; **and** ○ Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis; **and** ○ One of the following: ▪ Both of the following: – History of failure, contraindication, or intolerance to **one** of the following topical therapies: • Corticosteroids (e.g., betamethasone, clobetasol, desonide) • Vitamin D analogs (e.g., calcitriol, calcipotriene) • Tazarotene • Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ilumya® (Tildrakizumab-Asmn) (continued)	Jan. 1, 2027		• Anthralin • Coal tar **and** – History of failure to a 3-month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced **or** ▪ Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of plaque psoriasis [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] **and** ○ History of failure, contraindication, or intolerance to three of the following preferred biologic products: *(For Medicare reviews, refer to the CMS section of the policy.)* ▪ One of the preferred adalimumab products* ▪ Bimzelx (bimekizumab-bkzx) ▪ Cimzia (certolizumab) ▪ Cosentyx (secukinumab) ▪ Enbrel (etanercept) ▪ Icotyde (icotrokinra) ▪ Skyrizi (risankizumab) ▪ One of the preferred ustekinumab products* ▪ Tremfya (guselkumab) **and** ○ Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug; physician must submit explanation; **and** ○ Patient is not receiving Ilumya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ilumya® (Tildrakizumab-Asmn) (continued)	Jan. 1, 2027		the same indication; **and** ○ Dosing is in accordance with the FDA-approved labeling; **and** ○ Prescribed by or in consultation with a dermatologist; **and** ○ Initial authorization will be for no longer than 12 months • For **continuation of therapy**: ○ Documentation of positive clinical response to Ilumya therapy; **and** ○ Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug. Physician must submit explanation; **and** ○ Patient is not receiving Ilumya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication; **and** ○ Dosing is in accordance with the FDA-approved labeling; **and** ○ Reauthorization will be for no longer than 12 months *For a list of preferred products, reference drug coverage tools.
Intravenous Iron Replacement Therapy (Injectafer® & Monoferric®)	Dec. 1, 2026	**Coverage Rationale** • Revised coverage criteria for continuation of therapy; replaced criterion requiring: ○ "A documented history of intolerance, contraindication, or severe adverse event to all *three* preferred intravenous iron products" with "a documented history of intolerance, contraindication, or severe adverse event to all *four* preferred intravenous iron products" ○ "A documented history of treatment failure of at least two of the *three* preferred	This policy refers to the following intravenous iron replacements: • Injectafer® (ferric carboxymaltose) • Monoferric® (ferric derisomaltose) Refer to the policy for complete details.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Intravenous Iron Replacement Therapy (Injectafer® & Monoferric®) (continued)	Dec. 1, 2026	intravenous iron products" with "a documented history of treatment failure of at least two of the *four* preferred intravenous iron products" **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information	
Preventive Vaccines (Immunizations)	Dec. 1, 2026	**Coverage Rationale** ***Coverage Conditions*** • Revised coverage criteria for a vaccine (immunization) to be considered covered as a preventive care service benefit; replaced criterion requiring "the vaccine (immunization) is subject to explicit recommendations (e.g., should, shall, is) *and not permissive ('may') recommendations* by one of the [listed] organizations" with "the vaccine (immunization) is subject to explicit recommendations (e.g., should, shall, is) by one of the [listed] organizations"	**Coverage Conditions** A vaccine (immunization) is considered covered as a preventive care service benefit after **all** of the following conditions are satisfied: • The FDA has approved the vaccine (immunization); **and** • The vaccine (immunization) is not otherwise excluded by the plan as explained in the member specific benefit plan document; **and** • **One** of the following: ○ The vaccine (immunization) meets the requirements for coverage as a preventive service as set forth in the Medical Policy titled Preventive Care Services and is therefore listed in the *Preventive Care Services: Vaccine Codes* policy appendix; **or** ○ The vaccine (immunization) is subject to explicit recommendations (e.g., should, shall, is) by one of the following organizations: ▪ American Academy of Family Physicians ▪ American Academy of Pediatrics ▪ American College of Obstetricians and Gynecologists **Coverage Clarifications** • **Preventive**: In the case of a public health emergency (as defined by the Centers for Disease Control or state or local public health departments), UnitedHealthcare may choose to apply preventive benefits to a new vaccine if the vaccine has FDA approval, even when the above criteria have not been met. • **Therapeutic**: Certain vaccines are used as a medical treatment. For example, therapeutic treatment of an animal bite using the rabies vaccine. These vaccines are under the plan's treatment benefits, not under preventive care benefits. These vaccines are not subject to the

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Preventive Vaccines (Immunizations) (continued)	Dec. 1, 2026		coverage criteria in this section. • **Excluded**: Vaccines that fall under one of the exclusions in the member specific benefit plan document. For example, most plans exclude travel-specific vaccines.
Saphnelo® (Anifrolumab-Fnia)	Jan. 1, 2027	**Coverage Rationale** • Revised coverage criteria for: ***Initial Therapy*** ○ Added criterion requiring prescriber attestation that the patient or caregiver are not able to be trained or are physically unable to administer Saphnelo or Benlysta FDA-labeled for self-administration (prescriber must submit explanation) ○ Replaced criterion requiring "the patient has a contraindication, intolerance, or failure to Benlysta" with "the patient has a contraindication, intolerance, or failure to Benlysta *injection for intravenous infusion*" ***Continuation of Therapy*** ○ Added criterion requiring prescriber attestation that the patient or caregiver continue to not be able to be trained or are physically unable to administer Saphnelo or Benlysta FDA-labeled for self-administration	This policy refers to Saphnelo® (anifrolumab-fnia) injection for intravenous infusion. Saphnelo Pen (anifrolumab-fnia) for self-administered subcutaneous injection is 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 Saphnelo Pen (anifrolumab-fnia) may be obtained under the medical benefit. **Saphnelo (anifrolumab-fnia) is proven for the treatment of moderate to severe systemic lupus erythematosus (SLE) when all of the following criteria are met:** • For **initial therapy**, **all** of the following: ○ Diagnosis of moderate to severe systemic lupus erythematosus, without severe active central nervous system lupus or severe active lupus nephritis; **and** ○ Currently receiving at least **one** standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic; **and** ○ Patient is not receiving Saphnelo in combination with a biologic agent or Benlysta; **and** ○ Saphnelo is dosed according to FDA-labeled dosing for SLE; **and** ○ Initial authorization is for no more than 12 months • For **continuation of therapy**, **all** of the following: ○ Patient has previously received Saphnelo injection for intravenous infusion; **and** ○ Documentation of positive clinical response; **and** ○ Patient is without severe active central nervous system lupus or severe active lupus nephritis; **and** ○ Currently receiving at least **one** standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic; **and** ○ Patient is not receiving Saphnelo in combination with a biologic

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Saphnelo® (Anifrolumab-Fnia) (continued)	Jan. 1, 2027		agent or Benlysta; **and** ○ Saphnelo is dosed according to FDA-labeled dosing for SLE; **and** ○ Authorization is for no more than 12 months **Saphnelo (anifrolumab-fnia) is medically necessary for the treatment of moderate to severe systemic lupus erythematosus (SLE) when all of the following criteria are met:** ● For **initial therapy**, **all** of the following: ○ Diagnosis of moderate to severe systemic lupus erythematosus, without severe active central nervous system lupus or severe active lupus nephritis; **and** ○ Currently receiving at least **one** standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic; **and** ○ **Both** of the following: ▪ Prescriber attestation that the patient or caregiver are not able to be trained or are physically unable to administer Saphnelo or Benlysta FDA-labeled for self-administration; prescriber must submit explanation; **and** ▪ Patient has a contraindication, intolerance, or failure to Benlysta injection for intravenous infusion *(For Medicare reviews, refer to the CMS section of the policy.)* **and** ○ Patient is not receiving Saphnelo in combination with a biologic agent or Benlysta; **and** ○ Saphnelo is dosed according to FDA-labeled dosing for SLE; **and** ○ Prescribed by or in consultation with a rheumatologist; **and** ○ Initial authorization is for no more than 12 months ● For **continuation of therapy**, **all** of the following: ○ Patient has previously received Saphnelo injection for intravenous infusion; **and** ○ Documentation of positive clinical response; **and** ○ Prescriber attestation that the patient or caregiver continue to not be able to be trained or are physically unable to administer Saphnelo or Benlysta FDA-labeled for self-administration; **and** ○ Patient is without severe active central nervous system lupus or severe active lupus nephritis; **and**

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Saphnelo® (Anifrolumab-Fnia) (continued)	Jan. 1, 2027		○ Currently receiving at least **one** standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic; **and** ○ Patient is not receiving Saphnelo in combination with a biologic agent or Benlysta; **and** ○ Saphnelo is dosed according to FDA-labeled dosing for SLE; **and** ○ Prescribed by or in consultation with a rheumatologist; **and** ○ Authorization is for no more than 12 months **Saphnelo is unproven and not medically necessary for:** ● Severe active lupus nephritis ● Severe active central nervous system (CNS) lupus ● Use in combination with other biologics

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.