United Healthcare Community Plan

UnitedHealthcare Community Plan of Tennessee
Medical Policy Update Bulletin: October 2025

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Take Note

Annual ICD-10 and Quarterly HCPCS Code Updates

Beginning **Oct. 1, 2025**, the following Medical Benefit Drug Policies will be updated to reflect the annual ICD-10 and quarterly HCPCS code additions, revisions, and deletions. Refer to the following sources for information on the code updates:

- Centers for Medicare & Medicaid Services: Healthcare Common Procedure Coding System (HCPCS) Quarterly Update
- Centers for Medicare & Medicaid Services: International Classification of Diseases, Tenth Revision (ICD-10) Codes

Policy Title	Effective Date	Summary of Changes
Antiemetics for Oncology	Oct. 1, 2025	• Added ICD-10 diagnosis code R11.16
Botulinum Toxins A and B	Oct. 1, 2025	• Added ICD-10 diagnosis codes G35.A, G35.B0, G35.B1, G35.B2, G35.C0, G35.C1, G35.C2, and G35.D • Removed ICD-10 diagnosis code G35
Briumvi® (Ublituximab-Xiiy)	Oct. 1, 2025	• Added ICD-10 diagnosis codes G35.A, G35.B0, G35.B1, G35.B2, G35.C0, G35.C1, G35.C2, and G35.D • Removed ICD-10 diagnosis code G35
Cimzia® (Certolizumab Pegol)	Oct. 1, 2025	• Added ICD-10 diagnosis code M05.A
Denosumab	Oct. 1, 2025	• Replaced HCPCS codes C9399, J3490, and J3590 with Q5157
Encelto™ (Revakinagene Taroretcel-Lwey)	Oct. 1, 2025	• Replaced HCPCS codes C9399 and J3590 with J3403
Evkeeza® (Evinacumab-Dgnb)	Oct. 1, 2025	• Added ICD-10 diagnosis codes E78.010, E78.011, and E78.019 • Removed ICD-10 diagnosis code E78.01
Factor Mimetics and Rebalancing Agents for Hemophilia	Oct. 1, 2025	• Replaced HCPCS codes C9399, J3490, and J3590 with J7173 and J7174
Immune Globulin (IVIG and SCIG)	Oct. 1, 2025	• Added ICD-10 diagnosis codes G35.A, G35.B0, G35.B1, G35.B2, G35.C0, G35.C1, G35.C2, and G35.D • Removed ICD-10 diagnosis code G35
Infliximab	Oct. 1, 2025	• Added ICD-10 diagnosis code M05.A
Lemtrada® (Alemtuzumab)	Oct. 1, 2025	• Added ICD-10 diagnosis codes G35.A, G35.B0, G35.B1, G35.B2, G35.C0, G35.C1, G35.C2, and G35.D • Removed ICD-10 diagnosis code G35
Leqvio® (Inclisiran)	Oct. 1, 2025	• Added ICD-10 diagnosis codes E78.010, E78.011, and E78.019 • Removed ICD-10 diagnosis code E78.01
Long-Acting Injectable Antiretroviral Agents for HIV	Nov. 1, 2025	• Added HCPCS code J0738 • Revised description for HCPCS code J1961

Take Note

Policy Title	Effective Date	Summary of Changes
Medical Therapies for Enzyme Deficiencies	Oct. 1, 2025	**Nulibry** • Replaced HCPCS codes C9399, J3490, and J3590 with J1809
Ocrevus® (Ocrelizumab) and Ocrevus Zunovo™ (Ocrelizumab and Hyaluronidase-Ocsq)	Oct. 1, 2025	• Added ICD-10 diagnosis codes G35.A, G35.B0, G35.B1, G35.B2, G35.C0, G35.C1, G35.C2, and G35.D • Removed ICD-10 diagnosis code G35
Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors	Oct. 1, 2025	• Added ICD-10 diagnosis codes H40.841, H40.842, H40.843, and H40.849
Orencia® (Abatacept) Injection for Intravenous Infusion	Oct. 1, 2025	• Added ICD-10 diagnosis code M05.A
Oxlumo® (Lumasiran) and Rivfloza® (Nedosiran)	Oct. 1, 2025	• Added ICD-10 diagnosis codes E72.530, E72.538, E72.539, E72.540, E72.541, E72.548, and E72.549 • Added ICD-10 diagnosis code E72.53
Rituximab (Riabni®, Rituxan®, Ruxience®, & Truxima®)	Oct. 1, 2025	• Added ICD-10 diagnosis codes G35.A, G35.B0, G35.B1, G35.B2, G35.C0, G35.C1, G35.C2, G35.D, and M05.A • Removed ICD-10 diagnosis code G35
Simponi Aria® (Golimumab) Injection for Intravenous Infusion	Oct. 1, 2025	• Added ICD-10 diagnosis code M05.A
Tocilizumab (Actemra®, Tofidence™, and Tyenne®)	Oct. 1, 2025	• Added ICD-10 diagnosis code M05.A
Tysabri® (Natalizumab)	Oct. 1, 2025	• Added ICD-10 diagnosis codes G35.A, G35.B0, G35.B1, G35.B2, G35.C0, G35.C1, G35.C2, and G35.D • Removed ICD-10 diagnosis code G35
Xolair® (Omalizumab)	Oct. 1, 2025	• Added ICD-10 diagnosis codes Z91.0110, Z91.0111, Z91.0112, Z91.0120, Z91.0121, and Z91.0122 • Removed ICD-10 diagnosis codes Z91.011 and Z91.012

Medical Policy Updates

New

Policy Title	Effective Date	Coverage Rationale
Respiratory Pathogen Nucleic Acid Detection Testing (for Tennessee Only)	Jan. 1, 2026	**Respiratory pathogen panel testing of six or more targets in an outpatient setting is unproven and not medically necessary due to insufficient evidence of efficacy for all indications.**

Updated

Policy Title	Effective Date	Summary of Changes
Autologous Cellular Therapy (for Tennessee Only)	Nov. 1, 2025	**Applicable Codes** • Removed CPT code 27599 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Cognitive Rehabilitation and Coma Stimulation (for Tennessee Only)	Dec. 1, 2025	**Title Change** • Previously titled *Cognitive Rehabilitation (for Tennessee Only)* **Coverage Rationale** • Replaced language indicating "Coma Stimulation (also known as coma arousal, coma responsiveness, multisensory stimulation, and coma care therapy/programs) is unproven and not medically necessary for any *indication, including individuals who are comatose, in a vegetative or minimally conscious state*" with "Coma Stimulation (also known as coma arousal, coma responsiveness, multisensory stimulation, and coma care therapy/programs) is unproven and not medically necessary for any *Disorder of Consciousness (DOC)*"	**Note**: This policy applies to outpatient Cognitive Rehabilitation services only. **Cognitive Rehabilitation (CR) is proven and medically necessary under certain circumstances.** For medical necessity clinical coverage criteria, refer to the InterQual® LOC: Outpatient Rehabilitation & Chiropractic. Click here to view the InterQual® criteria. **Coma Stimulation (also known as coma arousal, coma responsiveness, multisensory stimulation, and coma care therapy/programs) is unproven and not medically necessary due to insufficient evidence of efficacy for any Disorder of Consciousness (DOC).**

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Cognitive Rehabilitation and Coma Stimulation (for Tennessee Only) (continued)	Dec. 1, 2025	**Definitions**
		• Added definition of "Disorder of Consciousness (DOC)"
		• Removed definition of:
		  ○ Coma/Persistent Vegetative State
		  ○ Minimally Conscious State
		Supporting Information
		• Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	

Glaucoma Surgical Treatments (for Tennessee Only)	Dec. 1, 2025	**Coverage Rationale**
		• Revised list of proven and medically necessary indications:
		  ○ Added:
		  ▪ Goniotomy, trabeculotomy, canaloplasty (ab interno), or combined canaloplasty (ab interno) and trabeculotomy (e.g., OMNI® Surgical System, Streamline Surgical System) for adults (age 19 years or more) when used in combination with cataract surgery for treating mild to moderate open-angle glaucoma (OAG) and cataract in adults currently being treated with ocular hypotensive medication
		  ▪ Laser trabeculoplasty (e.g., Argon, Selective)
		  ▪ Laser iridotomy/
			The following are proven and medically necessary:
			• Goniotomy or trabeculotomy for pediatric glaucoma (age 18 years or less)
			• Goniotomy, trabeculotomy, canaloplasty (ab interno), or combined canaloplasty (ab interno) and trabeculotomy (e.g., OMNI® Surgical System, Streamline Surgical System) for adults (age 19 years or more) when used in combination with cataract surgery for treating mild to moderate open-angle glaucoma (OAG) and cataract in adults currently being treated with ocular hypotensive medication
			• iStent®, iStent *inject*®, or Hydrus® Microstent when used in combination with cataract surgery for treating mild to moderate open-angle glaucoma (OAG) and cataract in adults currently being treated with ocular hypotensive medication
			• Glaucoma drainage devices (e.g., XEN® System, Ex-PRESS™, Molteno implant, Baerveldt tube shunt, Ahmed glaucoma valve implant, and Krupin-Denver valve implant) for treating refractory glaucoma when medical or surgical treatments have failed or are inappropriate
			• Laser trabeculoplasty (e.g., Argon, Selective)
			• Laser iridotomy/iridectomy (e.g., Nd: YAG)
			• Laser iridoplasty
			• Laser ciliary body destruction
			All other types of laser procedures are unproven and not medically necessary for treating any type of glaucoma due to insufficient evidence of efficacy and/or safety.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Glaucoma Surgical Treatments (for Tennessee Only) (continued)	Dec. 1, 2025	iridectomy (e.g., Nd: YAG) ▪ Laser iridoplasty ▪ Laser ciliary body destruction ○ Replaced "*some* glaucoma drainage devices (*specifically* XEN System, Ex-PRESS™, Molteno implant, Baerveldt tube shunt, Ahmed glaucoma valve implant, and Krupin-Denver valve implant) for treating refractory glaucoma when medical or surgical treatments have failed or are inappropriate" with "glaucoma drainage devices (*e.g.,* XEN System, Ex-PRESS™, Molteno implant, Baerveldt tube shunt, Ahmed glaucoma valve implant, and Krupin-Denver valve implant) for treating refractory glaucoma when medical or surgical treatments have failed or are inappropriate" • Added language to indicate all other types of laser procedures [not listed in the policy as proven and medically necessary] are unproven and not medically necessary for treating any type of glaucoma due to insufficient evidence of efficacy and/or safety • Removed language indicating the following are unproven and not medically necessary for treating	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Glaucoma Surgical Treatments (for Tennessee Only) (continued)	Dec. 1, 2025	any type of glaucoma due to insufficient evidence of efficacy and/or safety: ○ Canaloplasty (ab interno) ○ Combined; canaloplasty (ab interno) and trabeculotomy (e.g., OMNI® Surgical System, Streamline Surgical System) ○ Glaucoma drainage devices that are not FDA approved ○ Goniotomy or trabeculotomy (for indications not listed as proven and medically necessary) **Applicable Codes** • Added CPT codes 0621T, 0622T, 0730T, 65855, 66710, 66711, 66761, and 66762 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Hospital Services: Observation and Inpatient (for Tennessee Only)	Dec. 1, 2025	**Coverage Rationale** • Removed language indicating observation services are considered medically necessary for a member who requires the following care in any location within a hospital: ○ Short-term monitoring for a condition that is expected to require at least 6 hours of assessment or treatment and improve significantly within 24-48 hours; and	UnitedHealthcare uses InterQual® as a source of medical evidence to support medical necessity and level of care decisions, when applicable. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Click here to view the InterQual® criteria. **An observation level of care is often used to manage the following clinical conditions and symptoms (list is not all-inclusive)**: • Abdominal pain • Allergic reaction (generalized) • Altered mental status (confusion)

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Hospital Services: Observation and Inpatient (for Tennessee Only) (continued)	Dec. 1, 2025	○ At least one of the following: ▪ Acute treatment and reassessment ▪ Event monitoring (e.g., cardiac dysrhythmia) or response to therapy (e.g., from drug ingestion) that may require immediate intervention ▪ Diagnostic evaluation to establish a treatment plan	• Anemia • Asthma • Atrial fibrillation • Back pain • Bronchiolitis • Bronchitis • Cellulitis • Chest pain • Chronic obstructive pulmonary disease • Croup • Dehydration • Diabetes mellitus • Epistaxis • Febrile illness • Gastroenteritis • Heart failure • Hemoptysis • Migraine • Pneumonia • Poisoning/toxic ingestions • Renal colic, kidney stone • Seizures • Syncope and collapse • Transient ischemic attack (TIA) • Urinary tract infection • Vaginal bleeding (non-obstetrical) • Weakness If the individual's condition does not improve within 48 hours, additional clinical information should be submitted to support an inpatient level of care. **Observation services are not medically necessary for the convenience of the hospital, physicians, individuals, or individuals' families, or while awaiting placement to another health care facility.** **Note**: The observation services portion of this policy does not apply to an obstetric member during pregnancy, childbirth, or the post-partum period.

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Skin and Soft Tissue Substitutes (for Tennessee Only)	Nov. 1, 2025	**Coverage Rationale** • Revised list of skin and soft tissue substitutes that are unproven and not medically necessary for any indication; added: ○ AdvoGraft Dual and AdvoGraft One ○ AeroGuard and NeoGuard ○ AmchoPlast EXCEL ○ AmchoThick ○ AmnioDefend FT Matrix ○ AmnioPlast 3 ○ Duograft AA, duoGRAFT AC, and triGRAFT FT ○ Membrane Wrap-Lite ○ Renew FT Matrix **Applicable Codes** • Added HCPCS codes Q4368, Q4369, Q4370, Q4371, Q4372, Q4373, Q4375, Q4376, Q4377, Q4378, Q4379, Q4380, and Q4382 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	**EpiFix or Grafix® (GrafixPL, GrafixPRIME, and GrafixPL PRIME) (Non-Injectable)** **EpiFix or Grafix is proven and medically necessary for treating a diabetic foot ulcer when all of the following criteria are met:** • Adequate circulation to the affected extremity as indicated by one or more of the following: ○ Pedal pulses palpable or pulses confirmed with doppler examination ○ Ankle-brachial index (ABI) between 0.7 and 1.2 • Glycated hemoglobin test (HgA1c) < 12% (within the last 90 days) • Ulcer has failed to demonstrate adequate healing with at least 4 weeks of standard wound care which includes **all** of the following: ○ Application of dressings to maintain a moist wound environment ○ Debridement of necrotic tissue, if present ○ Offloading • No known contraindications which may include but are not limited to the following: ○ Active Charcot deformity or major structural abnormalities of the affected foot ○ Chronic infection to the ulcer site ○ Known or suspected malignancy of the current ulcer being treated ○ Ulcer being treated does not extend to tendon, muscle, capsule, or bone ***EpiFix and Grafix Application Limitations*** • EpiFix is limited to one application per week for up to 12 weeks. • Grafix is limited to one application per week for up to 12 weeks. **Due to insufficient evidence of efficacy, EpiFix and/or Grafix are unproven and not medically necessary for all other indications including but not limited to:** • EpiFix application more frequently than once a week or beyond 12 weeks • Grafix application more frequently than once a week or beyond 12 weeks **TransCyte™** **TransCyte is proven and medically necessary for treating surgically**

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Skin and Soft Tissue Substitutes (for Tennessee Only) (continued)	Nov. 1, 2025		**excised Full-Thickness Thermal Burn wounds and deep Partial-Thickness Thermal Burn wounds before autograft placement.** **TransCyte is unproven and not medically necessary for all other indications due to insufficient evidence of efficacy.** **Other Skin and Soft Tissue Substitutes** **Other skin and soft tissue substitutes listed in the policy are unproven and not medically necessary for any indication due to insufficient evidence of efficacy.** Refer to the Medical Policy titled Breast Reconstruction (for Tennessee Only) for information about coverage for skin and soft tissue substitutes used during post mastectomy breast reconstruction procedures. **Note**: Refer to the *Clinical Evidence* section of the policy for specific product information. Refer to the policy for complete details.

Retired

Policy Title	Effective Date	Summary of Changes
Electroretinography (for Tennessee Only)	Oct. 1, 2025	• Retired policy; electroretinography no longer requires clinical review

Medical Benefit Drug Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Leqvio® (Inclisiran)	Oct. 1, 2025	**Coverage Rationale** • Updated coverage criteria; replaced criterion requiring "[Leqvio is] prescribed by a *lipid specialist* (*e.g.,* cardiologist, endocrinologist, lipid specialist/*lipidologist*)" with "[Leqvio is] prescribed by *one of the following*: cardiologist, endocrinologist, or lipid specialist" **Applicable Codes** • Updated list of applicable ICD-10 diagnosis codes to reflect annual edits: ○ Added E78.010, E78.011, and E78.019 ○ Removed E78.01 **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Buprenorphine (Brixadi® & Sublocade®)	Nov. 1, 2025	**Coverage Rationale** • Replaced language indicating "Buprenorphine extended-release injection (e.g., Brixadi, Sublocade) is proven *and medically necessary* for the treatment of moderate to severe opioid use disorder in patients who meet all of the [listed] criteria" with "buprenorphine extended-release injection (e.g., Brixadi, Sublocade) is proven for the treatment of moderate to severe opioid use disorder in patients who meet all of the [listed] criteria" • Revised coverage criteria for: ***Initial Therapy*** ○ Replaced criterion requiring "the patient is *currently maintained on an oral, sublingual, or transmucosal* buprenorphine product" with "the patient is *already being*	This policy provides information about the use of buprenorphine formulations administered by subcutaneous (SC) injection. This policy refers to the following buprenorphine products: • Brixadi® • Sublocade® **Buprenorphine extended-release injection (e.g., Brixadi, Sublocade) is proven for the treatment of moderate to severe opioid use disorder in patients who meet all of the following criteria:** • For **initial therapy**, **all** of the following: ○ Patient is being treated for opioid use disorder; **and** ○ **One** of the following: ▪ **Both** of the following: – Patient is not currently receiving maintenance buprenorphine treatment; **and** – Patient has received a test dose of buprenorphine to establish that buprenorphine is tolerated without precipitated withdrawal **or** ▪ Patient is already being treated with buprenorphine **and** ○ Brixadi or Sublocade dosing is in accordance with the U.S. Food and Drug Administration approved labeling; **and** ○ Initial authorization will be for no more than 12 months

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Buprenorphine (Brixadi® & Sublocade®) (continued)	Nov. 1, 2025	*treated with* buprenorphine" ○ Removed criterion requiring the patient has neither received nor will receive supplemental, oral, sublingual, or transmucosal buprenorphine ***Continuation of Therapy*** ○ Removed criterion requiring the patient has neither received nor will receive supplemental, oral, sublingual, or transmucosal buprenorphine **Applicable Codes** • Added ICD-10 diagnosis code F11.23 **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information	• For **continuation of therapy**, **all** of the following: ○ Documentation of positive clinical response to buprenorphine extended-release therapy; **and** ○ Brixadi or Sublocade dosing is in accordance with the U.S. Food and Drug Administration approved labeling; **and** ○ Continuation authorization will be for no more than 12 months **Buprenorphine extended-release injection is unproven and not medically necessary for pain management.**
Factor Mimetics and Rebalancing Agents for Hemophilia	Nov. 1, 2025	**Coverage Rationale** • Revised coverage criteria for **concizumab-mtci (Alhemo)**; added criterion to allow coverage when the patient has a diagnosis of hemophilia A and has **not** developed high-titer factor VIII/IX inhibitors [i.e., patient has **not** developed factor VIII/IX inhibitors greater than or equal to 5 Bethesda units (BU)] **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to	This policy refers to the following products: • Antithrombin-directed small interfering ribonucleic acid (siRNA): Qfitlia® (fitusiran) • Bispecific factor IXa- and factor X-directed antibody: Hemlibra® (emicizumab-kxwh) • Tissue factor pathway inhibitor (TFPI) antagonist: Alhemo® (concizumab-mtci) and Hympavzi™ (marstacimab-hncq) Refer to the policy for complete details.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Factor Mimetics and Rebalancing Agents for Hemophilia (continued)	Nov. 1, 2025	reflect the most current information	
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®)	Nov. 1, 2025	**Coverage Rationale** ***Myasthenia Gravis*** • Revised coverage criteria for: Rystiggo ○ Added criterion for **initial therapy** requiring the patient will be given Rystiggo no sooner than 63 days from the start of the previous treatment cycle ○ Added criterion for **continuation of therapy** requiring the patient is not being given Rystiggo sooner than 63 days from the start of the previous treatment cycle Vyvgart and Vyvgart Hytrulo ○ Replaced criterion for **initial therapy** requiring "the patient will be given Vyvgart or Vyvgart Hytrulo no sooner than 50 days *after each treatment cycle*" with "the patient will be given Vyvgart or Vyvgart Hytrulo no sooner than 50 days *from the start of the previous treatment cycle*" ○ Added criterion for **continuation of therapy** requiring the patient is not being given Vyvgart or Vyvgart Hytrulo sooner than	This policy refers to the following drug products for administration by a healthcare professional: • Rystiggo (rozanolixizumab-noli) for intravenous (IV) 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) prefilled syringe for self-administered subcutaneous injection is obtained under the pharmacy benefit. **Myasthenia Gravis** **Rystiggo is proven and medically necessary for the treatment of generalized myasthenia gravis in patients who are anti-AChR antibody positive or anti-MuSK antibody positive when all of the following criteria are met:** • **Initial Therapy** ○ Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming **all** of the following: ▪ Patient has not failed a previous course of Rystiggo therapy; **and** ▪ Diagnosis of generalized myasthenia gravis (gMG); **and** ▪ **One** of the following: – Positive serologic test for anti-AChR antibodies; **or** – Positive serologic test for anti-MuSK antibodies **and** ▪ Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy; **and** ▪ Patient has a Myasthenia Gravis Activities of Daily Living scale (MG-ADL) total score ≥ 5 at initiation of therapy **and** ○ **One** of the following:

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Nov. 1, 2025	50 days from the start of the previous treatment cycle ***Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)*** • Revised coverage criteria for initial therapy to require: ○ Patient has not failed a previous course of Vyvgart Hytrulo therapy ○ Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) as confirmed by all of the following: ▪ Progressive symptoms present for at least 2 months ▪ Symptomatic polyradiculoneuropathy as indicated by progressive or relapsing motor or sensory impairment of more than one limb ▪ Electrodiagnostic findings (consistent with EFNS/PNS guidelines for definite CIDP) indicating the presence of at least one of the following: – Motor distal latency prolongation in 2 nerves – Reduction of motor conduction velocity in 2 nerves	▪ If anti-acetylcholine receptor (AChR) antibody positive, **one** of the following: – History of failure of at least **two** immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.); **or** – Patient has a history of failure of at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/plasma exchanges and/or immune globulin over the course of at least 12 months without symptom control **or** ▪ If anti-muscle-specific tyrosine kinase (MuSK) antibody positive: – History of failure of at least one immunosuppressive agent over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.) **and** ○ Patient is not receiving Rystiggo in combination with a complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]; **and** ○ Patient is not receiving Rystiggo in combination with another FcRn blocker [e.g., Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)]; **and** ○ Patient is not receiving Rystiggo in combination with an immune globulin; **and** ○ Patient will be given Rystiggo no sooner than 63 days from the start of the previous treatment cycle; **and** ○ Rystiggo is dosed according to the U.S. FDA labeled dosing for gMG; **and** ○ Prescribed by, or in consultation with, a neurologist; **and** ○ Initial authorization will be for no more than 12 months • **Continuation of Therapy** ○ Patient has previously been treated with Rystiggo; **and** ○ Submission of medical records (e.g., chart notes, laboratory tests) demonstrating **all** of the following: ▪ Improvement and/or maintenance of at least a 2-point

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Nov. 1, 2025	– Prolongation of F-wave latency in 2 nerves – Absence of F-waves in at least 1 nerve – Partial motor conduction block of at least 1 motor nerve – Abnormal temporal dispersion in at least 2 nerves – Distal CMAP duration increase in at least 1 nerve ○ Trial and failure (after a trial of at least two months), contraindication, or intolerance to corticosteroids ○ One of the following: ▪ Trial and failure (after a trial of at least three months) to an immune globulin (i.e., intravenous immunoglobulin or subcutaneous immunoglobulin) ▪ Both of the following: – Intolerance to all immune globulins (i.e., intravenous immunoglobulin or subcutaneous immunoglobulin) – Dose has been adjusted or escalated to the maximally allowable and/or	improvement (reduction in score) in the MG-ADL score from pre-treatment baseline; **and** ▪ Reduction in signs and symptoms of myasthenia gravis; **and** ▪ Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Rystiggo (**Note**: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on Rystiggo therapy will be considered as treatment failure) **and** ○ Patient is not receiving Rystiggo in combination with a complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]; **and** ○ Patient is not receiving Rystiggo in combination with another FcRn blocker [e.g., Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)]; **and** ○ Patient is not receiving Rystiggo in combination with an immune globulin; **and** ○ Patient is not being given Rystiggo sooner than 63 days from the start of the previous treatment cycle; **and** ○ Rystiggo is dosed according to the U.S. FDA labeled dosing for gMG; **and** ○ Prescribed by, or in consultation with, a neurologist; **and** ○ Reauthorization will be for no more than 12 months **Vyvgart and Vyvgart Hytrulo are proven and medically necessary for the treatment of generalized myasthenia gravis in patients who are anti-AChR antibody positive when all of the following criteria are met:** • **Initial Therapy** ○ Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming **all** of the following: ▪ Patient has not failed a previous course of Vyvgart therapy; **and** ▪ Patient has not failed a previous course of Vyvgart Hytrulo therapy; **and** ▪ Diagnosis of generalized myasthenia gravis (gMG); **and** ▪ Positive serologic test for anti-AChR antibodies; **and** ▪ Patient has a Myasthenia Gravis Foundation of America (MGFA)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Nov. 1, 2025	tolerated dose ▪ Contraindication to all immune globulins (i.e., intravenous immunoglobulin or subcutaneous immunoglobulin) ○ Patient is not receiving Vyvgart Hytrulo in combination with an immune globulin ○ Vyvgart Hytrulo is dosed according to the U.S. FDA labeled dosing for CIDP ○ Prescribed by, or in consultation with, a neurologist ○ Initial authorization will be for no more than 12 months **Applicable Codes** • Added HCPCS code C9305 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	Clinical Classification of class II, III, or IV at initiation of therapy; **and** ▪ Patient has a Myasthenia Gravis Activities of Daily Living scale (MG-ADL) total score ≥ 5 at initiation of therapy **and** ○ **One** of the following: ▪ History of failure of at least **two** immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.); **or** ▪ Patient has a history of failure of at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/plasma exchanges and/or immune globulin over the course of at least 12 months without symptom control **and** ○ Patient is not receiving Vyvgart or Vyvgart Hytrulo in combination with a complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]; **and** ○ Patient is not receiving Vyvgart or Vyvgart Hytrulo in combination with another FcRn blocker [e.g., Rystiggo (rozanolixizumab-noli)]; **and** ○ Patient is not receiving Vyvgart or Vyvgart Hytrulo in combination with an immune globulin; **and** ○ Patient will be given Vyvgart or Vyvgart Hytrulo no sooner than 50 days from the start of the previous treatment cycle; **and** ○ Vyvgart or Vyvgart Hytrulo is dosed according to the U.S. FDA labeled dosing for gMG; **and** ○ Prescribed by, or in consultation with, a neurologist; **and** ○ Initial authorization will be for no more than 12 months • **Continuation of Therapy** ○ Patient has previously been treated with Vyvgart or Vyvgart Hytrulo; **and** ○ Submission of medical records (e.g., chart notes, laboratory tests) demonstrating **all** of the following: ▪ Improvement and/or maintenance of at least a 2-point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline; **and** ▪ Reduction in signs and symptoms of myasthenia gravis; **and**

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Nov. 1, 2025		▪ Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Vyvgart or Vyvgart Hytrulo (**Note**: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on Vyvgart® or Vyvgart Hytrulo therapy will be considered as treatment failure) **and** ○ Patient is not receiving Vyvgart or Vyvgart Hytrulo in combination with a complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]; **and** ○ Patient is not receiving Vyvgart or Vyvgart Hytrulo in combination with another FcRn blocker [e.g., Rystiggo (rozanolixizumab-noli)]; **and** ○ Patient is not receiving Vyvgart or Vyvgart Hytrulo in combination with an immune globulin; **and** ○ Patient is not being given Vyvgart or Vyvgart Hytrulo sooner than 50 days from the start of the previous treatment cycle; **and** ○ Vyvgart or Vyvgart Hytrulo is dosed according to the U.S. FDA labeled dosing for gMG; **and** ○ Prescribed by or in consultation with a neurologist; **and** ○ Reauthorization will be for no more than 12 months **Vyvgart Hytrulo is proven and medically necessary for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) when all of the following criteria are met:** • **Initial Therapy** ○ Patient has not failed a previous course of Vyvgart Hytrulo therapy; **and** ○ Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) as confirmed by **all** of the following: ▪ Progressive symptoms present for at least 2 months; **and** ▪ Symptomatic polyradiculoneuropathy as indicated by progressive or relapsing motor or sensory impairment of more than one limb; **and** ▪ Electrodiagnostic findings (consistent with EFNS/PNS guidelines for definite CIDP) indicating the presence of at least **one** of the following: – Motor distal latency prolongation in 2 nerves; **or**

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FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Nov. 1, 2025		– Reduction of motor conduction velocity in 2 nerves; **or** – Prolongation of F-wave latency in 2 nerves; **or** – Absence of F-waves in at least 1 nerve; **or** – Partial motor conduction block of at least 1 motor nerve; **or** – Abnormal temporal dispersion in at least 2 nerves; **or** – Distal CMAP duration increase in at least 1 nerve **and** ○ Trial and failure (after a trial of at least two months), contraindication, or intolerance to corticosteroids; **and** ○ **One** of the following: ▪ Trial and failure (after a trial of at least three months) to an immune globulin (i.e., intravenous immunoglobulin or subcutaneous immunoglobulin); **or** ▪ **Both** of the following: – Intolerance to all immune globulins (i.e., intravenous immunoglobulin or subcutaneous immunoglobulin); **and** – Dose has been adjusted or escalated to the maximally allowable and/or tolerated dose **or** ▪ Contraindication to **all** immune globulins (i.e., intravenous immunoglobulin or subcutaneous immunoglobulin) **and** ○ Patient is not receiving Vyvgart Hytrulo in combination with an immune globulin; **and** ○ Vyvgart Hytrulo is dosed according to the U.S. FDA labeled dosing for CIDP; **and** ○ Prescribed by, or in consultation with, a neurologist; **and** ○ Initial authorization will be for no more than 12 months • **Continuation of Therapy** ○ Patient has previously been treated with Vyvgart Hytrulo; **and** ○ Documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]; **and** ○ Patient is not receiving Vyvgart Hytrulo in combination with an immune globulin; **and** ○ Vyvgart Hytrulo is dosed according to the U.S. FDA labeled dosing for CIDP; **and**

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FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Nov. 1, 2025		○ Prescribed by, or in consultation with, a neurologist; **and** ○ Reauthorization will be for no more than 12 months
Long-Acting Injectable Antiretroviral Agents for HIV	Nov. 1, 2025	**Coverage Rationale** • Revised list of applicable long-acting injectable antiretroviral products; added Yeztugo (lenacapavir) • Added language to indicate: ○ This policy refers to Sunlenca injection and Yeztugo injection for administration by a healthcare professional; Sunlenca oral tablets and Yeztugo oral tablets are obtained under the pharmacy benefit ○ Yeztugo (lenacapavir) is proven and medically necessary to reduce the risk of sexually acquired HIV-1 infection in at-risk adults and adolescents weighing at least 35kg when the following additional criteria are met: ***Initial Therapy*** ▪ Used for HIV-1 pre-exposure prophylaxis (PrEP) ▪ Patient has a negative HIV-1 test ▪ Provider confirms that the patient will be tested for HIV-1 infection with each subsequent injection ▪ Dosing is in accordance	This policy refers to the following long-acting injectable antiretroviral products: • Apretude (cabotegravir) • Cabenuva (cabotegravir/rilpivirine) • Sunlenca (lenacapavir) • Yeztugo (lenacapavir) This policy refers to Sunlenca injection and Yeztugo injection for administration by a healthcare professional. Sunlenca oral tablets and Yeztugo oral tablets are obtained under the pharmacy benefit. **Apretude (cabotegravir) is proven and medically necessary to reduce the risk of sexually acquired HIV-1 infection in at-risk adults and adolescents weighing at least 35 kg when the following criteria are met:** • For **initial therapy**, **all** of the following: ○ Used for HIV-1 pre-exposure prophylaxis (PrEP); **and** ○ Patient has a negative HIV-1 test; **and** ○ Provider confirms that the patient will be tested for HIV-1 infection with each subsequent injection; **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Initial authorization is for no more than 12 months • For **continuation therapy**, **all** of the following: ○ Patient has previously received treatment with Apretude; **and** ○ Patient has a negative HIV-1 test; **and** ○ Provider confirms that the patient will be tested for HIV-1 infection with each subsequent injection; **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Authorization is for no more than 12 months **Apretude is unproven and not medically necessary for the treatment of human immunodeficiency virus type-1 (HIV-1).**

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Long-Acting Injectable Antiretroviral Agents for HIV (continued)	Nov. 1, 2025	with the U.S. FDA approved labeling ▪ Initial authorization is for no more than 12 months ***Continuation of Therapy*** ▪ Patient has previously received treatment with Yeztugo ▪ Patient has a negative HIV-1 test ▪ Provider confirms that the patient will be tested for HIV-1 infection with each subsequent injection ▪ Dosing is in accordance with the U.S. FDA approved labeling ▪ Authorization is for no more than 12 months ○ Yeztugo is unproven and not medically necessary for the treatment of human immunodeficiency virus type-1 (HIV-1) **Applicable Codes** • Updated list of applicable HCPCS codes to reflect quarterly edits: ○ Added J0738 ○ Revised description for J1961 **Supporting Information** • Updated *Background*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	**Cabenuva (cabotegravir/rilpivirine) is proven and medically necessary for the treatment of a human immunodeficiency virus type-1 (HIV-1) in patients who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) when the following criteria are met:** • For **initial therapy**, **all** of the following: ○ Diagnosis of HIV-1 infection; **and** ○ Patient has no prior virologic failures or baseline resistance to either cabotegravir or rilpivirine; **and** ○ Patient is currently on a stable antiretroviral regimen; **and** ○ Provider attests that patient has achieved viral suppression (HIV-1 RNA less than 50 copies per mL) for at least 3 months prior to initiation of Cabenuva; **and** ○ Provider attests that patient demonstrates treatment readiness by **both** of the following: ▪ Patient understands the risks of missed doses of Cabenuva; **and** ▪ Patient has the ability to adhere to the required monthly or every 2 months injection appointments **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Initial authorization is for no more than 12 months • For **continuation therapy**, **all** of the following: ○ Patient has previously received treatment with Cabenuva; **and** ○ Provider confirms that the patient has achieved and maintained viral suppression (HIV-1 RNA less than 50 copies per mL) while on Cabenuva 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 **Cabenuva is unproven and not medically necessary for the treatment of human immunodeficiency virus type-1 (HIV-1) in patients who are not currently virally suppressed (HIV-1 RNA less than 50 copies per mL).** **Sunlenca (lenacapavir) is proven and medically necessary for the treatment of multi-drug resistant human immunodeficiency virus (HIV) in patients who meet all of the following criteria:**

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Long-Acting Injectable Antiretroviral Agents for HIV (continued)	Nov. 1, 2025		• For **initial therapy**, **all** of the following:
			  ○ **Both** of the following:
			  ▪ Diagnosis of HIV-1 infection; **and**
			  ▪ Provider attestation that the patient has multi-drug resistant HIV-1 infection
			  and
			  ○ Provider confirms that the patient has been prescribed an optimized background antiretroviral regimen, containing at least one antiretroviral agent that demonstrates full viral sensitivity/susceptibility; **and**
			  ○ Sunlenca initial and maintenance dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
			  ○ Initial authorization is for no more than 12 months
			• For **continuation therapy**, **all** of the following:
			  ○ Patient has previously received treatment with Sunlenca; **and**
			  ○ Provider confirms that the patient has achieved a clinically significant viral response to Sunlenca therapy; **and**
			  ○ Provider confirms that the patient will continue to take an optimized background antiretroviral regimen, in combination with Sunlenca; **and**
			  ○ Sunlenca maintenance dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
			  ○ Authorization is for no more than 12 months
			
			Sunlenca is unproven and not medically necessary for the treatment of human immunodeficiency virus type-1 (HIV-1) in patients who are virologically suppressed (HIV-1 RNA less than 50 copies per mL), for the treatment of HIV-1 in antiretroviral (ARV) naïve patients, and for HIV-1 pre-exposure prophylaxis (PrEP).
			
			Yeztugo (lenacapavir) is proven and medically necessary to reduce the risk of sexually acquired HIV-1 infection in at-risk adults and adolescents weighing at least 35kg when the following additional criteria are met:
			• For **initial therapy**, **all** of the following:
			  ○ Used for HIV-1 pre-exposure prophylaxis (PrEP); **and**
			  ○ Patient has a negative HIV-1 test; **and**
			  ○ Provider confirms that the patient will be tested for HIV-1 infection

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Long-Acting Injectable Antiretroviral Agents for HIV (continued)	Nov. 1, 2025		with each subsequent injection; **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Initial authorization is for no more than 12 months • For **continuation therapy**, **all** of the following: ○ Patient has previously received treatment with Yeztugo; **and** ○ Patient has a negative HIV-1 test; **and** ○ Provider confirms that the patient will be tested for HIV-1 infection with each subsequent injection; **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Authorization is for no more than 12 months **Yeztugo is unproven and not medically necessary for the treatment of human immunodeficiency virus type-1 (HIV-1).**
Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease	Nov. 1, 2025	**Coverage Rationale** • Replaced language indicating: ○ "Kisunla (donanemab-azbt)/Leqembi (lecanemab-irmb) *may be covered* for the treatment of Alzheimer's disease (AD) *in patients who meet* all of the [listed] criteria" with "Kisunla (donanemab-azbt)/Leqembi (lecanemab-irmb) *is medically necessary* for the treatment of Alzheimer's disease (AD) *when* all of the [listed] criteria *are met*" ○ "Kisunla (donanemab-azbt)/Leqembi (lecanemab-irmb) is unproven and not medically necessary for any indication other than *mild cognitive impairment due to* Alzheimer's disease *and mild*	**This policy refers to the following drug products:** • Kisunla™ (donanemab-azbt) • Leqembi® (lecanemab-irmb) **Kisunla (donanemab-azbt) is medically necessary for the treatment of Alzheimer's disease (AD) when all of the following criteria are met:** • For **initial therapy**, **all** of the following: ○ Diagnosis of **one** of the following based on National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria: ▪ Mild cognitive impairment (MCI) due to Alzheimer's disease; **or** ▪ Mild dementia due to Alzheimer's disease **and** ○ Submission of medical records (e.g., chart notes, laboratory values) documenting **one** of the following: ▪ Mini-Mental State Examination (MMSE) score of 20 to 30; **or** ▪ Montreal Cognitive Assessment (MoCA) score of 17 to 30; **or** ▪ Saint Louis University Mental Status (SLUMS) score of 17 to 30 **and** ○ Submission of medical records (e.g., chart notes, laboratory values) documenting the presence of amyloid beta pathology, as evidenced by positive amyloid positron emission tomography (PET) brain imaging; **and**

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (continued)	Nov. 1, 2025	*Alzheimer's disease dementia*" with "Kisunla (donanemab-azbt)/Leqembi (lecanemab-irmb) is unproven and not medically necessary for any indication other than Alzheimer's disease" • Revised medical necessity criteria: ○ Replaced references to "positron emission tomography (PET) brain *scan*" with "PET brain *imaging*" ***Initial Therapy*** ○ Removed criterion requiring submission of medical records (e.g., chart notes, laboratory values) documenting: ▪ Global Clinical Dementia Rating (CDR) score of 0.5 or 1.0 ▪ CDR Memory Box score of 0.5 or greater ○ Replaced criterion requiring: ▪ "Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following: Mini-Mental State Examination (MMSE) score of 20 *or greater*, Montreal Cognitive Assessment (MoCA) score of 17 *or greater*, or Saint Louis	○ Other differential diagnoses [e.g., dementia with Lewy bodies (DLB), frontotemporal dementia (FTD), vascular dementia, pseudodementia due to mood disorder, vitamin B12 deficiency, encephalopathy, etc.] have been ruled out; **and** ○ **One** of the following: ▪ Patient is not currently taking an anticoagulant (e.g., warfarin, dabigatran); **or** ▪ **Both** of the following: – Patient is currently taking an anticoagulant (e.g., warfarin, dabigatran); **and** – Counseling has been provided that the combined use of Kisunla with anti-coagulant drugs may increase the risk of cerebral macrohemorrhage and prescriber attests that the patient has shared in decision-making to initiate Kisunla therapy **and** ○ Patient has no history of intracerebral hemorrhage within the previous year prior to initiating treatment; **and** ○ Counseling has been provided on the risk of amyloid-related imaging abnormalities [ARIA characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin (ARIA-H)] and patient is aware to monitor for headache, dizziness, visual disturbances, nausea, and vomiting; **and** ○ **All** of the following: ▪ Counseling has been provided on how testing for apolipoprotein E (ApoE) epsilon 4 (ε 4) status informs the risk of developing ARIA when deciding to initiate treatment with Kisunla; **and** ▪ Testing for ApoE ε4 status has been offered to the patient and prescriber attests that the patient has shared in decision-making to initiate Kisunla therapy **and** ○ A baseline brain magnetic resonance imaging (MRI) has been completed within 12 months prior to initiating treatment; **and** ○ Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's disease (e.g., Leqembi); **and** ○ Prescribed by a neurologist, geriatric psychiatrist, or geriatrician who specializes in treating dementia; **and**

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Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (continued)	Nov. 1, 2025	University Mental Status (SLUMS) score of 17 *or greater*" with "submission of medical records (e.g., chart notes, laboratory values) documenting one of the following: Mini-Mental State Examination (MMSE) score of 20 *to 30*, Montreal Cognitive Assessment (MoCA) score of 17 *to 30*, or Saint Louis University Mental Status (SLUMS) score of 17 *to 30*" ▪ "Submission of medical records (e.g., chart notes, laboratory values) documenting the presence of *beta-amyloid protein deposition*" with "submission of medical records (e.g., chart notes, laboratory values) documenting the presence of *amyloid beta pathology*" ***Continuation of Therapy*** ○ Added criterion requiring both of the following: ▪ The patient has progressed into moderate or severe stages of dementia due to Alzheimer's disease ▪ The prescriber attests that the patient has	○ Kisunla dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Initial authorization will be for no more than 6 months • For **continuation of therapy**, **all** of the following: ○ One of the following [**Note**: diagnoses based on National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria]: ▪ Patient has mild cognitive impairment (MCI) due to Alzheimer's disease; **or** ▪ Patient has mild dementia due to Alzheimer's disease; **or** ▪ **Both** of the following: – Patient has progressed into moderate or severe stages of dementia due to Alzheimer's disease; **and** – Prescriber attests that the patient has shared in decision-making to continue Kisunla therapy **and** ○ **One** of the following: ▪ **Both** of the following: – Patient has received Kisunla therapy for less than or equal to 6 months; **and** – **One** of the following: • Post-treatment amyloid PET brain imaging is positive for amyloid based on visual read; **or** • Prescriber attests that amyloid PET imaging will be performed prior to 18 months of total treatment to assess for the effect of Kisunla treatment on amyloid plaque **or** ▪ **Both** of the following: – Patient has received Kisunla therapy for greater than 6 months; **and** – **Both** of the following: • Post-treatment amyloid PET brain imaging obtained between 12 and 18 months of total treatment is positive for amyloid based on visual read; **and** • For treatment beyond 18 months of therapy, post-treatment amyloid PET brain imaging is performed at least once per 12 months and is positive for amyloid based on visual read

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Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (continued)	Nov. 1, 2025	shared in decision-making to continue Kisunla/Leqembi therapy ○ Removed criterion requiring submission of current medical records (e.g., chart notes, laboratory values) documenting that the patient continues to meet all of the following (updated assessments must be measured no earlier than 4 weeks prior to a continuation request): ▪ Global Clinical Dementia Rating (CDR) score of 0.5 or 1.0 ▪ CDR Memory Box score of 0.5 or greater ▪ One of the following: – Mini-Mental State Examination (MMSE) score of 20 or greater – Montreal Cognitive Assessment (MoCA) score of 17 or greater – Saint Louis University Mental Status (SLUMS) score of 17 or greater ○ Replaced criterion for **Kisunla** requiring "post-treatment amyloid PET brain *scan performed < 1 month prior to request for continued treatment* is positive for amyloid based on visual read"	**and** ○ **Both** of the following: ▪ Submission of medical records (e.g., chart notes) confirming follow-up brain magnetic resonance imaging (MRI) has been completed after the initiation of therapy; **and** ▪ **One** of the following: – ARIA has not been observed on MRI; **or** – All of the following: • ARIA has been observed on MRI; **and** • Prescriber attests that continuation of therapy with Kisunla is appropriate based on the severity of the patient's clinical symptoms; **and** • **One** of the following: ○ Follow-up MRI demonstrates radiographic resolution and/or stabilization; **or** ○ Prescriber attests that continuation of therapy with Kisunla is appropriate based on the radiographic severity of ARIA **and** ○ Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's disease (e.g., Leqembi); **and** ○ Prescribed by a neurologist, geriatric psychiatrist, or geriatrician who specializes in treating dementia; **and** ○ Kisunla dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Reauthorization is for no more than 12 months **Kisunla (donanemab-azbt) is unproven and not medically necessary for any indication other than Alzheimer's disease.** **Leqembi (lecanemab-irmb) is medically necessary for the treatment of Alzheimer's disease (AD) when all of the following criteria are met:** • For **initial therapy**, **all** of the following: ○ Diagnosis of **one** of the following based on National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria: ▪ Mild cognitive impairment (MCI) due to Alzheimer's disease; **or** ▪ Mild dementia due to Alzheimer's disease **and**

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Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (continued)	Nov. 1, 2025	with "post-treatment amyloid PET brain *imaging* is positive for amyloid based on visual read" **Supporting Information** • Updated *Background*, *Clinical Evidence*, and *References* sections to reflect the most current information	○ Submission of medical records (e.g., chart notes, laboratory values) documenting **one** of the following: ▪ Mini-Mental State Examination (MMSE) score of 20 to 30; **or** ▪ Montreal Cognitive Assessment (MoCA) score of 17 to 30; **or** ▪ Saint Louis University Mental Status (SLUMS) score of 17 to 30 **and** ○ Submission of medical records (e.g., chart notes, laboratory values) documenting the presence of amyloid beta pathology, as evidenced by **one** of the following: ▪ Positive amyloid positron emission tomography (PET) brain imaging; **or** ▪ Cerebrospinal fluid (CSF) biomarker testing documents abnormalities suggestive of beta-amyloid accumulation in the brain (e.g., Aβ42/40 ratio, p-tau 181/Aβ42 ratio, t-tau/Aβ 42 ratio) **and** ○ Other differential diagnoses [e.g., dementia with Lewy bodies (DLB), frontotemporal dementia (FTD), vascular dementia, pseudodementia due to mood disorder, vitamin B12 deficiency, encephalopathy, etc.] have been ruled out; **and** ○ **One** of the following: ▪ Patient is not currently taking an anticoagulant (e.g., warfarin, dabigatran); **or** ▪ **Both** of the following: – Patient is currently taking an anticoagulant (e.g., warfarin, dabigatran); **and** – Counseling has been provided that the combined use of Leqembi with anti-coagulant drugs may increase the risk of cerebral macrohemorrhage and prescriber attests that the patient has shared in decision-making to initiate Leqembi therapy **and** ○ Patient has no history of intracerebral hemorrhage within the previous year prior to initiating treatment; **and** ○ Counseling has been provided on the risk of amyloid-related imaging abnormalities [ARIA characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin (ARIA-H)] and patient is aware to monitor for headache, dizziness, visual disturbances, nausea, and

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (continued)	Nov. 1, 2025		vomiting; **and** ○ **All** of the following: ▪ Counseling has been provided on how testing for apolipoprotein E (ApoE) epsilon 4 (ε 4) status informs the risk of developing ARIA when deciding to initiate treatment with Leqembi; **and** ▪ Testing for ApoE ε4 status has been offered to the patient and prescriber attests that the patient has shared in decision-making to initiate Leqembi therapy **and** ○ A baseline brain magnetic resonance imaging (MRI) has been completed within 12 months prior to initiating treatment; **and** ○ Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's disease (e.g., Kisunla); **and** ○ Prescribed by a neurologist, geriatric psychiatrist, or geriatrician who specializes in treating dementia; **and** ○ Leqembi dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Initial authorization will be for no more than 6 months • For **continuation of therapy**, **all** of the following: ○ **One** of the following [**Note**: diagnoses based on National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria]: ▪ Patient has mild cognitive impairment (MCI) due to Alzheimer's disease; **or** ▪ Patient has mild dementia due to Alzheimer's disease; **or** ▪ **Both** of the following: – Patient has progressed into moderate or severe stages of dementia due to Alzheimer's disease; **and** – Prescriber attests that the patient has shared in decision-making to continue Leqembi therapy **and** ○ **Both** of the following: ▪ Submission of medical records (e.g., chart notes) confirming follow-up brain magnetic resonance imaging (MRI) has been completed after the initiation of therapy; **and** ▪ **One** of the following: – ARIA has not been observed on MRI; **or** – **All** of the following:

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Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (continued)	Nov. 1, 2025		• ARIA has been observed on MRI; **and** • Prescriber attests that continuation of therapy with Leqembi is appropriate based on the severity of the patient's clinical symptoms; **and** • **One** of the following: ○ Follow-up MRI demonstrates radiographic resolution and/or stabilization; **or** ○ Prescriber attests that continuation of therapy with Leqembi is appropriate based on the radiographic severity of ARIA **and** ○ Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's disease (e.g., Kisunla); **and** ○ Prescribed by a neurologist, geriatric psychiatrist, or geriatrician who specializes in treating dementia; **and** ○ Leqembi dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Reauthorization is for no more than 12 months **Leqembi (lecanemab-irmb) is unproven and not medically necessary for any indication other than Alzheimer's disease.**
Synagis® (Palivizumab)	Nov. 1, 2025	**Coverage Rationale** • Revised coverage criteria; replaced criterion requiring "the patient has not previously received treatment with Beyfortus (nirsevimab-alip) during or entering the current RSV 'season'" with "the patient has not previously received treatment with Beyfortus (nirsevimab-alip) *or Enflonsia (clesrovimab-cfor)* during or entering the current RSV 'season'" ***Additional Information*** • Revised language pertaining to seasonality of RSV to indicate:	**Synagis (palivizumab) is proven and medically necessary to prevent serious lower respiratory tract disease caused by respiratory syncytial virus disease (RSV) in high risk infants and young children when all of the following are met:** • Administered during RSV "season" as defined by Centers for Disease and Prevention (CDC) surveillance reports (NREVSS Interactive Dashboard) or state or local health departments to confirm the start of the respiratory syncytial virus (RSV) "season"; **and** • Monthly dose of Synagis does not exceed 15 mg/kg per dose; **and** • Dosage of Synagis does not exceed 5 monthly doses per single RSV "season"; **and** (**Note**: Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the "season". Any subsequent doses received in the

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Synagis® (Palivizumab) (continued)	Nov. 1, 2025	○ Because the timing of the onset, peak, and decline of RSV activity might vary geographically, providers can adjust administration schedules based on local epidemiology ○ RSV seasonality in tropical climates (including southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and U.S. Virgin Islands) might differ from that of most of the continental United States or be unpredictable ○ In Alaska, RSV seasonality is less predictable, and the duration of RSV activity is often longer than the national average duration **Supporting Information** • Updated *Background*, *Clinical Evidence*, and *References* sections to reflect the most current information	hospital setting are also considered as part of the maximum 5 dose series. For infants born during the RSV "season", fewer than 5 monthly doses may be needed.) • **One** of the following clinical situations: ○ **Prematurity:** ▪ Infants born before 29 weeks, 0 day's gestation who are < 12 months of age at the start of RSV "season" ○ **Chronic Lung Disease (CLD):** ▪ Age 0 to < 12 months: – Prophylaxis may be considered during the RSV "season" during the first year of life for preterm infants who develop chronic lung disease (CLD) of prematurity defined as gestational age < 32 weeks, 0 days, and a requirement for > 21% oxygen for at least the first 28 days after birth. ▪ Age ≥ 12 to < 24 months: – Synagis is proven for use in pre-term infants born at < 32 weeks, 0 day's gestation who are ≥ 12 to < 24 months of age who required at least 28 days of oxygen after birth and who continue to require supplemental oxygen, diuretics, or chronic systemic corticosteroid therapy within 6 months of the start of the second RSV "season". ○ **Congenital Heart Disease (CHD):** ▪ Age 0 to < 12 months: – Infants and children with hemodynamically significant CHD who are born within 12 months of onset of RSV "season" and who will most likely benefit from immunoprophylaxis include: • Infants and children with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures • Infants and children with moderate to severe pulmonary hypertension • Documentation that decisions regarding Synagis prophylaxis for infants with cyanotic heart defects in the first year of life were made in consultation with a pediatric cardiologist ▪ Age < 24 months:

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Synagis® (Palivizumab) (continued)	Nov. 1, 2025		– A postoperative dose for children who still require prophylaxis and who have undergone surgical procedures should be administered Synagis prophylaxis after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation • Children who undergo cardiac transplantation during the RSV "season" may be considered for Synagis prophylaxis. ○ **Congenital abnormalities of the airway or neuromuscular disease:** ▪ Age 0 to < 12 months: – Infants and children with neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the lower airway because of ineffective cough may be considered for prophylaxis during the first year of life ○ **Immunocompromised children < 24 months of age:** ▪ Synagis may be administered when used for prophylaxis in children who are receiving cancer chemotherapy or are severely immunocompromised although the efficacy of prophylaxis in this population is unknown (e.g., children who are receiving chemotherapy or undergo hematopoietic stem cell transplantation or solid organ transplantation). ○ **Cystic fibrosis (CF) with other qualifying indications:** ▪ Age 0 to < 12 months: – Infants and children with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise in the first year of life may be considered for prophylaxis • Failure to thrive defined as weight for length less than the 10th percentile on a pediatric growth chart ▪ Age ≥ 12 to < 24 months: – Continued use of Synagis prophylaxis in the second year may be considered for infants and children with manifestations of severe lung disease including: • Previous hospitalization for pulmonary exacerbation in the first year of life • Abnormalities on chest radiography or chest computed tomography that persists when stable

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Synagis® (Palivizumab) (continued)	Nov. 1, 2025		• Weight for length less than the 10th percentile on a pediatric growth chart **and** • Patient has not previously received treatment with Beyfortus (nirsevimab-alip) or Enflonsia (clesrovimab-cfor) during or entering the current RSV "season" **Synagis is unproven for the following situations:** • Infants with chronic lung disease (CLD) who do not continue to require medical support in the second year of life • Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus) • Infants with cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure • Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy • Children in the second year of life unless otherwise indicated as proven above • Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (< 29 weeks, 0 day's gestation) is present] • Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present) • Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab • Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children • Synagis prophylaxis for prevention of nosocomial disease • When Synagis prophylaxis is administered in any of the following scenarios: o Outside of the RSV "season" o In doses greater than needed to provide protection in the RSV "season"

Medical Benefit Drug Policy Updates

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Synagis® (Palivizumab) (continued)	Nov. 1, 2025		○ In excess of 5 doses per single RSV "season" ○ To persons other than those at defined high risk, as specified above • Treatment of symptomatic RSV disease **Additional Information** Because the timing of the onset, peak, and decline of RSV activity might vary geographically, providers can adjust administration schedules based on local epidemiology. RSV seasonality in tropical climates (including southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and U.S. Virgin Islands) might differ from that of most of the continental United States or be unpredictable. In Alaska, RSV seasonality is less predictable, and the duration of RSV activity is often longer than the national average duration. For analysis of National Respiratory and Enteric Virus Surveillance System (NREVSS) reports in the CDC Morbidity and Mortality Weekly Report, season onset is defined as the first of 2 consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is ≥ 10% or the mean percentage of specimens testing positive for RSV by PCR is ≥ 3%, whichever occurs first. RSV "season" offset is defined as the last week during which the mean percentage of positive specimens by antigen is ≥ 10%, or the mean percentage of positive specimens by PCR is ≥ 3%, whichever occurs last. Use of specimens to determine the start of the RSV "season" requires that the number of specimens tested be statistically significant.

General Information

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

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

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

Policy Update Classifications

New

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

Updated

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

Revised

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

Replaced

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

Retired

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

The complete library of UnitedHealthcare Community Plan of Tennessee Medical Policies and Medical Benefit Drug Policies is available at **UHCprovider.com/TN** > Community Plan (Medicaid) > Current Policies and Clinical Guidelines > Medical & Drug Policies.