United Healthcare Community Plan

# *UnitedHealthcare Community Plan*
# Medical Policy Update Bulletin: July 2025

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# Take Note

## Quarterly CPT/HCPCS Code Updates

Effective **Jul. 1, 2025**, the following Medical Policies and Medical Benefit Drug Policies will be updated to reflect the quarterly Current Procedural Terminology (CPT®) and Healthcare Common Procedure Coding System (HCPCS) code additions, revisions, and deletions. Refer to the following sources for information on the code updates:

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

| Policy Title | Policy Type | Summary of Changes |
|---|---|---|
| Factor Mimetics and Rebalancing Agents for Hemophilia | Medical Benefit Drug Policy | • Added HCPCS code J7172<br>• Removed HCPCS code C9304 |
| Gastrointestinal Pathogen Nucleic Acid Detection Panel Testing for Infectious Diarrhea | Medical Policy | • Removed CPT code 0369U |
| Gonadotropin Releasing Hormone Analogs | Medical Benefit Drug Policy | • Revised description for HCPCS code J1954 |
| Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and Treatment Decisions | Medical Policy | • Added CPT codes 0560U and 0561U |
| Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions | Medical Policy | • Added CPT codes 0562U, 0565U, 0566U, 0569U, 0571U, and 0572U |
| Oncology Medication Clinical Coverage | Medical Benefit Drug Policy | • Added HCPCS code J9289<br>• Revised description for HCPCS codes J1954 and J9292 |
| Preimplantation Genetic Testing and Related Services | Medical Policy | • Added CPT codes 0552U, 0553U, 0554U, and 0555U |
| Ustekinumab | Medical Benefit Drug Policy | • Added HCPCS codes Q5098, Q5099, and Q5100<br>• Revised description for HCPCS code Q9998 |
| Whole Exome and Whole Genome Sequencing (Non-Oncology Conditions) | Medical Policy | • Added CPT code 0567U |

# Medical Policy Updates

## Updated

| Policy Title | Effective Date | Summary of Changes |
|---|---|---|
| Carrier Testing Panels for Genetic Diseases | Jul. 1, 2025 | **Medical Records Documentation Used for Reviews**<br>• Added language to indicate:<br>  ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service<br>  ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews<br>**Definitions**<br>• Updated definition of "Gene Panel"<br>**Supporting Information**<br>• Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information |
| Chromosome Microarray Testing (Non-Oncology Conditions) | Jul. 1, 2025 | **Medical Records Documentation Used for Reviews**<br>• Added language to indicate:<br>  ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service<br>  ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews<br>**Supporting Information**<br>• Updated *Clinical Evidence* and *References* sections to reflect the most current information |
| Manipulative Therapy | Jul. 1, 2025 | **Template Update**<br>• Removed content/language pertaining to the state of Mississippi<br>**Definitions**<br>• Added definition of "Upledger Technique"<br>**Supporting Information**<br>• Updated *Clinical Evidence* and *References* sections to reflect the most current information |
| Surgery of the Hand or Wrist | Jul. 1, 2025 | **Medical Records Documentation Used for Reviews**<br>• Added language to indicate:<br>  ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service<br>  ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews |

# Medical Policy Updates

## Revised

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| Cardiovascular Disease Risk Tests | Sep. 1, 2025 | **Coverage Rationale**<br>• Revised list of unproven and not medically necessary services; added "cardiovascular disease (HDL reverse cholesterol transport), cholesterol efflux capacity, LC-MS/MS, quantitative measurement of 5 distinct HDL-bound apolipoproteins (apolipoproteins A1, C1, C2, C3, and C4), with algorithm and reported as a risk score"<br>**Applicable Codes**<br>• Added CPT code 0541U<br>**Supporting Information**<br>• Updated *Clinical Evidence* and *References* sections to reflect the most current information | **The following are unproven and not medically necessary due to insufficient evidence of efficacy:**<br>• Arterial compliance testing, using waveform analysis as a method to determine risk for cardiovascular disease<br>• Carotid intima-media thickness (CIMT) measurement as an effective screening tool for the management of cardiovascular disease<br>• Advanced lipoprotein analysis [e.g., lipoprotein(a), subfractions, or particle size] as method to determine risk for cardiovascular disease<br>• Lipoprotein-associated phospholipase A2 (Lp-PLA2) enzyme as a method to determine risk for cardiovascular disease or ischemic stroke<br>• Endothelial function assessment using tools such as peripheral arterial tonometry (PAT) or brachial artery pressure ultrasound as a prognostic indicator to determine risk of cardiovascular disease<br>• Multi-protein diagnostic biomarker:<br>  ○ Analysis of protein biomarkers by aptamer-based microarray and algorithm<br>  ○ Cardiovascular disease (HDL reverse cholesterol transport), cholesterol efflux capacity, LC-MS/MS, quantitative measurement of 5 distinct HDL-bound apolipoproteins (apolipoproteins A1, C1, C2, C3, and C4), with algorithm and reported as a risk score<br>  ○ 3 proteins [high sensitivity (hs) troponin, adiponectin, and kidney injury molecule-1 (KIM-1)] with algorithm and reported as a risk score<br>  ○ 4-proteins [NT-proBNP, osteopontin, tissue inhibitor of metalloproteinase-1 (TIMP-1), and KIM-1] with algorithm and reported as a risk score<br>  ○ 7 proteins (IL-16, FAS, FASLigand, HGF, CTACK, EOTAXIN, and MCP-3) with algorithm and reported as a risk score |
| Prostate Surgeries and Interventions | Jul. 1, 2025 | **Notice of Revision**: The following summary of changes has been modified. Revisions to the previous policy update announcement are outlined in red below. Please take note of the additional updates to be applied on **Jul. 1, 2025**.<br>**Coverage Rationale**<br>• Removed coverage criteria for | **Transurethral Ablation**<br>**Transurethral ablation of the prostate is proven and medically necessary in certain circumstances.** For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Prostatectomy, Transurethral Ablation.<br><br>Click here to view the InterQual® criteria.<br><br>**Transurethral ablation of the prostate is unproven and not medically necessary for all other indications due to insufficient evidence of safety** |

**Revised**

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| Prostate Surgeries and Interventions (continued) | Jul. 1, 2025 | transperineal placement of biodegradable material<br>***Prostatic Urethral Lift***<br>• Revised coverage criteria for prostatic urethral lift; replaced criterion requiring "treating symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH), including lateral *and* median lobe hyperplasia, in men 45 years of age or older" with "treating symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH), including lateral, *with or without* median lobe hyperplasia, in men 45 years of age or older"<br>***Transurethral Water Jet Ablation***<br>• Replaced language indicating "transurethral water jet ablation is unproven and not medically necessary for all other indications [not listed as proven in the policy]" with "transurethral water jet ablation *for the treatment of malignant prostate tissue and* all other indications [not listed as proven in the policy] is unproven and not medically necessary *due to insufficient evidence of safety and/or efficacy*"<br>***Prostate Artery Embolization (PAE)***<br>• Replaced language indicating | **and/or efficacy.**<br><br>**Cryoablation**<br>**Cryoablation of the prostate is proven and medically necessary for recurrent prostate cancer diagnosed by biopsy.** For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Cryoablation, Prostate.<br><br>Click here to view the InterQual® criteria.<br><br>**Cryoablation of the prostate is unproven and not medically necessary for initial treatment of prostate cancer and for all other indications due to insufficient evidence of safety and/or efficacy.**<br><br>**Prostatic Urethral Lift**<br>**Prostatic urethral lift (PUL) is proven and medically necessary when performed according to the following U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions:**<br>• Treating symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH), including lateral, with or without median lobe hyperplasia, in men 45 years of age or older; and<br>• The following are not present:<br>○ Prostate volume of > 100 cc<br>○ A urinary tract infection<br>○ Urethra conditions that may prevent insertion of delivery system into bladder<br>○ Urinary incontinence due to incompetent sphincter<br>○ Current gross hematuria<br><br>**Prostatic urethral lift (PUL) is unproven and not medically necessary for all other indications due to insufficient evidence of safety and/or efficacy.**<br><br>**High Energy Water Vapor Thermotherapy**<br>**High-energy water vapor thermotherapy for the treatment of benign** |

**Revised**

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| Prostate Surgeries and Interventions (continued) | Jul. 1, 2025 | "prostate artery embolization is proven and medically necessary for individuals with ineligibility for other procedures due to surgical constraints (i.e., prostate size) or anesthesia risk (i.e., comorbidities)" with "prostate artery embolization is proven and medically necessary for individuals *with BPH who are* ineligible for other procedures due to surgical constraints (i.e., prostate size) or anesthesia risk (i.e., comorbidities)"<br>***Other Procedures***<br>• Revised list of unproven and not medically necessary procedures; added "transurethral thermal ultrasound ablation (TULSA)"<br>**Medical Records Documentation Used for Reviews**<br>• Added language to indicate:<br>○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service<br>○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to | **prostatic hyperplasia (BPH) is proven and medically necessary in certain circumstances.** For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Prostatectomy, Transurethral Ablation.<br><br>Click here to view the InterQual® criteria.<br><br>**High-energy water vapor thermotherapy for the treatment of malignant prostate tissue and all other indications is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.**<br><br>**Transurethral Water Jet Ablation**<br>**Transurethral water jet ablation of the prostate is proven and medically necessary for the resection and removal of prostate tissue for the treatment of lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia.**<br><br>**Transurethral water jet ablation for the treatment of malignant prostate tissue and all other indications is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.**<br><br>**Prostate Artery Embolization (PAE)**<br>**Prostate artery embolization is proven and medically necessary for individuals with any of the following:**<br>• Individuals with BPH who are ineligible for other procedures due to surgical constraints (i.e., prostate size) or anesthesia risk (i.e., comorbidities)<br>• Persistent gross hematuria originating from the prostate<br><br>**Prostate artery embolization is unproven and not medically necessary for all other indications due to insufficient evidence of safety and/or efficacy.**<br><br>**Other Procedures**<br>**The following procedures are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy:** |

# Medical Policy Updates

## Revised

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| Prostate Surgeries and Interventions (continued) | Jul. 1, 2025 | the guidelines titled Medical Records Documentation Used for Reviews<br>**Applicable Codes**<br>• Updated list of applicable CPT codes:<br>○ Added 51721, 53865*, 53866*, 55881, and 55882<br>○ Removed 55874<br>*(*annual edit)*<br>**Supporting Information**<br>• Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information | • Transperineal focal laser ablation<br>• Insertion of a temporary prostatic urethral stent<br>• Transperineal laser ablation (TPLA)<br>• Ablation of malignant prostate tissue by magnetic field induction<br>• Transurethral drug coated balloon dilation<br>• Transurethral thermal ultrasound ablation (TULSA) |

## Retired

| Policy Title | Effective Date | Summary of Changes |
|---|---|---|
| Intrauterine Fetal Surgery | Jul. 1, 2025 | • Retired policy; intrauterine fetal surgery no longer requires clinical review |
| Macular Degeneration Treatment Procedures | Jul. 1, 2025 | • Retired policy; macular degeneration treatment procedures no longer require clinical review |
| Pectus Deformity Repair | Jul. 1, 2025 | • Retired policy; pectus deformity repair no longer requires clinical review |

# Medical Benefit Drug Policy Updates

## New

| Policy Title | Effective Date | Coverage Rationale |
|---|---|---|
| Kebilidi™ (Eladocagene Exuparvovec-Tneq) | Aug. 1, 2025 | **Kebilidi is proven and medically necessary for the treatment of aromatic L-amino acid decarboxylase (AADC) deficiency in patients who meet all of the following criteria:**<br>• Submission of medical records documenting a diagnosis of AADC deficiency; **and**<br>• Submission of medical records documenting diagnosis has been confirmed by **all** of the following:<br>  ○ Presence of biallelic mutations in the dopa decarboxylase (*DDC*) gene; **and**<br>  ○ Patient has one or more of the following typical clinical characteristics associated with AADC deficiency (e.g., hypotonia, oculogyric crises, dystonia, hypokinesia, autonomic dysfunction, developmental delay); **and**<br>  ○ Decreased AADC enzyme activity in plasma per current laboratory standards<br>**and**<br>• Patient has achieved skull maturity, as confirmed by neuroimaging, necessary for stereotactic neurosurgical administration of Kebilidi; **and**<br>• Patient has persistent symptoms of AADC deficiency (e.g., hypotonia, oculogyric crises, dystonia, hypokinesia, autonomic dysfunction, developmental delay) despite use of standard medical therapy (e.g., dopamine agonists, monoamine oxidase inhibitors, pyridoxine, other forms of vitamin B6); **and**<br>• Patient is unable to ambulate independently; **and**<br>• Patient does not have an anti-adeno-associated virus, serotype 2 (anti-AAV2) antibody titer higher than 1:1200 or > 1 optical density value by enzyme-linked immunosorbent assay (ELISA); **and**<br>• Prescribed by a neurologist or neurosurgeon; **and**<br>• Patient has not previously received treatment with Kebilidi or other gene therapy for the treatment of AADC deficiency in their lifetime; **and**<br>• Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**<br>• Authorization will be issued for no more than one treatment per lifetime and for no longer than 60 days from approval |

## Updated

| Policy Title | Effective Date | Summary of Changes |
|---|---|---|
| Off-Label/Unproven Specialty Drug Treatment | Aug. 1, 2025 | **Application**<br>***Indiana***<br>• Added reference link to state-specific policy version<br>**Coverage Rationale**<br>• Removed notation indicating evidence limited to case studies or case series is not sufficient to meet the standard of this criterion (for peer-reviewed articles presented in a major peer-reviewed medical journal)<br>**Definitions**<br>• Updated definition of “Serious Rare Disease”<br>**Supporting Information**<br>• Updated *References* section to reflect the most current information |

# Medical Benefit Drug Policy Updates

## Revised

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| Factor Mimetics and Rebalancing Agents for Hemophilia | Aug. 1, 2025 | **Application**<br>***Arizona***<br>• Added language to indicate this policy does not apply to the state of **Arizona**<br>**Coverage Rationale**<br>• Revised list of applicable products and corresponding brand names; added antithrombin-directed small interfering ribonucleic acid (siRNA) [brand name Qfitlia® (fitusiran)]<br>• Added language to indicate:<br>○ **Concizumab-mtci [Alhemo]**, **Emicizumab-kxwh [Hemlibra]**, and **Marstacimab-hncq [Hympavzi]** are medically necessary for *routine prophylaxis to prevent or reduce the frequency of bleeding episodes* for the indications listed in the policy<br>○ **Fitusiran [Qfitlia]** is medically necessary for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with hemophilia A/hemophilia B when all of the criteria [listed in the policy] are met<br>• Revised coverage criteria for:<br>***Emicizumab-kxwh [Hemlibra]***<br>○ Removed criterion requiring | This policy refers to the following products:<br>• Antithrombin-directed small interfering ribonucleic acid (siRNA): Qfitlia® (fitusiran)<br>• Bispecific factor IXa- and factor X-directed antibody: Hemlibra® (emicizumab-kxwh)<br>• Tissue factor pathway inhibitor (TFPI) antagonists: Alhemo® (concizumab-mtci) and Hympavzi™ (marstacimab-hncq)<br><br>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) | Aug. 1, 2025 | prescriber attestation that the patient is not to receive extended half-life factor VIII replacement products (e.g., Adynovate, Afstyla, Altuviiio, Eloctate, Jivi) for the treatment of breakthrough bleeding episodes<br>***Marstacimab-hncq [Hympavzi]***<br>○ Removed criterion requiring prescriber attestation that the patient is not to receive extended half-life factor IX replacement products (e.g., Alprolix, Idelvion) for the treatment of breakthrough bleeding episodes<br>**Supporting Information**<br>• Updated *Background*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information | |
| FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) | Aug. 1, 2025 | **Title Change**<br>• Previously titled *Neonatal FC Receptor Blockers (Rystiggo®, Vyvgart®, & Vyvgart® Hytrulo)*<br>**Coverage Rationale**<br>• Replaced references to:<br>○ "*Neonatal* FC *receptor* blocker" with "*FcRn* blocker"<br>○ "*Soliris* (eculizumab)" with "eculizumab"<br>• Added language to indicate:<br>○ This policy refers to the following drug products for | This policy refers to the following drug products for administration by a healthcare professional:<br>• Rystiggo (rozanolixizumab-noli) for intravenous (IV) route<br>• Vyvgart (efgartigimod alfa-fcab) for intravenous (IV) route<br>• Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) vial for subcutaneous (SC) route<br><br>Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) prefilled syringe for self-administered subcutaneous injection is obtained under the pharmacy benefit.<br><br>**Myasthenia Gravis**<br>**Rystiggo is proven and medically necessary for the treatment of** |

**Revised**

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued) | Aug. 1, 2025 | administration by a healthcare professional:<br>▪ Rystiggo (rozanolixizumab-noli) for intravenous (IV) route<br>▪ Vyvgart (efgartigimod alfa-fcab) for intravenous (IV) route<br>▪ Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) vial for subcutaneous (SC) route<br>○ Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) prefilled syringe for self-administered subcutaneous injection is obtained under the pharmacy benefit<br>• Revised coverage criteria for:<br>***Rystiggo***<br>○ Added criterion requiring the patient is not receiving Rystiggo in combination with an immune globulin<br>○ Replaced criterion requiring "the patient has a history of failure of at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/plasma exchanges and/or *intravenous* immune globulin over the course of at least 12 months without symptom control" with "the patient has | **generalized myasthenia gravis in patients who are anti-AChR antibody positive or anti-MuSK antibody positive when all of the following criteria are met:**<br>• **Initial Therapy**<br>○ Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming **all** of the following:<br>▪ Patient has not failed a previous course of Rystiggo therapy; **and**<br>▪ Diagnosis of generalized myasthenia gravis (gMG); **and**<br>▪ **One** of the following:<br>– Positive serologic test for anti-AChR antibodies; **or**<br>– Positive serologic test for anti-MuSK antibodies<br>**and**<br>▪ Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy; **and**<br>▪ Patient has a Myasthenia Gravis Activities of Daily Living scale (MG-ADL) total score ≥ 5 at initiation of therapy<br>**and**<br>○ **One** of the following:<br>▪ If anti-acetylcholine receptor (AChR) antibody positive, **one** of the following:<br>– 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**<br>– 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<br>**or**<br>▪ If anti-muscle-specific tyrosine kinase (MuSK) antibody positive:<br>– 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.)<br>**and** |

**Revised**

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued) | Aug. 1, 2025 | 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"<br>***Vyvgart and Vyvgart Hytrulo for the Treatment of Generalized Myasthenia Gravis***<br>○ Added criterion requiring:<br>▪ The patient is not receiving Vyvgart or Vyvgart Hytrulo in combination with an immune globulin<br>▪ The patient will be given Vyvgart or Vyvgart Hytrulo no sooner than 50 days after each treatment cycle<br>○ Replaced criterion requiring "the patient has a history of failure of at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/plasma exchanges and/or *intravenous* immune globulin over the course of at least 12 months without symptom control" with "the patient has a history of failure of at least | ○ Patient is not receiving Rystiggo in combination with a complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]; **and**<br>○ 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**<br>○ Patient is **not** receiving Rystiggo in combination with an immune globulin; **and**<br>○ Rystiggo is dosed according to the U.S. FDA labeled dosing for gMG; **and**<br>○ Prescribed by, or in consultation with, a neurologist; **and**<br>○ Initial authorization will be for no more than 12 months<br>• **Continuation of Therapy**<br>○ Patient has previously been treated with Rystiggo; **and**<br>○ Submission of medical records (e.g., chart notes, laboratory tests) demonstrating **all** of the following:<br>▪ Improvement and/or maintenance of at least a 2-point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline; **and**<br>▪ Reduction in signs and symptoms of myasthenia gravis; **and**<br>▪ 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)<br>**and**<br>○ Patient is not receiving Rystiggo in combination with a complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]; **and**<br>○ 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**<br>○ Patient is **not** receiving Rystiggo in combination with an immune globulin; **and**<br>○ Rystiggo is dosed according to the U.S. FDA labeled dosing for gMG; **and** |

**Revised**

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued) | Aug. 1, 2025 | 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"<br>***Vyvgart Hytrulo for the Treatment of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)***<br>Initial Therapy<br>○ Added criterion requiring:<br>▪ Trial and failure (after a trial of at least two months), contraindication, or intolerance to corticosteroids<br>▪ Trial and failure (after a trial of at least three months), contraindication, or intolerance to immune globulin (i.e., intravenous immunoglobulin or subcutaneous immunoglobulin) based on both of the following:<br>– Dose has been adjusted or escalated to the maximally allowable and/or tolerated dose<br>– Failure to obtain an objective response to treatment in a disability assessment | ○ Prescribed by, or in consultation with, a neurologist; **and**<br>○ Reauthorization will be for no more than 12 months<br><br>**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:**<br>• **Initial Therapy**<br>○ Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming **all** of the following:<br>▪ Patient has not failed a previous course of Vyvgart therapy; **and**<br>▪ Patient has not failed a previous course of Vyvgart Hytrulo therapy; **and**<br>▪ Diagnosis of generalized myasthenia gravis (gMG); **and**<br>▪ Positive serologic test for anti-AChR antibodies; **and**<br>▪ Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy; **and**<br>▪ Patient has a Myasthenia Gravis Activities of Daily Living scale (MG-ADL) total score ≥ 5 at initiation of therapy<br>**and**<br>○ **One** of the following:<br>▪ 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**<br>▪ 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<br>**and**<br>○ Patient will be given Vyvgart or Vyvgart Hytrulo no sooner than 50 days after each treatment cycle; **and**<br>○ Patient is not receiving Vyvgart or Vyvgart Hytrulo in combination with a complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]; **and**<br>○ Patient is not receiving Vyvgart or Vyvgart Hytrulo in combination |

**Revised**

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued) | Aug. 1, 2025 | defined by one of the following:<br>• Inflammatory Rasch-built Overall Disability Scale (I-RODS): increase ≥ 4 centile points in a 48-point scale<br>• Inflammatory Neuropathy Cause and Treatment Disability Scale (INCAT): decrease ≥ 1 point<br>– Failure to obtain an objective response to treatment in an impairment assessment defined by one the following:<br>• Grip strength using handheld dynamometry in Martin Vigorimeter: increase ≥ 8 kilopascals (or ≥ 1.2 pounds/inch$^2$) or Jamar hand grip dynamometer: increase ≥ 10%<br>• Medical Research Council | with another FcRn blocker [e.g., Rystiggo (rozanolixizumab-noli)]; **and**<br>○ Patient is **not** receiving Vyvgart or Vyvgart Hytrulo in combination with an immune globulin; **and**<br>○ Vyvgart or Vyvgart Hytrulo is dosed according to the U.S. FDA labeled dosing for gMG; **and**<br>○ Prescribed by, or in consultation with, a neurologist; **and**<br>○ Initial authorization will be for no more than 12 months<br>• **Continuation of Therapy**<br>○ Patient has previously been treated with Vyvgart or Vyvgart Hytrulo; **and**<br>○ Submission of medical records (e.g., chart notes, laboratory tests) demonstrating **all** of the following:<br>▪ Improvement and/or maintenance of at least a 2-point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline; **and**<br>▪ Reduction in signs and symptoms of myasthenia gravis; **and**<br>▪ 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)<br>**and**<br>○ Patient is not receiving Vyvgart or Vyvgart Hytrulo in combination with a complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]; **and**<br>○ Patient is not receiving Vyvgart or Vyvgart Hytrulo in combination with another FcRn blocker [e.g., Rystiggo (rozanolixizumab-noli)]; **and**<br>○ Patient is **not** receiving Vyvgart or Vyvgart Hytrulo in combination with an immune globulin; **and**<br>○ Vyvgart or Vyvgart Hytrulo is dosed according to the U.S. FDA labeled dosing for gMG; **and**<br>○ Prescribed by or in consultation with a neurologist; **and**<br>○ Reauthorization will be for no more than 12 months |

**Revised**

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued) | Aug. 1, 2025 | (MRC) sum score (0-60): increase ≥ 2 to 4 points<br>• Modified INCAT Sensory Sum scale (mISS): decrease ≥ 2 points<br>▪ Immunological testing [e.g., nodal and paranodal antibodies, serum protein electrophoresis and immunofixation, spot urine immunofixation for light chains, measurement of serum free light chains (SFLC), anti-MAG antibody] has excluded other possible relevant neuropathies (e.g., anti-MAG IgM neuropathy, multiple myeloma, AL-amyloidosis, POEMS syndrome)<br>○ Removed criterion requiring trial and failure (after a trial of at least three months), contraindication, or intolerance to two of the following therapies used for CIDP:<br>▪ Corticosteroids<br>▪ Immune globulin (i.e., intravenous immunoglobulin or | **Vyvgart Hytrulo is proven and medically necessary for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) when all of the following criteria are met:**<br>• **Initial Therapy**<br>○ Patient has not failed a previous course of Vyvgart Hytrulo therapy; **and**<br>○ Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP); **and**<br>○ Diagnosis of CIDP is categorized as one of the following:<br>▪ Typical CIDP; **or**<br>▪ **One** of the following CIDP variants:<br>– Distal CIDP; **or**<br>– Multifocal CIDP; **or**<br>– Focal CIDP; **or**<br>– Motor CIDP; **or**<br>– Sensory CIDP<br>**and**<br>○ **One** of the following:<br>▪ Electrodiagnostic testing has confirmed at least two motor nerve abnormalities; **or**<br>▪ **All** of the following:<br>– Electrodiagnostic testing allows only for a diagnosis of possible CIDP having only one motor nerve abnormality; **and**<br>– **Two** of the following, consistent with EFNS/PNS guidelines, support a diagnosis of possible CIDP<br>• Objective response to treatment with immunomodulatory agents (e.g., corticosteroids, immune globulin, plasma exchange)<br>• Imaging with ultrasound or MRI<br>• Cerebrospinal fluid (CSF) analysis<br>• Nerve Biopsy<br>**and**<br>– Immunological testing [e.g., nodal and paranodal antibodies, serum protein electrophoresis and immunofixation, spot urine immunofixation for light chains, measurement of serum free light chains (SFLC), anti-MAG antibody] has excluded |

**Revised**

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued) | Aug. 1, 2025 | subcutaneous immunoglobulin)<br>▪ Plasma exchange<br>○ Replaced criterion requiring:<br>▪ "Electrodiagnostic testing has confirmed *a diagnosis of CIDP*" with "electrodiagnostic testing has confirmed *at least two motor nerve abnormalities*"<br>▪ "Electrodiagnostic testing allows only for a diagnosis of possible CIDP" with "electrodiagnostic testing allows only for a diagnosis of possible CIDP having only one motor nerve abnormality"<br>▪ "Two *supportive* criteria [e.g., objective response to treatment, imaging, cerebrospinal fluid (CSF), nerve biopsy] consistent with EFNS/PNS guidelines *confirm* diagnosis of CIDP" with "two *of the following* [criteria] consistent with EFNS/PNS guidelines *support a* diagnosis *of possible* CIDP: objective response to treatment *with immunomodulatory agents (e.g., corticosteroids, immune* | other possible relevant neuropathies (e.g., anti-MAG IgM neuropathy, multiple myeloma, AL-amyloidosis, POEMS syndrome)<br>**and**<br>○ Trial and failure (after a trial of at least two months), contraindication, or intolerance to corticosteroids; **and**<br>○ Trial and failure (after a trial of at least three months), contraindication, or intolerance to immune globulin (i.e., intravenous immunoglobulin or subcutaneous immunoglobulin) based on **both** of the following:<br>▪ Dose has been adjusted or escalated to the maximally allowable and/or tolerated dose; **and**<br>▪ **Both** of the following:<br>– Failure to obtain an objective response to treatment in a disability assessment defined by **one** of the following:<br>• Inflammatory Rasch-built Overall Disability Scale (I-RODS): increase ≥ 4 centile points in a 48-point scale; **or**<br>• Inflammatory Neuropathy Cause and Treatment Disability Scale (INCAT): decrease ≥ 1 point<br>**and**<br>– Failure to obtain an objective response to treatment in an impairment assessment defined by **one** the following:<br>• Grip strength using handheld dynamometry in Martin Vigorimeter: increase ≥ 8 kilopascals (or ≥ 1.2 pounds/inch$^2$) or Jamar hand grip dynamometer: increase ≥ 10%; **or**<br>• Medical Research Council (MRC) sum score (0-60): increase ≥ 2 to 4 points; **or**<br>• Modified INCAT Sensory Sum scale (mISS): decrease ≥ 2 points<br>**and**<br>○ Patient is **not** receiving Vyvgart Hytrulo in combination with an immune globulin; **and**<br>○ Vyvgart Hytrulo is dosed according to the U.S. FDA labeled dosing for CIDP; **and**<br>○ Prescribed by, or in consultation with, a neurologist; **and** |

# Medical Benefit Drug Policy Updates

## Revised

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued) | Aug. 1, 2025 | *globulin, plasma exchange)*, imaging *with ultrasound or MRI*, cerebrospinal fluid (CSF) *analysis*, and/or nerve biopsy"<br>**Continuation of Therapy**<br>○ Added criterion requiring the patient is not receiving Vyvgart Hytrulo in combination with an immune globulin<br>**Supporting Information**<br>• Updated *References* section to reflect the most current information | ○ Initial authorization will be for no more than 12 months<br>• **Continuation of Therapy**<br>○ Patient has previously been treated with Vyvgart Hytrulo; **and**<br>○ Documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]; **and**<br>○ Patient is **not** receiving Vyvgart Hytrulo in combination with an immune globulin; **and**<br>○ Vyvgart Hytrulo is dosed according to the U.S. FDA labeled dosing for CIDP; **and**<br>○ Prescribed by, or in consultation with, a neurologist; **and**<br>○ Reauthorization will be for no more than 12 months |
| Immune Globulin (IVIG and SCIG) | Aug. 1, 2025 | **Coverage Rationale**<br>• Added language to indicate immune globulin is proven for measles (rubeola) post-exposure prophylaxis; immune globulin is medically necessary for the prevention of measles (rubeola) post-exposure prophylaxis when all of the following criteria are met:<br>○ Patient has been exposed to measles (rubeola) less than 6 days previously<br>○ Patient weight is greater than 30 kg (for patients ≤ 30 kg, administer Intramuscular immune globulin)<br>○ One of the following nonimmune or severely immunocompromised individuals who are not | This policy refers to FDA-approved intravenous (IV) and subcutaneous (SC) immune globulin (IG) products including, but not limited to, the following (list not all inclusive):<br>• Alyglo™ (IV)<br>• Asceniv™ (IV)<br>• Bivigam® (IV)<br>• Cutaquig® (SC)<br>• Cuvitru® (SC)<br>• Flebogamma® DIF (IV)<br>• Gammagard® Liquid (IV, SC)<br>• Gammagard® S/D (IV)<br>• Gammaked™ (IV, SC)<br>• Gammaplex® (IV)<br>• Gamunex®-C (IV, SC)<br>• Hizentra® (SC)<br>• HyQvia® (SC)<br>• Octagam® (IV)<br>• Panzyga® (IV)<br>• Privigen® (IV)<br>• Xembify® (SC) |

# Medical Benefit Drug Policy Updates

| Revised | | | |
|---|---|---|---|
| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Immune Globulin (IVIG and SCIG) (continued) | Aug. 1, 2025 | already receiving immune globulin therapy:<br>▪ Patient is a pregnant woman without evidence of measles immunity<br>▪ Patient has received hematopoietic stem cell transplant (HSCT) and has finished all immunosuppressive treatment within 12 months<br>▪ Patient is a HSCT recipient with chronic graft-versus-host disease (GVHD)<br>▪ Patient has received chimeric antigen receptor T-cell (CAR T) therapy within 12 months<br>▪ Patient has acute lymphoblastic leukemia (ALL) and is completing or has completed chemotherapy within the last 6 months<br>▪ Patient with HIV infection and severe immunosuppression defined as a current CD4+ T-lymphocyte percentage < 15% (all ages) or a CD4+ T-lymphocyte count < 200 lymphocyte cells/mm3 (age > 5 years only)<br>▪ Patient with a primary | Refer to the policy for complete details. |

# Medical Benefit Drug Policy Updates

## Revised

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| Immune Globulin (IVIG and SCIG) (continued) | Aug. 1, 2025 | immunodeficiency (refer to the disease list within the policy)<br>○ Request is for an initial, one-time dose, not to exceed 400 mg/kg<br>**Applicable Codes**<br>• Added ICD-10 diagnosis codes B05.0, B05.1, B05.2, B05.3, B05.4, O98.511, O98.512, O98.513, and O98.519<br>**Supporting Information**<br>• Updated *Clinical Evidence* and *References* sections to reflect the most current information | |
| Intracanalicular and Intravitreal Corticosteroid Implants | Aug. 1, 2025 | **Coverage Rationale**<br>• Revised authorization guidelines; replaced language indicating "authorization is for no more than *one month*" with "authorization is for no more than *60 days*"<br>• Revised coverage criteria for **Iluvien**; added criterion requiring chronic non-infectious uveitis affecting the posterior segment of the eye<br>**Applicable Codes**<br>***Non-Infectious Uveitis Affecting the Posterior Segment of the Eye***<br>• Added ICD-10 diagnosis codes H30.141, H30.142, H30.143, H30.149, H30.21, H30.22, H30.23, H30.811, H30.812, H30.813, and H30.819 | This policy provides information about the use of certain specialty pharmacy medications administered by the intracanalicular and intravitreal route for certain ophthalmologic conditions.<br><br>This policy refers to the following intracanalicular and intravitreal corticosteroid implant products:<br>• Dextenza® (dexamethasone ophthalmic insert)<br>• Iluvien® (fluocinolone acetonide intravitreal implant)<br>• Ozurdex® (dexamethasone intravitreal implant)<br>• Retisert® (fluocinolone acetonide intravitreal implant)<br>• Yutiq® (fluocinolone acetonide intravitreal implant)<br><br>**Dextenza is proven and medically necessary when all of the following criteria are met:**<br>• **One** of the following diagnoses:<br>○ Ocular inflammation and pain following ophthalmic surgery; **or**<br>○ Ocular itching associated with allergic conjunctivitis<br>**and**<br>• Prescribed by or in consultation with an ophthalmologist; **and**<br>• Dose does not exceed one insert per eye; **and**<br>• Authorization is for no more than 60 days |

# Medical Benefit Drug Policy Updates

## Revised

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| Intracanalicular and Intravitreal Corticosteroid Implants (continued) | Aug. 1, 2025 | ***Ocular Inflammation and Pain Following Ophthalmic Surgery***<br>• Removed ICD-10 diagnosis codes G89.18 and H05.00<br>**Supporting Information**<br>• Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information | **Iluvien is proven and medically necessary when all of the following criteria are met:**<br>• **One** of the following:<br>  ○ Chronic non-infectious uveitis affecting the posterior segment of the eye; **or**<br>  ○ **Both** of the following:<br>  ▪ Diagnosis of diabetic macular edema (DME); **and**<br>  ▪ **Both** of the following:<br>  – Member has been previously treated with a course of corticosteroids; **and**<br>  – Member did not have a clinically significant rise in intraocular pressure<br>**and**<br>• Prescribed by or in consultation with an ophthalmologist; **and**<br>• Dose does not exceed one implant per eye; **and**<br>• Authorization is for no more than 60 days<br><br>**Ozurdex is proven and medically necessary when all of the following criteria are met:**<br>• Diagnosis of **one** of the following:<br>  ○ Macular edema following branch retinal vein occlusion (BRVO); **or**<br>  ○ Macular edema following central retinal vein occlusion (CRVO); **or**<br>  ○ Non-infectious uveitis affecting the posterior segment of the eye; **or**<br>  ○ Diabetic macular edema (DME)<br>**and**<br>• Prescribed by or in consultation with an ophthalmologist; **and**<br>• Dose does not exceed one implant per eye; **and**<br>• Authorization is for no more than 60 days<br><br>**Retisert is proven and medically necessary when all of the following criteria are met:**<br>• Diagnosis of chronic non-infectious uveitis affecting the posterior segment of the eye; **and**<br>• Prescribed by or in consultation with an ophthalmologist; **and**<br>• Dose does not exceed one implant per eye; **and**<br>• Authorization is for no more than 60 days |

# Medical Benefit Drug Policy Updates

| Revised | | | |
|---|---|---|---|
| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Intracanalicular and Intravitreal Corticosteroid Implants (continued) | Aug. 1, 2025 | | **Yutiq is proven and medically necessary when all of the following criteria are met:**<br>• Diagnosis of chronic non-infectious uveitis affecting the posterior segment of the eye; **and**<br>• Prescribed by or in consultation with an ophthalmologist; **and**<br>• Dose does not exceed one implant per eye; **and**<br>• Authorization is for no more than 60 days<br><br>**Intracanalicular and intravitreal corticosteroid implant products are unproven and not medically necessary for the treatment any other indication due to insufficient evidence of efficacy including, but not limited to, the following:**<br>• Cystoid macular edema after cataract surgery<br>• Radiation retinopathy |

# General Information

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

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

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

## Policy Update Classifications

### *New*

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

### *Updated*

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

### *Revised*

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

### *Replaced*

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

### *Retired*

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

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