United Healthcare Community Plan

UnitedHealthcare Community Plan of Indiana
Medical Policy Update Bulletin: September 2024

Take Note

Annual ICD-10 and Quarterly CPT/HCPCS Code Updates

Beginning **Oct. 1, 2024**, all applicable Medical Policies and Medical Benefit Drug Policies will be updated to reflect the annual ICD-10 and quarterly CPT/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
- Centers for Medicare & Medicaid Services: International Classification of Diseases, Tenth Revision (ICD-10) Clinical Modification (CM) (Diagnosis) Codes: 2025
- Centers for Medicare & Medicaid Services: International Classification of Diseases, Tenth Revision (ICD-10) Procedure Coding System (PCS) Codes: 2025

Complete details on impacted policies and corresponding code edits will be provided in the October 2024 edition of the Medical Policy Update Bulletin.

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Neonatal Fc Receptor Blockers (Rystiggo®, Vyvgart®, & Vyvgart® Hytrulo) (for Indiana Only)	Oct. 1, 2024	**Coverage Rationale** • Added language to indicate Vyvgart Hytrulo is proven for the treatment of **chronic inflammatory demyelinating polyneuropathy (CIDP)**; Vyvgart Hytrulo is medically necessary for the treatment of CIDP when all of the following criteria are met: ***Initial Therapy*** o Patient has not failed a previous course of Vyvgart Hytrulo therapy o Diagnosis of CIDP	**Myasthenia Gravis** **Rystiggo is proven and medically necessary for the treatment of generalized myasthenia gravis in patients who are anti-AChR antibody positive or antimuscle-specific tyrosine kinase (MuSK) antibody positive when all of the following criteria are met:** • **Initial Therapy** o 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**

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Neonatal Fc Receptor Blockers (Rystiggo®, Vyvgart®, & Vyvgart® Hytrulo) (for Indiana Only) (continued)	Oct. 1, 2024	o Diagnosis of CIDP is categorized as one of the following: § Typical CIDP § One of the following CIDP variants: – Distal CIDP – Multifocal CIDP – Focal CIDP – Motor CIDP – Sensory CIDP o One of the following: § Electrodiagnostic testing has confirmed a diagnosis of CIDP § Both of the following: – Electrodiagnostic testing allows only for a diagnosis of possible CIDP – Two supportive criteria [e.g., objective response to treatment, imaging, cerebrospinal fluid (CSF), nerve biopsy] consistent with EFNS/PNS guidelines confirm diagnosis of CIDP o Trial and failure (after a trial of at least three months), contraindication, or intolerance to two of the following therapies used for CIDP:	§ 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** o **One** of the following: § 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 intravenous 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** o Patient is not receiving Rystiggo in combination with a complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravulizumab, Zilbrysq (zilucoplan)]; **and** o Patient is **not** receiving Rystiggo in combination with another neonatal Fc receptor blocker [e.g., Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)]; **and** o Rystiggo is dosed according to the U.S. FDA labeled dosing for gMG; **and** o Prescribed by, or in consultation with, a neurologist; **and** o Initial authorization will be for no more than 12 months • **Continuation of Therapy** o Patient has previously been treated with Rystiggo; **and**

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Neonatal Fc Receptor Blockers (Rystiggo®, Vyvgart®, & Vyvgart® Hytrulo) (for Indiana Only) (continued)	Oct. 1, 2024	§ Corticosteroids § Immune globulin (i.e., intravenous immunoglobulin or subcutaneous immunoglobulin) § Plasma exchange o Vyvgart Hytrulo is dosed according to the U.S. FDA labeled dosing for CIDP o Prescribed by, or in consultation with, a neurologist o Initial authorization will be for no more than 12 months ***Continuation of Therapy*** o Patient has previously been treated with Vyvgart Hytrulo o Documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale] o Vyvgart Hytrulo is dosed according to the U.S. FDA labeled dosing for CIDP o Prescribed by, or in consultation with, a neurologist o Reauthorization will be for no more than 12 months **Applicable Codes** • Added ICD-10 diagnosis codes G61.81 and G70.01	o 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** § 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** o Patient is not receiving Rystiggo in combination with a complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]; **and** o Patient is **not** receiving Rystiggo in combination with another neonatal Fc receptor blocker [e.g., Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)]; **and** o Rystiggo is dosed according to the U.S. FDA labeled dosing for gMG; **and** o Prescribed by, or in consultation with, a neurologist; **and** o 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** o Submission of medical records (e.g., chart notes, laboratory values, etc.) **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**

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Neonatal Fc Receptor Blockers (Rystiggo®, Vyvgart®, & Vyvgart® Hytrulo) (for Indiana Only) (continued)	Oct. 1, 2024	**Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	§ 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** o **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 intravenous immune globulin over the course of at least 12 months without symptom control **and** o Patient is not receiving Vyvgart or Vyvgart Hytrulo in combination with a complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]; **and** o Patient is not receiving Vyvgart or Vyvgart Hytrulo in combination with another neonatal Fc receptor blocker [e.g., Rystiggo (rozanolixizumab-noli)]; **and** o Vyvgart or Vyvgart Hytrulo is dosed according to the U.S. FDA-labeled dosing for gMG; **and** o Prescribed by, or in consultation with, a neurologist; **and** o Initial authorization will be for no more than 12 months • **Continuation of Therapy** o Patient has previously been treated with Vyvgart or Vyvgart Hytrulo; **and** o 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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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 Indiana 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 Indiana Medical Policies and Medical Benefit Drug Policies is available at **UHCprovider.com/IN** > Community Plan (Medicaid) > Current Policies and Clinical Guidelines > Medical & Drug Policies.