United Healthcare Community Plan

UnitedHealthcare Community Plan of New Mexico
Medical Policy Update Bulletin: January 2025

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Annual CPT/HCPCS Code Updates

Effective **Jan. 1, 2025**, the following Medical Policies and Medical Benefit Drug Policies have been updated to reflect the 2025 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
Complement Inhibitors (PiaSky®, Soliris®, & Ultomiris®)	Medical Benefit Drug Policy	• Replaced HCPCS codes C9399, J3490, and J3590 with J1307
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for New Mexico Only)	Medical Policy	• Added HCPCS codes G0564 and G0565
Cosmetic and Reconstructive Procedures (for New Mexico Only)	Medical Policy	• Removed CPT code 15819
Gender Dysphoria Treatment (for New Mexico Only)	Medical Policy	• Removed CPT code 15819
Gene Therapies for Hemophilia B	Medical Benefit Drug Policy	• Removed HCPCS code C9172 • Replaced HCPCS codes J3490 and J3590 with J1414
Genetic Testing for Hereditary Cancer (for New Mexico Only)	Medical Policy	• Removed CPT codes 81433, 81436, and 81438 • Revised description for CPT codes 81432 ,81435, and 81437
Immune Globulin (IVIG and SCIG)	Medical Benefit Drug Policy	• Added HCPCS code J1552
Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and Treatment Decisions (for New Mexico Only)	Medical Policy	• Added CPT code 81195
Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions (for New Mexico Only)	Medical Policy	• Added CPT codes 0523U and 0530U • Removed CPT code 0428U
Nplate® (Romiplostim)	Medical Benefit Drug Policy	• Added HCPCS code J2802 • Removed HCPCS code J2796

Take Note

Policy Title	Policy Type	Summary of Changes
Omnibus Codes (for New Mexico Only)	Medical Policy	**Eye-Movement Analysis Without Spatial Calibration** • Revised description for CPT code 0615T **Fallopian Tube Occlusion With a Degradable Biopolymer Implant** • Replaced CPT code 0567T with 58999 **Implantable Wireless Pulmonary Artery Pressure (PAP) Sensor** • Added HCPCS code G0555 **Insertion of Iris Prosthesis** • Added CPT code 66683 • Removed CPT codes 0616T, 0617T, and 0618T **Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) Intracranial Stereotactic Ablation** • Added CPT code 61715 • Removed CPT code 0398T **Sonosalpingography** • Replaced CPT code 0568T with 58999
Oncology Medication Clinical Coverage	Medical Benefit Drug Policy	• Added HCPCS code Q5146
Pharmacogenetic Panel Testing (for New Mexico Only)	Medical Policy	• Removed CPT codes 0380U and 0456U
Stereotactic Body Radiation Therapy and Stereotactic Radiosurgery (for New Mexico Only)	Medical Policy	• Added HCPCS code G0563

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Electric Tumor Treatment Field Therapy (for New Mexico Only)	Jan. 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 **Jan. 1, 2025**. **Coverage Rationale** • Revised coverage criteria for: ○ Use of U.S. Food and Drug Administration (FDA) approved devices to generate electric tumor treatment fields (TTF) for treating: ***Newly Diagnosed Histologically Confirmed Supratentorial Glioblastoma (GBM)*** ▪ Added criterion requiring "debulking surgery has been completed" ▪ Replaced criterion requiring "the individual has been counselled that the device must be worn at least 18 hours daily" with "the individual has been counselled that the *electric TTF* device must be worn at least 18 hours daily" ***Radiologically Confirmed Recurrence of GBM (rGBM) in the Supratentorial Region of***	**The following is proven and medically necessary for treating newly diagnosed histologically confirmed Supratentorial glioblastoma (GBM):** • The use of U.S. Food and Drug Administration (FDA) approved devices to generate electric tumor treatment fields (TTF) when used according to FDA labeled indications, contraindications, warnings, and precautions and when **all** of the following criteria are met: ○ Debulking surgery has been completed; and ○ Treatment with radiation therapy has been completed; and ○ Individual is receiving Temozolomide (TMZ) as the only cancer drug; and ○ Individual has a Karnofsky Performance Status (KPS) score of ≥ 60 or Eastern Cooperative Oncology Group (ECOG) Performance Status ≤ 2; and ○ Individual has been counselled that the electric TTF device must be worn at least 18 hours daily When all of the above criteria are met for newly diagnosed GBM (ndGBM), an initial 3 months of electric TTF therapy will be approved. **The following is proven and medically necessary for treating radiologically confirmed recurrence of GBM (rGBM) in the Supratentorial region of the brain:** • The use of FDA approved devices to generate electric TTF after initial chemotherapy when used according to FDA labeled indications, contraindications, warnings, and precautions and when **all** of the following criteria are met: ○ The device is used as the only treatment; and ○ Individual has a KPS score of ≥ 60 or ECOG Performance Status of ≤ 2; and ○ Individual has been counselled that the electric TTF device must be worn at least 18 hours daily When all of the above criteria are met for rGBM, an initial 3 months of electric TTF therapy will be approved. **Subsequent approval(s) for continuation beyond the initial 3 months of electric TTF for treatment of histologically confirmed Supratentorial**

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Electric Tumor Treatment Field Therapy (for New Mexico Only) (continued)	Jan. 1, 2025	***the Brain*** ▪ Replaced criterion requiring "the individual has been counselled ▪ that the device must be worn at least 18 hours daily" with "the individual has been counselled that the *electric TTF* device must be worn at least 18 hours daily" ○ Subsequent approval(s) for continuation of electric TTF beyond the initial 3 months for treatment of histologically confirmed Supratentorial GBM; replaced criterion requiring "documentation that the individual has been using the device at least 18 hours daily" with "documentation that the individual has been using the *electric TTF* device at least 18 hours daily" **Definitions** • Updated definition of: ○ Eastern Cooperative Oncology Group (ECOG) Scale of Performance Status ○ Karnofsky Performance Status (KPS) **Applicable Codes** • Updated list of applicable HCPCS codes to reflect quarterly edits; added E0767	**GBM is based on:** • Magnetic resonance imaging (MRI) scan has been performed ≤ 2 months prior to request and documents no evidence of disease progression; and • Individual with ndGBM continues to receive TMZ as the only cancer drug or the device is used as the only treatment for an individual with rGBM; and • KPS score of ≥ 60 or ECOG Performance Status ≤ 2; and • Documentation that the individual has been using the electric TTF device at least 18 hours daily **Due to insufficient evidence of efficacy, the use of devices to generate electric TTF is unproven and not medically necessary when the criteria above are not met and for all other indications including but not limited to the following:** • Treatment of tumors other than GBM • Use of electric TTF therapy with concurrent medical therapy [e.g., bevacizumab (BEV) or chemotherapy] for treatment of rGBM **Computer software used for therapeutic radiology clinical treatment planning in conjunction with electric TTF therapy is unproven and not medically necessary due to insufficient evidence of efficacy.**

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Electric Tumor Treatment Field Therapy (for New Mexico Only) (continued)	Jan. 1, 2025	**Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Pharmacogenetic Panel Testing (for New Mexico Only)	Mar. 1, 2025	**Coverage Rationale** ***Multi-Gene Panels*** • Revised language to indicate the use of pharmacogenetic Multi-Gene Panels (five or more genes) for the evaluation of drug-metabolizer status is unproven and not medically necessary for any indication due to insufficient evidence of efficacy **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	**The use of pharmacogenetic Multi-Gene Panels (five or more genes) for the evaluation of drug-metabolizer status is unproven and not medically necessary for any indication due to insufficient evidence of efficacy.** **The use of the PrismRA® molecular signature test is unproven and not medically necessary for evaluating likelihood of inadequate response to anti-TNF therapies for rheumatoid arthritis due to insufficient evidence of efficacy.**

Surgery for the Prevention and Treatment of Lymphedema (for New Mexico Only)	Mar. 1, 2025	**Title Change**
		• Previously titled *Surgical Treatment of Lymphedema (for New Mexico Only)*
		Coverage Rationale
		• Revised list of unproven and not medically necessary surgical procedures for the prevention or treatment of Lymphedema; added "Axillary Reverse Mapping (ARM)"
		Definitions
		• Added definition of "Axillary Reverse Mapping"
		Supporting Information
		• Updated *Description of Services*,
			Surgical procedures for the prevention or treatment of Lymphedema are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy. These procedures include but are not limited to:
			• Axillary Reverse Mapping (ARM)
			• Liposuction/Lipectomy
			• Microsurgical treatment
			  ○ Lymphaticovenous Anastomosis
			  ○ Lymphovenous bypass
			• Vascularized Lymph Node Transfer

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgery for the Prevention and Treatment of Lymphedema (for New Mexico Only) (continued)	Mar. 1, 2025	*Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Adakveo® (Crizanlizumab-Tmca)	Feb. 1, 2025	**Coverage Rationale** • Revised coverage criteria for **initial therapy**; added criterion allowing coverage when the patient is transitioning from treatment with Oxbryta (voxelotor) to Adakveo **Supporting Information** • Updated *References* section to reflect the most current information	**Adakveo is proven and/or medically necessary to reduce the frequency of vasoocclusive crises in patients with sickle cell disease who meet all of the following criteria:** **Initial Therapy** • Patient is 16 years of age or older; **and** • Diagnosis of a sickle cell disease, including but not limited to homozygous hemoglobin S (HbSS), sickle hemoglobin C disease (HbSC), sickle beta^0 thalassemia, and sickle beta$^+$ thalassemia; **and** • **One** of the following: ○ Patient is transitioning from treatment with Oxbryta (voxelotor) to Adakveo; **or** ○ Patient has previously experienced 2 or more sickle cell-related vasoocclusive crises within the previous 12 months **and** • **One** of the following: ○ Patient is currently receiving hydroxyurea therapy; **or** ○ Patient has a history of treatment failure, intolerance, or contraindication to hydroxyurea therapy **and** • Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy; **and** • Patient is not receiving concomitant Oxbryta (voxelotor) therapy; **and** • Adakveo is prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease; **and** • Adakveo initial dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** • Initial authorization will be for no more than 12 months **Continuation Therapy** • Diagnosis of a sickle cell disease, including but not limited to homozygous hemoglobin S (HbSS), sickle hemoglobin C disease (HbSC), sickle beta^0 thalassemia, and sickle beta$^+$ thalassemia; **and** • Patient has experienced a reduction in sickle cell-related vasoocclusive crises and/or a decrease in severity of sickle cell-related vasoocclusive

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Adakveo® (Crizanlizumab-Tmca) (continued)	Feb. 1, 2025		crises from pretreatment baseline while on Adakveo; **and** • Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy; **and** • Patient is not receiving concomitant Oxbryta (voxelotor) therapy; **and** • Adakveo is prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease; **and** • Adakveo maintenance dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** • Reauthorization will be for no more than 12 months **Adakveo is not proven or medically necessary for the treatment of:** • Pediatric patients less than 16 years of age with sickle cell disease • Myelofibrosis
Ocrevus® (Ocrelizumab) and Ocrevus Zunovo™ (Ocrelizumab and Hyaluronidase-Ocsq)	Feb. 1, 2025	**Title Change** • Previously titled *Ocrevus® (Ocrelizumab)* **Coverage Rationale** ***Ocrevus*** Relapsing Forms of Multiple Sclerosis • Revised coverage criteria for initial therapy; removed criterion requiring rituximab step therapy for the states of Arizona, New Jersey, New York, Rhode Island, and Tennessee ***Ocrevus Zunovo*** • Added language to indicate: ○ Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq) is proven and medically necessary for **primary progressive multiple sclerosis** (PPMS) when all of	**Primary Progressive Multiple Sclerosis** **Ocrevus or Ocrevus Zunovo are proven and medically necessary for the treatment of primary progressive multiple sclerosis (PPMS) when all of the following criteria are met:** • For **initial therapy**, **all** of the following: ○ Diagnosis of primary progressive multiple sclerosis (PPMS); **and** ○ Patient is not receiving Ocrevus or Ocrevus Zunovo in combination with **any** of the following: ▪ Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide) ▪ B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab, ublituximab-xiiy) ▪ Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) **and** ○ Ocrevus or Ocrevus Zunovo dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Initial authorization is for no more than 6 months • For **continuation of therapy**, **all** of the following: ○ Patient has previously received treatment with Ocrevus or Ocrevus Zunovo; **and**

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ocrevus® (Ocrelizumab) and Ocrevus Zunovo™ (Ocrelizumab and Hyaluronidase-Ocsq) (continued)	Feb. 1, 2025	the following criteria are met: ***Initial Therapy*** ▪ Diagnosis of PPMS ▪ Patient is not receiving Ocrevus Zunovo in combination with any of the following: – Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, teriflunomide) – B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab, ublituximab-xiiy) – Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) ▪ Ocrevus Zunovo dosing is in accordance with the U.S. FDA approved labeling ▪ Initial authorization is for no more than 6 months ***Continuation of Therapy*** ▪ Patient has previously received treatment with Ocrevus Zunovo	○ Documentation of positive clinical response to Ocrevus or Ocrevus Zunovo therapy; **and** ○ Patient is not receiving Ocrevus or Ocrevus Zunovo in combination with **any** of the following: ▪ Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide) ▪ B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab, ublituximab-xiiy) ▪ Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) **and** ○ Ocrevus or Ocrevus Zunovo dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Authorization is for no more than 12 months **Relapsing Forms of Multiple Sclerosis** **Ocrevus or Ocrevus Zunovo are proven and medically necessary for the treatment of relapsing forms of multiple sclerosis (MS) when the following criteria are met:** • For **initial therapy**, **all** of the following: ○ Diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses); **and** ○ Patient is not receiving Ocrevus or Ocrevus Zunovo in combination with **any** of the following: ▪ Disease modifying therapy (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide) ▪ B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab, ublituximab-xiiy) ▪ Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) **and** ○ Ocrevus or Ocrevus Zunovo dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Initial authorization is for no more than 6 months

Medical Benefit Drug Policy Updates

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ocrevus® (Ocrelizumab) and Ocrevus Zunovo™ (Ocrelizumab and Hyaluronidase-Ocsq) (continued)	Feb. 1, 2025	▪ Documentation of positive clinical response to Ocrevus Zunovo therapy ▪ Patient is not receiving Ocrevus Zunovo in combination with any of the following: – Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, teriflunomide) – B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab, ublituximab-xiiy) – Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) ▪ Ocrevus Zunovo dosing is in accordance with the U.S. FDA approved labeling ▪ Authorization is for no more than 12 months ○ Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq) is	• For **continuation of therapy**, **all** of the following: ○ Patient has previously received treatment with Ocrevus or Ocrevus Zunovo; **and** ○ Documentation of positive clinical response to Ocrevus or Ocrevus Zunovo therapy; **and** ○ Patient is not receiving Ocrevus or Ocrevus Zunovo in combination with **any** of the following: ▪ Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide) ▪ B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab, ublituximab-xiiy) ▪ Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) **and** ○ Ocrevus or Ocrevus Zunovo dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Authorization is for no more than 12 months **Ocrevus or Ocrevus Zunovo are unproven and not medically necessary for the treatment of:** • Lupus nephritis • Rheumatoid arthritis • Systemic lupus erythematosus

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ocrevus® (Ocrelizumab) and Ocrevus Zunovo™ (Ocrelizumab and Hyaluronidase-Ocsq) (continued)	Feb. 1, 2025	proven and medically necessary for **relapsing forms of multiple sclerosis** (MS) when all of the following criteria are met: ***Initial Therapy*** ▪ Diagnosis of relapsing forms of MS (e.g., relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses) ▪ Patient is not receiving Ocrevus Zunovo in combination with any of the following: – Disease modifying therapy (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, teriflunomide) – B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab, ublituximab-xiiy) – Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) ▪ Ocrevus Zunovo dosing	

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Ocrevus® (Ocrelizumab) and Ocrevus Zunovo™ (Ocrelizumab and Hyaluronidase-Ocsq) (continued)	Feb. 1, 2025	is in accordance with the U.S. FDA approved labeling ▪ Initial authorization is for no more than 6 months ***Continuation of Therapy*** ▪ Patient has previously received treatment with Ocrevus Zunovo ▪ Documentation of positive clinical response to Ocrevus Zunovo therapy ▪ Patient is not receiving Ocrevus Zunovo in combination with any of the following: – Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, teriflunomide) – B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab, ublituximab-xiiy) – Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone)	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ocrevus® (Ocrelizumab) and Ocrevus Zunovo™ (Ocrelizumab and Hyaluronidase-Ocsq) (continued)	Feb. 1, 2025	▪ Ocrevus Zunovo dosing is in accordance with the U.S. FDA approved labeling ▪ Authorization is for no more than 12 months ○ Ocrevus Zunovo is unproven and not medically necessary for the treatment of: ▪ Lupus nephritis ▪ Rheumatoid arthritis ▪ Systemic lupus erythematosus **Applicable Codes** • Added HCPCS codes C9399, J3490, and J3590 **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information	
Roctavian® (Valoctocogene Roxaparvovec-Rvox)	Feb. 1, 2025	**Coverage Rationale** • Revised coverage criteria; replaced criterion: ○ Allowing coverage when the "patient is currently receiving chronic prophylactic Hemlibra (emicizumab) therapy" with "patient is currently receiving chronic prophylactic Hemlibra (emicizumab-*kxwh*) therapy *or Hympavzi (marstacimab-hncq)*" ○ Requiring "Roctavian is *delivered by or in consultation with* a Hemophilia Treatment Center (HTC)" with "Roctavian is *administered*	**Hemophilia A (i.e., Factor VIII Deficiency, Classical Hemophilia)** **Roctavian is proven and medically necessary for the treatment of hemophilia A (factor VIII deficiency) when all of the following criteria are met:** • Patient is 18 years of age or older; **and** • **Both** of the following: ○ Diagnosis of severe hemophilia A; **and** ○ Documentation of endogenous factor VIII levels less than 1% of normal factor VIII (< 0.01 IU/mL, < 1 IU/dL); **and** • **One** of the following: ○ Patient is currently receiving chronic prophylactic Hemlibra (emicizumab-kxwh) therapy or Hympavzi (marstacimab-hncq); **or** ○ **Both** of the following: ▪ Patient currently uses factor VIII prophylaxis therapy; **and** ▪ Patient has had a minimum of 150 exposure days to a factor VIII

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Roctavian® (Valoctocogene Roxaparvovec-Rvox) (continued)	Feb. 1, 2025	*within* a Hemophilia Treatment Center (HTC) *that holds Federal designation as evidenced by being listed within the CDC's HTC directory*" **Supporting Information** • Updated *References* section to reflect the most current information	agent **or** ○ Patient has been determined to be an appropriate candidate for Roctavian by the Hemophilia Treatment Center based on willingness to adhere to initial and long-term monitoring and management **and** • Patient does not have a history of inhibitors to factor VIII greater than or equal to 0.6 Bethesda units (BU); **and** • Patient does not screen positive for active factor VIII inhibitors as defined as greater than or equal to 0.6 Bethesda units (BU) prior to administration of Roctavian; **and** • Patient does not have pre-existing immunity to the AAV5 capsid as detected by the FDA-approved companion diagnostic test AAV5 DetectCDx®; **and** • Patient has not gone through Immune Tolerance Induction (ITI); **and** • Liver health assessments including enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), and total bilirubin] and hepatic ultrasound and elastography are performed to rule out radiological liver abnormalities and/or sustained liver enzyme elevations; **and** • **One** of the following: ○ Patient is not HIV positive; **or** ○ Patient is HIV positive and is virally suppressed with anti-viral therapy (i.e., < 200 copies of HIV per mL) **and** • The patient's hepatitis B surface antigen is negative; **and** • **One** of the following: ○ Patient's hepatitis C virus (HCV) antibody is negative; **or** ○ Patient's HCV antibody is positive, and the patient's HCV RNA is negative **and** • The patient is not currently using antiviral therapy for hepatitis B or C; **and** • Patient has not previously received treatment with Roctavian or other gene therapy product for the treatment of hemophilia A in the patient's lifetime; **and** • Roctavian is administered within a Hemophilia Treatment Center (HTC)

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Roctavian® (Valoctocogene Roxaparvovec-Rvox) (continued)	Feb. 1, 2025		that holds Federal designation as evidenced by being listed within the CDC's HTC directory; **and** • Prescriber attests that the patient's ALT and factor VIII activity will be monitored weekly for at least 26 weeks following administration of Roctavian and regularly thereafter per the monitoring schedule recommended in the prescribing information; **and** • Prescriber attests that counseling has been provided to the patient to abstain from consuming alcohol for at least one year following administration of Roctavian and regarding how much alcohol may be acceptable for the patient in the longer term; **and** • Roctavian dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** • Authorization will be issued for no more than one treatment per lifetime and for no longer than 45 days from approval Additional information relevant to the review process but not impacting the determination of medical necessity: • Prescriber attests that the patient, while under the care of the prescriber, will be assessed for treatment efficacy including but not limited to evaluation of factor VIII expression, breakthrough bleeding episodes, factor VIII product utilization, inhibitor development*; **and** • Prescriber acknowledges that UnitedHealthcare may request documentation, not more frequently than biannually, and not for a period to exceed 5 years of follow-up patient assessment(s) including but not necessarily limited to, evaluation of factor VIII expression, breakthrough bleeding episodes, factor VIII product utilization, inhibitor development while the patient is under the care of the prescriber* *For quality purposes only, this information will not be considered as part of the individual coverage decision. **Roctavian is not proven or medically necessary for:** • The treatment of hemophilia B • The treatment of mild or moderate hemophilia A • The repeat administration of Roctavian for the treatment of hemophilia A • The treatment of hemophilia A after previously receiving another factor VIII gene therapy product

Medical Benefit Drug Policy Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Roctavian® (Valoctocogene Roxaparvovec-Rvox) (continued)	Feb. 1, 2025		• The routine combination treatment with chronically administered prophylactic therapy for hemophilia A • The treatment of hemophilia A in patients less than 18 years of age • The treatment of hemophilia A in patients with elevated AAV5 antibodies

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 New Mexico 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 New Mexico Medical Policies and Medical Benefit Drug Policies is available at **UHCprovider.com/NM** > Community Plan (Medicaid) > Current Policies and Clinical Guidelines > Medical & Drug Policies.