Ocrevus® (Ocrelizumab) and Ocrevus Zunovo™ (Ocrelizumab and Hyaluronidase-Ocsq) (for Ohio Only)

Policy Number: CSOH2025D0056.C
Effective Date: February 1, 2025

➲ Instructions for Use

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Related Policies
None

Application

This Medical Benefit Drug Policy only applies to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

Coverage Rationale

Ocrevus® (ocrelizumab) is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline for Ocrevus®: CP: Specialty Rx Non-Oncology, Ocrelizumab (Ocrevus®).

Click here to view the InterQual® criteria.

Primary Progressive Multiple Sclerosis

Ocrevus Zunovo is 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 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 Zunovo dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
  - Initial authorization is for no more than 12 months
- For **continuation of therapy**, **all** of the following:
  - Patient has previously received treatment with Ocrevus Zunovo; **and**
  - Documentation of positive clinical response to Ocrevus Zunovo therapy; **and**
  - 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, or teriflunomide)

        - B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab, ublituximab-xiiy)
        - Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone)

      and
    - 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 Zunovo is 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 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 Zunovo dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
  - Initial authorization is for no more than 12 months
- For **continuation of therapy**, **all** of the following:
  - Patient has previously received treatment with Ocrevus Zunovo; **and**
  - Documentation of positive clinical response to Ocrevus Zunovo therapy; **and**
  - 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, or teriflunomide)
    - B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab, ublituximab-xiiy)
    - Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone)

    and
  - 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

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
C9399	Unclassified drugs or biologicals
J2350	Injection, ocrelizumab, 1 mg
J3490	Unclassified drugs
J3590	Unclassified biologics

References

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Policy History/Revision Information

Date	Summary of Changes
02/01/2025	**Title Change** • Previously titled *Ocrevus® (Ocrelizumab) (for Ohio Only)* **Coverage Rationale** • Added language to indicate: ○ Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq) is proven and medically necessary for **primary progressive multiple sclerosis** (PPMS) when all of 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)

Date	Summary of Changes
	▪ Ocrevus Zunovo dosing is in accordance with the U.S. FDA approved labeling ▪ Initial authorization is for no more than 12 months ***Continuation of Therapy*** ▪ Patient has previously received treatment with 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) ▪ 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 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 is in accordance with the U.S. FDA approved labeling ▪ Initial authorization is for no more than 12 months ***Continuation of Therapy*** ▪ Patient has previously received treatment with 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) ▪ Ocrevus Zunovo dosing is in accordance with the U.S. FDA approved labeling ▪ Authorization is for no more than 12 months **Applicable Codes** • Added HCPCS codes C9399, J3490, and J3590 **Supporting Information** • Added *References* section • Archived previous policy version CSOH2024D0056.B

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]), or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC), or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC), or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC), or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.