MetroPlus Health

Policy and Procedure

Title: Ocrevus (ocrelizumab)	Division: Medical Management Department: Pharmacy
Approval Date: 7/30/2021	LOB: Medicare
Effective Date: 7/30/2021	Policy Number: UM-MP321
Review Date: 7/30/2022	Cross Reference Number:
Retired Date:	Page 1 of 5

1. POLICY DESCRIPTION:

Ocrevus (ocrelizumab) is a CD20-directed cytolytic antibody indicated for the treatment of:

- Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- Primary progressive MS, in adults

2. RESPONSIBLE PARTIES:

Pharmacy

3. DEFINITIONS:

Off-label/Unlabled Use: Use of a drug is defined as a use for a non-FDA approved indication, that is, one that is not listed on the drug's official label/prescribing information.

Indication: a diagnosis, illness, injury, syndrome, condition, or other clinical parameter for which a drug may be given.

4. POLICY:

Documentation, including chart notes and lab results, MUST be submitted for approval.

INITIAL REQUEST

A. RELAPSING FORMS OF MULTIPLE SCLEROSIS (RMS): Ocrevus used for the treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease will be covered with prior authorization when the following criteria are met:

i. Patient is 18 years of age or older **AND**

ii. Patient has a confirmed diagnosis consistent with relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease as defined by the following:

1. History of two or more clinical MS attacks who have objective clinical evidence of two or more lesions or objective clinical evidence of one lesion with reasonable historical evidence of a prior attack involving a lesion in a distinct anatomic location, confirmed by an MRI of the brain **AND**

iii. Patient has tried and failed at least 3 of the preferred disease modifying agents for MS (see Appendix A), unless intolerant or contraindicated to the medications **AND**

iv. Patient will not concomitantly use any other disease modifying therapies while taking OCREVUS **AND**

v. Patient does not have active hepatitis B virus infection **AND**
vi. Patient must be pre-medicated with 100 mg of methylprednisolone (or an equivalent corticosteroid) administered intravenously approximately 30 minutes prior to each infusion of OCREVUS **AND**
vii. Dose is within approved FDA dosing:
    1. Initial dose: 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion

B. PRIMARY PROGRESSIVE MULTIPLE SCLEROSIS (PPMS): Ocrevus used for the treatment of primary progressive multiple sclerosis will be covered with prior authorization when the following criteria are met:
i. Patient is 18 years of age or older **AND**
ii. Patient has a confirmed diagnosis of primary progressive multiple sclerosis as defined by:
    1. Evidence of one year of disease progression (retrospectively or prospectively determined), independent of clinical relapse, plus **two** of the following criteria:
        a. One or more hyperintense T2 lesions characteristic of MS in one or more of the periventricular, cortical or juxtacortical, or infratentorial areas
        b. Two or more hyperintense T2 lesions in the spinal cord
        c. Presence of CSF-specific oligoclonal bands **AND**
iii. Patient has had additional testing/procedures performed to support the diagnosis of MS including the following:
    1. MRI (brain or spinal cord)
    2. Lumbar puncture
    3. Autoantibody determination for aquaporin-4 (AQP4) and myelin-oligodendrocyte glycoprotein (MOG) antibodies **AND**
iv. Patient does not have active hepatitis B virus infection* **AND**
v. Patient must be pre-medicated with 100 mg of methylprednisolone (or an equivalent corticosteroid) administered intravenously approximately 30 minutes prior to each infusion of OCREVUS **AND**
vi. Dose is within approved FDA dosing:
    1. Initial dose: 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion

INITIAL DURATION OF APPROVAL: 6 months

RENEWAL REQUEST

A. All initial conditions of coverage have been met.
AND
B. The patient's condition has **not** worsened while on therapy
AND
C. The patient has **not** developed significant adverse drug effects including:
   i. Anaphylaxis or other hypersensitivity reactions
   ii. Life-threatening or disabling infusion reactions
   iii. Development of an active infection, especially Hepatitis B virus
   iv. Reduction in immunoglobulins
   v. Malignancies
AND
D. Continued dosing is within FDA approved dosing:
   i. One 600 mg intravenous infusion every 6 months

RENEWAL DURATION OF APPROVAL: 12 months

5. APPENDIX A – FDA Approved Medications and Dosages for Relapsing Forms of MS 6.

Available Products	Dosage Form	Dosage and Administration
Aubagio (teriflunomide)	Oral tablet	7 mg or 14 mg orally once daily
Copaxone,Glatopa (glatiramer acetate)	Subcutaneous injection	20 mg subcutaneously daily or 40 mg subcutaneously three times per week at least 48 hours apart (doses are not interchangeable)
Betaseron, Extavia (interferon B-1b)	Subcutaneous injection	Patients should be started at 0.0625 mg subcutaneously every other day, and increased over a six-week period to 0.25 mg every other day
Gilenya (fingolimod)	Oral tablet	0.5 mg orally once daily
Avonex, Rebif (interferon B-1a)	Subcutaneous injection	Avonex(R), 30 mcg IM once weekly, OR, initial, 7.5 mcg IM on week 1, then increase dose by 7.5 mcg each week until 30 mcg once weekly is reached; pretreatment with analgesics or antipyretics on injection days may decrease flu-like symptoms. Rebif, 22 mcg or 44 mcg injected subcutaneously three times per week. Patients should be started at 20% of the prescribed dose three times a week and increased over a 4-week period to the

Available Products	Dosage Form	Dosage and Administration
		targeted dose, either 22 mcg or 44 mcg three times a week.
Tecfidera (dimethyl fumerate)	Oral capsule, delayed release	Starting dose: 120 mg orally twice daily for 7 days Maintenance dose: 240 mg twice daily

7. LIMITATIONS/ EXCLUSIONS:

A. Patient should not be on any other disease modifying therapy for MS while on OCREVUS.

8. APPLICABLE PROCEDURE CODES:

CPT	Description
J2786	INJECTION, OCREVUS, 1 MG: 1 BILLABLE UNIT = 1 MG

9. APPLICABLE DIAGNOSIS CODES:

CODE	Description
G35	Multiple sclerosis

10. REFERENCES:

1. Ocrevus (ocrelizumab) [package insert]. South San Francisco, California: Genentech, Inc. December 2020.
2. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018;17(2):162-173. doi:10.1016/S1474-4422(17)30470-2. Accessed on January 8, 2021.
3. Ocrevus. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed January 8, 2021.

REVISION LOG:

REVISIONS	DATE
Creation date	7/30/2021

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Approved:	**Date:**	**Approved:**	**Date:**
Glendon Henry Digitally signed by Glendon Henry Date: 2021.08.02 12:34:13 -04'00'		Sanjiv Shah MD Digitally signed by Sanjiv Shah MD Date: 2021.08.04 10:31:45 -04'00'	
Glendon Henry, MD **Clinical Medical Director**	**7/30/2021**	**Sanjiv Shah, MD** **Chief Medical Officer**	

Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered andor paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.

All coding and website links are accurate at time of publication.

MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.