CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Ocrevus (ocrelizumab)
BILLING CODE	J2350 (1 unit = 1 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Home/Freestanding facility or clinic
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— Max 600 mg every 6 months
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Ocrevus (ocrelizumab) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

PRIMARY PROGRESSIVE MULTIPLE SCLEROSIS (PPMS)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Member must have evidence of at least **one** year of disease progression (worsening of neurological function without remission) documented in chart notes; AND
3. Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
4. Member must have **two** of the following:
   a) One or more MRI T2-weighted lesion(s) dissemination in space in the brain in periventricular, juxtacortical or infratentorial regions;
   b) Two or more MRI T2-weighted lesions dissemination in space in lesions in the spinal cord;
   c) Evidence in the spinal fluid (and not in serum) of oligoclonal bands or an elevated IgG index; AND
5. Member must have documented negative results on Hepatitis B screening (negative results for both HBsAg and anti-HBV). For patients who are negative for surface antigen (HBsAg) and positive for HB core antibody (HBcAb+) or are carriers of HBV (HBsAg+), consult hepatologist and submit hepatologist's assessment for appropriateness of Ocrevus therapy before starting treatment; AND
6. Member has all necessary immunizations administered (according to immunization guidelines) at least 6 weeks prior to initiation of Ocrevus; AND
7. Member does not have an active infection; AND
8. Ocrevus is not being used in combination with other Multiple Sclerosis therapies (*Note:* When switching from drugs with prolonged immune effects, such as daclizumab, fingolimod, natalizumab, teriflunomide, or mitoxantrone, consider the duration and mode of action of these drugs because of additive immunosuppressive effects when initiating Ocrevus).
9. **Dosage allowed:** 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion; then 600 mg intravenous infusion every 6 months.

If member meets all the requirements listed above, the medication will be approved 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Doses of Ocrevus are separated by at least 5 months.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

RELAPSING-REMITTING MULTIPLE SCLEROSIS (RRMS), SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS (SPMS)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Member must have evidence of at least **one** year of disease progression (worsening of neurological function without remission) documented in chart notes; AND
3. Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
4. Member must have documented negative results on Hepatitis B screening (negative results for both HBsAg and anti-HBV). For patients who are negative for surface antigen (HBsAg) and positive for HB core antibody (HBcAb+) or are carriers of HBV (HBsAg+), consult hepatologist and submit hepatologist's assessment for appropriateness of Ocrevus therapy before starting treatment; AND
5. Member has all necessary immunizations administered (according to immunization guidelines) at least 6 weeks prior to initiation of Ocrevus; AND
6. Member does not have an active infection; AND
7. Ocrevus is not been used in combination with other multiple sclerosis therapies (*Note:* When switching from drugs with prolonged immune effects, such as daclizumab, fingolimod, natalizumab, teriflunomide, or mitoxantrone, consider the duration and mode of action of these drugs because of additive immunosuppressive effects when initiating Ocrevus); AND
8. Member has documented trial and failure or contraindication to at least **two** preferred multiple sclerosis agents (two injectable drugs OR two oral drugs OR one injectable and one oral drug).
9. **Dosage allowed:** 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion; then 600 mg intravenous infusion every 6 months.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Doses of Ocrevus are separated by at least 5 months.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Ocrevus (ocrelizumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Clinically Isolated Syndrome (CIS) in Multiple Sclerosis

DATE	ACTION/DESCRIPTION
05/09/2017	New policy for Ocrevus created.
12/06/2017	Age coverage expanded.

References:

1. Ocrevus [package insert]. San Francisco, CA; Genentech, Inc: March, 2017.

2. Freeman MS, Thompson EJ, Deisenhammer F, et al: Recommended Standard of Cerebrospinal Fluid Analysis in the Diagnosis of Multiple Sclerosis. A Consensus Statement. Arch Neurol. 2005;62(6):865-870.
3. Andersson M, Alvarez-Cermeno J, Bernardi G, et al: Cerebrospinal fluid in the diagnosis of multiple sclerosis: a consensus report. J Neurol Neurosurg Psychiatry 1994;57:897-902.
4. Fortini AS, Sanders EL, Weinshenker BG, Katzmann JA: Cerebrospinal fluid oligoclonal bands in the diagnosis of multiple sclerosis, isoelectric focusing with the IgG immunoblotting compared with high resolution agarose gel electrophoresis and cerebrospinal fluid IgG index. Am J Clin Pathol 2003:120:672-675.
5. Polman, C. H., Reingold, S. C., Banwell, B., Clanet, M., Cohen, J. A., Filippi, M., Fujihara, K., Havrdova, E., Hutchinson, M., Kappos, L., Lublin, F. D., Montalban, X., O'Connor, P., Sandberg-Wollheim, M., Thompson, A. J., Waubant, E., Weinshenker, B. and Wolinsky, J. S. (2011), Diagnostic criteria for multiple sclerosis: 2010 Revisions to the McDonald criteria. Ann Neurol., 69: 292–302. doi:10.1002/ana.22366.

Effective date: 02/01/2018
Revised date: 12/06/2017