Policy Title:	Ocrevus (ocrelizumab) (Intravenous)		
Policy Number:	000575	**Department:**	PHA
Effective Date:	09/12/2018		
Review Date:			
Revision Date:			

Purpose: To support safe, effective and appropriate use of Ocrevus (ocrelizumab) in the treatment of Multiple Sclerosis.

Scope: Medicaid, Exchange, Integrity

Policy Statement:

Ocrevus (ocrelizumab) is covered under the medical benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Ocrevus (ocrelizumab) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria Coverage:

- Patient is at least 18 years of age; and
- Patient is diagnosed with primary progressive multiple sclerosis (PPMS) or relapsing form of multiple sclerosis as documented by laboratory report (i.e. MRI); and
- Must be prescribed by a neurologist; and
- Will be used as single agent therapy; and
- For members with relapsing forms of multiple sclerosis, they will need to provide documentation of one of the following:
  - The Member is newly diagnosed with relapsing multiple sclerosis
  - The Member's current or previous disease modifying therapy does not adequately control the disease as evidenced by disease progression or the member is experiencing intolerable adverse events.
- Initial dose does not exceed 300mg(300 billable units) initially followed two weeks later by a second dose of 300 mg (300 billable units)
- Maintenance dose does not exceed 600mg (600 billable units) every 6 months

Continuation of therapy:

- Patient diagnosed with PPMS:
  - Patient has not received a dose of ocrelizumab within the past 5 months
  - Patient is tolerating treatment with ocrelizumab
  - Patient has experienced a slowing of disease worsening (eg, no decline in Expanded Disability Status Score [EDSS] or MRI findings) since initiating therapy.
- Patient diagnosed with a relapsing form of MS:
  - Patient has not received a dose of ocrelizumab within the past 5 months
  - Patient is tolerating treatment with ocrelizumab
  - Patient has experienced disease improvement or slowing of disease worsening (eg, no decline in Expanded Disability Status Score [EDSS] or MRI findings) since initiating therapy.

Coverage durations:

- Initial coverage criteria = 6 months
- Continuation of therapy = 12 months

Investigational use: All Multiple sclerosis therapies is considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in one of the above listed resources. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Additional information:

Indications:

- Orevus (ocrelizumab) is FDA approved for the treatment of adult patients with relapsing or primary progressive forms of multiple sclerosis.

Dosing:

- The recommended dose of Ocrevus (ocrelizumab) is an initial dose of 300 mg intravenous infusion, followed two weeks later by a second dose of 300 mg IV infusion and all subsequent doses are 600 mg IV infusion every 6 months.

Administration:

- Under the close supervision of an experienced healthcare professional with access to appropriate medical support to manage severe reactions such as serious infusion reactions.

Applicable Codes:

Below is a list of billing codes applicable to covered treatment options for multiple sclerosis. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria are provided in the procedure section.

Codes:

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis(specify substance or drug), initial, up to 1 hour
96366	Intravenous infusion ,Each additional hour
J2350	Injection, ocrelizumab, 1mg

References:

Thomas RH, Wakefield RA. Oral disease-modifying therapies for relapsing-remitting multiple sclerosis. Am J Health Syst Pharm. 2015 Jan;72(1):25-38. PubMed

1. Fox RJ, Cutter G, Chan A, et al. Comparative Effectiveness Using A Matching-Adjusted Indirect Comparison Between Delayed-Release Dimethyl Fumarate and Fingolimod for The Treatment of Relapsing-Remitting Multiple Sclerosis. Value Health. 2015 Nov;18(7):A750. Epub 2015 Oct 20. PubMed
2. Metin H, Huppertz H. Adjusted Indirect Comparison of Oral Multiple Sclerosis Agents. Value Health. 2015 Nov;18(7):A750. Epub 2015 Oct 20. PubMed
3. Tramacere I, Del Giovane C, Salanti G, et al. Immunomodulators and immunosuppressants for relapsing-remitting multiple sclerosis: a network meta-analysis. Cochrane Database Syst Rev. 2015. PubMed
4. Tolley K, Hutchinson M, You X, et al. A Network Meta-Analysis of Efficacy and Evaluation of Safety of Subcutaneous Pegylated Interferon Beta-1a versus Other Injectable Therapies for the Treatment of Relapsing-Remitting Multiple Sclerosis. PLoS One. 2015;10(6):e0127960.
5. Bainbridge JL, Miravalle A, Corboy JR. Multiple Sclerosis. In: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L, eds. Pharmacotherapy: A Pathophysiologic Approach. 9th ed. New York, NY: McGraw-Hill; 2014. http://accesspharmacy.mhmedical.com/content.aspx?bookid=689&Sectionid=45310489. Accessed May 18, 2016.
6. Goodin DS, Frohman EM, Garmany GP, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002;58(2):169-178.
7. Hauser SL, Bar-Or A, Comi G, Giovannoni G, Hartung HP, Hemmer B, Lublin F, Montalban X, Rammohan KW, Selmaj K, et al. Ocrevus versus Interferon Beta-1a in Relapsing Multiple Sclerosis. N Eng J Med. 2016;376(3):221–234. doi: 10.1056/NEJMoa1601277.
8. Montalban X, et al. Ocrevus versus Placebo in Primary Progressive Multiple Sclerosis. N Engl J Med. 2017;376:209–220. doi: 10.1056/NEJMoa1606468
9. Ocrevus [package insert] South San Francisco, CA: Genentech, Inc.; March 2018