Ocrelizumab (Ocrevus)

Policy ID: I-9171-004
Section: Injections
Effective Date: April 01, 2021
Revised Date: March 16, 2023
Revision Effective Date: April 01, 2023
Last Reviewed: March 23, 2023

Applies To: Commercial Only

Description

Ocrelizumab (Ocrevus®) is a CD20-directed cytolytic antibody indicated for relapsing or primary progressive forms of multiple sclerosis (MS).

Criteria

Coverage is subject to the specific terms of the member's benefit plan.

Federal Employee Program members (FEP) should check with their Retail Pharmacy Program to determine if prior approval is required by calling the Retail Pharmacy Program at 1-800-624-5060 (TTY: 1-800-624-5077). FEP members can also obtain the list through the www.fepblue.org website.

***Preferred generic agents**
dimethyl fumarate
fingolimod
glatiramer
teriflunomide

Ocrelizumab (Ocrevus) may be considered medically necessary when the following criteria are met:

- ONE of the following:

- Information has been provided that the individual has been treated with ocrelizumab (Ocrevus) within the past 210 days; **or**
- The prescriber states the individual has been treated with ocrelizumab (Ocrevus) within the past 210 days AND is at risk if therapy is changed; **or**
- The individual has a diagnosis of a relapsing form of multiple sclerosis (MS) AND BOTH of the following:
    - ONE of the following:
        - The individual has a diagnosis of clinically isolated syndrome (CIS) AND ALL of the following:
            - The individual had a single event that lasted at least 24 hours; **and**
            - The event was not due to fever or infection; **and**
            - The individual has MS-like brain lesion(s) confirmed by magnetic resonance imaging (MRI); **or**
        - The individual has a diagnosis of relapsing remitting multiple sclerosis (RRMS) or secondary progressive multiple sclerosis (SPMS); **and**
    - ONE of the following **:**
        - The individual has highly active MS disease activity AND BOTH of the following:
            - The individual has greater than or equal to two (2) relapses in the previous year; **and**
            - ONE of the following:
                - The individual has greater than or equal to one (1) gadolinium enhancing lesion on MRI; **or**
                - The individual has a significant increase in T2 lesion load compared with a previous MRI; **or**
        - The individual has been treated with at least three (3) MS agents form different drug classes; **or**
        - ONE of the following:
            - The individual has tried and had an inadequate response to ONE preferred generic agent* FDA approved for the treatment of the requested indication; **or**
            - The individual has an intolerance or hypersensitivity to ONE preferred generic agent FDA approved for the

treatment of the requested indication; **or**
    - The individual has an FDA labeled contraindication to ALL preferred generic agents that are FDA approved for the treatment of the requested indication; **or**
    - The prescriber has provided information in support of using ocrelizumab (Ocrevus) over ALL preferred generic agents FDA approved for the treatment of the requested indication; **or**
  - The individual has a diagnosis of primary progressive multiple sclerosis (PPMS); **or**
  - The individual has another FDA approved indication for ocrelizumab (Ocrevus); **and**
- If the individual has an FDA approved indication, then ONE of the following:
  - The individual's age is within FDA labeling for the requested indication for ocrelizumab (Ocrevus); **or**
  - The prescriber has provided information in support of using ocrelizumab (Ocrevus) for the individual's age and requested indication; **and**
- The prescriber is a specialist in the area of the individual's diagnosis (i.e., neurologist), or the prescriber has consulted with a specialist in the area of the individual's diagnosis; **and**
- The individual will NOT be using ocrelizumab (Ocrevus) in combination with another disease modifying agent (DMA) for the requested indication.

The use of ocrelizumab (Ocrevus) for all other indications not listed in this policy is considered experimental/investigational and therefore non-covered because the safety and/or effectiveness cannot be established by the available published peer-reviewed literature.

Procedure Codes

J2350

Reauthorization Criteria

Ocrelizumab (Ocrevus) may be considered medically necessary when the following criteria are met:

- The individual has been previously approved for ocrelizumab (Ocrevus) through Blue Cross Blue Shield of North Dakota's precertification process; **and**
- The individual has an FDA approved indication for ocrelizumab (Ocrevus); **and**
- The individual has had clinical benefit from treatment with ocrelizumab (Ocrevus); **and**
- The prescriber is a specialist in the area of the individual's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the individual's diagnosis; **and**
- The individual will NOT be using ocrelizumab (Ocrevus) in combination with another disease modifying agent (DMA) for the requested indication.

The use of ocrelizumab (Ocrevus) for all other indications not listed in this policy is considered experimental/investigational and therefore non-covered because the safety and/or effectiveness cannot be established by the available published peer-reviewed literature.

Procedure Codes

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NOTE: In addition to the above criteria, product specific dosage and/or frequency limits may apply in accordance with the U.S. Food and Drug Administration (FDA)-approved product prescribing information, national compendia, Centers for Medicare and Medicaid Services (CMS) and other peer reviewed resources or evidence-based guidelines.

Diagnosis Codes

G35

Professional Statements and Societal Positions Guidelines

MS Disease Modifying Agents drug classes

Class	Class Drug Agents
CD20 monoclonal antibody	
CD20 monoclonal antibody	BRIUMVI*ublituximab-xiiy soln for iv infusion
CD20 monoclonal antibody	KESIMPTA*Ofatumumab Soln Auto-Injector
CD20 monoclonal antibody	OCREVUS*Ocrelizumab Soln For IV Infusion
CD52 monoclonal antibody	
CD52 monoclonal antibody	LEMTRADA*Alemtuzumab IV Inj
Fumarates	
Fumarates	BAFIERTAM*Monomethyl Fumarate Capsule Delayed Release
Fumarates	TECFIDERA*Dimethyl Fumarate Capsule Delayed Release
Fumarates	VUMERITY*Diroximel Fumarate Capsule Delayed Release
Glatiramer	
Glatiramer	COPAXONE*Glatiramer Acetate Soln Prefilled Syringe
Glatiramer	GLATOPA*Glatiramer Acetate Soln Prefilled Syringe

Class	Class Drug Agents
IgG4k monoclonal antibody	
IgG4k monoclonal antibody	TYSABRI*Natalizumab for IV Inj Conc
Interferons	
Interferons	AVONEX*Interferon beta-1a injection
Interferons	BETASERON*Interferon beta-1b injection
Interferons	EXTAVIA*Interferon beta-1b injection
Interferons	PLEGRIDY*Peginterferon beta-1a injection
Interferons	REBIF*Interferon beta-1a injection
Purine antimetabolite	
Purine antimetabolite	MAVENCLAD*Cladribine Tab Therapy Pack
Pyrimidine synthesis inhibitor	
Pyrimidine synthesis inhibitor	AUBAGIO*Teriflunomide Tab
Sphingosine 1-phosphate (SIP) receptor modulator	
Sphingosine 1-phosphate (SIP) receptor modulator	GILENYA*Fingolimod HCl Cap

Class	Class Drug Agents
Sphingosine 1-phosphate (SIP) receptor modulator	MAYZENT*Siponimod Fumarate Tab
Sphingosine 1-phosphate (SIP) receptor modulator	PONVORY*Ponesimod Tab
Sphingosine 1-phosphate (SIP) receptor modulator	TASCENSO*fingolimod lauryl sulfate tablet disintegrating
Sphingosine 1-phosphate (SIP) receptor modulator	ZEPOSIA*Ozanimod capsule

Agents NOT to be used Concomitantly (subject to change)

MS Disease Modifying Agents
Aubagio (teriflunomide)
Avonex (interferon b-1a)
Bafiertam (monomethyl fumarate)
Betaseron (interferon b-1b)
Briumvi (ublituximab-xiiy)
Copaxone (glatiramer)
Dimethyl fumarate
Extavia (interferon b-1b)
fingolimod
Gilenya (fingolimod)
Glatopa (glatiramer)
Glatiramer
Kesimpta (ofatumumab)
Mavenclad (cladribine)
Mayzent (siponimod)
Plegridy (peginterferon b-1a)
Ponvory (ponesimod)
Rebif (interferon b-1a)
Tascenso ODT (fingolimod)
Tecfidera (dimethyl fumarate)a

Vumerity (diroximel fumarate)
Zeposia (ozanimod)

ND Committee Review

Internal Medical Policy Committee 3-17-2021 Adopted policy was previously policy number I-171 (same title)

Internal Medical Policy Committee 3-23-2022 Update criteria wording, removed preferred brand agent step

Internal Medical Policy Committee 11-29-2022 - ***Effective December 01, 2022***

- ***Added*** fingolimod as a preferred generic agent, **and**
- ***Removed*** hepatitis B criteria from the policy, **and**
- ***Removed*** FDA labeled contraindications criteria from the policy; **and**
- ***Added*** Agents NOT to be used Concomitantly list, **and**
- ***Updated*** experimental/investigational statement

Internal Medical Policy Committee 3-23-2023 ***Effective April 03, 2023***

- ***Added*** teriflunomide as a preferred generic agent
- ***Updated*** Agents NOT to be used Concomitantly list and MS Disease Modifying Agents drug classes table

Links

References (PDF)

Fargo (Headquarters)
4510 13th Ave. S.
Fargo, N.D., 58121

Non-Discrimination Notice

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