FirstChoice VIP CARE
by Select Health of South Carolina

Medical Policy Bulletin
Title:
Ocrelizumab (Ocrevus®)
Policy #:
MA08.088c

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.

The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.

MEDICALLY NECESSARY

Ocrelizumab (Ocrevus) is considered medically necessary and, therefore, covered for the treatment of adults with either relapsing forms of multiple sclerosis (RMS) (including clinically isolated syndrome (CIS), relapsing-remitting disease, and active secondary progressive disease) or primary progressive forms of multiple sclerosis (PPMS) when the individual is hepatitis B negative (i.e., has negative results for hepatitis B surface antigen [HBsAG] and anti-hepatitis B virus tests).

EXPERIMENTAL/INVESTIGATIONAL

All other uses for ocrelizumab (Ocrevus), including nonrelapsing secondary progressive MS, are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

Guidelines

There is no Medicare coverage determination addressing ocrelizumab (Ocrevus); therefore, the Company policy is applicable.

BENEFIT APPLICATION

Subject to the applicable Evidence of Coverage, ocrelizumab (Ocrevus) is covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria listed in this medical policy are met.

For Medicare Advantage members, certain drugs are available through either the member's medical benefit (Part B benefit) or pharmacy benefit (Part D benefit), depending on how the drug is prescribed, dispensed, or administered. This medical policy only addresses instances when ocrelizumab (Ocrevus) is covered under a member's medical benefit (Part B benefit). It does not address instances when ocrelizumab (Ocrevus) is covered under a member's pharmacy benefit (Part D benefit).

DRUG ADMINISTRATION

The dosing of ocrelizumab (Ocrevus) is as follows:

- Initial dose: 300 mg intravenous (IV) infusion, followed two weeks later by a second 300 mg IV infusion.
- Subsequent doses: single 600 mg IV infusion every six months.

HEPATITIS B SEROLOGIC MARKER DEFINITIONS

According to the Centers for Disease Control (CDC):

- Hepatitis B surface antigen (HBsAg): The presence of HBsAg, a protein on the surface of the hepatitis B virus (HBV), indicates that the person is infectious. It can be detected in high levels in serum during acute or chronic HBV infection. The body normally produces antibodies to HBsAg as part of the normal immune response to infection. HBsAg is the antigen used to make hepatitis B vaccine.
- Hepatitis B surface antibody (anti-HBs): The presence of anti-HBs is generally interpreted as indicating recovery and immunity from HBV infection. Anti-HBs also develops in a person who has been successfully vaccinated against hepatitis B.

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

Ocrelizumab (Ocrevus) was approved by the FDA on March 28, 2017 for the treatment of adults with relapsing or primary progressive forms of multiple sclerosis. Supplemental approvals for ocrelizumab (Ocrevus) have since been issued by the FDA.

PEDIATRIC USE
The safety and effectiveness of ocrelizumab (Ocrevus) in the pediatric population have not been established.

Description

MULTIPLE SCLEROSIS (MS) BACKGROUND

Multiple sclerosis (MS) is an inflammatory disease of the central nervous system (CNS) where the immune system attacks nerve fibers (called axons) and the protective coating that surrounds them (called myelin sheath). Myelin that has been damaged forms scar tissue called sclerosis or plaques that can be seen with a magnetic resonance imaging (MRI) scan of the brain in individuals with MS. The myelin sheath sends nerve impulses throughout the CNS. Once damaged, communication between the nerve impulses and the targeted area of the body are distorted or interrupted, producing a variety of symptoms. Symptoms of MS vary between individuals. Even in those who relapse, symptoms may differ with each episode. Examples of common symptoms include: motor weakness, limb ataxia, gait or balance problems, vertigo, bladder/bowel dysfunction, sensory loss, heat intolerance, fatigue, visual and cognitive impairment, depression, and pain. There are many hypotheses as to the causes of MS, including those with a basis

of infection, genetics, immunological, and environmental, however, the causes of MS have not been established. It is estimated that 250,000 to 400,000 individuals in the United States and 2.5 million individuals worldwide are affected by MS.

TYPES OF MULTIPLE SCLEROSIS (MS) AND THEIR TREATMENTS

There is currently no cure for MS. Medications can be used to treat acute relapses (e.g., corticosteroids), slow the progression of the disease and reduce the number and severity of relapses (e.g., MS disease-modifying therapies), and improve symptoms that occur, such as fatigue, pain, and depression.

The four major types of MS include:

- Clinical isolated syndrome (CIS) is the first episode of a neurologic event associated with inflammation and demyelination involving the central nervous system that lasts at least 24 hours. There is a high chance (60-80 percent) of developing a secondary episode and a diagnosis of relapsing/remitting MS (RRMS) when CIS is accompanied by lesions on a brain MRI that are similar to those seen in MS. When not accompanied by MS-like lesions on a brain MRI, there is a lower chance (20 percent) of developing MS.
    - Treatment of CIS may consist of the following medications:
        - Ocrelizumab (Ocrevus) and siponimod (Mayzent®) are US Food and Drug Administration (FDA)-approved for CIS; however, there is a paucity of published data for siponimod (Mayzent®)
        - Glatiramer acetate and interferon beta 1a (IFN-β-1a) are more effective than placebo in reducing the proportion of individuals converting to MS (Rae-Grant 2018)
        - Per the authors of the systematic review, the following disease modifying therapies (DMTs) are probably more effective than placebo in reducing the proportion of individuals converting to MS: cladribine (safety concerns), immunoglobulins, IFN- β-1a (Avonex®, Rebif®), IFN- β-1b (Betaseron®), and teriflunomide (Aubagio®) (Rae-Grant 2018)
- Relapsing-remitting MS (RRMS): RRMS is the most common form of MS, accounting for approximately 85 percent of all MS cases. It is characterized by recurrent attacks to the nervous system, followed by complete recovery or partial recovery where some symptoms become permanent. There is no or minimal disease progression during remission.
    - Treatment of RRMS progression may consist of the following medications (Filippini 2013, Rae-Grant 2018):
        - MS disease-modifying therapies (e.g., alemtuzumab [Lemtrada®], dimethyl fumarate [Tecfidera®], fingolimod [Gilenya®]), glatiramer acetate [Copaxone®], IFN- β-1a [Avonex®, Rebif®], IFN- β-1b [Betaseron®], natalizumab [Tysabri®], ocrelizumab [Ocrevus], rituximab [Rituxan®], siponimod (Mayzent®), teriflunomide [Aubagio®].
        - Azathioprine (Imuran®)
        - Cladribine
        - Intravenous immunoglobulin (IVIG)
        - Mitoxantrone
        - Stem cell transplantations
    - The results of a Cochrane review and Practice Guideline suggested an unfavorable risk-benefit balance for the following drugs: IFN- β-1a [Avonex®], IVIG, cyclophosphamide, and long-term steroids. The Cochrane review also noted the paucity of high-quality data regarding the use of azathioprine (Filippini 2013, Rae-Grant 2018)
- Primary progressive MS (PPMS): PPMS represents about 10-15 percent of all MS cases. It is characterized by gradual disease progression from symptom onset. There are periods of active disease, occasional plateaus, and temporary minor improvement of symptoms, but there are no distinct relapses or remissions.
    - Ocrelizumab (Ocrevus) was the first and only drug FDA-approved for the treatment of PPSM.
    - Some individuals may respond to the following treatments; however, randomized controlled trials have failed to show consistent benefit for the treatment of PPMS: azathioprine, cladribine, intravenous (IV) bimonthly glucocorticoid pulses, IV cyclophosphamide, MS disease-modifying therapies (e.g., interferons, glatiramer acetate [Copaxone®], fingolimod [Gilenya®]), IVIG, methotrexate, mitoxantrone, rituximab (Rituxan®), stem cell transplantations. The results of a Cochrane review in 2013 showed a paucity of high-quality data for the following drugs, since they were ineffective in preventing disability progression over two to three years: IFN- β-1a [Avonex®,

Rebif®], IFN- β-1b [Betaseron®], glatiramer acetate [Copaxone®]), mitoxantrone, methotrexate, cyclophosphamide, IVIG, rituximab (Rituxan®), and long-term corticosteroids. (Filippini 2013, Rae-Grant 2018)

- Secondary progressive MS (SPMS): SPMS initially presents as RRMS, but later transitions to a condition similar to PPMS. It is a progressive disease that may or may not have relapses. It is estimated that 80 percent of all individuals with RRMS will develop this type of MS.
    - Treatments for SPSM may consist of the following: MS disease-modifying therapies (e.g., ocrelizumab [Ocrevus], siponimod [Mayzent®]), cladribine, mitoxantrone, IV bimonthly glucocorticoid pulses, or IV cyclophosphamide
    - Some individuals may respond to the following treatments, however randomized controlled trials have failed to show consistent benefit for the treatment of PPMS: azathioprine, cladribine, IV cyclophosphamide, interferons, IVIG, methotrexate, mitoxantrone, stem cell transplantation (Rae-Grant 2018)

In addition to the major types of MS listed above, all types of MS can further be characterized into the following stages of disease:

- Active disease: i.e., whether there are relapses or MRI changes
- Not active disease: i.e., showing no evidence of disease activity
- Disease worsening, or with progression: e.g., increased disability over a specific time period, with or without relapses; or objective measure of disease worsening over a specific time period, with or without relapses
- Non-worsening or stable or without progression: e.g., no evidence of disease worsening or increased disability over a specific time period

OCRELIZUMAB (OCREVUS)
Ocrelizumab (Ocrevus) was approved by the FDA on March 28, 2017 for the treatment of adults with relapsing or primary progressive forms of multiple sclerosis. Ocrelizumab (Ocrevus) was the first drug FDA-approved for the treatment of PPMS. On July 16, 2019, the FDA expanded the indication of relapsing forms of MS to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Ocrelizumab (Ocrevus) is a recombinant humanized monoclonal antibody that selectively targets Cluster of Differentiation 20 (CD20), a cell surface antigen expressed on only certain B-cells (pre-B, mature B, and memory B-cells, but not lymphoid stem cells and plasma cells). Following cell surface binding to B lymphocytes, ocrelizumab (Ocrevus) is thought to cause apoptosis, antibody-dependent cellular cytolysis (cell membrane destruction), and complement-mediated lysis involving macrophages, natural killer cells, etc. to cause cell destruction. The specificity for targeting only certain B-cells allows the immune function to remain intact, since the levels of immunoglobulin G (IgG) and IgM are not diminished.

Peer-reviewed Literature
Summary

Primary Progressive Multiple Sclerosis (PPMS)
Montalban et al 2017 performed the ORATORIO trial, a Phase 3, randomized (2:1), double-blind, placebo-controlled trial that investigated the safety and effectiveness of ocrelizumab (Ocrevus) in the treatment of PPMS. Seven hundred thirty-two participants were diagnosed with PPMS per 2005 revised McDonald criteria and had a score on the Expanded Disability Status Scale (EDSS) of 3-6.5 at screening (range 0-10, where higher scores indicate greater disability). Approximately 88 percent of participants had not received a previous disease-modifying therapy for MS. Participants received ocrelizumab (Ocrevus) 600 mg (N=488) or placebo (N=244) every 24 weeks for at least 120 weeks. The primary endpoint of the study was the percentage of individuals with disability progression confirmed at 12 weeks in a time-to-event analysis where disability progression was defined as an increase in EDSS of at least one point from baseline if baseline was 5.5 or less, or an increase of 0.5 if baseline was more than 5.5. Disability progression at 12-weeks was confirmed in 32.9 percent of those in the ocrelizumab (Ocrevus) group and 39.3 percent in the placebo group, which was statistically significant. The adverse event that was most frequently reported was infusion-related reactions: 39.9 percent in the ocrelizumab (Ocrevus) group and 25.5 percent in the placebo group. There was an increase incidence of neoplasms in the ocrelizumab (Ocrevus) group (2.3 percent) compared to those in the placebo group (0.8 percent). No cases of progressive multifocal leukoencephalopathy (PML) have been reported during clinical studies. The authors reported that further evaluation of the occurrence of neoplasms and PML risk is warranted.

Relapsing Multiple Sclerosis (RMS)
Hauser et al 2017 investigated the safety and effectiveness of ocrelizumab (Ocrevus) in the treatment of relapsing

multiple sclerosis (RMS) in the OPERA I (N=821) and OPERA II (N=835) studies, which are identical, Phase 3, randomized (1:1) trials. Eligibility included a diagnosed of RMS per 2010 revised McDonald criteria, a score on the Expanded Disability Status Scale (EDSS) of 0-5.5 at screening (range 0-10, where higher scores indicate greater disability), and at least two documented clinical relapses within the previous two years or one clinical relapse within the year before screening. Approximately 73 percent of participants had not received a previous disease-modifying therapy for MS. Participants received ocrelizumab (Ocrevus) 600 mg every 24 weeks and placebo subcutaneous injection three times weekly or subcutaneous IFN- β-1a 44mcg three times weekly and placebo IV infusion every 24 weeks for 96 weeks. The primary endpoint was the annualized relapse rate by 96 weeks. Ocrelizumab (Ocrevus) significantly decreased the annualized relapse rate at week 96 as follows: Trial 1 (0.16 vs 0.29) 46 percent lower rate in the ocrelizumab (Ocrevus) group and Trial 2 (0.16 vs 0.29) 47 percent lower rate in the ocrelizumab (Ocrevus) group. Infusion reactions occurred more frequently in the ocrelizumab (Ocrevus) group (34.3 percent) compared to the IFN- β-1a group who received placebo IV infusions (9.7 percent). There was an increase incidence of neoplasms in the ocrelizumab (Ocrevus) group (0.5 percent) compared to those in the placebo group (0.2 percent). During the open-label extension study where all participants received ocrelizumab (Ocrevus), five more cases of neoplasm occurred. No cases of PML have been reported during clinical studies. The authors reported that further evaluation of the occurrence of neoplasms and PML risk is warranted.

OFF-LABEL INDICATIONS

There may be additional indications contained in the Policy section of this document due to evaluation of criteria highlighted in the Company's off-label policy, and/or review of clinical guidelines issued by leading professional organizations and government entities.

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Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)
N/A

ICD - 10 Procedure Code Number(s)
N/A

ICD - 10 Diagnosis Code Number(s)
G35 Multiple sclerosis

HCPCS Level II Code Number(s)
J2350 Injection, ocrelizumab, 1 mg

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Revenue Code Number(s)
N/A

Policy History

Revisions From MA08.088c:

05/07/2024	The policy has been reviewed and reissued to communicate the Company's continuing position on ocrelizumab (Ocrevus).
09/05/2023	The policy has been reviewed and reissued to communicate the Company's continuing position on ocrelizumab (Ocrevus).
06/15/2022	The policy has been reviewed and reissued to communicate the Company's continuing position on ocrelizumab (Ocrevus).
05/24/2021	The policy has been reviewed and reissued to communicate the Company's continuing position on ocrelizumab (Ocrevus).
06/17/2020	This version of the policy will become effective 06/17/2020. The policy has been reviewed and reissued to communicate the Company's continuing position on ocrelizumab (Ocrevus).
09/23/2019	This policy has undergone a routine review and the medical necessity criteria have been revised to reflect the updated FDA labeling for relapsing forms of multiple sclerosis (RMS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. Experimental/Investigational coverage position has been added for nonrelapsing secondary progressive MS.

Revisions From MA08.088b:

05/22/2019	This policy has been reissued in accordance with the Company's annual review process.
07/03/2018	The policy has been reviewed and reissued to communicate the Company's continuing position on Ocrelizumab (Ocrevus™). Definitions of two hepatitis B serologic markers have been added to the Guidelines Section.
01/01/2018	This policy has been identified for the HCPCS code update, effective 01/01/2018. The following HCPCS code has been **added** to this policy: J2350 Injection, ocrelizumab, 1 mg The following HCPCS codes have been **removed** from this policy: C9494 Injection, ocrelizumab, 1 mg J3590 Unclassified biologics

Revisions From MA08.088a:

10/01/2017	This policy has been identified for the HCPCS code update, effective 10/01/2017. The following HCPCS code has been **added** to this policy: C9494 Injection, ocrelizumab, 1 mg

Revisions From MA08.088:

08/23/2017	The following new policy has been developed to communicate the Company's coverage criteria for ocrelizumab (Ocrevus™).

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Version Issued Date:

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by Select Health of South Carolina
09/17/2019
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