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5.60.047

Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	October 9, 2020
Subject:	Kesimpta	**Page:**	1 of 5

Last Review Date: December 8, 2023

Kesimpta

Description

Kesimpta (ofatumumab)

Background
Kesimpta (ofatumumab) is a multiple sclerosis (MS) disease-modifying agent. Kesimpta can potentially alter the course of disease by lessening the frequency of relapses and disease progression. Kesimpta is a recombinant human monoclonal antibody that targets CD20 proteins on premature and mature B cells. Kesimpta binds to CD20 on B cells which results in antibody-dependent cellular cytolysis and complement-mediated lysis (1).

Regulatory Status
FDA-approved indication: Kesimpta 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 (1).

Kesimpta is contraindicated in patients with active hepatitis B virus (HBV) infection. Complete HBV screening prior to the initiation of Kesimpta. There are no reports of HBV reactivation in MS patients treated with Kesimpta. However, HBV reactivation has occurred in other anti-CD20 antibodies which resulted in fulminant hepatitis, hepatic failure, and death (1).

The administration of Kesimpta should be delayed in patients with active infections until the infection has resolved (1).

Administer all immunizations according to immunization guidelines at least 4 weeks prior to drug initiation for live or live-attenuated vaccines and whenever possible, at least 2 weeks prior to

initiation of Kesimpta for inactivated vaccines. Live or live-attenuated vaccines are generally not recommended during treatment and after discontinuation until B-cell repletion (1).

As expected with any B-cell depleting therapy, decreased immunoglobulin levels were observed. Monitor the levels of immunoglobulins at the beginning, during, and after discontinuation of treatment with Kesimpta until B-cell repletion (1).

According to the algorithm defined by Pharmacotherapy: A Pathophysiologic Approach for the management of clinically definite multiple sclerosis, it may be reasonable for patients with severe disease to use a monoclonal antibody without having tried other MS therapies (2).

Safety and effectiveness of Kesimpta in pediatric patients have not been established (1).

Related policies
Acthar Gel, Ampyra, Aubagio, Gilenya, Lemtrada, Mavenclad, Mayzent, MS Injectables, Ocrevus, Ponvory, Tecfidera, Tysabri, Zeposia

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Kesimpta may be considered **medically necessary** if the conditions indicated below are met.

Kesimpta may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Relapsing Multiple Sclerosis (RMS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
    a. Ineffective treatment response due to continued clinical relapse, intolerance, or contraindication to two or more MS drugs

i. Does not apply if the patient has advanced, progressive, or severe disease

AND ALL of the following:

1. Patient is not at risk for HBV infection **OR** patient is at risk for HBV infection and HBV infection has been ruled out or treatment for HBV infection has been initiated
2. Absence of active infection
3. Prescriber agrees to monitor immunoglobulins at the beginning, during and after discontinuation of therapy
4. **NOT** used in combination with another MS disease-modifying agent
5. **NOT** used in combination with other immune-modulating or immunosuppressive therapies, including immunosuppressant doses of corticosteroids
6. **NOT** given concurrently with live vaccines or live-attenuated vaccines

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Relapsing Multiple Sclerosis (RMS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AND ALL of the following:

1. Absence of active infection
2. Prescriber agrees to monitor immunoglobulins during and after discontinuation of therapy
3. **NOT** used in combination with another MS disease-modifying agent
4. **NOT** used in combination with other immune-modulating or immunosuppressive therapies, including immunosuppressant doses of corticosteroids
5. **NOT** given concurrently with live vaccines or live-attenuated vaccines

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Duration 2 years

Prior – Approval *Renewal* Limits
Same as above

Rationale

Summary
Kesimpta (ofatumumab) is a multiple sclerosis (MS) disease-modifying agent. Kesimpta can potentially alter the course of disease by lessening the frequency of relapses and disease progression. Kesimpta is a recombinant human monoclonal antibody that targets CD20 proteins on premature and mature B cells. Kesimpta binds to CD20 on B cells which results in antibody-dependent cellular cytolysis and complement-mediated lysis (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of the Kesimpta while maintaining optimal therapeutic outcomes.

References

1. Kesimpta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2022.
2. Bainbridge, Jacquelyn L., et al. "Multiple Sclerosis." Pharmacotherapy: A Pathophysiologic Approach, 11e, 2020. Available at: https://accesspharmacy.mhmedical.com/content.aspx?bookid=2577&sectionid=231921409.

Policy History

Date	Action
October 2020	Addition to PA
December 2020	Annual review
June 2021	Annual review

June 2022	Annual review
December 2022	Annual review and reference update. Changed policy number to 5.60.047. Per SME, added caveat that t/f of two MS drugs does not apply if the patient has advanced, progressive, or severe disease
June 2023	Annual review
December 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.