

5.60.047

Section:	Prescription Drugs	Effective Date:	January 1, 2023
Subsection:	Central Nervous System Drugs	Original Policy Date:	October 9, 2020
Subject:	Kesimpta	Page:	1 of 5

Last Review Date: December 2, 2022

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 cytotoxicity 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

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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** for patients 18 years of age or older for the treatment of relapsing multiple sclerosis and if the conditions indicated below are met.

Kesimpta may be considered **investigational** in patients less than 18 years of age and 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

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- 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

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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 cytotoxicity 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§ionid=231921409>.

Policy History

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

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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

Keywords

This policy was approved by the FEP[®] Pharmacy and Medical Policy Committee on December 2, 2022 and is effective on January 1, 2023.