Oscar Clinical Guideline: Kesimpta (ofatumumab) (PG225, Ver. 3)

Kesimpta (ofatumumab)

Summary

Multiple sclerosis (MS) is a chronic, inflammatory, demyelinating disease of the central nervous system. It typically presents in young adults (generally diagnosed before 50 years of age) with symptoms such as vision problems, muscle weakness, numbness, and difficulty with balance and coordination. The most common form is relapsing-remitting MS (occurring in about 85% of patients), characterized by acute attacks followed by periods of remission. Treatment goals include reducing relapses, slowing disability progression, and managing symptoms. Disease-modifying therapies (DMTs) are the primary treatment approach and include injectable medications (e.g., interferons, glatiramer acetate), oral medications (e.g., dimethyl fumarate, fingolimod, teriflunomide, etc.), and infusion therapies (e.g., natalizumab, ocrelizumab).

Kesimpta (ofatumumab) is a recombinant human anti-CD20 monoclonal antibody indicated for treating relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. It acts by binding to CD20 on B lymphocytes, causing B-cell depletion through antibody-dependent cellular cytotoxicity and complement-dependent cytotoxicity. Kesimpta is administered subcutaneously, offering a self-administered option among high-efficacy therapies.

Definitions

"Clinically isolated syndrome" refers to a first episode of neurologic symptoms lasting at least 24 hours caused by inflammation or demyelination in the central nervous system.

"Compendia" are summaries of drug information and medical evidence to support decision-making about the appropriate use of drugs and medical procedures. Examples include, but are not limited to:

1. American Hospital Formulary Service Drug Information
2. Clinical pharmacology
3. National Comprehensive Cancer Network Drugs and Biologics Compendium
4. Thomson Micromedex DrugDex
5. United States Pharmacopeia-National Formulary (USP-NF)

"Disease-modifying therapy" is a medication that modifies the course of MS by reducing relapses and slowing disability progression.

"Multiple sclerosis" is a chronic autoimmune disease of the central nervous system characterized by inflammation, demyelination, and neurodegeneration.

"Primary progressive MS" refers to worsening neurologic function from the onset of symptoms, without early relapses or remissions.

"Relapse" is defined as the appearance of new symptoms or the worsening of existing symptoms lasting at least 24 hours in the absence of fever or infection.

"Relapsing-remitting MS" refers to a disease course characterized by clearly defined attacks of new or increasing neurologic symptoms followed by periods of partial or complete recovery.

"Secondary progressive MS" is a disease course following relapsing-remitting MS that is characterized by a progressive worsening of neurologic function over time with or without relapses.

Medical Necessity Criteria for Initial Authorization

The Plan considers Kesimpta (ofatumumab) medically necessary when recent (within the last 3 months) clinical chart documentation provided indicates the member meets ALL of the following:

1. Prescribed by or in consultation with a neurologist or physician who specializes in the treatment of multiple sclerosis; *AND*
2. Is 18 years of age or older; *AND*
3. Has ONE of the following forms of multiple sclerosis:
    a. relapsing-remitting (RRMS)*; or*
    b. active secondary progressive disease (SPMS)*; or*

c. clinically isolated syndrome (CIS); *AND*

4. Meets ONE of the following:
    a. Documentation of highly active or aggressive disease, as demonstrated by at least ONE of the following:
        i. Frequent relapses (≥2 in the past year)*; or*
        ii. At least 1 relapse with incomplete recovery and MRI activity*; or*
        iii. Rapidly advancing disability or cognitive impairment*; or*
        iv. Disabling relapse with suboptimal response to corticosteroids*; or*
        v. MRI findings showing high disease activity (e.g., new/enlarging T2 lesions, enhancing lesions)*; or*
    b. Is unable to use, or has tried and failed at least ONE of the following:
        i. Dimethyl Fumarate (generic Tecfidera)*; and/or*
        ii. Fingolimod (generic Gilenya); *AND*
5. Has been screened for hepatitis B virus AND does not have active infection; *AND*
6. Kesimpta (ofatumumab) will be used as monotherapy for multiple sclerosis (i.e., member is not using and will not use other disease-modifying MS therapies while on Kesimpta); *AND*
7. Kesimpta (ofatumumab) is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature.
    - *20 mg/0.4 mL solution in a single-dose prefilled Sensoready pen or prefilled syringe.*
        i. Initial dosing: 20 mg at weeks 0, 1, and 2.
        ii. Maintenance dosing: 1 dose (20 mg) every 4 weeks starting at week 4.

<u>If the above prior authorization criteria are met, the requested medication will be approved for up to 12-months.</u>

Medical Necessity Criteria for Reauthorization

Reauthorization for up to 12-months will be granted if the member has recent (within the last 6-months) clinical documentation showing BOTH of the following:

1. The requested medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; *AND*
2. The member has experienced at least ONE of the following:
    a. Improvement in at least ONE objective measure, such as:
        i. Reduced disease activity on MRI*; and/or*
        ii. Improved or stable disability scores*; and/or*
        iii. Reduced relapse rate*; and/or*
        iv. Improved fatigue or walking assessments; *AND/OR*
    b. The member has shown stabilization or improvement in at least ONE MS symptom, such as:
        i. Motor function*; and/or*

ii. Fatigue*; and/or*
iii. Vision*; and/or*
iv. Bowel/bladder function*; and/or*
v. Spasticity*; and/or*
vi. Walking/gait*; and/or*
vii. Pain/numbness/tingling.

Experimental or Investigational / Not Medically Necessary

Kesimpta (ofatumumab) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Use in combination with other disease-modifying therapies for MS.
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- Treatment of non-relapsing forms of multiple sclerosis (e.g., primary progressive MS)
- Treatment of other autoimmune conditions not FDA-approved (e.g., rheumatoid arthritis, systemic lupus erythematosus).
- Use for the treatment of nephrotic syndrome.
- Use in pediatric members (under 18 years of age).

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