SAMPLE LETTER OF MEDICAL NECESSITY FOR PATIENTS NOT ACTIVELY ON RMS TREATMENT

[Date]
[Health plan name]
ATTN: [Department]
[Medical/Pharmacy Director Name (if available)]
[Health plan address]
[City, State, ZIP code]

[Patient's Name]
[Patient's plan-specific member ID]
[Date of birth]
[Case number]
[Dates of service]

Re: Letter of Medical Necessity for KESIMPTA® (ofatumumab)
Dear [Medical/Pharmacy Director Name],

I am writing this letter of medical necessity on behalf of [Patient's Name] to request coverage for KESIMPTA for the treatment of relapsing multiple sclerosis (RMS) [(ICD-10 code)]. This letter provides the clinical rationale and relevant information about the patient's medical history and treatment after reviewing your drug coverage policy.

I have been treating [Patient's Name], [a/an] [age]-year-old [male/female], since [Date] to manage multiple sclerosis (MS)/RMS [(ICD-10 code)].

My rationale for prescribing KESIMPTA is: [Include relevant medical information to support rationale for prescribing KESIMPTA. An example may include evidence that the patient's RMS symptoms and disabilities have been progressing despite current treatment. Additional information needed may include:

- A qualitative description of clinically evident progressive disability
- Breakthrough disease activity, including relapses and/or brain lesions on magnetic resonance imaging (MRI)
- A brief description of MRI results
- Changes in MS quality-of-life assessment
- Activities of daily living affected by current MS disease
- Underlying health issues and/or intolerable side effects
- MS treatments that have been tried and failed]

In my clinical opinion, [Patient's Name] should receive KESIMPTA for the following reasons: [Include a summary of reasons the preferred drugs on formulary are not appropriate and why KESIMPTA is clinically indicated for this patient]. I have included the US Food and Drug Administration (FDA) approval letter for KESIMPTA, as well as supporting clinical data.

If you have any further questions about this matter, please feel free to contact me at [physician phone number] or via email at [physician email]. Thank you for your time and consideration.

Sincerely,

[Physician's signature]

Enclosures

[List and attach medical records, lab work, imaging results, Prescribing Information, and the FDA approval letter.]

This letter is provided as an example and is meant for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to include the proper information and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Click here for full Prescribing Information, including Medication Guide.

Indication and Important Safety Information

INDICATION

KESIMPTA is 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.

IMPORTANT SAFETY INFORMATION

Contraindication

KESIMPTA is contraindicated in patients with active hepatitis B virus infection.

Warnings and Precautions

Infections

An increased risk of infections has been observed with other anti-CD20 B-cell depleting therapies. KESIMPTA has the potential for an increased risk of infections including serious bacterial, fungal, and new or reactivated viral infections; some have been fatal in patients treated with other anti-CD20 antibodies. The overall rate of infections and serious infections in KESIMPTA-treated patients was similar to teriflunomide-treated patients (51.6% vs 52.7%, and 2.5% vs 1.8%, respectively). The most common infections reported by KESIMPTA-treated patients in relapsing MS (RMS) trials included upper respiratory tract infection (39%) and urinary tract infection (10%). Delay KESIMPTA administration in patients with an active infection until resolved.

Consider the potential increased immunosuppressive effects when initiating KESIMPTA after an immunosuppressive therapy or initiating an immunosuppressive therapy after KESIMPTA.

Hepatitis B Virus

Reactivation: No reports of hepatitis B virus (HBV) reactivation in patients with MS treated with KESIMPTA. However, HBV reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, has occurred in patients treated with ofatumumab at higher intravenous doses for chronic lymphocytic leukemia (CLL) than the recommended dose in MS and in patients treated with other anti-CD20 antibodies.

Infection: KESIMPTA is contraindicated in patients with active hepatitis B disease. Fatal infections caused by HBV in patients who have not been previously infected have occurred in patients treated with ofatumumab at higher intravenous doses for CLL than the recommended dose in MS. Perform HBV screening in all patients before initiation of KESIMPTA. Patients who are negative for HBsAg and positive for HB core antibody [HBcAb+] or are carriers of HBV [HBsAg+], should consult liver disease experts before starting and during KESIMPTA treatment.

Progressive Multifocal Leukoencephalopathy

No cases of progressive multifocal leukoencephalopathy (PML) have been reported for KESIMPTA in RMS clinical studies; however, PML resulting in death has occurred in patients being treated with ofatumumab at higher intravenous doses for CLL than the recommended dose in MS. In addition, JC virus infection resulting in PML has also been observed in patients treated with other anti-CD20 antibodies and other MS therapies. If PML is suspected, withhold KESIMPTA and perform an appropriate diagnostic evaluation. If PML is confirmed, KESIMPTA should be discontinued.

Vaccinations

Administer all immunizations according to immunization guidelines: for live or live–attenuated vaccines at least 4 weeks and, whenever possible at least 2 weeks prior to starting KESIMPTA for inactivated vaccines. The safety of immunization with live or live-attenuated vaccines following KESIMPTA therapy has not been studied. Vaccination with live or live-attenuated vaccines is not recommended during treatment and after discontinuation until B-cell repletion.

Vaccination of Infants Born to Mothers Treated with KESIMPTA During Pregnancy

For infants whose mother was treated with KESIMPTA during pregnancy, assess B-cell counts prior to administration of live or live-attenuated vaccines. If the B-cell count has not recovered in the infant, do not administer the vaccine as having depleted B-cells may pose an increased risk in these infants.

Injection-Related Reactions

Injection-related reactions with systemic symptoms occurred most commonly within 24 hours of the first injection, but were also observed with later injections. There were no life-threatening injection reactions in RMS clinical studies.

The first injection of KESIMPTA should be performed under the guidance of an appropriately trained health care professional. If injection-related reactions occur, symptomatic treatment is recommended.

Reduction in Immunoglobulins

As expected with any B-cell depleting therapy, decreased immunoglobulin levels were observed. Monitor the levels of quantitative serum immunoglobulins during treatment, especially in patients with opportunistic or recurrent infections and after discontinuation of therapy until B-cell repletion. Consider discontinuing KESIMPTA therapy if a patient with low immunoglobulins develops a serious opportunistic infection or recurrent infections, or if prolonged hypogammaglobulinemia requires treatment with intravenous immunoglobulins.

Fetal Risk

Based on animal data, KESIMPTA can cause fetal harm due to B-cell lymphopenia and reduce antibody response in offspring exposed to KESIMPTA in utero. Transient peripheral B-cell depletion and lymphocytopenia have been reported in infants born to mothers exposed to other anti-CD20 B-cell depleting antibodies during pregnancy. Advise females of reproductive potential to use effective contraception while receiving KESIMPTA and for at least 6 months after the last dose.

Most common adverse reactions

(>10%) are upper respiratory tract infection, headache, injection-related reactions, and local injection-site reactions.

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