SAMPLE OUTLINE OF LETTER OF APPEAL
CHANGE OF 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: Appeal of Denial for KESIMPTA® (ofatumumab)
Dear [Medical/Pharmacy Director Name],

This letter of [level of appeal] is a formal appeal of your coverage decision for KESIMPTA for the patient referenced above. The reason(s) for the denial were [List reason(s) for the denial]. I request that [Insurance name]'s denial decision be reversed and coverage approved for KESIMPTA as it is medically necessary to treat the diagnosis of relapsing multiple sclerosis (RMS) [(ICD-10 code)]. At this time, the appropriate treatment plan is to discontinue [Current Drug] and to prescribe KESIMPTA.

I have been treating [Patient's Name], [a/an] [age]-year-old [male/female], since [Date] to manage RMS [(ICD-10 code)]. [He/She] has been on [Drug name] since [Date].

[Include relevant medical information to support your reason for discontinuing the current medication and prescribing KESIMPTA. If applicable, include evidence that the patient's RMS symptoms and disabilities have been progressing despite his/her current therapies. Additional information may include:

- Supporting information as requested by the plan in its denial letter
- Clinical attributes of KESIMPTA and relevance to patient]

History of previous multiple sclerosis (MS) therapies: _____

Reasons for discontinuation of previous therapies: _____

Duration of previous therapies: _____

Based on the patient's condition and medical history, as well as my experience in treating patients with RMS/MS [(ICD-10 code)], I believe treatment with KESIMPTA is appropriate and medically necessary.

Included with this letter of appeal for approval to change to KESIMPTA are relevant supporting medical documentation, including a letter of medical necessity, clinical trial information, and the US Food and Drug Administration (FDA) approval letter. I have also attached the original denial letter. [Summarize reasons for the patient to convert to KESIMPTA].

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 additional documents, which may include a denial letter, Letter of Medical Necessity, Prescribing Information, clinical notes/medical records, FDA approval letter, or clinical practice guidelines.]

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.

NOVARTIS

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