SAMPLE OUTLINE OF LETTER OF APPEAL

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]**

Re: Appeal of Denial for KESIMPTA® (ofatumumab)

Dear **[Medical/Pharmacy Director Name]**,

**[Patient’s Name]
[Patient’s plan-specific member ID]**

**[Date of birth] [Case number] [Dates of service]**

I am writing to request reconsideration of your denial of coverage of KESIMPTA, which I have prescribed for the patient referenced above. I have read and acknowledged your policy for responsible multiple sclerosis (MS) drug management. Your reason(s) for the denial were **[List reason(s) for the denial]**.

**[Patient’s Name]** is **[a/an] [age]**-year-old **[male/female]** patient who has been diagnosed with relapsing multiple sclerosis (RMS) as of **[Date]**. **[He/She]** has been in my care since **[Date]**.

**[Include relevant medical information to support your reason for treatment with KESIMPTA. An example may 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 MS therapies:

Reasons for discontinuation of previous therapies:

Duration of previous therapies:

This is my **[level of request]** letter of appeal. A copy of the **[level of denial]** denial letter is included along with
medical notes in response to the denial. 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.

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, US Food and Drug Administration approval letter, or
clinical practice guidelines.]**

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**](http://www.novartis.us/sites/www.novartis.us/files/kesimpta.pdf) **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**

Contraindications

KESIMPTA is contraindicated in patients with active hepatitis B virus (HBV) infection, or history of hypersensitivity to ofatumumab, or life-threatening
injection-related reaction to KESIMPTA. Hypersensitivity reactions have
included anaphylaxis and angioedema.

Warnings and Precautions

Infections

Serious, including life-threatening or fatal, bacterial, fungal, and new or reactivated viral infections have been observed during and following completion of treatment with anti-CD20 B-cell depleting therapies. 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 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 expertsbefore 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 and Hypersensitivity Reactions

KESIMPTA can result in systemic injection-related reactions and hypersensitivity
reactions, which may be serious or life-threatening. 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.

In the post-marketing setting, additional systemic injection-related reactions and hypersensitivity reactions have been reported, including anaphylaxis, angioedema, pruritus, rash, urticaria, erythema, bronchospasm, throat irritation, oropharyngeal
pain, dyspnea, pharyngeal or laryngeal edema, flushing, hypotension, dizziness,
nausea, and tachycardia. Most cases were not serious and occurred with the first
injection. Symptoms of systemic injection-related reactions may be clinically indistinguishable from acute hypersensitivity reactions.

The first injection of KESIMPTA should be performed under the guidance of an
appropriately trained health care professional. If systemic injection-related reactions occur, initiate appropriate therapy. Patients who experience symptoms of systemic injection-related reactions or hypersensitivity reactions with KESIMPTA should be instructed to seek immediate medical attention. If local 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 Pharmaceuticals Corporation**

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