Kesimpta® (ofatumumab) 20 mg injection

Authorization and Appeals Kit

To support patient access to KESIMPTA® (ofatumumab)

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.

The information herein is provided 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 select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Please see additional Important Safety Information on page 21 and click here for full Prescribing Information, including Medication Guide.

NOVARTIS

Included in This Kit

Alongside™ KESIMPTA® is available to help you and your patients with benefits verifications and financial assistance options. A committed Coordinator can also answer questions about PAs, appeals, and reimbursement options.

Connect with a Coordinator at 1-855-KESIMPTA (1-855-537-4678).

PA, prior authorization.

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Please see additional Important Safety Information on page 21 and click here for full Prescribing Information, including Medication Guide.

Using This Kit

Every health plan manages access to KESIMPTA® (ofatumumab) differently. Even if the decision to prescribe KESIMPTA to patients with RMS is the right decision clinically, you may run into restrictions put in place by a health plan, such as PAs, step edits, or no coverage at all.

This kit is meant to guide you through some common insurance restrictions and explain how to further initiate access to KESIMPTA, including sample letter templates if the health plan's formulary requires further documentation to support your clinical decision.

TREATMENT CHOICE

Based on the patient's medical condition, KESIMPTA is the treatment of choice for the patient.

COVERAGE ASSESSMENT

Confirm if the patient's health plan provides coverage for KESIMPTA.

Your practice should contact the health plan to understand your patient's specific coverage criteria. You can also enroll your patient in Alongside™ KESIMPTA®, through which a committed Alongside KESIMPTA Coordinator will call the health plan to identify your patient's specific coverage criteria for KESIMPTA.

TYPICAL DRUG COVERAGE POLICIES

Required

A PA is needed to confirm certain criteria have been met.

Submit a PA form requesting KESIMPTA.

OR

Not Covered

Coverage may not be granted because:

- KESIMPTA is excluded from the health plan's formulary
- NDC blocks are in place

In these instances, submit a Letter of Medical Necessity.

OR

Approved

KESIMPTA is a preferred treatment on the health plan's formulary and is covered for the patient.

No further action is needed on your part.

WHEN TO USE EACH LETTER

Letter of Appeal

If a plan has PA criteria and denies your PA request, submit a Letter of Appeal.

Letter of Medical Necessity

If KESIMPTA is not on formulary or NDC blocked, submit a Letter of Medical Necessity. If the Letter of Medical Necessity is denied, submit a Letter of Appeal.

NOTE: There are multiple levels of appeal. Please ensure you are selecting the most appropriate appeal letter and adapt as needed for higher-level appeals.

Novartis believes access support should be readily available. You can access the letters described above at kesimptahcp.com.

NDC, National Drug Code; PA, prior authorization; RMS, relapsing multiple sclerosis.

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KESIMPTA® (ofatumumab) CLINICAL OVERVIEW

Please see Important Safety Information on page 21 and click here for full Prescribing Information, including Medication Guide.

Kesimpta® (ofatumumab) 20 mg injection

The First Self-injectable, Fully Human, Anti-CD20 mAb B-cell Therapy in RMS[1,2]

INDICATION[2]

KESIMPTA® (ofatumumab) 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.

CLINICAL TRIAL OVERVIEW[1,2]

ASCLEPIOS I and II*: Two identical phase 3, randomized, double-blind, active-controlled, parallel-group, multicenter trials in patients with RMS. Patients were randomized 1:1 to double-dummy subcutaneous ofatumumab (20 mg every 4 weeks) or oral teriflunomide (14 mg daily) for up to 30 months.

PRIMARY END POINT[2]

KESIMPTA significantly reduced annual relapse rates (ARRs) vs teriflunomide,%

Percentage of Reduction in Relapse Rates

ASCLEPIOS I:
51% (*P*<.001)
- KESIMPTA 0.11 vs teriflunomide 0.22

ASCLEPIOS II:
58% (*P*<.001)
- KESIMPTA 0.10 vs teriflunomide 0.25†

SECONDARY END POINTS[1-3]

Reduction in 3- and 6-month CDP‡:

- Substantial slowing of disability progression vs teriflunomide:
  - **34.3%** (*P*=.003) risk reduction vs teriflunomide with 3-month CDP

Reduction of MRI inflammation:

- KESIMPTA showed significant, near-complete suppression of Gd+ T1 inflammatory lesions:
  - **98%** relative reduction vs teriflunomide in ASCLEPIOS I (*P*<.001)
  - **94%** relative reduction vs teriflunomide in ASCLEPIOS II (*P*<.001)
- KESIMPTA showed significant reduction in the number of new or enlarging T2 lesions:
  - **82%** relative reduction vs teriflunomide in ASCLEPIOS I (*P*<.001)
  - **85%** relative reduction vs teriflunomide in ASCLEPIOS II (*P*<.001)

SAFETY AND DOSING[2]

- 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.
- Most common AEs (>10%) are upper respiratory tract infections, injection-related reactions (systemic), headache, and injection-site reactions (local)
- Self-injectable dosing
- The first injection should be performed under the guidance of a health care provider
  - Monthly 20-mg subcutaneous dosing regimen after initial dosing§

AE, adverse event; Gd+, gadolinium-enhancing; HR, hazard ratio; mAb, monoclonal antibody; MRI, magnetic resonance imaging; RMS, relapsing multiple sclerosis.
*ASCLEPIOS I (N=927) and ASCLEPIOS II (N=955).
†An ARR of 0.1 is equivalent to 1 relapse in 10 years.
‡Confirmed disability progression is defined by an increase of ≥1.5 Expanded Disability Status Scale points for patients with a baseline score of 0, an increase of ≥1.0 points for patients with a baseline score of 1.0 to 5.0, and an increase of 0.5 points for patients with a baseline score of 5.5 or higher.[2]
§Initial dosing at Week 0, 1, and 2 followed by subsequent monthly dosing starting at Week 4.

Please see additional Important Safety Information on page 21 and click here for full Prescribing Information, including Medication Guide.

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ALONGSIDE™ KESIMPTA® AND THE PATIENT REIMBURSEMENT PROCESS

Please see Important Safety Information on page 21 and click here for full Prescribing Information, including Medication Guide.

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Support Your Patients With Alongside™ KESIMPTA®

The Alongside KESIMPTA Program helps patients get started on treatment and provides ongoing personalized support to them.

VERIFYING COVERAGE AND FINANCIAL SUPPORT

Reaching out to patients' insurance providers to determine coverage availability and requirements, while providing information on other financial assistance options, where eligible

GETTING STARTED ON TREATMENT

Coordinating medication delivery and supporting patients through their treatment

DELIVERING ONE-ON-ONE SUPPORT

Providing ongoing support to patients according to their specific needs by offering information, answers to treatment-specific questions, and dosing reminders. For live support, call **1-855-KESIMPTA (1-855-537-4678)**

VISIT kesimptahcp.com for additional information

$0 Eligible commercial patients prescribed KESIMPTA® (ofatumumab) may pay $0 out of pocket. Visit start.kesimpta.com for Program Terms and Conditions and more information.*

*Limitations apply. Up to a $18,000 annual limit. Offer not valid under Medicare, Medicaid, or any other federal or state program. Novartis reserves the right to rescind, revoke, or amend this Program without notice. See complete Terms & Conditions for details at start.kesimpta.com.

Please see additional Important Safety Information on page 21 and click here for full Prescribing Information, including Medication Guide.

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Understanding the Reimbursement Process

Use pages 8 through 10 to help you better understand how Alongside™ KESIMPTA® may help commercial, government, underinsured, and uninsured patients access KESIMPTA® (ofatumumab).

Identify your patient's coverage type

It's important to distinguish which type of coverage the patient has before proceeding with enrollment into Alongside KESIMPTA, as support resources will vary.

PATIENT COVERAGE TYPES	DEFINITION
COMMERCIAL	Patient has commercial insurance individually or through their employer (eg, HMO, PPO, EPO, POS, HDHP)[4,5]
GOVERNMENT	Reserved for specific groups (senior citizens, low income, disabled, current military and their families, government employees, and some federally recognized Native American tribes) receiving coverage through Medicare, Medicaid, TRICARE, the Veterans Health Administration program, and more[5]
UNDERINSURED	Patient has government or commercial insurance (eg, HDHP) but faces cost sharing and health care costs that are high relative to their income[6]
UNINSURED	Patient is without public or private health insurance[4]

Submit a Start Form (SF) through Alongside KESIMPTA

Completing an SF can be critical to ensuring timely patient initiation on KESIMPTA and enrollment in Alongside KESIMPTA.

Complete the SF for KESIMPTA, including the prescription

Submit the SF through CoverMyMeds.com or via fax to 1-833-318-0680

Alongside KESIMPTA conducts a benefits investigation/ verification

REMINDER: You and your patient must sign the SF prior to submitting to Alongside KESIMPTA. Incomplete SFs can cause a delay in the support process.

Download and print a KESIMPTA SF at kesimptahcp.com.

EPO, exclusive provider organization; HDHP, high-deductible health plan; HMO, health maintenance organization; POS, point-of-service plan; PPO, preferred provider organization.

Key considerations by coverage type

COMMERCIAL

- Commercially insured patients who qualify for the Access Card Program receive co-pay support if coverage is approved or, if coverage is denied, free medication for up to 1 year while pursuing coverage

The Access Card Program helps eligible commercially insured patients to*,†:

- **Pay as little as $0 co-pay until the annual limit is reached**
- **Receive free medication for up to 1 year while pursuing coverage**

Patients will receive one card for both programs.

GOVERNMENT

- Government-insured patients are not eligible for the Access Card Program, but may qualify for the Novartis Patient Assistance Foundation (NPAF).‡ The NPAF is an independent foundation that offers free Novartis medication to patients who are experiencing financial hardship and have limited or no prescription coverage

***For more information, patients can visit* PAP.Novartis.com.**

UNDERINSURED

- Patients pay out-of-pocket expenses if they can afford their medication
- If patients cannot afford their medication, or are uninsured, they are referred to the NPAF, which provides free medication to eligible uninsured or underinsured patients‡

If a prior authorization (PA) is not needed, or was needed and has been approved, the prescription is sent directly to the patient's preferred specialty pharmacy to dispense (insurance mandates may apply).

*__Bridge Program Terms & Conditions:__ Available to commercially insured patients experiencing denial of coverage due to PA requirements. See Start Form for eligibility and additional details.

†__Co-pay Program Terms & Conditions:__ Limitations apply. Up to a $18,000 annual limit. Offer not valid under Medicare, Medicaid, or any other federal or state program. Novartis reserves the right to rescind, revoke, or amend this Program without notice. See complete Terms & Conditions for details at start.kesimpta.com.

‡Patients must be a US resident and meet specific income requirements. Patients also must have limited or no private or public prescription coverage. Visit PAP.Novartis.com for additional details.

Please see additional Important Safety Information on page 21 and click here for full Prescribing Information, including Medication Guide.

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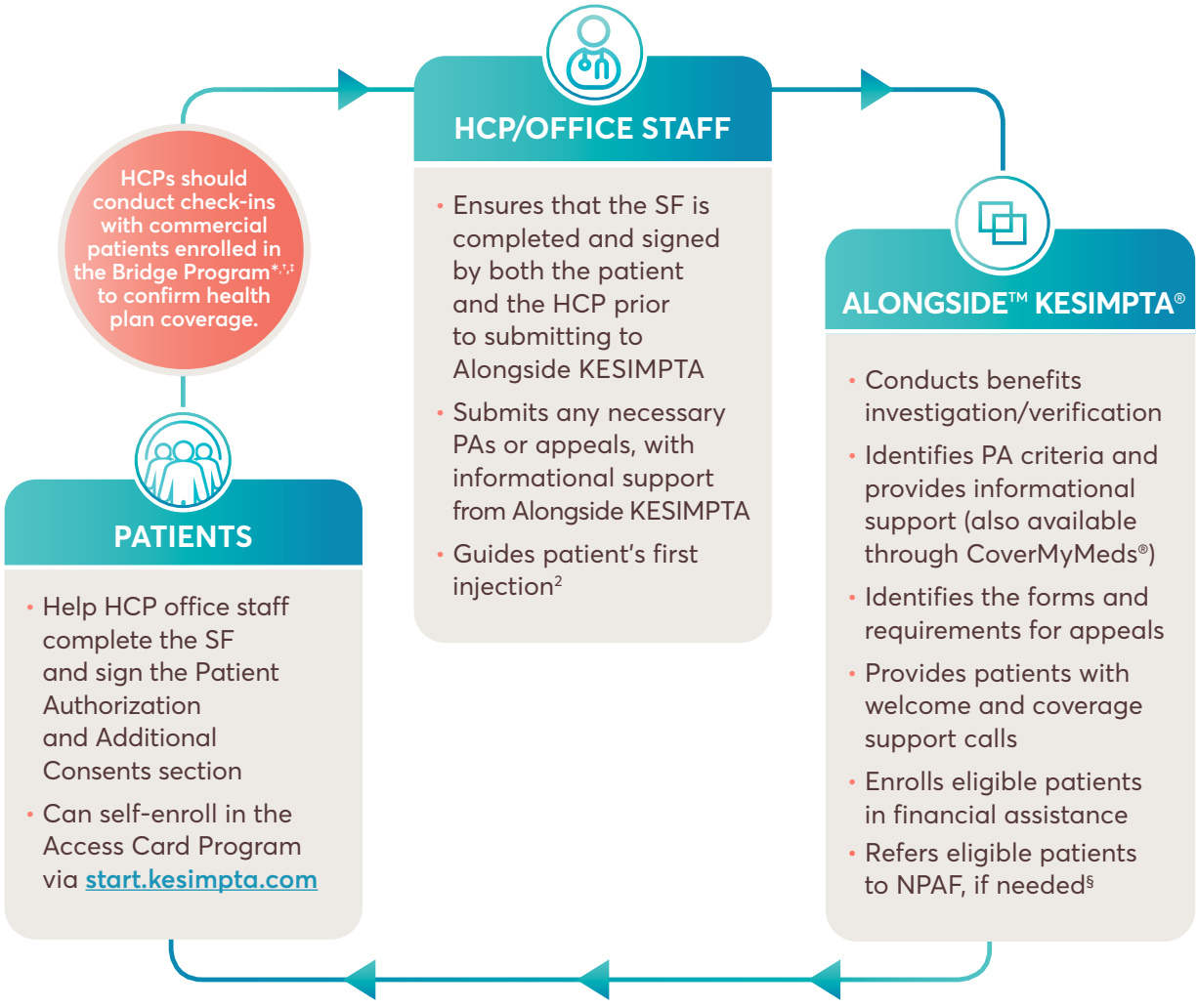
Review roles and responsibilities

You and your office should review the following roles and responsibilities to set expectations for when patients can anticipate treatment to begin.



For additional support and questions about dispensing options, please contact your Field Reimbursement Manager.

HCP, health care professional; NPAF, Novartis Patient Assistance Foundation; PA, prior authorization; SF, Start Form.

*If a PA is not started within 9 months, patients will lose eligibility for the Bridge Program.

†**Bridge Program Terms & Conditions:** Available to commercially insured patients experiencing denial of coverage due to PA requirements. See SF for eligibility and additional details.

‡**Co-pay Program Terms & Conditions:** Limitations apply. Up to a $18,000 annual limit. Offer not valid under Medicare, Medicaid, or any other federal or state program. Novartis reserves the right to rescind, revoke, or amend this Program without notice. See complete Terms & Conditions for details at start.kesimpta.com.

§Patients must be a US resident and meet specific income requirements. Patients also must have limited or no private or public prescription coverage. Visit PAP.Novartis.com for additional details.

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PRIOR AUTHORIZATION CHECKLIST

Please see Important Safety Information on page 21 and click here for full Prescribing Information, including Medication Guide.

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Prior Authorization Checklist

You must prove to the health plan that the health plan's specific PA requirements have been met or, if a step edit is being passed over, why KESIMPTA® (ofatumumab) is the treatment of choice for the patient.

For plans requiring a PA request for KESIMPTA:

- Complete a PA request using the health plan's PA form
- If a PA is denied, submit a Letter of Appeal (see pages 15 and 16 for sample letters)

Submitting a PA may be completed directly through the insurer or by using Alongside KESIMPTA or CoverMyMeds®.

Alongside™ KESIMPTA® is available to help.

Call 1-855-KESIMPTA (1-855-537-4678), 8:30 AM–8:00 PM ET, Monday–Friday for live support

Visit CoverMyMeds.com for questions about a particular health plan's PA form or process

Checklist for a complete PA submission

- ☐ Patient's name, date of birth, insurance ID number, insurance group number, and dates of service
- ☐ Patient's diagnosis and corresponding ICD-10 code(s)
- ☐ List of previous therapies

Each plan may have additional PA requirements for RMS, which may include 1 or more of the following, if applicable:

- ☐ History of at least 1 treatment failure (including any DMTs). Failure may be defined as:
  - New evidence of disease activity (eg, relapse or new MRI lesions) or evidence of increased disability
  - Continued worsening of symptoms
- ☐ One clinical relapse during the prior year (eg, functional disability, hospitalization, and acute steroid therapy)
- ☐ A single clinical demyelinating event and 2 or more brain lesions
- ☐ A brain MRI scan demonstrating at least 1 Gd+ lesion within the past 6 months
- ☐ Additional forms and documents, such as:
  - Patient Authorization and Notice of Release of Information
  - Copy of patient's health plan or Rx card (front and back)
  - Other supporting documentation (eg, Letter of Medical Necessity, chart notes, test and lab results, and any ED notes)

Avoid Further Delays in Treatment

Missing or incomplete information or documentation can lead to a PA being denied.
Ensure all requested PA information is completed, if applicable, including prior treatment history, testing history, and ICD-10 code(s). In the event a health plan denies the request for coverage, your office may submit an appeal on behalf of the patient.

Need additional support? Please contact your Access & Reimbursement Manager or Associate Director Access & Reimbursement.
For more information about KESIMPTA, visit kesimptahcp.com.

DMT, disease-modifying therapy; ED, emergency department; Gd+, gadolinium-enhancing; ICD-10, International Classification of Diseases, 10th Revision; ID, identification; MRI, magnetic resonance imaging; PA, prior authorization; RMS, relapsing multiple sclerosis; Rx, prescription.

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SAMPLE LETTERS OF APPEAL

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Sample Letters of Appeal

If a patient is denied coverage, you are required to explain your clinical rationale for prescribing KESIMPTA (ofatumumab) through a Letter of Appeal. This letter should address each specific reason for the denial and demonstrate why the health plan's existing formulary does not represent the most appropriate treatment for the patient.

Included in this section are 2 sample Letters of Appeal for patients with RMS. One sample letter is for MS patients naive to DMT therapy and the other is for MS patients previously treated with another DMT. Regardless of the patient's status, each letter should be submitted with a copy of the patient's relevant medical records and a Letter of Medical Necessity (see pages 17 through 20).

Keep in mind there can be multiple levels of appeal, and you should refer to the health plan's specific appeal guidelines. Many health plans will accept up to 3 levels of appeal of PA denials. The third level of appeal may include a review by an independent, non–insurance-affiliated external review board or hearing. Submitting an appeal may be completed on your own or by using Alongside KESIMPTA or CoverMyMeds®.

Alongside™ KESIMPTA® is available to help.

Call 1-855-KESIMPTA (1-855-537-4678), 8:30 AM–8:00 PM ET, Monday–Friday for live support

Visit CoverMyMeds.com for questions about a particular health plan's PA form or process

Checklist for writing a letter of appeal

- ☐ Patient's name, date of birth, insurance ID number, insurance group number, and dates of service
- ☐ Patient's medical records and accompanying ICD-10 code(s)
- ☐ Copies of relevant medical records
- ☐ Clinical support for prescribing KESIMPTA, including previous failed therapies, if applicable
- ☐ A list of previous therapies, their duration, and explanation for discontinuation
  - Explain why other treatments are inappropriate for the patient
- ☐ A Letter of Medical Necessity and the US Food and Drug Administration approval letter for KESIMPTA
- ☐ Additional information and documents, such as:
  - Reference number of existing claim decision, if applicable
  - Patient Authorization and Notice of Release of Information
  - Copy of patient's health plan or Rx card (front and back)
  - Appeal letter signed by the patient or authorized representative
  - Denial information, including the denial letter or explanation of benefits notification
  - Other supporting documentation, such as chart notes, current medications, test and lab results, and ED notes

Need additional support? Please contact your Access & Reimbursement Manager or Associate Director Access & Reimbursement.
For more information about KESIMPTA, visit kesimptahcp.com.

DMT, disease-modifying therapy; ED, emergency department; ICD-10, International Classification of Diseases, 10th Revision; ID, identification; MS, multiple sclerosis; PA, prior authorization; RMS, relapsing multiple sclerosis; Rx, prescription.

Please see additional Important Safety Information on page 21 and click here for full Prescribing Information, including Medication Guide.

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Sample Letter of Appeal
For patients not actively on RMS treatment

Address the letter to the PA department or the contact person from the denial letter.

Acknowledge the health plan's reason(s) for denial up front.

Explain why each therapy was discontinued and give the duration of therapy for each agent.

If this is a second- or third-level appeal, include the original denial letter and specific medical notes in response to the denial. Give the physician's contact information in case there are questions that need to be answered.

[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]**,

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.

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East Hanover, New Jersey 07936-1080

10/25 FA-11487579

PA, prior authorization; RMS, relapsing multiple sclerosis.

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Sample 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.]

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.

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10/25

FA-11488396

Remember to include which therapies the patient is currently on up front.

If needed, include a broken-down list of previous MS therapies, reasons for discontinuation, and duration.

MS, multiple sclerosis.

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SAMPLE LETTERS OF MEDICAL NECESSITY

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Sample Letters of Medical Necessity

In cases where PA appeals may be expended or where KESIMPTA (ofatumumab) is not covered or has an NDC block, you may need to prepare a Letter of Medical Necessity to document the medical need for KESIMPTA based on the patient's specific medical history and diagnosis.

Use this letter to communicate your clinical decision to prescribe KESIMPTA in regards to the patient's specific medical record.

Checklist for writing a letter of medical necessity

- ☐ Include patient's name, date of birth, insurance ID number, insurance group number, and dates of service
- ☐ Include ICD-10 code
- ☐ Clearly state the rationale for treatment with KESIMPTA and why it is appropriate for the patient
- ☐ List previous therapies with the reasons why each therapy was discontinued and the duration for each agent
- ☐ Include any failure with previous therapies, with failure defined as continued occurrence of relapses despite treatment with a product indicated for RMS
  - Explain why other treatments are inappropriate for the patient
- ☐ Include a Letter of Medical Necessity and the FDA approval letter for KESIMPTA
- ☐ Provide clinical support for your recommendation
  - This can be clinical trial data from the KESIMPTA Prescribing Information or the FDA approval letter
- ☐ Summarize your recommendation and provide a phone number in case any additional information is needed

Need additional support? Please contact your Access & Reimbursement Manager or Associate Director Access & Reimbursement.
For more information about KESIMPTA, visit kesimptahcp.com.

FDA, US Food and Drug Administration; ICD-10, International Classification of Diseases, 10th Revision; ID, identification; NDC, National Drug Code; PA, prior authorization; RMS, relapsing multiple sclerosis.

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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.

It may be helpful to include the FDA approval letter and data from the KESIMPTA® (ofatumumab) clinical trial(s) to support your decision.

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Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

10/25

FA-11488402

FDA, US Food and Drug Administration; RMS, relapsing multiple sclerosis.

Please see additional Important Safety Information on page 21 and click here for full Prescribing Information, including Medication Guide.

Kesimpta® (ofatumumab) 20 mg injection

Sample Letter of Medical Necessity
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: 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)]. I have reviewed your drug coverage policy and believe that the appropriate treatment decision for my patient at this time is to discontinue [Current drug name] and begin treatment with KESIMPTA. This letter provides the clinical rationale and relevant information about the patient's medical history and treatment.

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 magnetic resonance imaging (MRI) brain lesions
- A brief description of MRI results
- Changes in MS quality of life assessment
- MS treatments that have been tried and failed
- Underlying health issues and/or intolerable side effects]

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].

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 US Food and Drug Administration approval letter.]

It may be helpful to include the FDA approval letter and data from the KESIMPTA® (ofatumumab) clinical trial(s) to support your decision.

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.

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FA-11488359

FDA, US Food and Drug Administration.

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Kesimpta® (ofatumumab) 20 mg injection

IMPORTANT SAFETY INFORMATION (cont)

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 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 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.

Liver Injury

Clinically significant liver injury, without findings of viral hepatitis, has been reported in the post-marketing setting. Signs of liver injury have occurred weeks to months after administration. Patients treated with KESIMPTA found to have an alanine aminotransferase or aspartate aminotransferase greater than 3 times the upper limit of normal (ULN) with serum total bilirubin greater than 2 times the ULN are potentially at risk for severe drug-induced liver injury. Obtain liver function tests prior to initiating treatment. Monitor for signs and symptoms of hepatic injury during treatment, including new or worsening fatigue, anorexia, nausea, vomiting, right upper abdominal discomfort, dark urine, or jaundice. If symptoms of liver injury are reported, measure serum aminotransferases, alkaline phosphatase, and bilirubin levels. Discontinue KESIMPTA if liver injury is present and an alternative etiology is not identified.

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

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

Kesimpta® (ofatumumab) 20 mg injection

Click here for full Prescribing Information, including Medication Guide.

Alongside KESIMPTA is here to support you in navigating your patient's coverage and reimbursement process.

Call
1-855-KESIMPTA
(1-855-537-4678),
8:30 AM-8:00 PM ET,
Monday-Friday for live support

Visit
kesimptahcp.com for
questions about access and
reimbursement support

Need additional support? Please contact your Access & Reimbursement Manager or Associate Director Access & Reimbursement.
For more information about KESIMPTA, visit kesimptahcp.com.

Please see Important Safety Information on page 21 and click here for full Prescribing Information, including Medication Guide.

References: 1. Hauser SL, Bar-Or A, Cohen JA, et al; for the ASCLEPIOS I and ASCLEPIOS II Trial Groups. Ofatumumab versus teriflunomide in multiple sclerosis. *N Engl J Med*. 2020;383(6):546-557. **2.** Kesimpta [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp. **3.** Data on file. OMB157 (ofatumumab). Novartis Pharmaceuticals Corp; 2019. **4.** Mayo Clinic. Glossary of billing and insurance terms. Updated February 28, 2020. Accessed May 4, 2020. https://www.mayoclinic.org/patient-visitor-guide/billing-insurance/glossary **5.** Medical Billing and Coding Certification. Understanding commercial health insurance. Accessed May 4, 2020. https://www.medicalbillingandcoding.org v/health-insurance-guide/commercial-health-insurance/ **6.** Underinsured rate rose from 2014-2018, with greatest growth among people in employer health plans. Commonwealth Fund website. Posted February 7, 2019. Accessed May 4, 2020. https://www.commonwealthfund.org/press-release/2019/underinsured-rate-rose-2014-2018-greatest-growth-among-people-employer-health

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