

Guide to completing the **KESIMPTA® (ofatumumab)** Start Form



Phone:
855-KESIMPTA (855-537-4678)



Fax:
833-318-0680



Online:
www.kesimptahcp.com



Portal:
www.covermymeds.health



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.

Please see additional Important Safety Information on the last pages.
Please see full Prescribing Information, including Medication Guide.

 **Kesimpta®**
(ofatumumab) 20 mg
injection

Getting patients started

Novartis Patient Support will work with your practice to help your patient start on KESIMPTA. Begin the process by completing the Start Form. We have outlined the key information below to help ensure a smoother process for your office and your patient.

All REQUIRED fields must be filled out for the Start Form to be processed as complete. An incomplete Start Form may delay the start of treatment.

Look for this symbol as you fill out the Start Form. It indicates a required field.

Complete this section if the patient has someone who assists with care and may speak or be contacted on the patient's behalf.

Get patient and/or authorized representative consent.

Patients can check this box to sign up for the Co-Pay Plus offer, which includes access to the Bridge Program.

Don't forget your patient's insurance information. We need to verify all their benefits.

Indicate your patient's preferred Specialty Pharmacy.

Complete the Pharmacy Prescription table, including both loading and maintenance doses.

Complete the prescription table for the Bridge Program or Novartis Patient Assistance Foundation (NPAF) program, including loading and/or maintenance doses.

Please don't forget to sign and date the provider attestation.

Novartis Patient Support™

Send Fax
833-318-0680

Enroll Online
CoverMyMeds.health

Questions? Call
855-KESIMPTA
(855-537-4678)

**KESIMPTA® (ofatumumab)
Prescription Start Form**

1. Patient Information (Please complete lab screenings specified in the Prescribing Information before initiating KESIMPTA) = REQUIRED

First Name Last Name Email

Sex: Male Female Date of Birth (MM/DD/YYYY) Phone Number—We'll keep you informed through non-marketing calls and texts:
OK to Leave Voicemail on: Home Phone Cell Phone

Address (No PO Box)

City State ZIP

Preferred Language: English Spanish Other:

Caregiver First Name Caregiver Last Name Caregiver Email

2. Patient Authorization and Additional Consents* I have read and agree to the Patient Authorization on [page 2](#).

Patient/Legal Guardian Signature Date of Signature (MM/DD/YYYY)

CO-PAY PLUS[†] FOR KESIMPTA Pay as little as \$0 (This box is required to access the Bridge and Co-Pay Programs) I have read and agree to the \$0 Co-Pay Plus Terms and Conditions on page 2.

Get access to ongoing support[†] I'd like to sign up for ongoing support. I'll get KESIMPTA tips, resources, and reminders from Novartis Patient Support at the mobile phone number(s) I gave above.

*By checking this box, I agree to receive recurring marketing calls and texts from and on behalf of Novartis Pharmaceuticals Corporation. These calls and texts may be automatic or recorded in advance. The number of calls and message frequency varies. My consent is not a condition of getting any goods or services from Novartis. I can opt out of the program at any time by calling 855-537-4678. I can also text "STOP" to any Novartis Patient Support Dingling Support message to opt out of texts or text "HELP" for more information about this service. Message and data rates may apply.

3. Insurance Information (Please include a copy of both sides of the insurance card)

Cardholder Name Prescription (Rx) Cardholder Name

Insurance Carrier Phone Number Rx Insurance Carrier Rx Phone Number

Cardholder ID Number Group Number Rx BIN Number Rx PCN Number

Rx Group Number Rx ID Number

4. Provider Information

First Name Last Name Practice Name

Address Office Contact Name

City State ZIP Office Contact Phone Office Fax

NPI Number State License # (Puerto Rico offices only) Email

5. Prescription Information

Specialty Pharmacy: Preferred Specialty Pharmacy

Phone Fax

Diagnosis Code: ICD-10: G35.A Relapsing-Remitting Multiple Sclerosis Other:

Shipping Preferences: Provider Address Patient Address

Pharmacy Prescription: (Complete this section for pharmacy fill only)

KESIMPTA SensorReady[®] Pen
20 mg/0.4 mL single-dose pre-filled pen NDC 0078-1007-88

Loading Doses:

No, patient already on therapy Yes, 20 mg (0.4 mL)

SIG: 1 SC injection at week 0, 1, and 2
Qty: 3 units (No refills)

Maintenance Dose:
20 mg (0.4 mL)
SIG: 1 SC injection monthly starting at week 4
Qty: 1 SC injection, then 12 refills, or ____ refills

Bridge to Commercial Coverage or Novartis Patient Assistance Foundation (NPAF): (For Bridge to Commercial Coverage or NPAF, please select applicable dose(s).)

For Bridge to Commercial Coverage ONLY: Eligible patients may receive KESIMPTA for free while pursuing insurance coverage via the Bridge Program. Eligible patients must have private insurance, a valid prescription for KESIMPTA, and a prior authorization.

Loading Doses: No, patient already on therapy Yes, 20 mg (0.4 mL)

Yes, 20 mg (0.4 mL) **Maintenance Dose:**
SIG: 1 SC injection at week 0, 1, and 2
Qty: 1 SC injection, then 12 refills, or ____ refills

6. Provider Attestation
Prescriber must authorize these instructions by signing at the end of this section.

I certify the above therapy is medically necessary and this information is accurate to the best of my knowledge. I certify I am the provider who has prescribed KESIMPTA to the previously identified patient and I provided the patient with a description of Novartis Patient Support. For the purposes of transmitting these prescriptions, I authorize NPAF, Novartis Pharmaceuticals Corporation, and its affiliates, business partners, and agents to forward as my agent, for these limited purposes, the prescriptions electronically, by facsimile, or by mail to the appropriate dispensing pharmacies. I will not attempt to seek reimbursement for free product provided to my office.

Provider Signature (Dispense as Written) (Substitution Permissible) **Provider Name (Print Name)** **Date (MM/DD/YYYY)**

ATTN: New York and Iowa providers, please submit electronic prescription to Homescripts Pharmacy, NPI #1528362076.

SC, subcutaneous.

FA-11606506

Complete entire form and fax to Novartis Patient Support at **833-318-0680**
An incomplete Start Form may delay the start of treatment.

Kesimpta®
(ofatumumab) 20 mg injection

Your patients are our top priority

Novartis Patient Support is a comprehensive program that is designed to help your eligible patients start, stay, and save on KESIMPTA.

We support you and your patient's journey with:

- ▶ Dedicated assistance with access and reimbursement
- ▶ Personalized support for your patients on therapy
- ▶ Single points of contact for you and your patients

Our offerings include:



Insurance Support

Help navigating the insurance process, including benefits verification and support with the prior authorization and appeals processes



Financial Support

Assistance with relevant savings options for your eligible patients, including \$0 Co-Pay Plus* offer and affordability programs



Ongoing Support

Dedicated assistance from our team and educational resources to help your patients get started on treatment and guide them along the way



CAYLEE R.
Actual KESIMPTA patient.



Questions?

For more information, call Novartis Patient Support at **855-KESIMPTA (855-537-4678)**, Monday-Friday, 8:30 AM-8:00 PM ET, excluding holidays, or visit www.kesimptahcp.com.

*Limitations apply. Offer not valid under Medicare, Medicaid, or any other federal or state health insurance program. Patients with commercial insurance who are initially denied coverage may receive free KESIMPTA for up to 15 doses while seeking coverage. Patients with commercial insurance who have coverage for KESIMPTA may receive up to \$18,000 in annual co-pay benefits. Novartis reserves the right to rescind, revoke, or amend this program without notice. Additional limitations may apply. See complete Terms & Conditions at start.kesimpta.com.

The information herein is provided for educational purposes only. Novartis cannot guarantee health plan or reimbursement. Coverage and reimbursement may vary significantly by health 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.

Your doctor has prescribed **KESIMPTA[®] (ofatumumab)**

Once you've been prescribed KESIMPTA, you or your loved one can sign up for Novartis Patient Support. It's a comprehensive program with a dedicated team in your corner. When you have questions, you can talk to them directly.

Expect help with:



Getting Started

- ▶ Learning about Novartis Patient Support
- ▶ Informing you about requirements for treatment, if applicable
- ▶ Signing up for Novartis Patient Support
- ▶ Expect a call from Novartis Patient Support



Insurance Support

- ▶ Help navigating your insurance process
- ▶ Assistance accessing medication
- ▶ Support with benefits verification and prior authorization



Financial Support

- ▶ Educating you on Co-Pay Plus
- ▶ Helping you find financial support



Ongoing Support

- ▶ Dedicated support throughout your treatment
- ▶ Helpful resources



Questions?

Call Novartis Patient Support at **855-KESIMPTA (855-537-4678)**, Monday-Friday, 8:30 AM-8:00 PM ET, excluding holidays. Or visit www.KESIMPTA.com for more information.



Give this page to your patient!

1. Patient Information (Please complete lab screenings specified in the Prescribing Information before initiating KESIMPTA) * = REQUIRED

* First Name _____ * Last Name _____ Email _____
 * Sex: Male Female _____ * Date of Birth (MM/DD/YYYY) _____ * Phone Number—We'll keep you informed through non-marketing calls and texts.* _____
 * Address (No PO Box) _____ **OK to Leave Voicemail on:** Home Phone Cell Phone
 * City _____ * State _____ * ZIP _____ **Preferred Language:** English Spanish Other: _____
 Caregiver First Name _____ Caregiver Last Name _____ Caregiver Email _____

2. Patient Authorization and Additional Consents* I have read and agree to the Patient Authorization on [page 2](#).

X
 * **Patient/Legal Guardian Signature** _____ * **Date of Signature (MM/DD/YYYY)** _____
CO-PAY PLUS[†] FOR KESIMPTA **Get access to ongoing support***
 Pay as little as \$0 (This box is required to access the Bridge and Co-Pay Programs) I'd like to sign up for ongoing support. I'll get KESIMPTA tips, resources, and reminders from Novartis Patient Support at the mobile phone number(s) I gave above.
 I have read and agree to the \$0 Co-Pay Plus Terms and Conditions on page 2.
†By checking this box, I agree to receive recurring marketing calls and texts from and on behalf of Novartis Pharmaceuticals Corporation. These calls and texts may be automatic or recorded in advance. The number of calls and message frequency varies. My consent is not a condition of getting any goods or services from Novartis. I can opt out of the program at any time by calling 855-537-4678. I can also text "STOP" to any Novartis Patient Support Ongoing Support message to opt out of texts or text "HELP" for more information about this service. Message and data rates may apply.

3. Insurance Information (Please include a copy of both sides of the insurance card)

Cardholder Name _____ Prescription (Rx) Cardholder Name _____
 Insurance Carrier _____ Phone Number _____ Rx Insurance Carrier _____ Rx Phone Number _____
 Cardholder ID Number _____ Group Number _____ Rx BIN Number _____ Rx PCN Number _____
 Rx Group Number _____ Rx ID Number _____

4. Provider Information

* First Name _____ * Last Name _____ Practice Name _____
 * Address _____ Office Contact Name _____
 * City _____ * State _____ * ZIP _____ * Office Contact Phone _____ * Office Fax _____
 * NPI Number _____ State License # (* Puerto Rico offices only) _____ Email _____

5. Prescription Information

Specialty Pharmacy: _____
 Preferred Specialty Pharmacy _____
 Phone _____ Fax _____
 * **Diagnosis Code:** ICD-10: G35.A Relapsing-Remitting Multiple Sclerosis
 Other: _____
Shipping Preferences:
Loading Doses: Provider Address Patient Address
 * **Pharmacy Prescription:** OR **Bridge to Commercial Coverage or Novartis Patient Assistance Foundation (NPAF):**
 (Complete this section for pharmacy fill only)
 KESIMPTA Sensoready[®] Pen
 20 mg/0.4 mL single-dose prefilled pen NDC 0078-1007-68
Loading Doses: No, patient already on therapy Yes, 20 mg (0.4 mL)
SIG: 1 SC injection at week 0, 1, and 2
Qty: 3 units (No refills)
Maintenance Dose: No, patient already on therapy Yes, 20 mg (0.4 mL)
SIG: 1 SC injection monthly starting at week 4
Qty: 1 SC injection, then 12 refills, or _____ refills
For Bridge to Commercial Coverage or NPAF, please select applicable dose(s).
For Bridge to Commercial Coverage ONLY: Eligible patients may receive KESIMPTA for free while pursuing insurance coverage via the Bridge Program. Eligible patients must have private insurance, a valid prescription for KESIMPTA, and a prior authorization.
 * **Loading Doses:** No, patient already on therapy Yes, 20 mg (0.4 mL)
SIG: 1 SC injection at week 0, 1, and 2
Qty: 3 units (No refills)
 * **Maintenance Dose:** No, patient already on therapy 20 mg (0.4 mL)
SIG: 1 SC injection monthly starting at week 4
Qty: 1 SC injection, then 12 refills, or _____ refills

6. Provider Attestation

Prescriber must authorize these instructions by signing at the end of this section.
 I certify the above therapy is medically necessary and this information is accurate to the best of my knowledge. I certify I am the provider who has prescribed KESIMPTA to the previously identified patient and I provided the patient with a description of Novartis Patient Support. For the purposes of transmitting these prescriptions, I authorize NPAF, Novartis Pharmaceuticals Corporation, and its affiliates, business partners, and agents to forward as my agent, for these limited purposes, the prescriptions electronically, by facsimile, or by mail to the appropriate dispensing pharmacies. I will not attempt to seek reimbursement for free product provided to my office.
X
 * **Provider Signature (Dispense as Written)** _____ (Substitution Permissible) * **Provider Name (Print Name)** _____ * **Date (MM/DD/YYYY)** _____
ATTN: New York and Iowa providers, please submit electronic prescription to Homescrpts Pharmacy, NPI #1528362076.

SC, subcutaneous.

Patient Authorization. I authorize my health care professionals, pharmacies and health insurers, and their service providers (“Providers”) to disclose information relating to my insurance benefits, medical condition, treatment and prescription details (“Personal Information”) to Novartis Pharmaceuticals Corporation, its affiliates and service providers (“Novartis”) and the Novartis Patient Assistance Foundation, Inc., and its service providers (“NPAF”) so they can provide the following support services (the “Services”):

- Help coordinate insurance coverage for, access to, and receipt of my medication.
- Communicate with me about possible financial assistance, including Novartis copay or NPAF programs, and, if I am enrolled, administer my participation in those programs.
- Communicate with me about my medication and treatment, including reminders, health and lifestyle tips, and product and other related information. Communications may be customized based on Personal Information obtained from my Providers.
- Conduct quality assurance and other internal business activities and ask for feedback related to the Services or my treatment.

In delivering the Services, Novartis and NPAF may share my Personal Information with each other, with my Providers, or with government agencies or other financial assistance programs that might help me pay for my medication. They may combine information collected from me with information collected from other sources and use that information to administer the Services. My pharmacies or other health care professionals may receive payment from Novartis or NPAF for providing certain Services, such as medication or refill reminders, based on my enrollment or participation. Once I authorize disclosure of my Personal Information, it may no longer be protected by federal health privacy law and applicable state laws.

I understand I do not have to sign this Authorization to get my medication or insurance coverage, that I have a right to a copy, and can cancel this Authorization at any time by calling 855-537-4678 or by writing to:

PO Box 2971
850 Twin Rivers Dr
Columbus, OH 43216-9532

OR

Novartis Patient Support
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080

This Authorization will expire 5 years after I sign it, or earlier if required by state law, unless I cancel it sooner. If I cancel it, I may no longer qualify for Services from Novartis or NPAF, but it will not impact my Provider’s treatment or my insurance benefits. I also understand that if a Provider is disclosing my Personal Information to Novartis or NPAF on an authorized, ongoing basis, my cancellation will be effective with respect to that Provider as soon as they receive notice of my cancellation. Cancellation will not affect prior uses or disclosures.

*Novartis Patient Support may call and text you at the numbers provided for non-marketing purposes (eg, to help you access and start on KESIMPTA). Calls may be autodialed or prerecorded. Message and data rates may apply. You may change your communication preferences at any time by calling 855-537-4678.

Co-Pay Plus Terms and Conditions

†Limitations apply. Offer not valid under Medicare, Medicaid, or any other federal or state health insurance program. Patients with commercial insurance who are initially denied coverage may receive free KESIMPTA for up to 15 doses while seeking coverage. Patients with commercial insurance who have coverage for KESIMPTA may receive up to \$18,000 in annual co-pay benefits. Novartis reserves the right to rescind, revoke, or amend this program without notice. Additional limitations may apply. See complete Terms & Conditions at start.kesimpta.com.

Bridge Program: Must have commercial insurance, a valid prescription for KESIMPTA, and a denial of insurance coverage based on a prior authorization requirement to qualify. Eligible patients may receive up to 15 doses or until insurance coverage approval. Not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, VA, DoD or any other federal or state program, or where prohibited by law. No purchase necessary. Program is not health insurance, nor is participation a guarantee of insurance coverage. Other limitations may apply. Novartis reserves the right to rescind, revoke, or amend this Program without notice.

IMPORTANT SAFETY INFORMATION (cont)

Warnings and Precautions (cont)

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.

Please see full Prescribing Information, including Medication Guide.

IMPORTANT SAFETY INFORMATION (cont)

Warnings and Precautions (cont)

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.

Please see full Prescribing Information, including Medication Guide.