



Start Forms

Initiate treatment and patient support with a one-page form

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 <u>the last page</u>. Please see full Prescribing Information including Medication Guide <u>here</u>.

Get started with the Start Form

It's pretty straightforward, but we highlighted a few things to keep in mind. We're only asking for essential information to make it faster for you. Fill it out completely to make getting started **faster for your patients.**

Get patient and/or quardian consent.

Check this box to sign patients up for the \$0 Access Card, which includes access to the Bridge Program.

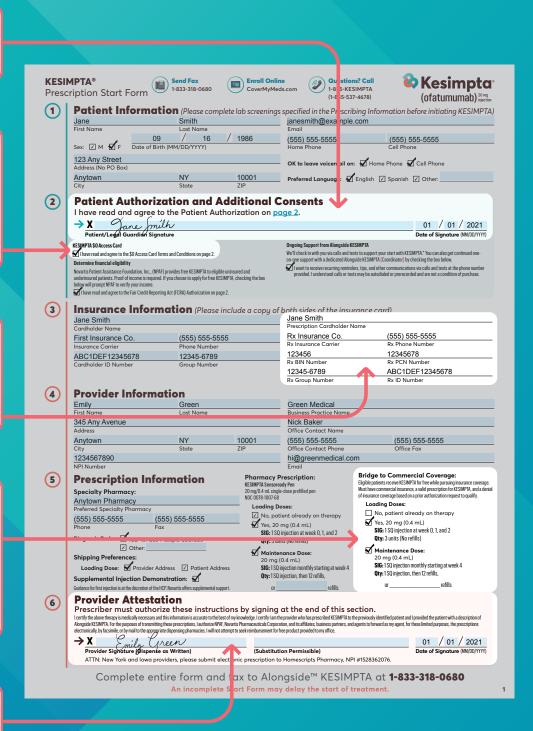
Don't skip the prescription insurance info!

We need it to verify all your patient's benefits.

Sign up for our Bridge Program, including both loading and maintenance doses.

Be sure to check both if needed.

Make sure to provide a prescriber signature, too!







Your doctor has prescribed KESIMPTA®

It comes with membership in Alongside™ KESIMPTA.

If your doctor signed you up, here's what happens next:



We'll check your benefits

> Expect a call from us to discuss your options, including potential savings and product delivery



We'll mail you a welcome package

With some important information about your program and quick tips for using KESIMPTA. It should arrive in a day or two



You'll get a call from your dedicated Coordinator

Who has access to your membership materials, additional training resources, and answers to any questions about KESIMPTA and Alongside KESIMPTA

We're in this together.



Questions? Call us.

▶ 1-855-KESIMPTA (1-855-537-4678)
8:30 AM-8:00 PM ET, Monday-Friday



Visit www.KESIMPTA.com for more information



KESIMPTA®

Prescription Start Form









	Last Name /	/	Email	
Sex: M F Date of Birt	th (MM/DD/YYYY)	/	Home Phone	Cell Phone
			OK to leave voicemail on	: Home Phone Cell Phone
Address (No PO Box)			_	
City	State	ZIP	Preferred Language:	English Spanish Other:
Patient Authoriz	ation and A	dditiona	l Consents	
I have read and agree to	o the Patient Auth	norization o	n <u>page 2</u> .	
→ X				/ /
Patient/Legal Guardian Sign	ature			Date of Signature (MM/DI
KESIMPTA \$0 Access Card			Ongoing Support from Alongside KI	ESIMPTA
☐ I have read and agree to the \$0 Access Card To	erms and Conditions on page 2.		We'll check in with you via calls and te	xts to support your start with KESIMPTA.* You can also get continued o
Determine financial eligibility			''	gside KESIMPTA [Coordinator] by checking the box below.
Novartis Patient Assistance Foundation, Inc., (NPAF) provides free KESIMPTA to eligible uninsure underinsured patients. Proof of income is required. If you choose to apply for free KESIMPTA, ch below will prompt NPAF to verify your income. I have read and agree to the Fair Credit Reporting Act (FCRA) Authorization on page 2.				
Insurance Inforn	nation (Please in	nclude a cop <u>i</u>	y of both sides of the insu	rance card)
Cardholder Name			Prescription Cardholder N	Name
Insurance Carrier	Phone Number		Rx Insurance Carrier	Rx Phone Number
			Rx BIN Number	Rx PCN Number
Cardholder ID Number	Group Number			
Provider Informo	·		Rx Group Number	Rx ID Number
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Patient Authorization. I authorize my healthcare providers, 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 healthcare providers 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 1-855-537-4678 or by writing to:

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

OR

Customer Interaction Center 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.

\$0 Access Card Terms and Conditions

Copay Program: Limitations apply. Valid only for those with private insurance. The Program includes the \$0 Access Card and Rebate, with a combined annual limit of \$18,000. Patient is responsible for any costs once limit is reached in a calendar year. Program not valid (i) under Medicare, Medicaid, TRICARE, VA, DoD, or any other federal or state health care program, (ii) where patient is not using insurance coverage at all, (iii) where the patient's insurance plan reimburses for the entire cost of the drug, or (iv) where product is not covered by patient's insurance. The value of this Program is exclusively for the benefit of patients and is intended to be credited toward patient out-of-pocket obligations and maximums, including applicable copayments, coinsurance, and deductibles. Program is not valid where prohibited by law. Patient may not seek reimbursement for the value received from this Program from other parties, including any health insurance program or plan, flexible spending account, or health care savings account. Patient is responsible for complying with any applicable limitations and requirements of their health plan related to the use of the Program. Valid only in the United States and Puerto Rico. This Program is not health insurance. Program may not be combined with any third-party rebate, coupon, or offer. Proof of purchase may be required. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

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 a monthly maintenance dose for up to 12 months or until insurance coverage approval, whichever occurs first. 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.

Fair Credit Reporting Act (FCRA) Authorization

Lunderstand that Lam providing "written instructions" that authorize NPAF and its vendor, under the FCRA, to obtain information from my credit profile or other information from the vendor, solely for the purpose of determining financial qualifications for programs administered by NPAF. I understand that I must affirmatively agree to these terms in order to proceed with this financial screening process.

*Alongside KESIMPTA 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 1-855-537-4678.

IMPORTANT SAFETY INFORMATION (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 of atumumab 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.

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.

Please see additional Important Safety Information on <u>the first page</u>. Please see accompanying full Prescribing Information including Medication Guide <u>here</u>.

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