



# **Start Form**

# Initiate treatment and patient support with a 1-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 here.

# 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 easier on you. Fill it out completely to help make getting started **faster for your patients**.

Get patient and/or guardian consent.

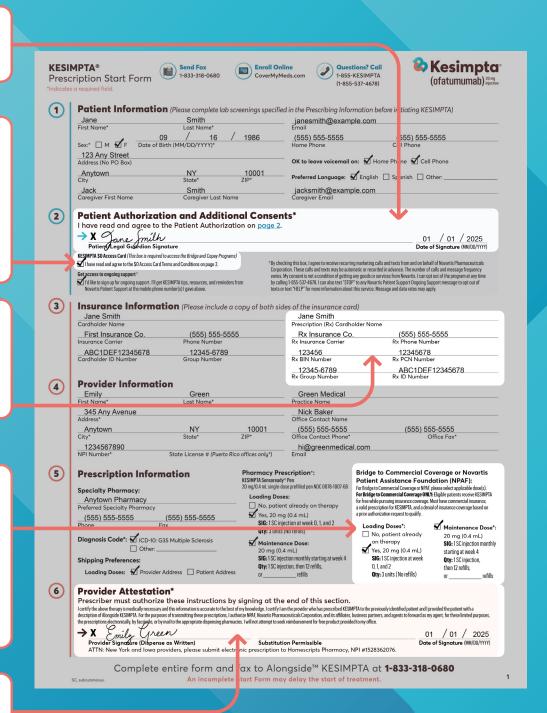
Check this box to sign patients up for the \$0 Access Card, which includes access to the Bridge and Copay Programs.

# Don't skip the prescription insurance info!

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

Sign up for Bridge to Commercial Coverage and the Novartis Patient Assistance Foundation (NPAF) for access to loading and/or maintenance doses.

Make sure to provide a prescriber signature, too!







# Your doctor has prescribed KESIMPTA®

It comes with membership in Alongside™ KESIMPTA, a Novartis Patient Support program.

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









First Name*	Last Name*		Email		
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Get access to ongoing support	t		ooration. These calls and texts may be auto es. My consent is not a condition of getting		
	support. I'll get KESIMPTA tips, resources, and rem e mobile phone number(s) I gave above.	ninders from by c	alling 1-855-537-4678. I can also text "STO s or text "HELP" for more information abou	P" to any Novartis Patient Support	Ongoing Support message to opt out
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**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 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**

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® (ofatumumab) for up to 12 months while seeking coverage. Patients with commercial insurance who have coverage for KESIMPTA may receive up to \$18,000 in annual copay 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 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.

#### **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.

**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 additional Important Safety Information on <a href="the-front cover">the front cover</a>. Please see full Prescribing Information, including Medication Guide <a href="here">here</a>.



