

**Once you
decide,
we deliver.**

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

Alongside™ gets your patient started
and supports them along the way.

Our people are here for your people.

Your priority is your patient,
so our goal is to make
treatment support simple—for
them and for you.

Tap to get to know our team.

Tap to see our support resources.

What is Alongside?
● ● ● ● ●

Initiating
● ● ● ● ●

Coverage
● ● ● ● ●

Ongoing Support
● ● ● ● ●

Resources
● ●

Indication and
Important Safety Information
● ●



Who's Who

A quick guide to who supports your office and your patient.

Sales Specialist



Your central point of contact, pointing you to the right resources at the right time.



Field Reimbursement Manager (FRM)

Helps with navigating the Prior Authorization (PA) and appeals processes.

- Helps troubleshoot issues
- Guides your office through the processes



Patient Access Coordinator (PAC)

Coordinates access to treatment.

- Completes benefits verification
- Informs patient of coverage status and next steps



Alongside Coordinator

Helps your patient start and stay on track with KESIMPTA® as prescribed.

- Performs supplemental injection demonstration over video chat
- Provides 1-on-1 tailored support for up to 2 years

10
9
out of

patients were satisfied with services provided
by the Alongside™ KESIMPTA Coordinators*†‡

*Data on file. Patient market research survey. Novartis Pharmaceuticals Corp; East Hanover, NJ. September 2021.

†Alongside KESIMPTA Patient Support Services offers educational and financial resources for up to two years, such as supplemental injection training, monthly calls, copay, and insurance support.

‡Based on a market research survey conducted online from January to September 2021 among 200 relapsing multiple sclerosis patients who recently initiated on KESIMPTA. Participants were asked questions about the Alongside KESIMPTA Patient Program, including the onboarding process, ease of initiation process for KESIMPTA, and support from their coordinators. Participants were asked to rate various features of the Alongside KESIMPTA Patient Program. Respondents were compensated for their participation.

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(ofatumumab) 20 mg
injection

What is Alongside?



Initiating



Coverage



Ongoing Support



Resources




Indication and
Important Safety Information



Our goal is to make onboarding simple, so nothing stands between your patient and KESIMPTA.

The steps to getting your patient started

YOUR OFFICE




1 Choose KESIMPTA

Submit a [Start Form](#) via [CoverMyMeds®](#) or by fax.

OR

Prescribe directly to a specialty pharmacy (SP).



START WITHIN 5 DAYS:

80% of commercial patients get KESIMPTA in 5 days or less*

Based on prescription and dispense data as of November 2021

*Data on file. Program data. Novartis Pharmaceuticals Corp; East Hanover, NJ. August 2021.

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(ofatumumab) 20 mg injection

What is Alongside?



Initiating



Coverage



Ongoing Support



Resources



Indication and
Important Safety Information



The steps to getting your patient started

ALONGSIDE & YOUR OFFICE



2 Coverage and financial support

Eligible commercial patients are automatically enrolled in our Bridge Program and \$0* copay support when you submit a [Start Form](#).



Your dedicated **Field Reimbursement Manager (FRM)** will work with you to submit a Prior Authorization or file an appeal, if needed.



Direct to pharmacy? Encourage patient to self-enroll [online](#) for copay and ongoing support.

*Limitations apply. Offer not valid under Medicare, Medicaid, or any other federal or state health insurance program. Patients with commercial insurance coverage for KESIMPTA may receive up to \$18,000 in annual copay benefits. Patients with commercial insurance and an initial denial of coverage may receive up to 12 months of free product while coverage is pursued. Novartis reserves the right to rescind, revoke, or amend this program without notice. See complete Terms & Conditions at [start.kesimpta.com](#).

Alongside™
Kesimpta®
(ofatumumab) 20 mg injection

What is Alongside?



Initiating



Coverage



Ongoing Support



Resources



Indication and
Important Safety Information



The steps to getting your patient started

ALONGSIDE & YOUR PATIENT



3

Ongoing support for the next 2 years



Help Patient With Coverage



Getting Started Call



Supplemental Injection Demo

2

years

Support Keeps Going

Our **Patient Access Coordinator (PAC)** will let patients know when to expect their first covered dose.

Your patient's **Coordinator** will walk them through their Member Welcome Package.

Their **Coordinator** will help your patient, 1-on-1, feel confident about starting KESIMPTA.*

Your patient's **Coordinator** will provide 1-on-1 tailored support, checking in for up to 2 years.

90% OF PATIENTS WERE SATISFIED with their supplemental Alongside injection training^{*†‡§}

Direct to pharmacy? We'll give your patient ongoing support for up to 2 years.

*The first injection should be performed under the guidance of a health care professional.

†Data on file. Patient market research survey. Novartis Pharmaceuticals Corp; East Hanover, NJ. September 2021.

‡Alongside KESIMPTA Patient Support Services offers educational and financial resources for up to 2 years, such as supplemental injection training, monthly calls, copay, and insurance support.

§Based on a market research survey conducted online from January to September 2021 among 200 patients with RMS who recently initiated on KESIMPTA. Participants were asked questions about the Alongside KESIMPTA Patient Program, including the onboarding process, ease of initiation process for KESIMPTA, and support from their coordinators. Participants were asked to rate various features of the Alongside KESIMPTA Patient Program. Respondents were compensated for their participation.

Alongside™
Kesimpta®
(ofatumumab) 20 mg injection

What is Alongside?



Initiating



Coverage



Ongoing Support



Resources



Indication and
Important Safety Information



INITIATING

80% of commercial patients
GET KESIMPTA (ofatumumab)
IN 5 DAYS OR LESS.*†

“I have been pleasantly surprised at how quickly my KESIMPTA patients can get their medication.”

— **Dr Robert Shin,‡** Neurologist, Washington, DC

*Data on file. Program data. Novartis Pharmaceuticals Corp; East Hanover, NJ. August 2021.

†Based on prescription and dispensing data as of November 2021.

‡Dr Shin is a paid consultant for Novartis.

What is Alongside?



Initiating



Coverage



Ongoing Support



Resources



Indication and
Important Safety Information



Ready to prescribe KESIMPTA?

Two blood tests, and your patient can be ready to go.



Prior to initiating KESIMPTA, perform hepatitis B virus (HBV) screening and test for quantitative serum immunoglobulins, and vaccinate (at least 4 weeks prior for live or live-attenuated vaccines and at least 2 weeks prior for inactivated vaccines).

The first injection should be performed under the guidance of a health care professional.

Questions? Reach out to your Sales Specialist.



The flexibility is fantastic—once a month,
KESIMPTA checks all the boxes for me.*



—Sean C., high school science teacher,
KESIMPTA patient[†]

*After 3 weekly starter doses.

[†]Actual KESIMPTA patient who was compensated for their time. Individual results may vary.

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.

Please see additional [Important Safety Information](#) and full [Prescribing Information](#), including Medication Guide.

Alongside™
Kesimpta®
(ofatumumab) 20 mg
injection



The right resources for your KESIMPTA patient.

Our goal is to get your patient started on treatment quickly and easily.



Sensoready® Training Pen

Use it for in-office training—it might help your patient feel comfortable with self-injection.

- > Request one from your Sales Specialist
- > [Video](#) shows your staff how to use it
- > [Quick Tips for Use brochure](#)



19 out of **10** nurses preferred the **Sensoready Pen attributes**, based on a survey^{*†}

^{*}Based on a survey of multiple sclerosis (MS) nurses (N = 50) and patients (N = 80) in the United States, Germany, France, and Italy. Participants were asked to compare attributes of the KESIMPTA Sensoready autoinjector pen with those of other disease-modifying therapy autoinjectors, some of which are not available in the United States. The Sensoready Pen was not used during the survey nor were all devices compared against each other by participants. A total of 17 attributes were assessed, with "easy to perform the self-injection with the pen," "ease of preparation and set-up," and "ease of training patient in use" among those most preferred.

[†]Ross AP, Besser C, Stoneman S, Gaunt H, Barker N. Patient and nurse preferences for the Sensoready® autoinjector pen versus other autoinjectors in multiple sclerosis: results from a multicenter survey.

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Kesimpta®
 (ofatumumab) 20 mg injection



Once you decide, Alongside KESIMPTA delivers.

From receiving KESIMPTA to getting dedicated support, our goal is to help make things go smoothly for your patient—enroll them in one of 2 ways:



Via fax to **1-833-318-0680**

Use our annotated **Start Form** to make enrollment easy. We've pointed out a few things to keep in mind.

Download the **Start Form** [here](#).



Or online at **CoverMyMeds.com**

You can submit your form via CoverMyMeds.com, an online service created to streamline the onboarding and prior authorization processes.

That's it; we've got it from here.



Start today

Request KESIMPTA samples from your Sales Specialist for use with your appropriate patients.

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 guardian 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!



Direct to pharmacy?

Remind your patient to [self-enroll](#) in Alongside KESIMPTA to get their Access Card and ongoing support.

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(ofatumumab) 20 mg injection



COVERAGE



Eligible commercially insured patients
GET STARTED RIGHT AWAY
with our
BRIDGE PROGRAM.*

*Limitations apply. Offer not valid under Medicare, Medicaid, or any other federal or state health insurance program. Patients with commercial insurance coverage for KESIMPTA® (ofatumumab) may receive up to \$18,000 in annual copay benefits. Patients with commercial insurance and an initial denial of coverage may receive up to 12 months of free product while coverage is pursued. Novartis reserves the right to rescind, revoke, or amend this program without notice. See complete Terms & Conditions at start.kesimpta.com.

What is Alongside?



Initiating



Coverage



Ongoing Support



Resources



Indication and
Important Safety Information



As soon as you submit a Start Form, Alongside gets to work.

Our goal is to make onboarding seamless so you can focus on your patient.



Your patient will get a call from their Patient Access Coordinator (PAC) within 24 hours. They will verify benefits and:

- > Work with your patient's insurance provider to sort out coverage
- > Discuss financial assistance options with your patient
- > Keep your patient informed of where their coverage stands
- > Send you status updates (if you'd like)

The KESIMPTA Access Card keeps our \$0 copay and Bridge Program savings in one convenient place.* Patients enrolled with a Start Form automatically receive these benefits.



We'll get your eligible commercially insured patient started right away—at no cost—with our Bridge Program.

Make sure you've checked the box for our Bridge Program on the Start Form.

Your patient will get a welcome call from their PAC letting them know they'll receive their treatment—usually within 5 days[†]—via our partner pharmacy.

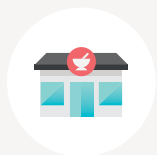
92% of patients with commercial insurance are covered^{‡§}

* Limitations apply. Offer not valid under Medicare, Medicaid, or any other federal or state health insurance program. Patients with commercial insurance coverage for KESIMPTA may receive up to \$18,000 in annual copay benefits. Patients with commercial insurance and an initial denial of coverage may receive up to 12 months of free product while coverage is pursued. Novartis reserves the right to rescind, revoke, or amend this program without notice. See complete Terms & Conditions at start.kesimpta.com.

[†] Based on prescription and dispensing data as of November 2021.

[‡] Data on file. Market access. Novartis Pharmaceuticals Corp; East Hanover, NJ. September 2021.

[§] Unrestricted or single-step edit coverage from internal formulary tracker data as of September 2021.



Direct to pharmacy?

Have a patient that's not enrolled in Alongside KESIMPTA? Don't worry, they can self-enroll [here](#) to access our benefits.

Alongside™
Kesimpta®
(ofatumumab) 20 mg injection

What is Alongside?



Initiating



Coverage



Ongoing Support



Resources



Indication and
Important Safety Information





“It was great that I had the option to start KESIMPTA right away, in my doctor's office.”

—Kristin C., mother, real estate agent, KESIMPTA patient[†]

[†]Actual KESIMPTA patient who was compensated for their time. Individual results may vary.

Your eligible commercially insured patient gets KESIMPTA for as little as \$0* out of pocket with the KESIMPTA Access Card.

Once coverage has been established, your commercially insured patient can start saving on their prescription.

Have an uninsured or underinsured patient who needs financial assistance? Ask your Sales Specialist about the Novartis Patient Assistance Foundation, Inc. (NPAF).



*Limitations apply. Offer not valid under Medicare, Medicaid, or any other federal or state health insurance program. Patients with commercial insurance coverage for KESIMPTA may receive up to \$18,000 in annual copay benefits. Patients with commercial insurance and an initial denial of coverage may receive up to 12 months of free product while coverage is pursued. Novartis reserves the right to rescind, revoke, or amend this program without notice. See complete Terms & Conditions at start.kesimpta.com.

Alongside™
Kesimpta®
(ofatumumab) 20 mg injection

What is Alongside?



Initiating



Coverage



Ongoing Support



Resources



Indication and
Important Safety Information



Need help navigating a PA or filing an appeal?

That's what we're here for.



Your dedicated Field Reimbursement Manager (FRM) will be with you every step of the way to:

- > Help troubleshoot any access or reimbursement issues
- > Guide you through the Prior Authorization (PA) and appeal process

Our Authorization and Appeals Kit streamlines the process with:

- > A PA checklist
- > Sample letters of appeal
- > Sample letters of medical necessity



Direct to pharmacy?

If your patient is an Alongside™ member, they'll follow the same path from here on in. Remind any patient who hasn't enrolled to become a member [here](#).



What is Alongside?



Initiating



Coverage



Ongoing Support



Resources



Indication and
Important Safety Information



We help deliver KESIMPTA—fast.

We'll help coordinate delivery of the first covered dose.



As soon as coverage has been obtained, your patient will hear from their Patient Access Coordinator (PAC) with:

- > Their specialty pharmacy's phone number
- > Information about next steps

“The medication is delivered to my doorstep. I don't even have to go to the pharmacy and get it.”

—Ananda B., KESIMPTA patient*

*Actual KESIMPTA patient who was compensated for their time. Individual results may vary.



Alongside™
Kesimpta®
(ofatumumab) 20 mg injection

What is Alongside?



Initiating



Coverage



Ongoing Support



Resources



Indication and
Important Safety Information



ONGOING SUPPORT



**90% OF PATIENTS
WERE SATISFIED WITH**
services provided by the
ALONGSIDE™
KESIMPTA® (ofatumumab)
COORDINATORS*†‡

“I’m here to make the KESIMPTA
journey as stress-free as possible.”

— **Leticia**, Alongside Coordinator

*Data on file. Patient market research survey. Novartis Pharmaceuticals Corp; East Hanover, NJ. September 2021.

†Alongside KESIMPTA Patient Support Services offers educational and financial resources for up to two years, such as supplemental injection training, monthly calls, copay, and insurance support.

‡Based on a market research survey conducted online from January to September 2021 among 200 patients with RMS who recently initiated on KESIMPTA. Participants were asked questions about the Alongside KESIMPTA Patient Program, including the onboarding process, ease of initiation process for KESIMPTA, and support from their coordinators. Participants were asked to rate various features of the Alongside KESIMPTA Patient Program. Respondents were compensated for their participation.

What is Alongside?



Initiating



Coverage



Ongoing Support



Resources



Indication and
Important Safety Information



We're by your patient's side when they need us.

A dedicated Coordinator will have your patient's back for up to 2 years.



Dedicated Coordinators reach out to welcome patients into Alongside, providing tailored support and resources, including:

- > A clear road map of what to expect
- > Supplemental injection demonstration
- > Treatment reminders
- > Personalized emails based on your patient's individual needs
- > Support resources, including our Member Welcome Package

Your patient can request an On-the-Go cooler and sharps container.



I had a great experience with my Alongside™ KESIMPTA® Coordinator. She made it so I felt comfortable.



—Ananda B., KESIMPTA patient*

*Actual KESIMPTA patient who was compensated for their time. Individual results may vary.



Direct to pharmacy?

Make sure your patient [self-enrolls](#) in Alongside KESIMPTA, so they can take advantage of our support.

Alongside™
Kesimpta®
(ofatumumab) 20 mg
injection

What is Alongside?



Initiating



Coverage



Ongoing Support



Resources



Indication and
Important Safety Information



Supplemental injection demonstration: Our goal is to make your patient feel comfortable.

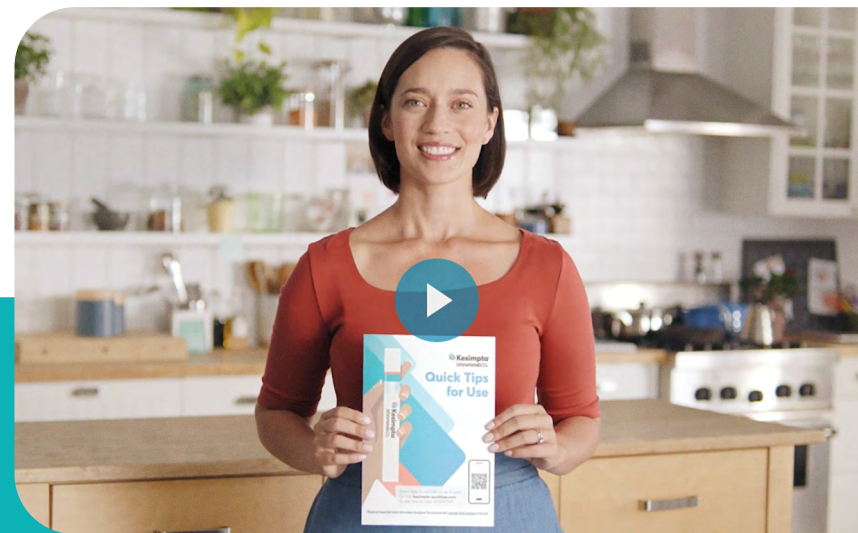
Over 90% of patients were satisfied with their supplemental Alongside injection training.*†§



We'll give your patient as much or as little training as they feel they need by offering:

- > **1-on-1 support** via video chat or an in-home visit
- > [Step-by-step videos](#)
- > [Quick Tips for Use brochure](#)

As always, a Coordinator can answer any questions your patient may have about taking KESIMPTA or about Alongside KESIMPTA.



*Data on file. Patient market research survey. Novartis Pharmaceuticals Corp; East Hanover, NJ. September 2021.

†Alongside KESIMPTA Patient Support Services offers educational and financial resources for up to 2 years, such as supplemental injection training, monthly calls, copay, and insurance support.

‡The first injection should be performed under the guidance of a health care professional.

§Based on a market research survey conducted online from January to September 2021 among 200 patients with RMS who recently initiated on KESIMPTA. Participants were asked questions about the Alongside KESIMPTA Patient Program, including the onboarding process, ease of initiation process for KESIMPTA, and support from their coordinators. Participants were asked to rate various features of the Alongside KESIMPTA Patient Program. Respondents were compensated for their participation.

Alongside™
Kesimpta®
(ofatumumab) 20 mg injection

What is Alongside?



Initiating



Coverage



Ongoing Support



Resources



Indication and
Important Safety Information



With Alongside KESIMPTA, your office always knows what to expect.

Reach out to your Sales Specialist within the first month of treatment and ask for a Service Status Report.



It can tell you if your patient has:

- ☒ Been contacted by their Coordinator
- ☒ Received a Supplemental Injection Demonstration
- ☒ Received their KESIMPTA
- ☒ Completed their first dose
- ☒ Enrolled in ongoing support

Alongside KESIMPTA (ofatumumab)

FAX

TO: Dr. Emily Green FROM: Alongside KESIMPTA® (ofatumumab) Support Program

FAX: (555) 555-5555 FAX: (555) 555-5555 PHONE: (555) 555-5555

PHONE: (555) 555-5555 Sender phone number: (555) 555-5555

SUBJECT: Alongside KESIMPTA Service Status Report DATE: 01/01/2022

The following patient has received the services or had the following materials sent from the Alongside KESIMPTA® (ofatumumab) patient support program.

Patient: Jane Smith
Address: 123 Any Street Apt. 1A
Anytown, NY 10001
Phone Number: 1-(555) 555-5555
DOB: 09/10/1985

Activity	Status
Has an Alongside KESIMPTA Coordinator reached out to your patient, Jane Smith?	Yes. 12/11/21
Has Jane Smith received a supplemental Injection Demonstration?	Yes. 12/15/21
Has Jane Smith reported receiving KESIMPTA?	Yes. 12/08/21
Has Jane Smith reported self-administering their first dose?	Yes. 12/15/21
Has Jane Smith enrolled for Alongside KESIMPTA® ongoing support?	Yes

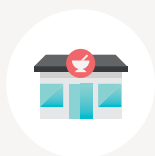
Note: Date of KESIMPTA® loading doses receipt and first injection dose taken is patient reported. If the statuses above indicate that your patient has not received one or more of the above services, it may be due to inability to contact the patient to secure the most recent status. Please reach out to your Novartis Field Reimbursement Manager or your patient for the most up-to-date service status and clarification.

Your Alongside KESIMPTA Team
1-855-537-4678
CoverMyMeds.com

IMPORTANT NOTICE: This message is intended for the use of the professional or entity to which it is addressed and may contain information that is personal, privileged, and/or confidential. If the reader of this message is not the intended recipient, or the employee or agent responsible to deliver it to the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this information is STRICTLY PROHIBITED. If you received this document in error, please notify us immediately and destroy this document.

NOVARTIS
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, New Jersey 07930-1080

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Direct to pharmacy?

Service Status Reports are not available if you've taken this route. Encourage any patient who hasn't self-enrolled in Alongside KESIMPTA to do so [here](#).



What is Alongside?

Initiating

Coverage

Ongoing Support

Resources

Indication and
Important Safety Information



Alongside helps while your patient is on KESIMPTA, not just when they're getting started.

Customized support for up to 2 years.



- > **Dosing reminders via text message**
- > **Personalized resources**
 - Topics may include:
 - Tips such as exercise and stress management
 - Work and finance info, including workplace rights
 - Coping strategies, like tips for building resilience and setting realistic goals
- > **Regular check-ins**



My Alongside KESIMPTA Coordinator was so helpful... She went above and beyond...In the most friendly, compassionate and most knowledgeable way.



—Jennie B., former film crew member, KESIMPTA patient*

*Actual KESIMPTA patient who was compensated for their time. Individual results may vary.

We have your patient's back.



From starting your patient on treatment right away to supplemental injection training to a dedicated Coordinator, our goal is to help patients stay on track with KESIMPTA as prescribed.

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(ofatumumab) 20 mg injection

What is Alongside?



Initiating



Coverage



Ongoing Support



Resources



Indication and
Important Safety Information





Our mission is to keep support simple.

The resources that make your experience seamless.

Sensoready® Training Pen

Teach your patients how to administer KESIMPTA®

> [Contact your Sales Specialist to order](#)

Start Form

Initiate treatment and patient support with a one-page form

Authorization and Appeals Kit

Supports patient access to KESIMPTA

Health Care Professional Site

Helpful KESIMPTA information, from efficacy and safety to Alongside™ support

KESIMPTA Samples

> [Contact your Sales Specialist to order](#)



What is Alongside?



Initiating



Coverage



Ongoing Support



Resources



Indication and
Important Safety Information





When patients are Alongside members, we're right there with them.

The resources and guidance we offer your patient.

Considering KESIMPTA® Patient Brochure

Helps your patient see what KESIMPTA is all about

Step-by-Step Injection Training Videos

See how your patient learns to use the Sensoready® Pen

Dosing Reminders Via

- > Texts from your patient's Coordinator

Member Welcome Package

Resources to get your patient started

- > Alongside KESIMPTA [brochure](#)
- > [Quick Tips for Use brochure](#)
- > Wellness Journal

Emails

- > Regular emails based on common issues patients face
- > Tailored emails based on your patient's specific needs



INDICATION

KESIMPTA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

IMPORTANT SAFETY INFORMATION

Contraindications

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

Warnings and Precautions

Infections

Serious, including life-threatening or fatal, bacterial, fungal, and new or reactivated viral infections have been observed during and following completion of treatment with anti-CD20 B-cell depleting therapies. The overall rate of infections and serious infections in KESIMPTA-treated patients was similar to teriflunomide-treated patients (51.6% vs 52.7%, and 2.5% vs 1.8%, respectively). The most common infections reported by KESIMPTA-treated patients in relapsing MS (RMS) trials included upper respiratory tract infection (39%) and urinary tract infection (10%). Delay KESIMPTA administration in patients with an active infection until resolved.

Consider the potential increased immunosuppressive effects when initiating KESIMPTA after an immunosuppressive therapy or initiating an immunosuppressive therapy after KESIMPTA.

Hepatitis B Virus

Reactivation: No reports of HBV reactivation in patients with MS treated with KESIMPTA. However, HBV reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, has occurred in patients treated with ofatumumab at higher intravenous doses for chronic lymphocytic leukemia (CLL) than the recommended dose in MS and in patients treated with other anti-CD20 antibodies.

Infection: KESIMPTA is contraindicated in patients with active hepatitis B disease. Fatal infections caused by HBV in patients who have not been previously infected have occurred in patients treated with ofatumumab at higher intravenous doses for CLL than the recommended dose in MS. Perform HBV screening in all patients before initiation of KESIMPTA. Patients who are negative for HBsAg and positive for HB core antibody [HBcAb+] or are carriers of HBV [HBsAg+], should consult liver disease 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.

Please see additional Important Safety Information on the following screen and full [Prescribing Information](#).



IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

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 previous screen and full [Prescribing Information](#).



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