Permanent J-code available for OCREVUS ZUNOVO®

Effective April 1, 2025

J2351* Injection, ocrelizumab, 1 mg and hyaluronidase-ocsq

ACCESS AND REIMBURSEMENT REFERENCE GUIDE

COMMITTED TO SUPPORTING YOUR PATIENTS AND PRACTICE AFTER OCREVUS® AND OCREVUS ZUNOVO® ARE PRESCRIBED

*These codes are not all-inclusive; appropriate codes can vary by patient, setting of care and payer. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Genentech does not make any representation or guarantee concerning reimbursement or coverage for any item or service.

Indications

OCREVUS and OCREVUS ZUNOVO are 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
- Primary progressive MS, in adults.

Contraindications

Treatment with ocrelizumab is contraindicated in patients with active hepatitis B virus infection and in patients with a history of life-threatening administration reactions to ocrelizumab. OCREVUS ZUNOVO is also contraindicated in patients with a history of hypersensitivity to ocrelizumab, hyaluronidase, or any component of OCREVUS ZUNOVO.

Please see additional Important Safety Information throughout and click here for full OCREVUS Prescribing Information and Medication Guide. For OCREVUS ZUNOVO, click here for full Prescribing Information and Medication Guide.

OCREVUS® ocrelizumab 300MG/10ML INJECTION FOR IV

OCREVUS ZUNOVO™ ocrelizumab & hyaluronidase-ocsq Subcutaneous injection 920mg

HELPING PATIENTS ACCESS
THE MEDICINE THEY HAVE BEEN PRESCRIBED IS OUR TOP PRIORITY

No matter which route of administration you choose—OCREVUS® [IV] or OCREVUS ZUNOVO®, the subcutaneous formulation—you can expect the same commitment to patient support from Genentech.

We work every day to help people who need our medicines, so they can focus on what matters most. Our dedicated team is available to help at any point in the treatment journey, so your patients can begin and continue to access the OCREVUS or OCREVUS ZUNOVO they have been prescribed.

For **nearly 40 years**, Genentech has been dedicated to supporting patient access to our medicines. For OCREVUS and OCREVUS ZUNOVO, we offer **industry-recognized* support** and tools to help minimize access barriers, including:

Helpful **access and reimbursement support** to meet the needs of patients and practices throughout the treatment journey after OCREVUS or OCREVUS ZUNOVO is prescribed

Financial support to help eligible patients afford our products regardless of insurance type—including co-pay assistance for eligible commercially insured patients†

Dedicated people to help online, on the phone or in person, giving you the flexibility to choose how to work with us

A proven commitment to **evolving our support** to address the changing needs of patients and practices

To help simplify the experience for every patient prescribed OCREVUS or OCREVUS ZUNOVO, we have continued to improve our processes and tools to enable patient access.

Look for this icon throughout this brochure to learn about specific enhancements.

FDA=US Food and Drug Administration.

*Genentech achieved "best-in-class" status in patient support for neurology in 2023 according to the Nuvera Life Sciences Patient services Utilization, Recognition and Experience (PURE) Report.

†Eligibility criteria apply. Not valid for patients using federal or state government programs to pay for their medicine and/or administration of their Genentech medicine. Patients must be taking the Genentech medicine for an FDA-approved indication. Please visit the Co-pay Program website for the full list of Terms and Conditions.

Please see additional Important Safety Information throughout and click here for full OCREVUS Prescribing Information and Medication Guide. For OCREVUS ZUNOVO, click here for full Prescribing Information and Medication Guide.

WHAT'S IN
THIS GUIDE

This guide is for anyone who works to help patients access the OCREVUS or OCREVUS ZUNOVO they have been prescribed, including practice managers, administrative staff, billers and patient financial coordinators.

Looking for more information?

Resources are also available to go into more detail on the following topics. Scan or click the QR codes or ask your OCREVUS representative to learn more.

Detailed Dosing and Administration Guide for OCREVUS and OCREVUS ZUNOVO

Considerations for Incorporating OCREVUS ZUNOVO Into Your Practice Workflow

Information about the clinical benefits of OCREVUS and OCREVUS ZUNOVO

OCREVUS® ocrelizumab 300MG/10ML INJECTION FOR IV

OCREVUS ZUNOVO™ ocrelizumab & hyaluronidase-ocsq Subcutaneous injection 920mg

OVERVIEW OF
OCREVUS ZUNOVO®

A new option for people living with MS: OCREVUS ZUNOVO is a 2X-yearly, ~10-minute,* HCP-administered subcutaneous formulation of OCREVUS.
With a shorter administration time and no split first dose, OCREVUS ZUNOVO offers scheduling flexibility for your patients and practice.

*Does not include all aspects of the treatment. Actual injection time may vary.

Genentech can help your practice get ready for OCREVUS in either route of administration—including understanding coverage and reimbursement.

Because OCREVUS and OCREVUS ZUNOVO are primarily covered under the medical benefit, the acquisition and reimbursement process is the same, despite having different coding. Considerations about incorporating OCREVUS ZUNOVO into your practice are detailed throughout this brochure.

With OCREVUS ZUNOVO, patients and prescribers have increased choice and flexibility—along with the same steadfast commitment to access and support.

EXPERIENTIAL DEMONSTRATION OF OCREVUS ZUNOVO ADMINISTRATION

Demonstrations designed to support familiarity and confidence in appropriate administration for your medical staff who will administer OCREVUS ZUNOVO are available. Contact your OCREVUS representative to learn more.

Learn more about the clinical benefits of OCREVUS ZUNOVO by scanning or clicking this QR code or visiting OCREVUS-HCP.com.

Select Important Safety Information

The warnings and precautions for ocrelizumab are infusion reactions (OCREVUS) or injection reactions (OCREVUS ZUNOVO) and infections, which include respiratory tract infections, herpes, hepatitis B virus (HBV) reactivation, and a warning for progressive multifocal leukoencephalopathy (PML). Additional warnings are possible increased risk of immunosuppressant effects with other immunosuppressants, reduction in immunoglobulins, malignancies, and immune-mediated colitis.

Please see additional Important Safety Information throughout and click here for full OCREVUS Prescribing Information and Medication Guide. For OCREVUS ZUNOVO, click here for full Prescribing Information and Medication Guide.

WHAT IS UNIQUE ABOUT
OCREVUS ZUNOVO vs. OCREVUS® [IV]?

Some considerations for incorporating OCREVUS ZUNOVO into your practice include:

	WHAT'S THE SAME?	WHAT'S UNIQUE?
Genentech support	• Patient Navigators • OCREVUS Access Solutions • Patient financial assistance programs* • Support program enrollment process (OCREVUS Start Form) • Patient one-on-one supplemental education	• OCREVUS ZUNOVO Starter Program† • OCREVUS ZUNOVO Sampling Program‡ • OCREVUS ZUNOVO injection training via experiential demonstration
Administration	• HCP administered	• Subcutaneous administration • Administration time • Post-dose observation time after the first injection • No split first dose • No reconstitution • Ancillary supplies • Potential to use syringe pump§
Scheduling	• Ability to administer in-office or via home health • Ability to refer to alternate treatment centers	• Total treatment time • No infusion-specific setting needed • First dose is not split between two appointments
Acquisition	• Available via authorized distributors and specialty pharmacies	
Benefit type	• Mainly covered under the medical benefit	
Claims submission	• ICD-10-CM diagnosis codes	• HCPCS codes • NDCs • CPT administration codes
Payer coverage	• Genentech's commitment to parity access to preserve patient and provider choice	• Payers are continuing to update their policies to include OCREVUS ZUNOVO

Correct coding is the responsibility of the provider submitting the claim for the item or service. Genentech does not make any representation or guarantee concerning reimbursement or coverage for any item or service.

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code.

*Each option has its own eligibility criteria that must be met for patients to receive assistance.

†Subject to eligibility requirements and terms and conditions. This program is void where prohibited by law and may not be used in or by residents of restricted states, if applicable.

‡A free sample dose allows you to become familiar with OCREVUS ZUNOVO and start building experience for your eligible patients with MS. OCREVUS ZUNOVO sample doses must be used according to the approved indications.

§The B. Braun Perfusor® Space Syringe Pump was used in the OCARINA II clinical trial. Genentech does not endorse or recommend any particular pumps. Please refer to the syringe pump manufacturer's instructions for the most up-to-date information and to ensure appropriate use of any drug or device.

OCREVUS® ocrelizumab 300MG/10ML INJECTION FOR IV

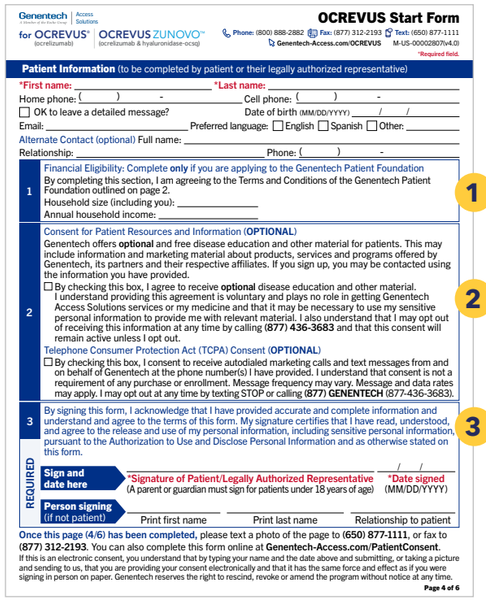
OCREVUS ZUNOVO™ ocrelizumab & hyaluronidase-ocsq Subcutaneous injection 920mg

GET STARTED WITH
OCREVUS PATIENT SUPPORT

To get support for your OCREVUS® and OCREVUS ZUNOVO® patients, ensure the OCREVUS Start Form is completed in full by both the health care provider and the patient or caregiver. The OCREVUS Start Form is a 6-page document that contains instructions, important terms and conditions, and forms for the patient and provider to complete.

SUBMITTING THE OCREVUS START FORM

ONLINE	PAPER FORM
• My Patient Solutions® for Health Care Practices • eSubmit	• Text at **(650) 877-1111** • Fax at **(877) 312-2193**


Genentech | Access Solutions

for OCREVUS® (ocrelizumab) | OCREVUS ZUNOVO™ (ocrelizumab & hyaluronidase-ocsq)

OCREVUS Start Form

Phone: (800) 888-2882 Fax: (877) 312-2193 Text: (650) 877-1111
Genentech-Access.com/OCREVUS M-US-00002807(v4.0)
*Required field.

Patient Information (to be completed by patient or their legally authorized representative)

*First name: _____ *Last name: _____
Home phone: ( ) - Cell phone: ( ) -
☐ OK to leave a detailed message? Date of birth (MM/DD/YYYY) / /
Email: _____ Preferred language: ☐ English ☐ Spanish ☐ Other: _____
Alternate Contact (optional) Full name: _____
Relationship: _____ Phone: ( ) -

1 Financial Eligibility: Complete **only** if you are applying to the Genentech Patient Foundation
By completing this section, I am agreeing to the Terms and Conditions of the Genentech Patient Foundation outlined on page 2.
Household size (including you): _____
Annual household income: _____

2 Consent for Patient Resources and Information (**OPTIONAL**)
Genentech offers **optional** and free disease education and other material for patients. This may include information and marketing material about products, services and programs offered by Genentech, its partners and their respective affiliates. If you sign up, you may be contacted using the information you have provided.
☐ By checking this box, I agree to receive **optional** disease education and other material. I understand providing this agreement is voluntary and plays no role in getting Genentech Access Solutions services or my medicine and that it may be necessary to use my sensitive personal information to provide me with relevant material. I also understand that I may opt out of receiving this information at any time by calling **(877) 436-3683** and that this consent will remain active unless I opt out.
Telephone Consumer Protection Act (TCPA) Consent (**OPTIONAL**)
☐ By checking this box, I consent to receive autodialed marketing calls and text messages from and on behalf of Genentech at the phone number(s) I have provided. I understand that consent is not a requirement of any purchase or enrollment. Message frequency may vary. Message and data rates may apply. I may opt out at any time by texting STOP or calling **(877) GENENTECH** (877-436-3683).

3 By signing this form, I acknowledge that I have provided accurate and complete information and understand and agree to the terms of this form. My signature certifies that I have read, understood, and agree to the release and use of my personal information, including sensitive personal information, pursuant to the Authorization to Use and Disclose Personal Information and as otherwise stated on this form.

REQUIRED
Sign and date here _____ / /
*Signature of Patient/Legally Authorized Representative (A parent or guardian must sign for patients under 18 years of age) *Date signed (MM/DD/YYYY)
Person signing (if not patient) _____ _____ _____
Print first name Print last name Relationship to patient

Once this page (4/6) has been completed, please text a photo of the page to **(650) 877-1111**, or fax to **(877) 312-2193**. You can also complete this form online at **Genentech-Access.com/PatientConsent**.
If this is an electronic consent, you understand that by typing your name and the date above and submitting, or taking a picture and sending to us, that you are providing your consent electronically and that it has the same force and effect as if you were signing in person on paper. Genentech reserves the right to rescind, revoke or amend the program without notice at any time.
Page 4 of 6

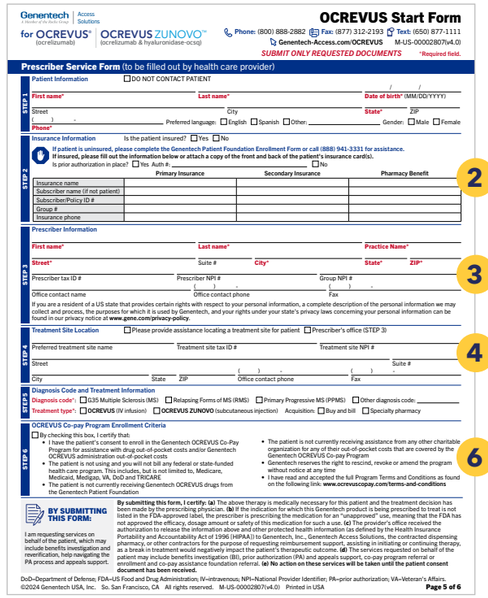
PAGE 4: THE PATIENT CONSENT FORM*

Be sure to review and share pages 1 through 3 of the Start Form with the patient or caregiver prior to completion, including the instructions and terms and conditions.

- **Step 1** contains required information for the Genentech Patient Foundation
- **Step 2** can be completed to enroll in optional and free programs from Genentech related to the use of OCREVUS and OCREVUS ZUNOVO, including educational emails and local events about the disease state and treatment
  - This also includes support from a Clinical Education Manager (see page 9)
- **Step 3** must be signed and dated to complete the Patient Consent Form

*The patient portion of the Start Form is valid for 6 years, except in Maryland, where it is valid for 1 year.

Please see additional Important Safety Information throughout and click here for full OCREVUS Prescribing Information and Medication Guide. For OCREVUS ZUNOVO, click here for full Prescribing Information and Medication Guide.


Genentech | Access Solutions

for OCREVUS® (ocrelizumab) | OCREVUS ZUNOVO™ (ocrelizumab & hyaluronidase-ocsq)

OCREVUS Start Form

Phone: (800) 888-2882 Fax: (877) 312-2193 Text: (650) 877-1111
Genentech-Access.com/OCREVUS M-US-00002807(v4.0)
SUBMIT ONLY REQUESTED DOCUMENTS *Required field.

Prescriber Service Form (to be filled out by health care provider)

STEP 2 Patient Information ☐ DO NOT CONTACT PATIENT
First name* Last name* Date of birth* (MM/DD/YYYY)
Street City State* ZIP
Phone* Preferred language: ☐ English ☐ Spanish ☐ Other: Gender: ☐ Male ☐ Female

STEP 2 Insurance Information Is the patient insured? ☐ Yes ☐ No
If patient is uninsured, please complete the Genentech Patient Foundation Enrollment Form or call (888) 941-3331 for assistance.
If insured, please fill out the information below or attach a copy of the front and back of the patient's insurance card(s).
Is prior authorization in place? ☐ Yes Auth #: ☐ No

	Primary Insurance	Secondary Insurance	Pharmacy Benefit
Insurance name			
Subscriber name (if not patient)			
Subscriber/Policy ID #			
Group #			
Insurance phone			

2

STEP 3 Prescriber Information
First name* Last name* Practice Name*
Street* Suite # City* State* ZIP*
Prescriber tax ID # Prescriber NPI # Group NPI #
Office contact name Office contact phone Fax

3

If you are a resident of a US state that provides certain rights with respect to your personal information, a complete description of the personal information we may collect and process, the purposes for which it is used by Genentech, and your rights under your state's privacy laws concerning your personal information can be found in our privacy notice at **www.gene.com/privacy-policy**.

STEP 4 Treatment Site Location ☐ Please provide assistance locating a treatment site for patient ☐ Prescriber's office (STEP 3)
Preferred treatment site name Treatment site tax ID # Treatment site NPI #
Street Suite #
City State ZIP Office contact phone Fax

4

STEP 5 Diagnosis Code and Treatment Information
Diagnosis code*: ☐ G35 Multiple Sclerosis (MS) ☐ Relapsing Forms of MS (RMS) ☐ Primary Progressive MS (PPMS) ☐ Other diagnosis code: _____
Treatment type*: ☐ **OCREVUS** (IV infusion) ☐ **OCREVUS ZUNOVO** (subcutaneous injection) Acquisition: ☐ Buy and bill ☐ Specialty pharmacy

STEP 6 OCREVUS Co-pay Program Enrollment Criteria
☐ By checking this box, I certify that:
- I have the patient's consent to enroll in the Genentech OCREVUS Co-Pay Program for assistance with drug out-of-pocket costs and/or Genentech OCREVUS administration out-of-pocket costs
- The patient is not using and you will not bill any federal or state-funded health care program. This includes, but is not limited to, Medicare, Medicaid, Medigap, VA, DoD and TRICARE
- The patient is not currently receiving Genentech OCREVUS drugs from the Genentech Patient Foundation
- The patient is not currently receiving assistance from any other charitable organization for any of their out-of-pocket costs that are covered by the Genentech OCREVUS Co-pay Program
- Genentech reserves the right to rescind, revoke or amend the program without notice at any time
- I have read and accepted the full Program Terms and Conditions as found on the following link: **www.ocrevuscopay.com/terms-and-conditions**

6

BY SUBMITTING THIS FORM:
I am requesting services on behalf of the patient, which may include benefits investigation and reverification, help navigating the PA process and appeals support.

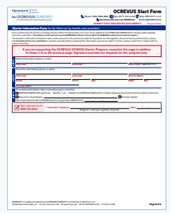
By submitting this form, I certify: (a) The above therapy is medically necessary for this patient and the treatment decision has been made by the prescribing physician. **(b)** If the indication for which this Genentech product is being prescribed to treat is not listed in the FDA-approved label, the prescriber is prescribing the medication for an "unapproved" use, meaning that the FDA has not approved the efficacy, dosage amount or safety of this medication for such a use. **(c)** The provider's office received the authorization to release the information above and other protected health information (as defined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA)) to Genentech, Inc., Genentech Access Solutions, the contracted dispensing pharmacy, or other contractors for the purpose of requesting reimbursement support, assisting in initiating or continuing therapy, as a break in treatment would negatively impact the patient's therapeutic outcome. **(d)** The services requested on behalf of the patient may include benefits investigation (BI), prior authorization (PA) and appeals support, co-pay program referral or enrollment and co-pay assistance foundation referral. **(e) No action on these services will be taken until the patient consent document has been received.**

DoD=Department of Defense; FDA=US Food and Drug Administration; IV=intravenous; NPI=National Provider Identifier; PA=prior authorization; VA=Veteran's Affairs.
 M-US-00002807(v4.0) Printed in USA
Page 5 of 6

PAGE 5: THE PRESCRIBER SERVICE FORM

Although the Start Form should be completed in its entirety, these are some areas to note.

- **Step 2** should include the primary, secondary and pharmacy benefit insurance information, if available
- **Step 3** should include providing the prescriber's National Provider Identifier (NPI) and tax ID numbers to facilitate the benefits investigation (BI) process
- **Step 4** should be completed to indicate whether you would like assistance in locating a treatment site
  - Indicate whether you have a preferred site of treatment and provide the appropriate tax ID and NPI numbers, if available
  - If you select treatment site assistance, your Patient Navigator will provide 3 sites geographically close to the patient as options for you to consider
- **Step 6** allows you to request enrollment for commercially insured patients into the OCREVUS Co-pay Program



OCREVUS ZUNOVO STARTER PROGRAM ENROLLMENT

If you think your patient qualifies, complete **page 6** of the OCREVUS Start Form to apply for the OCREVUS ZUNOVO Starter Program. See page 12 for more details about the program.

Scan or click this QR code or visit **OCREVUS.com/Forms** to enroll your patients.

OCREVUS® ocrelizumab 300MG/10ML INJECTION FOR IV

OCREVUS ZUNOVO™ ocrelizumab & hyaluronidase-ocsq Subcutaneous injection 920mg

OUR TEAM IS **READY TO HELP**

Online, on the phone, or in person, Genentech gives you the flexibility to choose how you want to connect with us. Our knowledgeable and experienced Specialists are Genentech employees focused on assisting patients and practices who need access to OCREVUS® and OCREVUS ZUNOVO®.

PATIENT NAVIGATORS

Your Patient Navigator is a point of contact for assistance throughout your patients' treatment. They offer support in Spanish and several other languages. They can:

- Facilitate enrollment in OCREVUS Access Solutions
- Address patient-specific access questions
- Conduct benefits investigations (BIs) and offer support for prior authorizations (PAs)
- Identify an appropriate specialty pharmacy (SP) and follow up with the SP regarding fulfillment status
- Connect patients to appropriate financial assistance options
- Locate site of treatment options for you to consider and coordinate the treatment

Camille, Patient Navigator

Email us

For your convenience, patient-related communications can be securely* emailed directly to your Patient Navigator, without the need for a login or portal.

*Genentech uses a secure server to send, store and receive all emails.

Please see additional Important Safety Information throughout and click here for full OCREVUS Prescribing Information and Medication Guide. For OCREVUS ZUNOVO, click here for full Prescribing Information and Medication Guide.

LIVE SUPPORT FOR **YOUR PATIENTS AND PRACTICE**

Clinical education for your practice

Therapeutic Area Managers (TAMs)

Provide education on the clinical efficacy, safety, dosing and the design of OCREVUS and OCREVUS ZUNOVO

- Can also provide local payer coverage information and an overview of our support services, including the OCREVUS Co-pay Program and the OCREVUS ZUNOVO Starter Program

Reimbursement support for your practice

Field Reimbursement Managers (FRMs)

Provide live support for local coverage and reimbursement expertise for OCREVUS and OCREVUS ZUNOVO and information on using Genentech patient support services

Patient education

Clinical Education Managers (CEMs)†

Provide administration support and supplemental education for patients, including helping them prepare for their first treatments and information about local MS resources

- Can also provide experiential demonstrations of OCREVUS ZUNOVO to medical staff

OCREVUS Account Access Data Report

Your FRM can provide a practice-specific report to help diagnose potential access challenges for patients enrolled in OCREVUS Access Solutions, including information about:

- BI turnaround time
- Time to first treatment
- Payer coverage details

Note: Details about OCREVUS ZUNOVO will be available once your practice begins enrolling patients.

Scan or click this QR code to contact your **OCREVUS TAM** and set up a meeting with them or another member of our team.

†This program is intended primarily for patients prescribed OCREVUS or OCREVUS ZUNOVO and who are in their first year of treatment. CEMs are Genentech employees and do not provide medical advice.

OCREVUS® ocrelizumab 300MG/10ML INJECTION FOR IV

OCREVUS ZUNOVO™ ocrelizumab & hyaluronidase-ocsq Subcutaneous injection 920mg

OUR ONLINE PORTAL:
MY PATIENT SOLUTIONS®

My Patient Solutions helps you **enroll patients** in OCREVUS Access Solutions and **manage your service requests** online. We offer 2 versions of this tool:

My Patient Solutions for Health Care Practices: used by prescribing practices

My Patient Solutions for Sites of Care: used by administration sites

My Patient Solutions gives you the flexibility to submit and check the status of your OCREVUS Access Solutions service requests when it's convenient for you.

Using My Patient Solutions to enroll patients into OCREVUS Access Solutions has been shown to **decrease time to enrollment completion**, which may lead to shorter time to infusion for OCREVUS® [IV].*

Experience the enhanced My Patient Solutions

Several enhancements to the portal have been made to address feedback we've heard from practices like yours and improve your overall experience, including:

- Easier understanding of which services your patients were enrolled in
- Improved filtering and export functions
- Ability to quickly check a patient's insurance eligibility without a full benefits investigation (BI)
- Ability to apply multiple actions to multiple patients, such as prescriber changes
- Upfront quick alerts and next steps

Scan or click this QR code or visit **OCREVUS.com/MPS** to get started with My Patient Solutions.

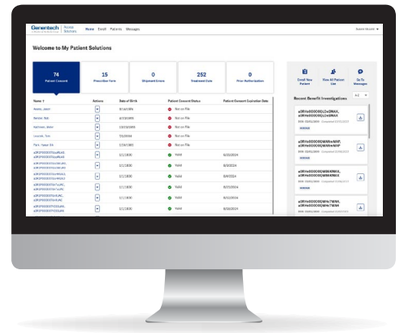
*Decreased time to enrollment compared to completing a paper form, based on an average of 2024 Genentech Access Solutions enrollment data on file across all Genentech products. Time-to-infusion data is based on 2024 OCREVUS Access Solutions data.

Please see additional Important Safety Information throughout and click here for full OCREVUS Prescribing Information and Medication Guide. For OCREVUS ZUNOVO, click here for full Prescribing Information and Medication Guide.

MY PATIENT SOLUTIONS FOR HEALTH CARE PRACTICES

Practices that prescribe OCREVUS® or OCREVUS ZUNOVO® can:

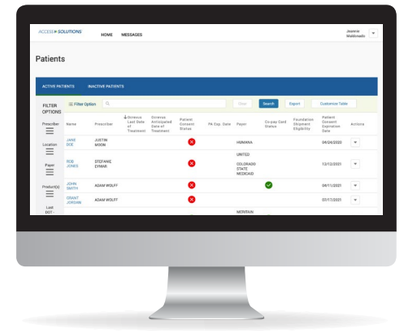
- **Message** your Patient Navigator
- **Enroll** and re-enroll patients
- **Send** your patients a link to eSubmit the Patient Consent Form
- **Customize**, filter, sort and export your patient list
- **Manage** administration dates
- **Request** benefits reverifications for multiple patients at once
- **Follow up** on the status of prior authorizations (PAs) and appeals
- **View** co-pay assistance referrals†
- **View** treatment coordination milestones
- **View** Genentech Patient Foundation eligibility and coordinate shipments



MY PATIENT SOLUTIONS FOR SITES OF CARE‡

Sites that administer OCREVUS or OCREVUS ZUNOVO can:

- **Message** your Patient Navigator
- **Track** administration dates
- **View** treatment coordination milestones
- **Download** PA forms (if available)
- **View** co-pay assistance referrals†
- **View** Genentech Patient Foundation eligibility and shipping information



†You may also view enrollment dates for patients enrolled in certain programs.
‡Patients cannot be enrolled in OCREVUS Access Solutions via My Patient Solutions for Sites of Care.

OCREVUS® ocrelizumab 300MG/10ML INJECTION FOR IV

OCREVUS ZUNOVO™ ocrelizumab & hyaluronidase-ocsq Subcutaneous injection 920mg

HELP UNDERSTANDING **COVERAGE**

96% Nationwide, OCREVUS® [IV] is covered for over 96% of patients, with the majority having **unrestricted first-line access**.*

Genentech supports parity coverage for OCREVUS and OCREVUS ZUNOVO® to enable you to choose the option that works best for your patients and practice.

Medicare Fee-for-Service (FFS) had established its policy for OCREVUS ZUNOVO at the time of its approval. The majority of patients with multiple sclerosis have coverage for OCREVUS ZUNOVO. National payers, including UnitedHealthcare, Cigna, Anthem BCBS and Humana, along with multiple regional payers are covering OCREVUS ZUNOVO at parity with OCREVUS [IV].

Your Field Reimbursement Manager (FRM) can help keep you up to date on the evolving payer policies for OCREVUS ZUNOVO.

The OCREVUS ZUNOVO Starter Program†

Patients awaiting a health insurance coverage determination for >5 business days may be eligible‡ to receive free medicine through the OCREVUS ZUNOVO Starter Program. You can apply for the program on page 6 of the OCREVUS Start Form.

The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and health care provider. Genentech makes no representation or guarantee concerning coverage or reimbursement for any service or item.

*Approximate national coverage. Formulary information is provided by MMIT analyses. Number of lives are provided by DRG as of December 2023. Does not include Kaiser Permanente covered lives.

†Subject to eligibility requirements and terms and conditions. This program is void where prohibited by law and may not be used in or by residents of restricted states, if applicable.

‡If your patient does not receive a coverage decision within 5 business days, they may be eligible for the OCREVUS ZUNOVO Starter Program while awaiting insurance verification. Eligible patients are required to be new to OCREVUS ZUNOVO or been off of OCREVUS ZUNOVO for at least 12 months. The provider's office will not attempt to seek reimbursement for free product provided to the patient. For full eligibility criteria and Terms and Conditions, please visit www.Genentech-pro.com/starter or speak to your Genentech representative. Genentech reserves the right to rescind, revoke or amend the program without notice at any time.

Please see additional Important Safety Information throughout and click here for full OCREVUS Prescribing Information and Medication Guide. For OCREVUS ZUNOVO, click here for full Prescribing Information and Medication Guide.

COVERAGE RESOURCES **FOR YOUR PRACTICE**

BENEFITS INVESTIGATIONS

Once your patient is enrolled in OCREVUS Access Solutions, your Patient Navigator can:

- Provide a benefits investigation (BI) to determine coverage for both the drug and administration, whether a prior authorization (PA) is required and if financial assistance might be needed
- Walk your patient through his or her insurance coverage for OCREVUS or OCREVUS ZUNOVO
- Identify potential treatment locations using our treatment site locator tool, if applicable

PRIOR AUTHORIZATIONS

A Patient Navigator can:

- Help you determine if a PA is necessary
- Help identify the required forms and documents for your submission to the health insurance plan
- Offer resources as you request the PA for your patient
- Follow up with a patient's health insurance plan about the status of the PA

Note that OCREVUS and OCREVUS ZUNOVO will likely require separate BIs and PAs. We can help you obtain a BI to determine if a PA is needed before you initiate therapy.

APPEALS§

If your patient's health insurance plan has issued a denial, your FRM or Patient Navigator can provide resources as you prepare an appeal submission, as per your patient's plan requirements. They have local payer coverage expertise and can help you determine specific appeal requirements for your patient.

REVERIFICATIONS AND ONGOING PATIENT SUPPORT

Patient Navigators can assist with reverifications to help ensure continued coverage is not delayed. Based on the patient's actual date of treatment that you provide, they can complete the reverification of benefits approximately 6 weeks prior to the next treatment date.

Patient Navigators can also help coordinate with alternate treatment centers for the patient's subsequent treatments, if needed. (See page 20 for more details.)

Scan or click this QR code or visit OCREVUS.com/Forms for considerations for composing letters of medical necessity and appeal letters, as well as sample letters.

§Appeals cannot be completed or submitted by OCREVUS Access Solutions on your behalf.

OCREVUS® ocrelizumab 300MG/10ML INJECTION FOR IV | OCREVUS ZUNOVO™ ocrelizumab & hyaluronidase-ocsq Subcutaneous injection 920mg

EXAMPLE CODING FOR
OCREVUS® [IV]

This coding information may assist you as you complete the payer forms for OCREVUS [IV].

TYPE	CODE	DESCRIPTION
Diagnosis: ICD-10-CM	G35	Multiple sclerosis
Drug: HCPCS	J2350	Injection, ocrelizumab, 1 mg
Drug: NDC	10-digit	Ocrelizumab, 300 mg single-dose vial
	50242-150-01	
	11-digit	
	50242-0150-01	
Administration procedures: CPT*	96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
	96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)
	96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
	96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
	99601	Home infusion/specialty drug administration, per visit (up to 2 hours)
	99602	Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour (List separately in addition to code for primary procedure)
Home Infusion: HCPCS	S9329	Home infusion therapy, chemotherapy infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem (do not use this code with S9330 or S9331)
	S9379	Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
HCPCS Modifier†	JZ	Zero drug amount discarded/not administered to any patient

Check your billable units on the claim: Generally, a 300-mg dose of OCREVUS [IV] is billed at 300 units and a 600-mg dose of OCREVUS [IV] is billed at 600 units.

CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code.

*For payers who do not recognize OCREVUS [IV] as approved for chemotherapy administration codes 96413 and 96415, other administration codes, such as 96365 and 96366, may be used depending on individual payer policy.

†The JZ modifier is required on claims for all single-dose containers or single-use drugs when no drug is discarded/administered to any patient as of July 1, 2023. For more information on the JZ modifier, visit CMS.gov.

These codes are not all-inclusive; appropriate codes can vary by patient, setting of care and payer. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Genentech does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

Many payers will not accept unspecified codes. If you use an unspecified code, please check with your payer.

Please see additional Important Safety Information throughout and click here for full OCREVUS Prescribing Information and Medication Guide. For OCREVUS ZUNOVO, click here for full Prescribing Information and Medication Guide.

EXAMPLE CODING FOR
OCREVUS ZUNOVO®

This list of codes may assist you as you complete the payer forms for OCREVUS ZUNOVO. The permanent J-code for OCREVUS ZUNOVO is J2351 and is effective for dates of service beginning April 1, 2025. For dates of service prior to April 1, 2025, bill using the appropriate miscellaneous J-code or permanent C-code for Medicare claims for hospital outpatient departments.

TYPE	CODE	DESCRIPTION
Diagnosis: ICD-10-CM	G35	Multiple sclerosis
Drug: HCPCS	**J2351**	**Injection, ocrelizumab, 1 mg and hyaluronidase-ocsq**
Drug: NDC	10-digit	Ocrelizumab, 920 mg and hyaluronidase 23,000 units single-dose vial
	50242-554-01	
	11-digit	
	50242-0554-01	
Administration Procedures: CPT	96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
Home Injection: HCPCS	G0089 (initial)	Professional services, initial visit, for the administration of subcutaneous immunotherapy or other subcutaneous infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes
	G0069 (subsequent)	Professional services for the administration of subcutaneous immunotherapy or other subcutaneous infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes
HCPCS Modifier*	JZ	Zero drug amount discarded/not administered to any patient
	25	Significant, separately identifiable evaluation and management service by the same physician or other qualified health care professional on the same day of the procedure or other service

Check your billable units on the claim: Generally, a 920-mg dose of OCREVUS ZUNOVO is billed at 920 units.

Learn more by scanning or clicking this QR code or asking your OCREVUS Representative for the **OCREVUS and OCREVUS ZUNOVO Coding and Billing Guide**.

OCREVUS® ocrelizumab | OCREVUS ZUNOVO™ ocrelizumab & hyaluronidase-ocsq Subcutaneous injection 920mg

COMMITTED TO HELPING PATIENTS– **REGARDLESS OF THEIR ABILITY TO PAY**

Genentech is committed to helping patients afford OCREVUS® and OCREVUS ZUNOVO®—no matter the formulation or the patient's health insurance type. We offer the same patient financial assistance programs for both products. A Patient Navigator can identify the most appropriate patient assistance option to help your patient get the treatment they need.

	COMMERCIAL Insurance	PUBLIC Insurance	NO Insurance
OCREVUS Co-pay Program	✓		
Referrals to Independent Co-pay Assistance Foundations	✓	✓	
Genentech Patient Foundation	✓	✓	✓

*The Co-pay Program ("Program") is valid ONLY for patients with commercial (private or non-governmental) insurance who have a valid prescription for a Food and Drug Administration (FDA)-approved indication of a Genentech medicine. The Program is not available to patients whose prescriptions are reimbursed under any federal, state, or government-funded insurance programs (included but not limited to Medicare, Medicare Advantage, Medigap, Medicaid, TRICARE, Department of Defense, or Veterans Affairs Programs) or where prohibited by law or by the patient's health insurance provider. If at any time a patient begins receiving prescription drug coverage under any such federal, state or government-funded healthcare programs, the patient will no longer be eligible for the Program.

Under the Program, the patient may be required to pay a co-pay. The final amount owed by a patient may be as little as $0 for the Genentech medicine (see Program specific details available at the Program website). The total patient out-of-pocket cost is dependent on the patient's health insurance plan. The Program assists with the cost of the Genentech medicine only. It does not assist with the cost of other medicines, procedures or office visit fees. After reaching the maximum annual Program benefit amount, the patient will be responsible for all remaining out-of-pocket expenses. The Program benefit amount cannot exceed the patient's out-of-pocket expenses for the Genentech medicine.

Please see additional Important Safety Information throughout and click here for full OCREVUS Prescribing Information and Medication Guide. For OCREVUS ZUNOVO, click here for full Prescribing Information and Medication Guide.

THE OCREVUS **CO-PAY PROGRAM**

The OCREVUS Co-pay Program may help eligible commercially insured patients who have been prescribed OCREVUS or OCREVUS ZUNOVO with their drug and drug administration costs.* The Program works the same way for both products.

$0

As little as **$0** per **drug** co-pay for each OCREVUS or OCREVUS ZUNOVO treatment

- Up to **$20,000** per calendar year

$0

As little as **$0** per **drug administration** co-pay for each OCREVUS or OCREVUS ZUNOVO treatment

- Up to **$1,500** in the first calendar year and up to **$1,000** each calendar year after

We've streamlined the enrollment process

Enroll eligible patients directly using the OCREVUS Start Form or by calling your Patient Navigator.

Learn more by scanning or clicking this QR code or visiting **OCREVUS.com/Copay**.

All participants are responsible for reporting the receipt of all Program benefits as required by any insurer or by law. The Program is only valid in the United States and U.S. Territories, is void where prohibited by law and shall follow state restrictions in relation to AB-rated generic equivalents (e.g., MA, CA) where applicable. No party may seek reimbursement for all or any part of the benefit received through the Program. The value of the Program is intended exclusively for the benefit of the patient. The funds made available through the Program may only be used to reduce the out-of-pocket costs for the patient enrolled in the Program. The Program is not intended for the benefit of third parties, including without limitation third party payers, pharmacy benefit managers, or their agents. If Genentech determines that a third party has implemented a program that adjusts patient cost-sharing obligations based on the availability of support under the Program and/or excludes the assistance provided under the Program from counting towards the patient's deductible or out-of-pocket cost limitations, Genentech may impose a per fill cap on the cost-sharing assistance available under the Program. Submission of true and accurate information is a requirement for eligibility and Genentech reserves the right to disqualify patients who do not comply with Genentech Program Terms and Conditions. Genentech reserves the right to rescind, revoke or amend the Program without notice at any time.

Additional terms and conditions apply. Please visit the Co-pay Program website for the full list of Terms and Conditions.

†Depending on how the health insurance plan applies manufacturer co-pay assistance for out-of-pocket costs or if the patients' health care costs exceed the maximum benefit of the program, patients may owe more than $0.

OCREVUS® ocrelizumab 300MG/10ML INJECTION FOR IV

OCREVUS ZUNOVO™ ocrelizumab & hyaluronidase-ocsq Subcutaneous injection 920mg

REFERRALS TO INDEPENDENT CO-PAY

ASSISTANCE FOUNDATIONS

OCREVUS Access Solutions offers referrals to independent co-pay assistance foundations for eligible patients who are commercially or publicly insured, including those covered by Medicare and Medicaid.

Eligibility requirements, all aspects of the application process, turnaround times and the type or amount of assistance available (if any) offered can vary by independent co-pay assistance foundation.

Learn about available co-pay assistance foundations by scanning or clicking this QR code or visiting **OCREVUS.com/Access**.

Independent co-pay assistance foundations have their own rules for eligibility. Genentech has no involvement or influence in independent foundation decision-making or eligibility criteria and does not know if a foundation will be able to help your patient. We can only refer your patient to a foundation that supports their disease state. Genentech does not endorse or show preference for any particular foundation. The foundations to which we refer your patient may not be the only ones that might be able to help.

Please see additional Important Safety Information throughout and click here for full OCREVUS Prescribing Information and Medication Guide. For OCREVUS ZUNOVO, click here for full Prescribing Information and Medication Guide.

GENENTECH

PATIENT FOUNDATION

FREE OCREVUS® OR OCREVUS ZUNOVO® FOR ELIGIBLE PATIENTS

Is My Patient Eligible?

Genentech Patient Foundation eligibility depends on your patient's health insurance and financial situation. They may qualify if they are in 1 of the 3 groups below.

1. "I have **no insurance.**"

For a household of 1 to 4 people, total yearly income is under $150,000.

- For households with more than 4 people, add $25,000 to the yearly income limit for each additional person

2. "I **have insurance**, but it doesn't cover my Genentech medicine."

3. "I **have insurance** that covers my Genentech medicine, but the out-of-pocket maximum set by my health insurance plan is more than 7.5% of my yearly income."

Household size	Yearly income
1 person	Under $75,000
2 people	Under $100,000
3 people	Under $125,000
4 people	Under $150,000

For households with more than 4 people, add $25,000 to the yearly income limit for each additional person.

Not sure if your patient is eligible?

- Call **(888) 941-3331** to speak with a live Foundation Specialist – We offer support in many different languages
- Scan or click this QR code or visit **GenentechPatientFoundation.com** for more information

To be eligible for free Genentech medicine from the Genentech Patient Foundation, insured patients who have coverage for their medicine should try to pursue other forms of financial assistance, if available. Genentech reserves the right to modify or discontinue the program at any time and to verify the accuracy of information submitted.

OCREVUS® ocrelizumab 300MG/10ML INJECTION FOR IV

OCREVUS ZUNOVO™ ocrelizumab & hyaluronidase-ocsq Subcutaneous injection 920mg

HELP COORDINATING WITH **ALTERNATE TREATMENT SITES**

Your Patient Navigator can help you find potential sites of treatment for your OCREVUS® and OCREVUS ZUNOVO® patients, if necessary. Regardless of the formulation, you can track your patients' treatment status get help understanding next steps via your Patient Navigator or My Patient Solutions®.

For OCREVUS ZUNOVO, Clinical Education Managers offer training to sites of care to help them learn about the administration process.

Considerations for coordinating with the treatment site

Your Patient Navigator can identify a few treatment site options based on your patient's geographic location. They can work with you and your patient to help coordinate the treatment and prepare the patient for their appointment by reviewing the treatment process and providing an appointment checklist.

Before the treatment

- Be sure to provide any necessary documentation to the site to ensure patients can receive timely treatment, including:
  - Insurance information
  - Benefits investigation (BI) and prior authorization (PA) information
  - Physician orders and other patient-specific clinical instructions
  - Current MRI and laboratory results
- Check with the site to determine any special requirements

After the treatment

After the patient receives their treatment, be sure to confirm the actual date of treatment via My Patient Solutions or with your Patient Navigator to help coordinate follow-ups as needed.

For additional resources to help you coordinate with alternate treatment sites, scan or click these QR codes or obtain them from your OCREVUS representative.

Treatment Referral Form

Day-of-Treatment Checklist

Please see additional Important Safety Information throughout and click here for full OCREVUS Prescribing Information and Medication Guide. For OCREVUS ZUNOVO, click here for full Prescribing Information and Medication Guide.

ACQUIRING **OCREVUS® AND OCREVUS ZUNOVO®**

OCREVUS and OCREVUS ZUNOVO can be acquired via specialty distributors or specialty pharmacy (SP). If you are administering OCREVUS or OCREVUS ZUNOVO in your practice, a Patient Navigator can help you determine if your patient's health insurance plan requires a specific acquisition method, or if you have a choice.

For the most up-to-date list of authorized distributors and specialty pharmacies, scan or click this QR code to visit **OCREVUS.com/Access**.

Or, ask your OCREVUS representative for the **OCREVUS and OCREVUS ZUNOVO Distribution Quick Reference Guide**.

OCREVUS® ocrelizumab 300MG/10ML INJECTION FOR IV

OCREVUS ZUNOVO™ ocrelizumab & hyaluronidase-ocsq Subcutaneous injection 920mg

INDICATIONS AND IMPORTANT SAFETY INFORMATION

Indications

OCREVUS and OCREVUS ZUNOVO are 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
- Primary progressive MS, in adults.

Contraindications

Treatment with ocrelizumab is contraindicated in patients with active hepatitis B virus infection and in patients with a history of life-threatening administration reactions to ocrelizumab. OCREVUS ZUNOVO is also contraindicated in patients with a history of hypersensitivity to ocrelizumab, hyaluronidase, or any component of OCREVUS ZUNOVO.

Warnings and Precautions

Injection Reactions (OCREVUS ZUNOVO) OR Infusion Reactions (OCREVUS)

OCREVUS ZUNOVO can cause injection reactions, which can be local or systemic. Common symptoms of local injection reactions reported by patients treated with OCREVUS ZUNOVO in multiple sclerosis (MS) clinical trials included erythema, pain, swelling, and pruritus. Common symptoms of systemic injection reactions reported by patients included headache and nausea. In an open-label, active-controlled trial, injection reactions were more frequently reported with the first injection; 49% of patients experienced an injection reaction with the first injection.

In OCREVUS MS clinical trials, the incidence of infusion reactions in patients [who received methylprednisolone (or an equivalent steroid) and possibly other pre-medication to reduce the risk of infusion reactions prior to infusion] was 34% to 40%, with the highest incidence with the first infusion. There were no fatal infusion reactions, but 0.3% of intravenous ocrelizumab-treated MS patients experienced infusion reactions that were serious, some requiring hospitalization. Symptoms of infusion reactions can include pruritus, rash, urticaria, erythema, bronchospasm, throat irritation, oropharyngeal pain, dyspnea, pharyngeal or laryngeal edema, flushing, hypotension, pyrexia, fatigue, headache, dizziness, nausea, tachycardia, and anaphylaxis.

Monitor OCREVUS ZUNOVO patients during and after injections. Observe patients treated with OCREVUS for infusion reactions during the infusion and for at least one hour after completion of the infusion. Inform patients that administration reactions can occur during or within 24 hours of treatment.

Reducing the Risk and Managing Injection or Infusion Reactions

For OCREVUS ZUNOVO, administer oral pre-medication (e.g., dexamethasone or an equivalent corticosteroid, and an antihistamine) at least 30 minutes prior to each OCREVUS ZUNOVO injection to reduce the risk of injection reactions. The addition of an antipyretic (e.g., acetaminophen) may also be considered.

For OCREVUS, administer pre-medication (e.g., methylprednisolone or an equivalent corticosteroid, and an antihistamine) to reduce the frequency and severity of infusion reactions. The addition of an antipyretic (e.g., acetaminophen) may also be considered.

Management recommendations depend on the type and severity of the reaction. For life-threatening reactions, immediately and permanently stop OCREVUS ZUNOVO or OCREVUS and administer appropriate supportive treatment. For less severe OCREVUS ZUNOVO injection reactions, the injection should be interrupted immediately, and the patient should receive symptomatic treatment. The injection should be completed at the healthcare provider's discretion and only after all symptoms have resolved. For less severe OCREVUS infusion reactions, management may involve temporarily stopping the infusion, reducing the infusion rate, and/or administering symptomatic treatment.

Infections

Serious, including life-threatening or fatal, bacterial, viral, parasitic and fungal infections have been reported in patients receiving ocrelizumab. An increased risk of infections (including serious and fatal bacterial, fungal, and new or reactivated viral infections) has been observed in patients during and following completion of treatment with anti-CD20 B-cell depleting therapies.

A higher proportion of OCREVUS-treated patients experienced infections compared to patients taking REBIF or placebo. In RMS trials, 58% of OCREVUS-treated patients experienced one or more infections compared to 52% of REBIF-treated patients. In the PPMS trial, 70% of OCREVUS-treated patients experienced one or more infections compared to 68% of patients on placebo. OCREVUS was not associated with an increased risk of serious infections in MS patients in controlled trials.

Ocrelizumab increases the risk for upper respiratory tract infections, lower respiratory tract infections, skin infections, and herpes-related infections. Delay administration of ocrelizumab in patients with an active infection until the infection has resolved.

Please see additional Important Safety Information throughout and click here for full OCREVUS **Prescribing Information** and **Medication Guide**. For OCREVUS ZUNOVO, click here for full **Prescribing Information** and **Medication Guide**.

INDICATIONS AND IMPORTANT SAFETY INFORMATION (CONT)

Warnings and Precautions (cont)

Respiratory Tract Infections

A higher proportion of OCREVUS-treated patients experienced respiratory tract infections compared to patients taking REBIF or placebo. In RMS trials, 40% of OCREVUS-treated patients experienced upper respiratory tract infections compared to 33% of REBIF-treated patients, and 8% of OCREVUS-treated patients experienced lower respiratory tract infections compared to 5% of REBIF-treated patients. In the PPMS trial, 49% of OCREVUS-treated patients experienced upper respiratory tract infections compared to 43% of patients on placebo and 10% of OCREVUS-treated patients experienced lower respiratory tract infections compared to 9% of patients on placebo. The infections were predominantly mild to moderate and consisted mostly of upper respiratory tract infections and bronchitis.

Herpes

In active-controlled (RMS) clinical trials, herpes infections were reported more frequently in OCREVUS-treated patients than in REBIF-treated patients, including herpes zoster (2.1% vs. 1.0%), herpes simplex (0.7% vs. 0.1%), oral herpes (3.0% vs. 2.2%), genital herpes (0.1% vs. 0%), and herpes virus infection (0.1% vs. 0%). Infections were predominantly mild to moderate in severity. In the placebo-controlled (PPMS) clinical trial, oral herpes was reported more frequently in the OCREVUS-treated patients than in the patients on placebo (2.7% vs 0.8%).

Serious cases of infections caused by herpes simplex virus and varicella zoster virus, including central nervous system infections (encephalitis and meningitis), intraocular infections, and disseminated skin and soft tissue infections, have been reported in the postmarketing setting in multiple sclerosis patients receiving ocrelizumab. Serious herpes virus infections may occur at any time during treatment with ocrelizumab. Some cases were life-threatening.

If serious herpes infections occur, treatment with ocrelizumab should be discontinued or withheld until the infection has resolved, and appropriate treatment should be administered.

Hepatitis B Virus Reactivation

Hepatitis B virus (HBV) reactivation has been reported in MS patients treated with ocrelizumab in the postmarketing setting. Fulminant hepatitis, hepatic failure, and death caused by HBV reactivation have occurred in patients treated with anti-CD20 antibodies. Perform HBV screening in all patients before initiation of treatment with ocrelizumab. Do not administer ocrelizumab to patients with active HBV confirmed by positive results for HBsAg and anti-HB tests. For patients who are negative for surface antigen [HBsAg] and positive for HB core antibody [HBcAb+] or are carriers of HBV [HBsAg+], consult liver disease experts before starting and during treatment.

Possible Increased Risk of Immunosuppressant Effects With Other Immunosuppressants

When initiating treatment with ocrelizumab after an immunosuppressive therapy or initiating an immunosuppressive therapy after ocrelizumab-containing products, consider the potential for increased immunosuppressive effect. Treatment with ocrelizumab has not been studied in combination with other MS therapies.

Vaccinations

Administer all immunizations according to immunization guidelines at least 4 weeks prior to initiation of ocrelizumab treatment for live or live-attenuated vaccines and, whenever possible, at least 2 weeks prior to initiation of ocrelizumab treatment for non-live vaccines. Ocrelizumab may interfere with the effectiveness of non-live vaccines. The safety of immunization with live or live-attenuated vaccines following treatment with ocrelizumab has not been studied, and vaccination with live-attenuated or live vaccines is not recommended during treatment and until B-cell repletion.

Vaccination of Infants Born to Mothers Treated With Ocrelizumab Products During Pregnancy

In infants of mothers exposed to ocrelizumab during pregnancy, do not administer live or live-attenuated vaccines before confirming the recovery of B-cell counts as measured by CD19+ B-cells. Depletion of B-cells in these infants may increase the risks from live or live-attenuated vaccines.

You may administer non-live vaccines, as indicated, prior to recovery from B-cell depletion, but you should consider assessing vaccine immune responses, including consultation with a qualified specialist, to assess whether a protective immune response was mounted.

Progressive Multifocal Leukoencephalopathy

Cases of progressive multifocal leukoencephalopathy (PML) have been reported in patients with MS treated with ocrelizumab in the postmarketing setting. PML is an opportunistic viral infection of the brain caused by the JC virus (JCV) that typically occurs only in patients who are immunocompromised, and that usually leads to death or severe disability. PML has occurred in ocrelizumab-treated patients who had not been treated previously with natalizumab, (which has a known association with PML), were not taking any immunosuppressive or immunomodulatory medications associated with risk of PML prior to or concomitantly with ocrelizumab and did not have any known ongoing systemic medical conditions resulting in compromised immune system function.

JCV infection resulting in PML has also been observed in patients treated with other anti-CD20 antibodies and other MS therapies.

At the first sign or symptom suggestive of PML, withhold treatment with ocrelizumab-containing products and perform an appropriate diagnostic evaluation. Typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.

Magnetic resonance imaging (MRI) findings may be apparent before clinical signs or symptoms of PML. Monitoring with MRI for signs consistent with PML may be useful, and any suspicious findings should lead to further investigation to allow for an early diagnosis of PML, if present. If PML is confirmed, treatment with ocrelizumab should be discontinued.

Please see additional Important Safety Information throughout and click here for full OCREVUS Prescribing Information and Medication Guide. For OCREVUS ZUNOVO, click here for full Prescribing Information and Medication Guide.

INDICATIONS AND IMPORTANT SAFETY INFORMATION (CONT)

Warnings and Precautions (cont)

Reduction in Immunoglobulins

As expected with any B-cell depleting therapy, decreased immunoglobulin levels are observed with ocrelizumab treatment. The pooled data of OCREVUS clinical studies (RMS and PPMS) and their open-label extensions (up to approximately 7 years of exposure) have shown an association between decreased levels of immunoglobulin G (IgG<LLN) and increased rates of serious infections. Monitor the levels of quantitative serum immunoglobulins during treatment with ocrelizumab and after discontinuation of treatment, until B-cell repletion, and especially in the setting of recurrent serious infections. Consider discontinuing treatment with ocrelizumab- in patients with serious opportunistic or recurrent serious infections, and if prolonged hypogammaglobulinemia requires treatment with intravenous immunoglobulins.

Malignancies

An increased risk of malignancy with ocrelizumab may exist. In controlled trials, malignancies, including breast cancer, occurred more frequently in OCREVUS-treated patients. Breast cancer occurred in 6 of 781 females treated with OCREVUS and none of 668 females treated with REBIF or placebo. Patients should follow standard breast cancer screening guidelines.

Immune-Mediated Colitis

Immune-mediated colitis, which can present as a severe and acute-onset form of colitis, has been reported in patients receiving ocrelizumab in the postmarketing setting. Some cases of colitis were serious, requiring hospitalization, with a few patients requiring surgical intervention. Systemic corticosteroids were required in many of these patients. The time from treatment initiation to onset of symptoms in these cases ranged from a few weeks to years. Monitor patients for immune-mediated colitis during ocrelizumab treatment and evaluate promptly if signs and symptoms that may indicate immune-mediated colitis, such as new or persistent diarrhea or other gastrointestinal signs and symptoms, occur.

Use in Specific Populations

Pregnancy

There are no adequate data on the developmental risk associated with use of ocrelizumab in pregnant women. There are no data on B-cell levels in human neonates following maternal exposure to ocrelizumab-containing products. However, transient peripheral B-cell depletion and lymphocytopenia have been reported in infants born to mothers exposed to other anti-CD20 antibodies during pregnancy. Ocrelizumab is a humanized monoclonal antibody of an immunoglobulin G1 subtype and immunoglobulins are known to cross the placental barrier.

Lactation

There are no data on the presence of ocrelizumab or hyaluronidase in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. Ocrelizumab was excreted in the milk of ocrelizumab-treated monkeys. Human IgG is excreted in human milk, and the potential for absorption of ocrelizumab to lead to B-cell depletion in the infant is unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ocrelizumab and any potential adverse effects on the breastfed infant from ocrelizumab or from the underlying maternal condition.

Females and Males of Reproductive Potential

Women of childbearing potential should use effective contraception while receiving ocrelizumab and for 6 months after the last dose of ocrelizumab. Instruct patients that if they are pregnant or plan to become pregnant while taking OCREVUS or OCREVUS ZUNOVO, they should inform their healthcare provider.

Most Common Adverse Reactions

In patients treated with OCREVUS:

- **RMS:** The most common adverse reactions (≥10% and >REBIF): upper respiratory tract infections and infusion reactions.
- **PPMS:** The most common adverse reactions (≥10% and >placebo): upper respiratory tract infections, infusion reactions, skin infections, and lower respiratory tract infections.

The most common adverse reaction observed with OCREVUS ZUNOVO in patients with RMS and PPMS was injection reactions (incidence of 49%).

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

Please see additional Important Safety Information throughout and click here for full OCREVUS Prescribing Information and Medication Guide. For OCREVUS ZUNOVO, click here for full Prescribing Information and Medication Guide.

YOUR DIRECT CONNECTION TO
GENENTECH IN-HOUSE SPECIALISTS

Visit **OCREVUS.com/Access**

Work with us online at **OCREVUS.com/MPS**

Call **(844) OCREVUS** (844-627-3887) to speak with a **Patient Navigator**, Monday through Friday, 9 a.m.–8 p.m. ET

- Help is available in English and Spanish

Contact your **OCREVUS representative**

OCREVUS® ocrelizumab 300MG/10ML INJECTION FOR IV

OCREVUS ZUNOVO™ ocrelizumab & hyaluronidase-ocsq Subcutaneous injection 920mg

Genentech
A Member of the Roche Group