INCORPORATING OCREVUS ZUNOVO® INTO YOUR PRACTICE WORKFLOW

Considerations for the subcutaneous route of administration for ocrelizumab

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

WHAT IS INCLUDED
IN THIS WORKFLOW RESOURCE

As with any product, there will be some updates to logistics and workflow processes for your practice associated with OCREVUS ZUNOVO®. This brochure reviews some of the unique considerations to keep in mind once your organization has decided to begin prescribing OCREVUS ZUNOVO for your patients.

1

Pre-prescription and acquisition

- EHR and practice management system updates
- Acquiring OCREVUS ZUNOVO
- Storing OCREVUS ZUNOVO
- Ancillary supplies

2

Administration logistics

- Staff training
- Scheduling
- Pretreatment counseling
- Oral premedications
- Post-dose observation

3

Coverage and reimbursement

- Formulary coverage
- Coding and billing
- Payer ID for co-pay assistance

EHR=electronic health record.

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**.

2×-YEARLY
OCREVUS ZUNOVO®

With a shorter administration time than OCREVUS® [IV] and no split first dose, OCREVUS ZUNOVO offers scheduling flexibility for your patients and practice.

Key Attributes

NO split first dose

NO reconstitution

NO IV infusion-specific supplies needed

OCREVUS ZUNOVO offers ~10-minute HCP-administered subcutaneous injection (SC) with no split first dose

	1st dose (no split dose)	All subsequent doses
Oral Premedication	At least 30 min prior	At least 30 min prior
	+	+
Injection*	~10 min	~10 min
	↓	↓
Post-Injection Monitoring†	At least 60 min	At least 15 min
Overall Time	~1 hr 40 min	~55 min

- OCREVUS ZUNOVO is for subcutaneous use in the abdomen only
- OCREVUS ZUNOVO has different dosage and administration instructions than intravenous ocrelizumab
- OCREVUS ZUNOVO should be administered via subcutaneous injection by an HCP

HCP=health care professional; IV=intravenous.

*Infusion/injection time may take longer if the treatment is interrupted or slowed.

†For all doses, post-injection observation with access to appropriate medical support to manage severe injection reactions after injection is recommended.

For more information, please view the video:
How to Administer OCREVUS ZUNOVO

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.

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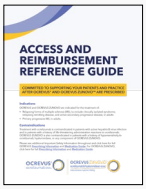
LOOKING FOR **ADDITIONAL RESOURCES?**

Resources are also available to go into more detail on the following topics.
Click on the links below or ask your OCREVUS® (ocrelizumab) representative to learn more.

Access and Reimbursement Resources



Access and Reimbursement Guide

This resource provides details about the various programs and services Genentech offers to help patients access OCREVUS and OCREVUS ZUNOVO, including co-pay assistance.*

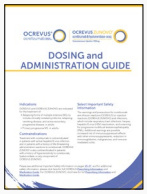
Coding and Billing Guide

This example coding information may assist you as you complete the payer forms for OCREVUS and OCREVUS ZUNOVO.

Authorized Distributors

This resource provides details about specialty distributors and pharmacies for OCREVUS and OCREVUS ZUNOVO.

Dosing and Administration Resource



Dosing and Administration Guide

Find detailed information about dosing and administering OCREVUS and OCREVUS ZUNOVO, from pre- to post-infusion/injection including safety outcomes.

Helpful Videos

How to Administer OCREVUS ZUNOVO

This video provides guidance for health care professionals on how to prepare and administer OCREVUS ZUNOVO.

What Does an Injection Appointment Look Like?

This video describes what your patient can expect when they get an OCREVUS ZUNOVO injection.

FOR MORE INFORMATION:

Visit **OCREVUS-HCP.com/OCREVUS-ZUNOVO**

*Eligibility criteria and benefit limits apply. Not valid for patients whose prescriptions are reimbursed under any federal or state government programs to pay for 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.

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WHAT IS UNIQUE ABOUT OCREVUS ZUNOVO®?

If your practice currently administers OCREVUS® [IV], there are many similarities to OCREVUS ZUNOVO. However, this resource helps walk through some of the differences and considerations for the workflow specific to OCREVUS ZUNOVO. Some of those considerations 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 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 2 appointments
Acquisition	• Available via authorized distributors and specialty pharmacies	
Benefit type	• Mainly covered under the medical benefit	
Claims submission	• ICD-10-CM 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.

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EHR AND PRACTICE MANAGEMENT
SYSTEM UPDATES

As one of the key tools for decision-making and process in the practice, **it is important to integrate OCREVUS ZUNOVO® into your EHR system to enable HCPs to consider it for their appropriate patients**.

CONSIDERATIONS FOR YOUR PRACTICE

- Ensure your organization's IT staff and EHR and/or practice management systems vendors have updated your:
  - Order sets
  - Billing software
  - If you anticipate having eligible patients use the program, load the OCREVUS Co-pay Program Payer ID (82694) into your system*
  - Appointment scheduling tools
  - Other necessary systems

- Notify and train appropriate staff as needed once all updates are made

ADDITIONAL CONSIDERATIONS

Consider adding:

- OCREVUS ZUNOVO to the same dropdown fields in the EHR where OCREVUS® (ocrelizumab) [IV] appears today

For example codes for OCREVUS ZUNOVO, please see **OCREVUS and OCREVUS ZUNOVO Example Coding and Billing**.

IT=information technology.

*Eligibility criteria and benefit limits apply. Not valid for patients whose prescriptions are reimbursed under any federal or state government programs to pay for 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.

ACQUIRING OCREVUS ZUNOVO®

OCREVUS ZUNOVO has the **same specialty distributor and specialty pharmacy networks** as OCREVUS® (ocrelizumab) [IV].

CONSIDERATIONS FOR YOUR PRACTICE

- Determine how to acquire OCREVUS ZUNOVO (e.g., purchasing through a specialty distributor or specialty pharmacy)
- Stay up-to-date on your product inventory
- OCREVUS ZUNOVO is priced at annual wholesale acquisition cost (WAC) parity with OCREVUS [IV]. Please check with your distributors for the latest information on purchase pricing

ADDITIONAL CONSIDERATIONS

- Consider your organization's procedure for procuring HCP-administered injectables when determining how to acquire OCREVUS ZUNOVO
- An OCREVUS Patient Navigator can help you determine if your patient's health insurance plan requires a specific acquisition method, or if you have a choice

OCREVUS ZUNOVO SAMPLES ARE AVAILABLE

A free sample dose allows prescribing HCPs to become familiar with OCREVUS ZUNOVO and start building experience for eligible patients with multiple sclerosis.

OCREVUS ZUNOVO sample doses must be used according to the approved indications.*

FOR MORE INFORMATION:

Visit **OCREVUS.com/Access** | Call **(844) OCREVUS** (844-627-3887) to speak with a Patient Navigator

Published WAC information does not include negotiated discounts or rebates, or other price concessions. Actual price paid by patients, third-party payers and pharmacies may vary and may not correlate with WAC.

*Drug samples may not be sold, purchased, traded, or offered for sale, purchase, or trade, utilized to seek reimbursement, or otherwise distributed in a manner not permitted by applicable law. Samples may only be distributed to practitioners who are licensed or authorized under applicable state law to prescribe the drug product and whose practices are relevant to the FDA-approved product labeling for OCREVUS ZUNOVO. Distribution of the sample does not obligate use or continuing use of OCREVUS ZUNOVO. You may not advertise or otherwise use the program as a means of promoting your services or Genentech's products to patients. Genentech reserves the right to deny fulfillment of the sample to anyone deemed ineligible in accordance with stated program criteria. Annual sample limits per HCP and brand apply.

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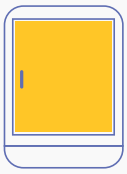
STORING
OCREVUS ZUNOVO®

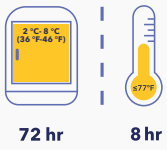
OCREVUS ZUNOVO has the **same storage needs** as OCREVUS® (ocrelizumab) [IV].



Ensure you have adequate refrigeration space to accommodate the vials needed for patient treatments when they are scheduled. The carton dimensions are 53 × 64 × 87 mm (W × D × H)

Store OCREVUS ZUNOVO vials at 2 °C to 8 °C (36 °F to 46 °F) in the original carton to protect from light

If necessary, OCREVUS ZUNOVO can be removed and placed back into the refrigerator. The total combined time out of the refrigerator of the OCREVUS ZUNOVO vial must not exceed 12 hours at ≤25 °C (77 °F)



If not used immediately, the closed syringe can be refrigerated (2 °C to 8 °C [36 °F to 46 °F]) for up to 72 hours followed by 8 hours at ambient temperatures at or below 25 °C (77 °F) in diffuse daylight

The Genentech Spoilage Replacement Program provides for replacement of infused, injected and self-administered products.* If a Genentech product purchased for use in an FDA-approved indication was spoiled, and no product was administered, the product may be eligible for replacement through the Genentech Spoilage Program.

More information can be found **here**

*The Genentech Spoilage Replacement Program provides for replacement of infused, injected and self-administered products, which are prescribed and prepared for a labeled indication, yet not administered due to unforeseen patient clinical circumstances, subject to certain limitations and conditions set forth by Genentech. The purpose of the program is to support our commitment to protecting patient safety by preventing the use of spoiled, damaged or contaminated products.

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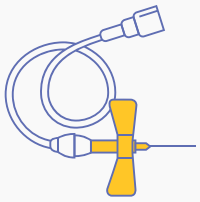
ANCILLARY SUPPLIES FOR **OCREVUS ZUNOVO®**

These supplies **are not co-packaged with the vial and may take time to acquire**. Contact your distributor to learn more about purchasing the injection supplies.

SUPPLIES NEEDED INCLUDE:

Syringe

21-gauge transfer needle



24- to 26-gauge winged infusion set

You also have the option of using a syringe pump in lieu of the manual injection.

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.

ANCILLARY SUPPLIES FOR **OCREVUS ZUNOVO®** (CONT)

EQUIPMENT NEEDED FOR EACH ADMINISTRATION METHOD

Syringe pump-assisted administration	Manual administration
• OCREVUS ZUNOVO subcutaneous injection vial	• OCREVUS ZUNOVO subcutaneous injection vial
• Transfer needle (21 G recommended)	• Transfer needle (21 G recommended)
• Syringe (Please ensure that the syringe is compatible with the syringe pump)*	• Syringe
• Subcutaneous infusion set (e.g., winged/butterfly) containing a 24-24 G needle for injection • **The residual hold-up volume must NOT exceed 0.8 mL**	• Subcutaneous infusion set (e.g., winged/butterfly) containing a 24-26 G needle for injection • **The residual hold-up volume must NOT exceed 0.8 mL**
• Syringe pump (with occlusion limit >6 psi, compatible with the chosen syringe, and a flow rate capability of 1 to 5 mL/min)	
• 2 antiseptic pads • Cotton ball/gauze pad • Plaster/adhesive bandage • Gloves	• 2 antiseptic pads • Cotton ball/gauze pad • Plaster/adhesive bandage • Gloves

OCREVUS ZUNOVO requires **different supplies** from OCREVUS® (ocrelizumab) [IV]. They may also be different from other subcutaneous products you administer in your practice.

G=gauge.

*Depending on the syringe pump, please check that the syringe is compatible with the chosen pump and can be selected in the settings of the pump. Syringe pumps might not support a flow rate of 180 mL/hour for syringes smaller than 50 mL and a lower flow rate and extended administration time might be the consequence.

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STAFF TRAINING

Additional considerations for staff training and treatment scheduling, as administration of OCREVUS ZUNOVO® differs from OCREVUS® (ocrelizumab) [IV]

CONSIDERATIONS FOR YOUR PRACTICE

- Identify qualified medical personnel at the office to perform the injection; they must be able to administer a complex biologic like OCREVUS ZUNOVO

- Ensure relevant staff are trained on appropriate subcutaneous administration of OCREVUS ZUNOVO

Experiential demonstrations of OCREVUS ZUNOVO manual administration are available from your OCREVUS representative

TREATMENT SCHEDULING

WHEN SCHEDULING PATIENTS, CONSIDER:

- The need for dedicated space for administration, such as an exam room or infusion chair
  - If you have an open layout, consider ways you might accommodate the need for patient privacy

- The impact of total treatment time on nurse/administration personnel bandwidth

- The number of schedule blocks available and how many patients you may be able to schedule based on total treatment time

- Whether your organization's or the payer's policies allow you to schedule administration on the same day as an office visit, and the billing documentation logistics involved

PRETREATMENT COUNSELING

Before their OCREVUS ZUNOVO® injection, be sure to discuss treatment with patients so they know what to expect.

TOPICS TO DISCUSS WITH PATIENTS

- Remind patients to bring their health insurance card and other documentation if needed and notify you of any changes to their insurance
- Let patients know they may want to bring activities to help them pass the time, as well as water, food, snacks or gum (if your facility allows them)
- Remind patients to wear loose-fitting clothing that allows for ease of access for injection into the abdomen

What Does an Injection Appointment Look Like?

This video describes what your patient can expect when they get an OCREVUS ZUNOVO injection.

Select Important Safety Information

OCREVUS: Infusion Reactions

Management recommendations for infusion reactions depend on the type and severity of the reaction. Permanently discontinue OCREVUS if a life-threatening or disabling infusion reaction occurs.

OCREVUS ZUNOVO: Injection Reactions

Management recommendations for injection reactions depend on the type and severity of the reaction. Permanently discontinue OCREVUS ZUNOVO if a life-threatening or disabling injection reaction occurs.

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ORAL
PREMEDICATIONS

Although patients must take the **same types of premedications** as they do for OCREVUS® (ocrelizumab) [IV], the premedications for OCREVUS ZUNOVO® are **administered orally**.

Administer at least 30 minutes prior to each OCREVUS ZUNOVO administration

20 mg dexamethasone (or equivalent corticosteroid)

An antihistamine (e.g., desloratadine)

The addition of an antipyretic (e.g., acetaminophen) may also be considered

Oral premedications can be taken at home or in office, subject to the prescribing physician's discretion. Consider how the patient has been instructed to take the premedications by their prescriber prior to the scheduled visit.

POST-DOSE **OBSERVATION**

For the initial dose, patients should be observed for at least one hour post-injection. For subsequent doses, patients should be observed for at least 15 minutes post-injection. Patients should be monitored closely during injections, with access to appropriate medical support to manage severe injection reactions.

CONSIDERATIONS FOR YOUR PRACTICE

- Identify where the patient will be observed during the post-dose observation—this may be in the same room as the administration or another area depending on your office setup

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- Patients should be observed for injection reactions, including but not limited to:
  - Local reactions such as erythema, pain, swelling or pruritus
  - Systemic reactions such as headache or nausea

- Ensure access to and provide appropriate supportive or symptomatic treatment as necessary

Please note: In the clinical trial (OCARINA II), all injection reactions were of mild or moderate severity. Most injection reactions required no treatment and all that occurred were resolved.

LEARN MORE ABOUT OCREVUS ZUNOVO® SAFETY HERE:

Visit **OCREVUS-HCP.com/OCREVUS-ZUNOVO/safety**

PAYER COVERAGE

Genentech supports **parity coverage** for OCREVUS ZUNOVO® and OCREVUS® (ocrelizumab) to **enable you to choose** the option that's right for your patients and practice.

IMPORTANT POINTS TO REMEMBER

- The majority of patients have coverage for OCREVUS ZUNOVO
- OCREVUS ZUNOVO has been covered for Medicare Fee-for-Service patients since launch
- National payers, including UnitedHealthcare, Cigna, Anthem BCBS and Humana, along with multiple regional payers are covering OCREVUS ZUNOVO at parity with OCREVUS. Check with individual payers to understand their requirements or contact your Field Reimbursement Manager (FRM) for more information

To apply for the OCREVUS ZUNOVO Starter Program, complete the OCREVUS Start Form.

- Patients awaiting a health insurance coverage determination for >5 business days may be eligible to receive free medicine through the OCREVUS ZUNOVO Starter Program*

BCBS=Blue Cross Blue Shield; MAC=Medicare Administrative Contractor.

*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.

CODING AND **BILLING**

While OCREVUS ZUNOVO® and OCREVUS® (ocrelizumab) use **the same ICD-10-CM diagnosis code, the drug-specific and administration coding is different**. Be sure to check with individual payers for specific requirements.

IMPORTANT POINTS TO REMEMBER ABOUT BILLING AND CODING

- CMS issues new HCPCS codes each quarter, and practices should routinely check the updated CMS HCPCS lists for new codes. **The permanent J-code for OCREVUS ZUNOVO is J2351, and is available and is effective for dates of service beginning April 1, 2025***
- When billing for OCREVUS ZUNOVO, check with the payer that the medication is known and loaded in their system, and provide the approved Prescribing Information
- Check any contracts you may have with the payer to understand any specific terms and reimbursement rates
- **Some additional information might be needed when submitting claims, including:**
  - A Letter of Medical Necessity
  - Full Prescribing Information
  - FDA approval letter
  - Pricing information
  - Peer-reviewed articles
  - Patient records
- **Your Field Reimbursement Manager (FRM)** can provide you with additional considerations for billing and coding. You can also download a **detailed coding and billing guide**

If you are considering scheduling OCREVUS ZUNOVO administration on the same day as an office visit, keep in mind that payers may require:

- Additional codes or modifiers, such as modifier 25
- Clear documentation of patient evaluation and management (E/M) above what is included in the injection CPT code

CMS=Centers for Medicare & Medicaid Services; FDA=US Food and Drug Administration.

*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.

PERMANENT J-CODE CONSIDERATIONS FOR **OCREVUS ZUNOVO®**

- ☐ 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
- ☐ For injection dates of service on or after April 1, 2025, use J-code J2351 when submitting claims for OCREVUS ZUNOVO
- ☐ Be sure to bill according to the amount of OCREVUS ZUNOVO administered when using the permanent J-code (one J-code unit = 1 mg; 920 units should be billed for a 920-mg vial). Keep in mind that CMS does not use fractional billing units; units should be rounded up to the nearest whole number
- ☐ When using the permanent J-code J2351, Box 19 on the CMS-1500 and Box 80 on the CMS-1450 are no longer required to be populated
- ☐ Inform relevant practice staff of the permanent J-code for OCREVUS ZUNOVO, J2351
- ☐ Update your billing software to reflect the permanent J-code J2351 units: one J-code unit = 1 mg; 920 units per 920 mg
- ☐ During the benefits verification process, confirm the permanent J-code J2351 has been added to the health plan's system to help with the adjudication process
- ☐ Understand your payer contracts and how they may be adjusted by the permanent J-code J2351
- ☐ Review claims to verify that they are processed correctly according to the permanent J-code J2351
- ☐ Please check with respective payers to understand if the prior authorization (PA) needs to be resubmitted or revalidated, especially if a patient needed a PA for current therapy (including OCREVUS® [IV])

If you have any questions about the permanent J-code J2351 for OCREVUS ZUNOVO, reach out to your Field Reimbursement Manager

EXAMPLE CODING FOR **OCREVUS ZUNOVO®**

This coding information may assist you as you complete the payer forms for OCREVUS ZUNOVO.

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.		

*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.

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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.

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**.

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INDICATIONS AND IMPORTANT **SAFETY INFORMATION** (CONT)

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.

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.

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INDICATIONS AND IMPORTANT **SAFETY INFORMATION** (CONT)

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.

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.

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INDICATIONS AND IMPORTANT **SAFETY INFORMATION** (CONT)

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.

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

- Help is available in English and Spanish

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