

CONSIDER A NEW SITE OF TREATMENT FOR YOUR OCREVUS ZUNOVO® PATIENTS

Keep your patients' treatment in your practice by administering a 2X-yearly, HCP-administered, ~10-minute* subcutaneous injection

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

Indications

OCREVUS ZUNOVO is indicated for the treatment of:

- Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- 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.

HCP=health care professional; IV=intravenous.

Please see additional Important Safety Information throughout and click here for full OCREVUS ZUNOVO [Prescribing Information](#) and [Medication Guide](#).

Permanent J-code available for OCREVUS ZUNOVO

Effective April 1, 2025

J2351[†]

Injection, ocrelizumab, 1 mg and hyaluronidase-ocsq

[†]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 makes no representation or guarantee concerning reimbursement or coverage for any item or service.

OCREVUS ZUNOVO™
ocrelizumab & hyaluronidase-ocsq

Subcutaneous injection 920mg/23,000 units



OCREVUS ZUNOVO® OFFERS CHOICE AND FLEXIBILITY FOR YOUR PRACTICE AND PATIENTS

OCREVUS ZUNOVO offers:

~10-minute,* HCP-administered subcutaneous injection with¹:

- NO** split first dose
- NO** reconstitution/dilution
- NO** No IV infusion-specific supplies

- > **The only subcutaneous option approved for both RMS and PPMS**
- > **Accommodation of different patient preferences and unique needs**

Consider for patients with MS who²⁻⁴:

- Want a non-IV option or have poor venous access
- Prefer a ~10-minute injection
- Could benefit from an HCP-administered aCD20 to help monitor adherence

Keeping OCREVUS ZUNOVO administration at your practice enables:



Continuity of patient care by administering OCREVUS ZUNOVO in the prescribing physician's office (vs. referring out)



Potential to accommodate treatment at a time that works for you and your patients due to ~10-minute injection* time¹



Familiarity of care teams for patients who prefer to be treated at their prescribing physician clinic vs. managing self-administration



Potentially less travel time for patients who live in areas lacking infusion clinic access (e.g., patients who live in rural areas)

A free sample dose allows you to become familiar with OCREVUS ZUNOVO and start building experience for your eligible patients with MS.[†]

FDA=US Food and Drug Administration; PPMS=primary progressive multiple sclerosis (MS); RMS=relapsing forms of MS.

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

[†]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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READY TO GET STARTED?

Considerations to keep in mind when administering OCREVUS ZUNOVO® at your practice:

ACQUISITION AND SETUP

- **Determine acquisition method*:**
 - Specialty distributor using buy and bill
 - Specialty pharmacy
- **Identify appropriate staff to:**
 - Manage patient scheduling
 - Secure prior authorizations
 - Submit relevant paperwork
- **Ensure cold storage availability** for the OCREVUS ZUNOVO vial
 - Store vials refrigerated at 2 °C to 8 °C (36 °F to 46 °F) in the original carton to protect from light. Do not freeze or shake

CLINICAL LOGISTICS

- **Identify and train appropriate medical personnel** to administer a complex biologic like OCREVUS ZUNOVO
- **Consider premedication protocol:**
 - Determine where patients will take recommended oral premedication (home or in-office)
 - Premedication must be taken at least 30 minutes before their injection
- **Designate appropriate injection and post-dose observation space**
 - Initial dose: Patients should be observed for at least one hour post-injection
 - Subsequent doses: Patients should be observed for at least 15 minutes post-injection

BILLING LOGISTICS

- **Train staff on how to appropriately bill** for OCREVUS ZUNOVO
- **If considering same-day administration:**
 - Review payer requirements, including any documentation needed for additional codes and modifiers (e.g., Modifier 25)[†]
- **Determine payer coding requirements** and set up specific payer contracts as needed

*Genentech does not influence or advocate the use of any one specialty distributor or specialty pharmacy. We make no representation or guarantee of service or coverage of any item.

[†]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.

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LOOKING FOR MORE INFORMATION?

Resources are also available to go into more detail on the following topics. [Click on the links below](#) or visit [OCREVUS-HCP.com/Resources](https://www.ocrevus-hcp.com/Resources) or ask your OCREVUS® representative to learn more.

ACCESS AND REIMBURSEMENT



[Access and Reimbursement Reference Guide](#)

This resource provides details about the various programs and services Genentech offers to help patients access OCREVUS and OCREVUS ZUNOVO® after they have been prescribed.



[Example Coding and Billing for OCREVUS and OCREVUS ZUNOVO](#)

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

PRACTICE LOGISTICS



[Incorporating OCREVUS ZUNOVO Into Your Practice Workflow](#)

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.

DOSING AND ADMINISTRATION



[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.

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COMMITTED TO HELPING PATIENTS GET STARTED ON OCREVUS ZUNOVO® AFTER IT HAS BEEN PRESCRIBED

THE SAME SUPPORT YOU KNOW ONCE OCREVUS® (ocrelizumab) [IV] HAS BEEN PRESCRIBED



Patient Navigator

Your point of contact for assistance throughout your patients' treatment.



Coverage and reimbursement support

A range of support from OCREVUS Access Solutions to help patients begin treatment as soon as possible.*



Patient financial assistance

Options are available for eligible patients with commercial insurance, public insurance or no insurance,[†] including the OCREVUS Co-pay Program.[‡]



Starter Program

May provide free medicine to eligible patients who are waiting >5 business days for a health insurance coverage determination.[§]



Injection training

Experiential demonstration of OCREVUS ZUNOVO manual injection for medical staff designed to build familiarity and confidence in appropriate administration.

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

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

[‡]Eligibility criteria apply. Not valid for patients using federal or state government programs to pay for their Genentech 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.

[§]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.

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IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Injection Reactions

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 where ocrelizumab was administered intravenously, 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 patients during and after injections. Inform patients that injection reactions can occur during or within 24 hours of the injection.

Reducing the Risk of Injection Reactions and Managing Injection Reactions

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.

Management recommendations for injection reactions depend on the type and severity of the reaction. For life-threatening injection reactions, immediately and permanently stop OCREVUS ZUNOVO and administer appropriate supportive treatment. For less severe 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.

Infections

Serious, including life-threatening or fatal, bacterial, viral, parasitic and fungal infections have been reported in patients receiving intravenous 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 intravenous ocrelizumab-treated patients experienced infections compared to patients taking REBIF or placebo. In RMS trials, 58% of intravenous ocrelizumab-treated patients experienced one or more infections compared to 52% of REBIF-treated patients. In the PPMS trial, 70% of intravenous ocrelizumab-treated patients experienced one or more infections compared to 68% of patients on placebo. Intravenous ocrelizumab 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 OCREVUS ZUNOVO administration in patients with an active infection until the infection has resolved.

Respiratory Tract Infections

A higher proportion of intravenous ocrelizumab-treated patients experienced respiratory tract infections compared to patients taking REBIF or placebo. In RMS trials, 40% of intravenous ocrelizumab-treated patients experienced upper respiratory tract infections compared to 33% of REBIF-treated patients, and 8% of intravenous ocrelizumab-treated patients experienced lower respiratory tract infections compared to 5% of REBIF-treated patients. In the PPMS trial, 49% of intravenous ocrelizumab-treated patients experienced upper respiratory tract infections compared to 43% of patients on placebo, and 10% of intravenous ocrelizumab-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 intravenous ocrelizumab-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 intravenous ocrelizumab-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 OCREVUS ZUNOVO. Some cases were life-threatening.

If serious herpes infections occur, OCREVUS ZUNOVO 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-containing products. Do not administer ocrelizumab-containing products 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 OCREVUS ZUNOVO after an immunosuppressive therapy or initiating an immunosuppressive therapy after OCREVUS ZUNOVO, consider the potential for increased immunosuppressive effect. OCREVUS ZUNOVO 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. OCREVUS ZUNOVO may interfere with the effectiveness of non-live vaccines. The safety of immunization with live or live-attenuated vaccines following treatment with OCREVUS ZUNOVO 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 OCREVUS ZUNOVO During Pregnancy

In infants of mothers exposed to OCREVUS ZUNOVO 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.

Please see additional Important Safety Information throughout and click here for full OCREVUS ZUNOVO [Prescribing Information](#) and [Medication Guide](#).



IMPORTANT SAFETY INFORMATION (cont)

Warnings and Precautions (cont)

Vaccinations

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 OCREVUS ZUNOVO 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 OCREVUS ZUNOVO should be discontinued.

Reduction in Immunoglobulins

As expected with any B-cell depleting therapy, decreased immunoglobulin levels are observed with OCREVUS ZUNOVO. The pooled data of intravenous ocrelizumab 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 OCREVUS ZUNOVO treatment and after discontinuation of treatment, until B-cell repletion, and especially in the setting of recurrent serious infections. Consider

discontinuing OCREVUS ZUNOVO therapy 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 OCREVUS ZUNOVO may exist. In controlled trials, malignancies, including breast cancer, occurred more frequently in patients treated with intravenous ocrelizumab. Breast cancer occurred in 6 of 781 females treated with intravenous ocrelizumab 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 treatment with ocrelizumab-containing products 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.

Liver Injury

Clinically significant liver injury, without findings of viral hepatitis, has been reported in the postmarketing setting in patients treated with anti-CD20 B-cell depleting therapies approved for the treatment of MS, including ocrelizumab. Signs of liver injury, including markedly elevated serum hepatic enzymes with elevated total bilirubin, have occurred from weeks to months after administration.

Patients treated with OCREVUS ZUNOVO found to have an alanine aminotransferase (ALT) or aspartate aminotransferase (AST) greater than 3x the upper limit of normal (ULN) with serum total bilirubin greater than 2x ULN are potentially at risk for severe drug-induced liver injury.

Obtain liver function tests prior to initiating treatment with OCREVUS ZUNOVO and monitor for signs and symptoms of any hepatic injury during treatment. Measure serum aminotransferases, alkaline phosphatase, and bilirubin levels promptly in patients who report symptoms that may indicate liver injury, including new or worsening fatigue, anorexia, nausea, vomiting, right upper abdominal discomfort, dark urine, or jaundice. If liver injury is present and an alternative etiology is not identified, discontinue OCREVUS ZUNOVO.

Use in Specific Populations

Pregnancy

There are no adequate data on the developmental risk associated with use of OCREVUS ZUNOVO in pregnant women. There are no data on B-cell levels in human neonates following maternal exposure to OCREVUS ZUNOVO or ocrelizumab. 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 OCREVUS ZUNOVO and any potential adverse effects on the breastfed infant from OCREVUS ZUNOVO or from the underlying maternal condition.

Females and Males of Reproductive Potential

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

Most Common Adverse Reactions

In patients treated with OCREVUS:

- **RMS:** The most common adverse reactions ($\geq 10\%$ and $>REBIF$): upper respiratory tract infections and infusion reactions
- **PPMS:** The most common adverse reactions ($\geq 10\%$ 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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OCREVUS ZUNOVO® is an HCP-administered subcutaneous injection that can be delivered in ~10 minutes* and offers:

NO split first dose

NO reconstitution/dilution

NO IV infusion-specific supplies

For more information:



Visit [OCREVUS-HCP.com/OCREVUS-ZUNOVO](https://www.ocrevus-hcp.com/ocrevus-zunovo)



Call (844) 627-3887

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

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References: **1.** OCREVUS ZUNOVO. Prescribing Information. South San Francisco, CA: Genentech, Inc. 2024. **2.** Armenteros-Yeguas V, Gárate-Echenique L, Tomás-López MA, et al. Prevalence of difficult venous access and associated risk factors in highly complex hospitalised patients. *J Clin Nurs*. 2017;26(23-24):4267-4275. doi:10.1111/jocn.13750 **3.** Data on file. Genentech, Inc. August 2023. **4.** Gold R, Schmidt S, Deisenhammer F, et al. Real-world evidence and patient preference for subcutaneous versus intravenous natalizumab in the treatment of relapsing-remitting multiple sclerosis - initial results from the observational SISTER study. *Ther Adv Neurol Disord*. 2024;17:1-19. doi:10.1177/17562864241241382

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