OCREVUS® ocrelizumab | ACCESS SOLUTIONS®

OCREVUS Sample Coding

Multiple Sclerosis (MS)

TYPE	CODE		DESCRIPTION
ICD-10-CM	G35		Multiple sclerosis
Permanent HCPCS (EFFECTIVE JANUARY 1, 2018)	J2350		Injection, ocrelizumab, 1 mg
Miscellaneous HCPCS (FOR DATES OF SERVICE DECEMBER 31, 2017 OR EARLIER)	J3590		Unclassified biologics
	J3490		Unclassified drugs
	J9999		Not otherwise classified, antineoplastic drugs
Hospital Outpatient HCPCS*	C9494		Injection, ocrelizumab, 1 mg
NDC	**10-digit**	**11-digit**	
	50242-150-01	50242-0150-01	ocrelizumab, 300 mg vial
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)

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.

*The C-code is used primarily in the Medicare hospital outpatient setting. However, some payers accept C9494 instead of unclassified J- or C-codes when billing for OCREVUS. Please check with your payers to verify codes and special billing requirements.

†For payers who do not yet recognize OCREVUS 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.[1]

Reference:

1. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 12 – Physicians/Nonphysician Practitioners. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf. Revised April 14, 2017. Accessed September 11, 2017.

Important Safety Information & Indication

Indication

OCREVUS is indicated for the treatment of adult patients with relapsing or primary progressive forms of multiple sclerosis.

Contraindications

OCREVUS is contraindicated in patients with active hepatitis B virus infection and/or a in patients with a history of life threatening infusion reaction to OCREVUS.

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Important Safety Information

WARNINGS AND PRECAUTIONS

Infusion Reactions

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

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 infusion reactions can occur up to 24 hours after the infusion.

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. For life-threatening infusion reactions, immediately and permanently stop OCREVUS and administer appropriate supportive treatment. For less severe infusion reactions, management may involve temporarily stopping the infusion, reducing the infusion rate, and/or administering symptomatic treatment.

Infections

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 increased the risk for upper respiratory tract infections, lower respiratory tract infections, skin infections, and herpes-related infections. OCREVUS was not associated with an increased risk of serious infections in MS patients. Delay OCREVUS administration in patients with an active infection until the infection is 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. There were no reports of disseminated herpes.

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%).

Progressive Multifocal Leukoencephalopathy (PML)

PML is an opportunistic viral infection of the brain caused by the John Cunningham (JC) virus that typically only occurs in patients who are immunocompromised, and that usually leads to death or severe disability. Although no cases of PML were identified in OCREVUS clinical trials, JC virus infection resulting in PML has been observed in patients treated with other anti-CD20 antibodies and other MS therapies and has been associated with some risk factors (e.g., immunocompromised patients, polytherapy with immunosuppressants). At the first sign or symptom suggestive of PML, withhold OCREVUS and perform an appropriate diagnostic evaluation. MRI findings may be apparent before clinical signs or symptoms. 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. (per USPI)

Hepatitis B Virus (HBV) Reactivation

There were no reports of hepatitis B reactivation in MS patients treated with OCREVUS. Fulminant hepatitis, hepatic failure and death, caused by HBV reactivation have occurred in patients treated with other anti-CD20 antibodies. Perform HBV screening in all patients before initiation of treatment with OCREVUS. Do not administer OCREVUS 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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Possible Increased Risk of Immunosuppressant Effects with Other Immunosuppressants

When initiating OCREVUS after an immunosuppressive therapy or initiating an immunosuppressive therapy after OCREVUS, consider the potential for increased immunosuppressive effect. OCREVUS has not been studied in combination with other MS therapies.

Vaccinations

Administer all immunizations according to immunization guidelines at least 6 weeks prior to initiation of OCREVUS.

The safety of immunization with live or live-attenuated vaccines following OCREVUS therapy has not been studied and vaccination with live-attenuated or live vaccines is not recommended during treatment and until B-cell repletion.

No data are available on the effects of live or non-live vaccination in patients receiving OCREVUS.

Malignancies

An increased risk of malignancy with OCREVUS 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.

USE IN SPECIFIC POPULATIONS

Pregnancy

There are no adequate data on the developmental risk associated with use of OCREVUS in pregnant women. There are no data on B-cell levels in human neonates following maternal exposure to OCREVUS. However, transient peripheral B-cell depletion and lymphocytopenia have been reported in infants born to mothers exposed to other anti-CD20 antibodies during pregnancy. OCREVUS 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 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 and any potential adverse effects on the breastfed infant from OCREVUS or from the underlying maternal condition.

Females and Males of Reproductive Potential

Women of childbearing potential should use contraception while receiving OCREVUS and for 6 months after the last infusion of OCREVUS.

Most Common Adverse Reactions

RMS: The most common adverse reactions in RMS trials (incidence ≥ 10% and > REBIF) were upper respiratory tract infections (40%) and infusion reactions (34%)

PPMS: The most common adverse reactions in PPMS trials (incidence ≥ 10% and > placebo) were upper respiratory tract infections (49%), infusion reactions (40%), skin infections (14%), and lower respiratory tract infections (10%)

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555.

For additional safety information, please see the full Prescribing Information and Medication Guide.