



## FAQ – Ocrelizumab (OCREVUS\*) for Primary Progressive Multiple Sclerosis (PPMS)

Updated March 2018

### 1. What is ocrelizumab?

Ocrelizumab is a [monoclonal antibody](#) that specifically targets CD20, a protein found on the surface of white blood cells called B lymphocytes or B cells. Because of this property, ocrelizumab acts as an [immunomodulatory](#) drug by targeting and removing potentially harmful B cells in people living with multiple sclerosis (MS). Ocrelizumab is developed by Hoffmann-La Roche's subsidiary [Genentech](#) and is marketed under the brand name Ocrevus.

Ocrelizumab's first dose of 600 mg is given as an initial infusion of 300 mg intravenous (IV) infusion, followed two weeks later by a second IV infusion of 300 mg. Subsequent doses of 600 mg are given as a single 600 mg IV infusion every six months. Administration of ocrelizumab is closely supervised by an experienced healthcare professional with access to appropriate medical support to manage severe reactions such as serious infusion reactions.

### 2. What is the Health Canada approval status of ocrelizumab for use in multiple sclerosis (MS)?

On February 14, 2018 ocrelizumab was approved, with conditions, by Health Canada as monotherapy for the management of adult patients with **early primary progressive multiple sclerosis (PPMS)** as defined by disease duration and level of disability, in conjunction with imaging features characteristic of inflammatory activity.

Health Canada previously approved ocrelizumab for the treatment of **relapsing-remitting MS (RRMS)** in August 2017.

### 3. Why are there conditions associated with the Health Canada approval of ocrelizumab for PPMS?

Health Canada has approved ocrelizumab under provisions made within its Notice of Compliance with Conditions (NOC/c) policy. This policy facilitates earlier access to promising new medicines that treat, prevent or diagnose serious, life-threatening and/or severely debilitating diseases for which there is no alternative medicine available in Canada, or where the new medicine offers an overall benefit/risk profile, which is improved over existing therapies.

Health Canada has provided access to ocrelizumab on the condition that the company will carry out an additional clinical study to provide further confirmation of the benefits of OCREVUS.<sup>i</sup>

Please visit the Health Canada website for more information about [Notice of Compliance with conditions](#) (NOC/c).

**4. What data did Health Canada use to form the basis of their approval of ocrelizumab for PPMS?**

Health Canada based its authorization, with conditions, on a phase III clinical trial called ORATORIO, in which 732 PPMS patients were randomly selected to receive either ocrelizumab or a mock drug (placebo). The trial looked at 12-week confirmed disability progression as the primary endpoint, as determined by an increase in [EDSS score](#). The results of the trial, published in the [New England Journal of Medicine](#), found that treatment with ocrelizumab significantly reduced the risk of 12-week confirmed disability progression by 24% compared with placebo. Treatment with ocrelizumab also resulted in improvements in a number of secondary outcomes, such as the Timed 25-foot Walk test which looks at mobility, and imaging measures like lesion volume and brain volume loss.

**5. Is ocrelizumab indicated for all adults living with PPMS?**

Ocrelizumab is indicated for adults between the ages of 18 and 55, with early PPMS, as defined by disease duration (length of time in years since diagnosis), and level of disability in addition to magnetic resonance imaging (MRI) features characteristic of inflammatory activity (indicating active disease). Individuals are encouraged to speak with their neurologists to determine if ocrelizumab is a suitable treatment option given their specific disease course.

**6. Why is there an age range for treatment of ocrelizumab in adults with PPMS?**

In clinical trials for ocrelizumab, individuals younger than 18, and adults over 55 were not studied and as such the safety and efficacy of ocrelizumab outside of the age range of 18 to 55 is unknown. Individuals interested in ocrelizumab but who are over the age of 55 are encouraged to speak to their neurologist.

**7. How can I access ocrelizumab for PPMS now that it has been approved?**

Although ocrelizumab was previously approved for RRMS, the authorization application for PPMS was a separate submission. As with all new drug submissions, once Health Canada has approved a medication, decisions around government reimbursement will be informed by the [Common Drug Review](#) conducted by the Canadian Agency for Drugs and Technologies in Health (CADTH). Quebec conducts an independent review through the Institut national d'excellence en santé et en services sociaux (INESSS). The review process for ocrelizumab for PPMS has been initiated by both CADTH and INESSS. The MS Society is monitoring its status with both agencies.

**8. What side effects have been reported for ocrelizumab?**

The most common adverse events reported in treatment with ocrelizumab were infusion-related adverse events (primarily relating to itchy skin, rash, throat irritation, and flushing) and increase risk of certain infections (most common were upper respiratory tract infection, common cold and flu).

Other serious side effects and medical events may occur as a result of treatment with ocrelizumab. For a comprehensive list of all possible side effects of ocrelizumab please see the [product monograph \(available soon\)](#).

**9. Can I get progressive multifocal leukoencephalopathy (PML) if I take ocrelizumab?**

Although no cases of PML were reported in the clinical trials of ocrelizumab, risk cannot be ruled out. Genentech reported one case of PML in Europe, in an MS patient who was anti-JCV antibody-positive and was previously treated with natalizumab for 3.5 years. The patient then received one dose of ocrelizumab in April 2017. The case was reported as a carry-over from natalizumab by the treating physician and was also reported as unrelated to ocrelizumab by the physician.

**10. Can I switch from my current therapy to ocrelizumab?**

Any decisions regarding treatments should be made in collaboration with your healthcare team, as it depends on a variety of personal health and lifestyle-related factors, potential risks and benefits, as well as cost and reimbursement. Currently there have been no MS studies looking at the safety and efficacy of switching to ocrelizumab from another therapy.

**11. How much does ocrelizumab cost?**

The list price of the medicine varies by country and province. For more information please contact the Ocrevus patient support program, COMPASS at 1-888-334-5956.

---

<sup>1</sup> Government of Canada. Health Canada. Notice of Compliance with Conditions - NOC/c. <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/notice-compliance-conditions.html>. Last accessed January 23, 2018.