



Imbruvica[®] (ibrutinib) – Expanded indication

- On August 27, 2018, [AbbVie announced](#) the FDA approval of [Imbruvica \(ibrutinib\)](#) plus [Rituxan[®] \(rituximab\)](#), for the treatment of adult patients with Waldenström’s macroglobulinemia (WM).
 - Previously, Imbruvica was only approved as single agent therapy for WM.
- Imbruvica is also indicated for adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic leukemia (SLL), CLL/SLL with 17p deletion, previously-treated mantle cell lymphoma, marginal zone lymphoma who have received at least one prior anti-CD20-based therapy, and previously-treated chronic graft versus host disease.
- WM is a rare and incurable type of non-Hodgkin’s lymphoma. According to the [American Cancer Society](#), WM has an incidence rate of about 3 cases per million people per year in the U.S. About 1,000 to 1,500 people are diagnosed with WM each year in the U.S. and the average age of diagnosis is 70 years old.
- The expanded indication is supported by efficacy data from the INNOVATE study, that evaluated Imbruvica in combination with Rituxan vs Rituxan alone in 150 treatment naïve or previously treated patients with WM. The primary efficacy endpoint was progression-free survival (PFS).
 - At the median follow-up time of 26.5 months, PFS was not evaluable in the Imbruvica + Rituxan arm vs. 20.3 months in the Rituxan alone arm (HR = 0.20 [95% CI: 0.11, 0.38]; p < 0.0001).
 - In addition, response rate was 72% in the Imbruvica + Rituxan arm vs. 32% in the Rituxan arm (p < 0.0001).
- The recommended dose of Imbruvica when used in combination with Rituxan or as a single agent for the treatment of WM is 420 mg orally once daily until disease progression or unacceptable toxicity.
 - When administering Imbruvica in combination with Rituxan, consider administering Imbruvica prior to Rituxan when given on the same day.
 - Consult the Rituxan drug label for dosing recommendations.
 - Consult the Imbruvica drug label for dosing information for all other indications.



OptumRx[®] specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum[®] company — a leading provider of integrated health services. Learn more at [optum.com](#).

All Optum[®] trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews[®] is published by the OptumRx Clinical Services Department.

©2018 Optum, Inc. All rights reserved.