

Imbruvica® (ibrutinib) – New Indication

- On January 19, 2017, <u>AbbVie announced</u> the FDA approval of <u>Imbruvica (ibrutinib)</u> for the treatment of patients with marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy.
- Imbruvica is also FDA-approved for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy, chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), CLL/SLL with 17p deletion, and Waldenström's macroglobulinemia (WM).
- According to the <u>Lymphoma Research Foundation</u>, MZLs are a group of slow-growing non-Hodgkin's B-cell lymphomas, which account for approximately 12% of all B-cell lymphomas. The median age of diagnosis is 65 years old.
- Approval of the new indication was based on a safety and efficacy study of 63 patients with MZL who were treated with at least one prior anti-CD20-based therapy.
 - The overall response rate was achieved in 46% of the patients (95% CI: 33.4, 59.1).
 - The median duration of response was not reached (range 16.7 months NR).
 - The median follow-up time was 19.4 months.
- The recommended dose for Imbruvica for MZL and MCL is 560 mg (four 140 mg capsules) orally once daily until disease progression or unacceptable toxicity.
- The recommended dose of Imbruvica for CLL/SLL and WM is 420 mg (three 140 mg capsules) orally once daily until disease progression or unacceptable toxicity.



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