

Imbruvica® (ibrutinib) – New indication

- On August 2, 2017, the <u>FDA announced</u> the approval of <u>Pharmacyclics' Imbruvica (ibrutinib)</u> for the treatment of adult patients with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy.
- Imbruvica is also FDA-approved for the treatment of adult 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, marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy, and Waldenström's macroglobulinemia (WM).
- cGVHD is a severe, potentially life-threatening consequence of stem cell or bone marrow transplant. cGVHD occurs when cells from the stem cell transplant attack healthy cells in a patient's tissues. Symptoms of cGVHD can occur in the skin, eyes, mouth, gut, liver, and lungs. The condition is estimated to occur in 30 – 70% of all patients who receive a stem cell transplant.
- Imbruvica is a Bruton's tyrosine kinase inhibitor and the first therapy approved for the treatment of cGVHD.
- Approval for the new indication was based on an efficacy and safety single-arm study of 42 patients with cGVHD whose symptoms persisted despite standard treatment with corticosteroids.
 - Overall response rate was seen in 67% (95% CI: 51, 80) of patients.
 - In 48% of patients, sustained response rate lasted for at least 20 weeks.
- The most common adverse reactions (≥ 20%) with Imbruvica use in cGVHD were fatigue, bruising, diarrhea, thrombocytopenia, muscle spasms, stomatitis, nausea, hemorrhage, anemia, and pneumonia.
- The recommended dose of Imbruvica for cGVHD, CLL/SLL and WM is 420 mg (three 140 mg capsules) orally once daily until disease progression or unacceptable toxicity.
- 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.



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