

Calquence[®] (acalabrutinib) – New drug approval

- On October 31, 2017, the [FDA announced](#) the approval of [AstraZeneca's Calquence \(acalabrutinib\)](#) for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.
 - This indication is approved under accelerated approval based on overall response rate (ORR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- MCL is a rare, fast-growing form of non-Hodgkin lymphoma (NHL) and represents 3% – 10% of all NHL cases in the U.S. MCL affects the lymph system. By the time MCL is diagnosed, it usually has spread to the lymph nodes, bone marrow, and other organs. MCL.
- Calquence is a Bruton's tyrosine kinase (BTK) inhibitor. BTK is an enzyme that is necessary for B-cell proliferation, trafficking, chemotaxis, and adhesion. By blocking this enzyme, Calquence prevents the cancer from multiplying and spreading.
- The FDA approval of Calquence was based on a single-arm trial involving 124 patients with MCL who received at least one prior treatment. The primary endpoint was ORR.
 - Based on an independent committee review, the ORR was 80% of which 40% were complete responses.
 - At the time of analysis, the median duration of response had not been reached.
- Warnings and precautions of Calquence include hemorrhage, infection, cytopenias, secondary primary malignancies, and atrial fibrillation and flutter.
- The most common adverse reactions (≥ 20%) with Calquence use were anemia, thrombocytopenia, headache, neutropenia, diarrhea, fatigue, myalgia, and bruising.
- The recommended dose of Calquence is 100 mg orally every 12 hours until disease progression or unacceptable toxicity.
 - Patients should be advised to swallow the capsules whole with water. Patients should not open, break, or chew the capsules.
- The wholesale acquisition cost for Calquence is \$14,260 per month.
- AstraZeneca's launch plans for Calquence are pending. Calquence will be available as 100 mg capsules.