Acalabrutinib (Calquence) for Mantle Cell Lymphoma

The FDA has approved the Bruton tyrosine kinase (BTK) inhibitor acalabrutinib (Calquence – AstraZeneca) for oral treatment of relapsed or refractory mantle cell lymphoma. Acalabrutinib is the second BTK inhibitor to be approved for this indication; ibrutinib (Imbruvica) was approved in 2013.

Ibrutinib inhibits other kinases in addition to BTK and has been associated with severe adverse effects, particularly atrial fibrillation, infection, rash, and bleeding, that may be related to inhibition of kinases other than BTK.1 Acalabrutinib is a more selective BTK inhibitor than ibrutinib; whether this improved selectivity results in fewer adverse events is unclear.2

FDA approval of acalabrutinib was based on the results of a single-arm trial in 124 patients who had received a median of 2 previous therapies for mantle cell lymphoma. After a median follow-up of 15.2 months, 81% of patients treated with acalabrutinib 100 mg twice daily achieved an overall response and 40% achieved a complete response. The Kaplan-Meier estimated median overall survival rate at 12 months was 87%.3

The most common severe adverse events in the pivotal trial were neutropenia (10%), anemia (9%), and pneumonia (5%). There were no cases of atrial fibrillation and one case of severe hemorrhage. No head-to-head trials comparing acalabrutinib with ibrutinib are available to date.

The cost of 30 days’ treatment with Calquence (100 mg bid) is $14,064 and with Imbruvica (560 mg once daily) is $12,180.4

4. Approximate WAC. WAC = wholesale acquisition cost or manufacturer’s published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. October 5, 2018. Reprinted with permission by First Databank, Inc. All rights reserved. ©2018. www.fdbhealth.com/policies/drug-pricing-policy.