

Hemlibra for hemophilia A without FVIII inhibitors approved

Oct. 5, 2018—[Roche](#) announced the FDA's approval of Hemlibra (emicizumab-kxwh) for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children, ages newborn and older, with hemophilia A without factor VIII inhibitors. Hemlibra is the only prophylactic treatment for people with hemophilia A with and without factor VIII inhibitors that can be administered subcutaneously and at multiple dosing options (once weekly, every two weeks or every four weeks), the company reports. The approval is based on results from the phase three HAVEN 3 and HAVEN 4 studies. Hemlibra prophylaxis led to statistically significant and clinically meaningful reductions in treated bleeds compared with no prophylaxis (primary endpoint) and across all other bleed-related endpoints in the HAVEN 3 study and showed a clinically meaningful control of bleeding in the HAVEN 4 study.

"Many preventative treatment options for people with hemophilia A without factor VIII inhibitors require intravenous infusions several times a week. Even then, people can still experience bleeds, and there has been a need for more treatment options," Michael Callaghan, MD, hematologist, Children's Hospital of Michigan, Detroit, said in a press release from Roche. "The approval of Hemlibra is an important advancement for the entire hemophilia A community, as we now have a new class of medicine for the first time in nearly 20 years. Hemlibra can reduce bleeds, and it offers a new subcutaneous administration once weekly, every two weeks, or every four weeks."

Hemlibra was first approved in 2017 for patients with hemophilia A with FVIII inhibitors.