

Verquvo™ (vericiguat) – New drug approval

- On January 20, 2021, [Merck announced](#) the FDA approval of [Verquvo \(vericiguat\)](#), to reduce the risk of cardiovascular (CV) death and heart failure (HF) hospitalization following a hospitalization for HF or need for outpatient intravenous diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.
- Verquvo is a first-in-class stimulator of soluble guanylate cyclase (sGC), an important enzyme in the nitric oxide (NO) signaling pathway. By directly stimulating sGC, vericiguat leads to smooth muscle relaxation and vasodilation.
- The efficacy of Verquvo was established in a randomized, placebo-controlled, double-blind, event-driven study (VICTORIA) in 5,050 adult patients with symptomatic chronic HF (New York Heart Association [NYHA] class II to IV) and left ventricular ejection fraction (LVEF) less than 45% following a worsening HF event. Patients were randomized to Verquvo or placebo. The primary endpoint was a composite of time to first event of CV death or hospitalization for HF. The median follow-up for the primary endpoint was 11 months.
 - Verquvo was superior to placebo in reducing the risk of CV death or HF hospitalization based on a time-to-event analysis (hazard ratio [HR]: 0.90, 95% CI: 0.82, 0.98; p = 0.019). Over the course of the study, the event rate (percentage of patients per year) was 33.6% with Verquvo vs. 37.8% with placebo.
- Verquvo carries a boxed warning for embryo-fetal toxicity.
- Verquvo is contraindicated in patients with concomitant use of other sGC stimulators and in pregnancy.
- The most common adverse reactions (≥ 5%) with Verquvo use were hypotension and anemia.
- The recommended starting dose of Verquvo is 2.5 mg orally once daily with food. The dose of Verquvo should be doubled approximately every 2 weeks to reach the target maintenance dose of 10 mg once daily, as tolerated by the patient.
- Merck's launch plans for Verquvo are pending. Verquvo will be available as a 2.5 mg, 5 mg, and 10 mg tablets.