340B Limited Distribution Notice for Corlanor® (ivabradine)
Oral Solution 5 mg (NDC 55513-0813-28)

Through this Limited Distribution Notice, Amgen USA Inc. (“Amgen”) describes how eligible 340B covered entities can access our product Corlanor® (ivabradine) Oral Solution 5 mg (NDC 55513-0813-28, henceforth referred to as Corlanor® Oral Solution) at the 340B price.

Corlanor® Oral Solution is indicated for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients aged 6 months and older, who are in sinus rhythm with an elevated heart rate. Pediatric dilated cardiomyopathy is an orphan indication with incidence of fewer than 2,000 patients per year with approximately 200 patients per year advancing to heart failure. Corlanor® Oral Solution was approved by the U.S. Food and Drug Administration on April 22, 2019. Corlanor® Oral Solution is particularly sensitive to environmental factors such as light. To avoid degradation, stringent conditions for storage and dispensing are necessary.

To ensure that patients being treated with Corlanor® Oral Solution and their caregivers receive the best possible care, and to ensure optimal drug regimen titration, appropriate drug and clinical counseling, and therapeutic adherence, Amgen has developed a limited distribution arrangement through a dedicated and trained specialty pharmacy. All prescribers of Corlanor® Oral Solution—340B-eligible and otherwise— are subject to this limited distribution plan.

Corlanor® Oral Solution is available exclusively through Avella Specialty Pharmacy. Corlanor® Oral Solution may only be dispensed by Avella Specialty Pharmacy directly to patients. No other dispensaries may inventory or dispense Corlanor® Oral Solution.

Cardinal Health Specialty Pharmaceutical Distribution is the sole distributor of Corlanor® Oral Solution to Avella Specialty Pharmacy. A covered entity with a contract pharmacy relationship with Avella Specialty Pharmacy may place bill to/ship to replenishment orders for Corlanor® Oral Solution at the 340B price through Cardinal Health Specialty Pharmaceutical Distribution pursuant to its contract pharmacy agreement. Covered entities may not place orders for Corlanor® Oral Solution from Cardinal Health Specialty Pharmaceutical Distribution for delivery to any location other than Avella Specialty Pharmacy.

340B covered entities that do not have such contract pharmacy relationships may submit prescriptions for Corlanor® Oral Solution (via facsimile at 877-546-5780 or electronically at ERx NPI: 178-003-0163) that will be filled by Avella Specialty Pharmacy. The main number for Avella Specialty Pharmacy is 877-546-5779.