

New Drug Manufacturer Report

| Section | Data element | Field type | Drug #1 |
|----------------------------|--|------------|--|
| 1. Drug identification | National drug code (11-digit NDC) | Numeric | 72572-0035-10 |
| | Drug name | Text | Bivalirudin Trifluoroacetate |
| 2. Drug Launch Information | Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally | Text | Civica selects products (including Bivalirudin) that are identified and prioritized by Civica's member health systems - by doctors and pharmacists on the front lines - as the medications most important for quality patient care. Each Civica member health system has the option to make a long-term commitment to purchase Bivalirudin from Civica by executing a Purchase Commitment Form. The Purchase Commitment Form contains the required duration of the purchase commitment and the expected annual minimum volume purchase commitment for each participating member (based on the member's historical pro rata usage volume relative to the other members). Civica sets a single, transparent price per Bivalirudin product for each of its members, regardless of the volume purchased. Civica sets its Bivalirudin prices at approximately cost plus a margin to cover Civica's overhead and research and development expenses. |
| | Estimated volume of patients who may be prescribed the drug | Numeric | 808 - per an estimated 427,081 total Bivalirudin patients in 2020 across the US |
| | Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval | Text | N/A |
| | Date and price of acquisition if the drug was not developed by the manufacturer | Text | Civica is selling under a product supply agreement under the manufacturer. There was no licensing fee, or acquisition price, only a fee per unit purchased from the manufacturer. |