Manufacturer	NDC 11	Drug Name	Commercial Launch Date
Celltrion USA	72606-025-010	Zymfentra 120 mg.mL/w 1 Needle Shield PFS	3/15/2024
Celltrion USA	72606-025-001	Zymfentra 120 mg.mL/w AutoInjector	3/15/2024
Celltrion USA	72606-025-002	Zymfentra 2 x 120 mg.mL/w AutoInjector	3/15/2024

Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally
In support of the introduction of Zymfentra to the market, Celltrion USA studied the patient journey by looking at referral assumptions, treatment cycle, and benefit design for patients with Irritable Bowel Disease. Celltrion plans to have visual aides and other interactive materials available for both prescribers and patients such as leave behind brochures and implementation guides, a payer/access fact sheet that includes the FDA approval announcement, a Peer-to-Peer promotional deck, and patient centric materials such as an instruction for use video as well as a patient assistance program. Since Zymfentra is the first and only subcutaneous infliximab product available in the US, pricing was based on studies and analysis of the European market where subcutaneous infliximab product is available as well as some comparison against current available therapies in the US.
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The estimated volume of patients who may be prescribed the drug
14,500 patients per year
14,500 patients per year
14,500 patients per year

Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval
N
N
N

Date and price of acquisition if the drug was not developed by the manufacturer
N/A
N/A
N/A