vizient

Evaluating the impact of the oncology drug shortage

A call for transparency

Reducing the impact of future shortages

A lack of transparency exists within the supply chain for healthcare organizations, regulatory bodies and even suppliers themselves. Connecting with our advocacy contacts, monitoring your inventory exposure through analytic tools and acquiring medications from manufacturers through our Novaplus Enhanced Supply program are all ways to prepare for and address drug shortages. Additional suggestions include the following:

Manufacturers

Provide frequent updates about product availability and estimated release dates. Invest resources into quality management programs

Wholesalers

Implement and communicate allocation processes when order quantities exceed certain thresholds

Healthcare providers

Evaluate inventory management practices utilizing principles of Drug Shortage Stewardship and align ordering based on necessary par levels determined by patient volume

Group purchasing organizations (GPOs)

Share market insights on current and future demand to help manufacturers, wholesalers and providers gain insight into ways to optimize supply distribution and purchasing behaviors

U.S. Food and Drug Administration (FDA)

Increase access to information related to drug shortage mitigation efforts received from manufacturers; provide anticipated impact regarding Form 483 findings; further develop the Quality Management Maturity (QMM) program to foster quality in pharmaceutical manufacturing

Background: Why are there shortages for seven oncology drugs?

As of July 2023, there is a national shortage of many foundational oncology drugs. Some of the affected drugs include:

Docetaxel

Fludarabine

Capecitabine

- Fluorouracil
 - Methotrexate

CarboplatinCisplatin

Based on 2022 U.S. sales data, affected medications can be sourced through multiple suppliers including Accord Healthcare (the U.S.-based distributor for Intas Pharmaceuticals), Pfizer, Fresenius Kabi and Hikma.

The market for six of the seven identified medications – capecitabine, carboplatin, cisplatin, docetaxel, fluorouracil and methotrexate – became significantly disrupted in December 2022 when an FDA inspection of the Intas Pharmaceuticals facility in the Special Economic Zone (SEZ) near Ahmedabad, India made note of multiple issues pertaining to quality control. Shortly after, Intas Pharmaceuticals temporarily ceased manufacturing and distribution of products manufactured at that facility.

On June 2, 2023, Intas Pharmaceuticals was officially issued a letter from FDA which references an import alert. This alert states that 24 products, including the six listed above, may be imported into the U.S. market following testing by independent third parties. At the time of this publication, Accord Healthcare officials had not provided guidance on when production and distribution of medications from the facility in India may resume.

Demand insights using Vizient analytics

Purchasing data from Vizient pharmacy program participants and the Vizient Clinical Data Base (CDB) were queried to gain insight into recent purchasing patterns, growth in oncology patients and demand trends. When aggregating wholesaler and Vizient CDB data for all seven products, the following trends were found:

- An **increase of 12%** was observed in total number of units sold for these medications in January through May 2023 compared with January through May 2022
- The number of unique patients receiving antineoplastics in the outpatient setting showed relatively flat **1.5% growth** quarter-over-quarter between 2022 and March 2023
- Starting in December 2022, demand began to increase by over 136% compared with historical purchase patterns and remained elevated year-to-date 2023
- Vizient Pharmacy Program Participants receiving less than 50% of historical order quantities reached 57% in May 2023

The disruption in product availability is exacerbated by the lack of public information and transparency into the timeline for recovery. This information includes quantities of additional product produced by alternate manufacturers, manufacturing facility production schedules and manufacturer / wholesaler allocation strategies. Hospitals and health systems are unable to know whether a drug shortage will improve or deteriorate at any given time for the duration of a drug shortage.

One strategy to reduce the longevity of a drug shortage is demand reduction. Drug shortage stewardship may collectively reduce the national demand for the affected drug and limit drug shortage impact. Vizient has published several resources related to drug shortage stewardship, including a blog post and podcast.

Additional Vizient pharmacy program participant insights

In April 2023, Vizient issued a survey to better understand the severity of the shortage and its impact on operations and patient care capacity.

95%

of survey respondents report being **impacted by drug shortages of carboplatin and cisplatin**

56%

of respondents were required to implement mitigation strategies for **cisplatin**, including **delaying therapy**, **using an alternative agent or using reduced doses of medication**



Access the full report document by scanning the QR code.

The full report includes additional Vizient pharmacy program participant insights and mitigation strategies.



