

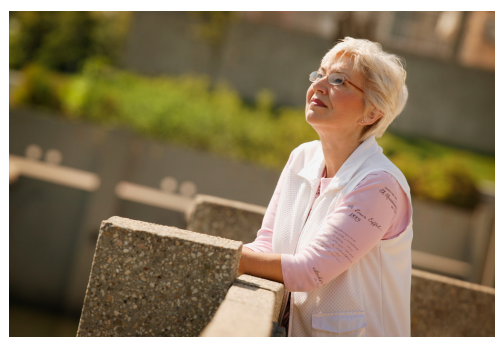
Economics of Drug Shortages

Drug shortages continue to have a significant impact on cancer patients, causing difficult decisions that have included rationed drugs, reduced or skipped doses, and altered treatment regimens. Drug choices, doses, and schedules are based on evidence and what has been shown to work best. **Changes to treatment regimens due to drug shortages can lead to increased costs, less effective treatment, and worse patient outcomes.** The majority of oncology drug shortages have occurred in older, multi-source generic sterile injectables (GSIs) that serve as the core backbone for treatment regimens that have high-efficacy cure rates. One characteristic shared by most GSIs is that their cost is extremely low relative to name-brand drugs. These low prices have led many manufacturers to exit the market and some of those that remain to underinvest in maintaining resilient manufacturing.

The following fictional illustration, based on real oncology clinical guidelines and the January 2024 Medicare ASP Pricing File, aims to highlight GSI cost to Medicare for a patient with ovarian cancer.

Jane

Jane is a 65-year-old woman enrolled in Medicare Part B and was recently diagnosed with stage III ovarian cancer. After surgery to remove most of her tumor, Jane’s oncologist decided to give her 5 cycles of chemotherapy, *paclitaxel/carboplatin* every 3 weeks. The plan was to give the chemotherapy at an outpatient clinic over a total of 15 weeks for the 5 cycle treatment course. **However, due to shortages of *paclitaxel* and *carboplatin*, several of her scheduled treatments were delayed and her cancer developed resistance to *paclitaxel/carboplatin*.** Jane needed another treatment option.



First-line Treatment with GSIs

Drug	Paclitaxel	Carboplatin
Medicare Payment Limit	\$0.108 / 1 MG	\$3.599 / 50 MG
Drug Cost Per Treatment	\$34.45	\$35.99
Patient OOP Cost Per Treatment	\$14.09	

OOP (out-of-pocket) Medicare beneficiaries without supplemental coverage would pay 20% of the cost of the drug (in addition to other charges) per treatment.

Paclitaxel and carboplatin are each older, multi-source GSIs that are currently experiencing or have recently experienced shortages.

Second-line Treatment with Targeted Therapy

Treatment with Targeted Therapy

In search of a second-line treatment, Jane’s oncologist ordered additional testing that revealed that her cancer was FRa positive which made her eligible for treatment with, *mirvetuximab soravtansine-gynx*, a recently approved intravenous targeted therapy only for cancers that are FRa positive and resistant to her previous treatment regimen.

Drug	mirvetuximab soravtansine-gynx
Medicare Payment Limit	\$65.710 / 1 MG
Drug Cost Per Treatment	\$30,358.02
Patient OOP Cost Per Treatment	\$6,071.60

Mirvetuximab soravtansine-gynx is marketed under the brand name Elahere. Medicare beneficiaries without supplemental coverage would pay 20% of the cost of the drug (in addition to other charges) per treatment.

Impact of paclitaxel/carboplatin Shortage

The drug shortage interrupted Jane's treatment regimen, contributing to the failure of the first-line treatment for her cancer and prompting a switch to a second-line treatment, which significantly increased costs to her and the Medicare program.

Methodology

Jane

Height: 161.8 cm

Weight: 77 kg

BSA: 1.82 m²

Age: 65

GFR: 66 mg/mmol

Target AUC: 5.0 mg/ML/min

Chemotherapy regimens are based on NCCN Guidelines Version 1.2024 Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer

paclitaxel dose (mg) per cycle: 175 mg/m² ■■■ ➔ **318.5 mg**

carboplatin dose (mg) per cycle: (target AUC) x (GFR + 25) ■■■ ➔ **455 mg**

mirvetuximab soravtansine-gynx dose (mg) per treatment: 6 mg/kg ■■■ ➔ **462 mg**

HCPCS Code*	Drug	HCPCS Code Dosage*	Payment Limit*	Jane's Dose (MG)	Round Up Dose [^]	Drug Cost Per Treatment = Round Up Dose x Payment Limit) / HCPCS Code Dosage
J9267	paclitaxel	1 MG	\$0.108	318.5 MG	319 MG	\$34.45
J9045	carboplatin	50 MG	\$3.599	455 MG	500 MG	\$35.99
J9063	mirvetuximab soravtansine-gynx dose	1 MG	\$65.710	462 MG	462 MG	\$30,358.02

*January 2024 Medicare ASP Pricing File

[^] For the purposes of calculating cost, once a unit of drug is used, cost is rounded up to the next whole dose.