

# Impact of single-dose vial size availability on drug costs

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## Background

Via Pathways' Disease Committees request cost comparison data from the staff at Via Oncology (VIA) only when two drug regimens are considered comparable in efficacy and toxicity. For Medicare Part B drugs, VIA calculates cost to the payer and patient by assessing estimated units to be billed using current CMS allowables per billable unit. When a drug is available only in a single-dose vial (SDV), VIA assumes that the residual drug within the smallest combination of vial sizes must be wasted and, therefore, billable to CMS. In 2015, the 50 mg SDV of pembrolizumab (PEM) was discontinued by the manufacturer, leaving only a 100 mg SDV available. Based on this change, VIA updated the cost calculation of PEM to determine whether the change in available vial size affected the cost of the drug.

### Single-Dose Vials (SDV) vs. Multiple-Dose Vials (MDV)

#### Single-Dose Vials

- Leftover medication is discarded after a single use
- Typically do not contain an antimicrobial preservative
- VIA assumes the full vial size is billed to CMS when calculating the cost of a drug available in a SDV

#### Multiple-Dose Vials

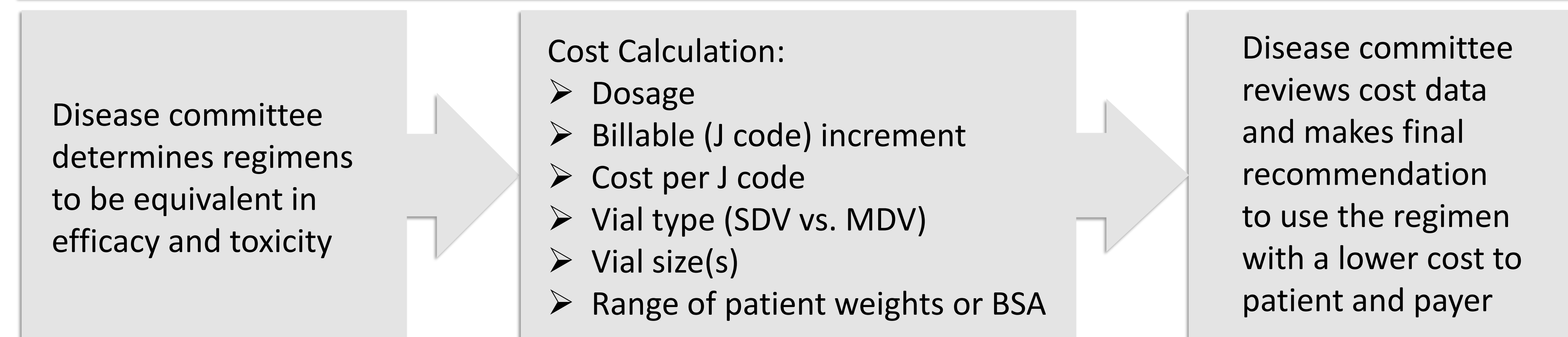
- Leftover medication can be stored and used later in accordance with manufacturer instructions
- Typically contain an antimicrobial preservative
- VIA assumes a partial vial may be billed to CMS (to the nearest billable increment) when calculating the cost of a drug available in a MDV

## Methods

VIA calculated the cost of PEM assuming 2 mg/kg dose every three weeks. A total of 24 weeks of therapy were assumed. A range of weight assumptions from 70 kg to 95 kg was used to reflect expected patient weights. For the previous period when the 50 mg vial was available, VIA assumed 3 vials of 50 mg were used and billed for doses up to 150 mg, and that 4 vials were used and billed for doses of 150 mg or higher. For the period after the 50 mg vial was discontinued, VIA assumed 200 mg of drug were billed (using two 100 mg vials) for all weights between 70 kg and 95 kg.

VIA then reviewed data entered by providers from the UPMC CancerCenter network into the VIA Portal to determine the most commonly initiated IV drugs and reviewed manufacturer information to determine the approved dosage, vial type, and vial size. The typical dose of given of these agents was calculated using the FDA-approved dosage(s) multiplied by a weight of 82 kg or a body surface area (BSA) of 1.96 m<sup>2</sup>.

### Calculating Cost



## Results

The change in availability from a 50 mg vial size to a 100 mg vial size increased the average cost to Medicare and the patient by 6%, or approximately \$4,000, over a 24-week course of therapy. For patients weighing less than 75 kg, the cost of therapy when both 50 mg and 100 mg SDVs were available was \$54,838.80 for a 24-week course as shown in Figure 1. Once the 50 mg SDV was no longer available, the cost increased to \$73,118.40 for a 24-week course.

## Results

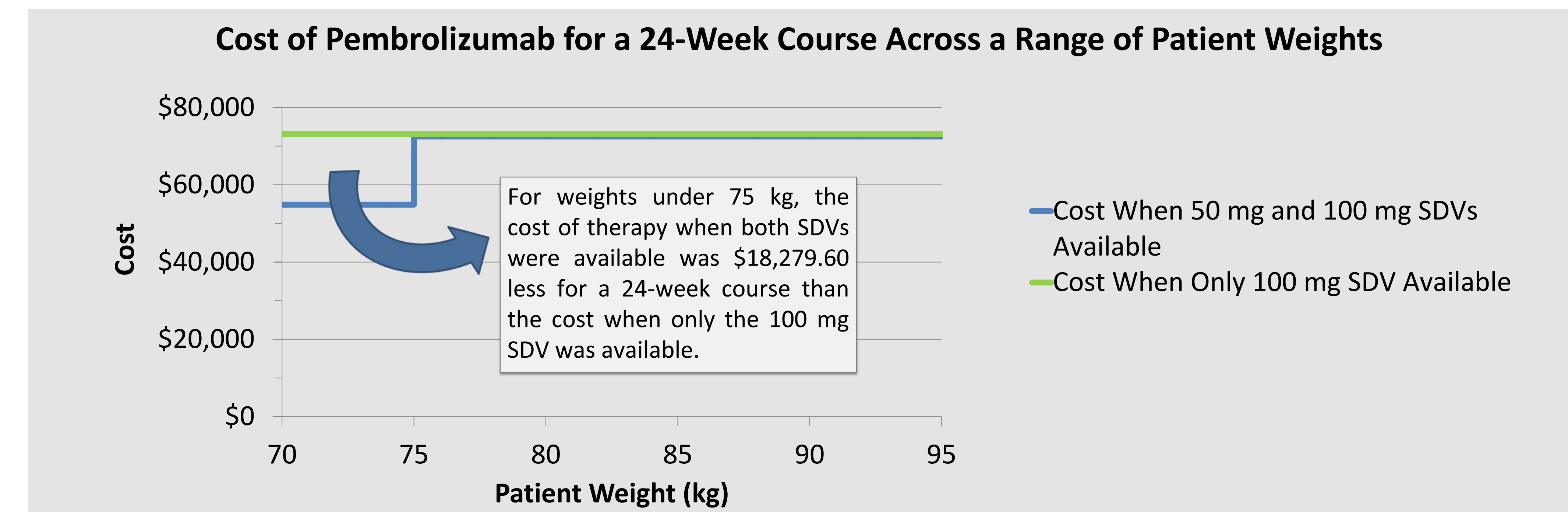


Figure 1: Cost as a function of patient weight for a 24-week course of pembrolizumab given size of available SDVs

The 25 most commonly initiated IV drugs (by volume, not dollar amount) utilized within UPMC were identified. Of these, 17 were available in SDVs only. Of these, 8 were branded single-source drugs. Table 1 shows the typical dose given, available single dose vial sizes, number of doses given per 24 week period, total cost per mg to Medicare and the patient and the estimated waste over the 24 week period.

Table 1:

Drug Name	Typical Dose*	Available Vial Size(s)	Number of Doses per 24 Weeks Treatment	Cost per mg at ASP+6%	Estimated Waste Cost
Rituximab	735 mg	100 mg, 500 mg	4 doses^	\$8.16	\$2,121.60
Bevacizumab	410 mg	100 mg, 400 mg	12 doses	\$7.52	\$8,121.60
Nivolumab	246 mg	40 mg, 100 mg	12 doses	\$27.15	\$11,077.20
Pemetrexed	980 mg	100 mg, 500 mg	4 doses^	\$6.54	\$523.20
Nab-paclitaxel	245 mg	100 mg	18 doses	\$10.60	\$10,494.00
Pembrolizumab	164 mg	100 mg	8 doses	\$48.44	\$13,950.72
Pertuzumab	420 mg	420 mg	6-8 doses	\$11.07	\$0
Cetuximab	490 mg	100 mg, 200 mg	24 doses	\$5.76	\$1,382.40

\*Based on commonly-used FDA-approved dosage(s) and average patient weight of 82 kg or BSA of 1.96 m<sup>2</sup>

^Calculations based on four total doses only received

## Conclusions

Decisions by drug manufacturers about which vial sizes to manufacture can have a significant impact on the total cost to the patient and payer, particularly if the change leads to waste and the need to bill the patient and payer for the unused portion of a larger single-dose vial. Many of the most commonly used cancer therapies are available only in SDVs in a limited number of different vial sizes.

### Key Points

- Lack of smaller single-dose vial sizes increases cost to payer and potentially patients
- Single-dose vials result in waste for drug not given to subsequent patients due to inability to reuse remaining drug in the vial
- Almost all new oncology drugs are only manufactured as single dose vials