Branded Epoprostenol Transitions: Specialty Pharmacy Support During a Drug Shortage

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BACKGROUND:

The COVID-19 pandemic led to significant supply chain disruption[1]. These disruptions have proven to be especially impactful to the pharmaceutical industry. Increased medication backorders resulted in the need for specialty pharmacy agility to avoid gaps-in-care and maintain drug access – particularly for life-sustaining medications. On December 12, 2023, specialty pharmacies were notified of a branded epoprostenol (original approval 1995) backorder requiring the need for patients to convert to an alternate prostanoid for the treatment of pulmonary arterial hypertension (PAH).

Evaluate the benefit of specialty pharmacy involvement in transitioning patients from legacy epoprostenol to an alternate prostacyclin.

METHODS:

Patients stabilized on the originally branded epoprostenol are transitioned to alternate prostacyclin therapy – most often the thermostable version of epoprostenol (approved in 2010) or treprostinil.

Prior to transition, comprehensive counseling from a PAH specialty-trained pharmacist is provided. As part of this interaction, the following are reconciled with the patient to confirm accuracy: current epoprostenol dose in ng/kg/min, concentration of infusion in mg/mL, and ambulatory infusion pump rate in mL/24 hours. Patient reported in-home quantity of branded epoprostenol vials is also documented in furtherance of calculation to days supply.

Pharmacist-prescriber collaboration occurs to assure dose equivalence is achieved post transition. Timing of the transition is established to maximize depletion of branded epoprostenol. As needed, a PAH specialist nurse is engaged to monitor the transition in real time and/or provide administration education.

Data for the analysis was taken directly from documentation in the electronic medical record memorializing these interactions. Review period was June 1, 2023, to February 16, 2024.

Data was collected via a standardized data collection tool and include the following: prostacyclin to which patient transitioned, final dose equivalence, timing of the transition, level of patient training required, and the site of service for that training. Additionally, waste avoidance was evaluated and a cost assigned by applying the Average Wholesale Price (AWP) for original branded epoprostenol[2].

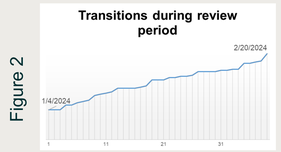
RESULTS:

Fifty-nine patients met criteria for review. The average start of care year on originally branded epoprostenol was 2008, with the full sample spanning over a decade (figure 1).

Figure 1

Thirty-nine (66% [39/59]) patients received or scheduled a first shipment of alternate prostacyclin within the 8.5-month review period (figure 2).

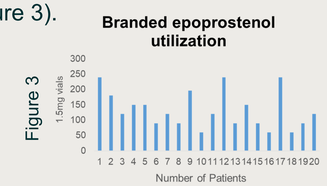
Figure 2



Twenty (34% [20/59]) patients did not receive or schedule a first shipment, however 80% (16/20) of this group had a prescription on file for an alternate prostacyclin.

Twenty (36% [20/55]) patients received originally branded epoprostenol post receipt of orders for the alternate the prostacyclin (figure 3).

Figure 3



Providing originally branded epoprostenol to facilitate extension of the transition period allowed for impactful reduction of specialty pharmacy inventory and avoidance of product destruction.

WASTE AVOIDANCE TO HEALTHCARE SYSTEM

- 2,656 VIALS (1.5MG)
- $143,875 (AWP)

Thirty-six (92% [36/39]) patients transitioned from originally branded epoprostenol to thermostable epoprostenol. Secondary to identical pharmacokinetics between the two products, twenty-two (61% [22/36]) patients were able to transition without nursing intervention. At the discretion of the prescriber, thirteen (36% [13/36]) patients were provided in-home training from a PAH specialty trained nurse. Figure 4 and 5.

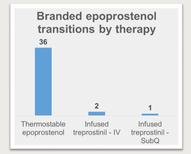


Figure 4

Figure 5

All three patients who transitioned to infused treprostinil (2 IV, 1 SubQ) required in-home training in support of the new therapy.

Clinical training included pump education, review of supplies and resource materials designed to prevent errors to dose, admixture or administration.

Thirty-two (89% [32/36]) patients converted to thermostable epoprostenol at an equivalent (1:1) dose: two patients (5.5% [2/36]) converted to a higher dose and two (5.5% [2/36]) patients transitioned to a lower dose. All three patients who transitioned to infused treprostinil achieved a maintenance dose of 10% or greater than their previous branded epoprostenol dose.

CONCLUSIONS:

Specialty pharmacy support during a supply chain disruption resulted in conversions from originally branded epoprostenol to an appropriate alternative with no gaps in care or undesired dose reductions. PAH specialty trained clinicians worked collaboratively with prescribers, counseled patients, and provided clinical support to confirm that appropriate mixing techniques and safety precautions were followed.

Specialty pharmacy support will continue to prove valuable in the avoidance of therapy interruptions while simultaneously allowing for inventory management avoidances to the health care system of waste in terms of destroyed product.

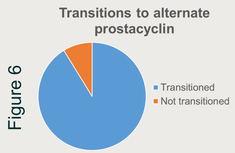
REFERENCES:
Moosavi J, Fathollahi-Fard AM, Dulebenets MA. Supply chain disruption during the COVID-19 pandemic: Recognizing potential disruption management strategies. Int J Disaster Risk Reduct. 2022;75:102983. doi:10.1016/j.ijdrr.2022.102983
Average Wholesale Price – April 2024

POST-HOC ANALYSIS:

This post-hoc analysis is a summary of follow-up data on *the same sample*; review period is extended to April 19, 2024.

Fifty-two patients (88% [52/59]) transitioned to an alternate prostacyclin. Forty-nine (83% [49/59]) patients transitioned from originally branded epoprostenol to thermostable epoprostenol (figure 6).

Figure 6



Of note, two (3% [2/59]) patients fell from the sample (one expired and one transitioned to non-infused prostanoid).

An additional 1,378 vials of 1.5mg originally branded epoprostenol shipped post-receipt of orders for the alternate prostacyclin, resulting in and additional $74,646 of waste avoidance to the healthcare system through avoidance of product destruction.

CUMULATIVE WASTE AVOIDANCE TO HEALTHCARE SYSTEM

- 4,034 VIALS (1.5MG)
- $218,521 (AWP)

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