[External] [URGENT] Addition of Plerixafor to NMDP PBSC Protocol

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NMDP is committed to creating a world where every patient can receive a life-saving cell therapy. Donor mobilization can impact the ability to deliver a high-quality product. In NMDP domestic apheresis donor cases, approximately 5-10% of mobilized donors have poor mobilization on collection day, following the prescribed and administered doses of filgrastim similars.

To ensure all patients receive an optimal stem cell product, NMDP has added plerixafor, an additional mobilizing agent, to the NMDP PBSC Protocol, effective July 29, 2024. In a minor number of cases, plerixafor may be used, in conjunction with filgrastim similars, when initial mobilization is not sufficient to provide a quality dose of cells to a patient. Plerixafor will not be used standardly to facilitate high dose requests.

Based upon the donor's mobilization, the unplanned use of plerixafor may be warranted. In those instances, the decision to administer plerixafor will be made collaboratively between the

Transplant Medical Services (TMS) team and the Apheresis Center (AC).

Unplanned use of plerixafor on collection day:

- Unplanned use of plerixafor may be considered when the peripheral CD34+ absolute count, or pre-collection WBC x peripheral CD34+%, is less than 30cells/uL.
- Upon receipt of lab values meeting this criterion, the AC must immediately inform TMS.
- Using the Day of Collection Notification form (F01095), the AC should communicate donor CD34+ count, available inventory of plerixafor, capacity for a next-day collection, and confirmation the donor is willing to proceed.
- TMS will evaluate appropriateness of plerixafor administration, considering AC, donor, transplant center and patient factors.
- In collaboration with the AC, TMS will finalize the decision to administer plerixafor.

Administering plerixafor:

- Plerixafor must only be administered with prior approval from NMDP.
- NMDP, via contract specialty pharmacies, will supply Apheresis Centers with a single dose of plerixafor to maintain in AC's inventory.
- Plerixafor is administered 12 hours, plus or minus 6 hours, prior to the next day's collection start time.
- Donor receives a single dose of plerixafor, dosing 0.24 mg per donor weight (kg).
- Donor must be observed for a minimum of 60 minutes after plerixafor injection.
- Plerixafor administration will be tracked through CIBMTR forms and FormsNet3.
- A second collection day will occur the next day after administration of plerixafor.

NMDP is providing advanced notice of this PBSC Protocol change to ensure successful implementation. NMDP needs your help to clearly understand questions, barriers to implementation, and individual centers' willingness to prescribe and administer plerixafor. Please send questions, concerns, and your center's willingness to implement this new process to your center's assigned Partner Liaison or email the team at PartnerLiaisons@nmdp.org.

More information about the PBSC Protocol updates, impacted documents, and specific process additions will be shared on May 30 within the 60-day notice from NMDP, with watermarks provided on the network website.

With your help, NMDP can create a world where every patient can receive their life-saving cell therapy.