



To: Transfusion Services Managers
From: Hospital Relations Department
Date: May 7, 2020
Re: Cold Stored Platelets

Background

Carter BloodCare continues to receive an increasing number of requests from facilities to keep onsite inventories of apheresis platelets. This is to comply with maternal levels of care designation requirements, massive transfusion protocols, and trauma level designations. Against the background of continuing challenges to maintaining adequate inventories at hospitals, made more acute by increasing demand for product and aging of the apheresis platelet donor base, we are submitting an FDA variance to implement the use of 14 day cold stored platelets. Our target FDA submission period is Q2 2020.

Impact to Client

Our goals include maintaining prices at a competitive level, honoring the donor, and meeting platelet needs as requested. Our approach to achieving these goals is to process and distribute cold stored platelets to eligible facilities. Facilities that elect to maintain a stock of apheresis platelets on-site and whose monthly usage percentage is <30% will be automatically enrolled in the cold-stored platelets program. This means that at least one of the apheresis platelets maintained on-site will be substituted with a cold-stored apheresis platelet. A separate email will be sent directly to each facility required to participate in this program.

In order to minimize the risk of outdate, these products can be used to fill STAT orders when active bleeding is present or no other platelet product is available. Additionally, we intend to re-distribute primarily to trauma hospitals as their likelihood of usage is increased.

Platelet orders for prophylactic treatment require your facility to place an ad-hoc request for fulfillment and delivery.

These strategies should help reduce outdates while increasing availability without having to increase donor collections.

Cold stored apheresis platelets

- Store the apheresis platelet products continuously at refrigerated temperatures (1-6°C)
- Store up to 14 days without agitation
- Bacterial detection testing is not required
- Platelets are approved for the treatment of actively bleeding patients through day 14 of storage or when conventional platelet products are unavailable or their use is not practical.
- Eligible for return/re-stock at day 10

Client Action

- Laboratory and/or blood bank information systems must be updated to accept the ISBT product codes associated with cold-stored apheresis platelets. Example labels are attached for your reference.
- Review and update policies associated with platelet storage and indications for use.
- Inform laboratory medical directors and clinicians of the anticipated new component and its indications for use.

We will keep you informed on the progress of the FDA variance submission.

Please do not hesitate to contact me with any questions or concerns.