To: Transplant Center Medical Directors and Data Managers

From: Douglas Rizzo, MD, MS

Date: February 8, 2010

RE: Preparative Regimen Data Reporting - UPDATE

When a drug is used for the preparative regimen where pharmacokinetics will be tested, it is important to distinguish whether the testing will be done using the first dose of the preparative regimen or if the drug will be given with a “test dose” distinct from the beginning of the preparative regimen. This helps distinguish whether the dose is part of the therapeutic regimen, or not. Depending upon how the dose of the drug used to monitor drug levels is given, it can be reported in one of two different ways on the CIBMTR Pre-TED (2400) and Baseline (2000) forms.

1. If the first dose of the preparative regimen will be used to determine pharmacokinetics, the following should be reported:
   - On the Pre-TED (2400) form, the total prescribed dose per protocol would include the dose used for monitoring.
   - On the Baseline (2000) form, the start date of the chemotherapy agent should be reported as the date the first dose was administered. The actual dose received would include the dose used for monitoring.

2. The test dose is given ≥ 24 hours prior to the intended therapeutic dosing.
   - On the Pre-TED (2400) form, the total prescribed dose per protocol would NOT include the test dose.
   - On the Baseline (2000) form, the start date of the chemotherapy agent should be reported as the date the first therapeutic dose was administered. The actual dose received would NOT include the test dose.

Test doses must be reported consistently at your center. Since most centers follow a consistent approach to pharmacokinetic testing, it should be straightforward for the center to adopt a consistent approach to the reporting of “test doses.”