2000: Recipient Baseline

A transplant center designated as a Comprehensive Report Form center will submit data on the Pre-TED Form, followed by either the Post-TED Form or the Comprehensive Report Forms. The type of follow-up form used for a specific recipient is determined by the CIBMTR's form selection algorithm (see General Instructions, Center Type and Data Collection Forms).

The Baseline Form is one of the Comprehensive Report Forms. This form captures pre-HCT data such as: recipient demographics, organ function and hematologic status, preparative regimen, and socioeconomic information. The Baseline Form is due within 60 days after HCT.

Manual Updates:
Sections of the Forms Instruction Manual are frequently updated. The most recent updates to the manual can be found below. For additional information, select the manual section and review the updated text.

If you need to reference the historical Manual Change History for this form, please click here or reference the retired manual section on the Retired Forms Manuals webpage.

Date	Manual Section	Add/ Remove/ Modify	Description
4/4/ 2024	2000: Recipient Baseline	Add	Plasma vs Serum Samples blue box added above Q4
7/28/ 2023	2000: Recipient Baseline	Add	Red warning box added above Q115 to clarify question is now disabled: *Specify the recipient's combined household gross annual income is disabled. This question will be updated with the next revision of the Recipient Baseline (2000) Form.*
5/1/ 2023	2000: Recipient Baseline	Add	Instructions for Q87 and 95 updated to define peri-transplant period: *Report the total dose actually given during the peri-transplant period (before and after infusion). Do not report the prescribed dose or the daily dose. The pharmacy record or Medication Administration Record (MAR) should be used for determining the exact total dose given.*

5/1/2023	2000: Recipient Baseline	Add	Instructions above Q86 updated to define peri-transplant period: *Drugs may be given during the peri-transplant (before and after infusion) period to prevent transplant-related complications or facilitate engraftment.*
5/6/2021	2000: Recipient Baseline	Add	Question 2 updated with instructions on how to report use of naswar or paan: *Indicate the recipient's smoking and / or chewing tobacco use from the options listed. Select "chewing tobacco" if the recipient has a history using naswar and / or paan. If "cigarettes" is selected, continue with question 3.*
10/23/2020	2000: Recipient Baseline	Modify	Version 4 of the 2000: Recipient Baseline section of the Forms Instruction Manual released. Version 4 corresponds to revision 6 of the Form 2000.

Last modified: Apr 04, 2024

Q1-3:Clinical Status of Recipient Prior to the Preparative Regimen (Conditioning)

Infusion Without a Preparative Regimen
Questions 1-3 must be answered even if no preparative regimen was given.

Question 1: Does the recipient have a history of smoking cigarettes?

The intent of this question is to determine the recipient's history of smoking, including cigars, pipe tobacco, e-cigarettes, and marijuana, and / or use of chewing tobacco. The recipient's smoking and / or chewing history is usually documented on the transplant admission summary.

Indicate whether the recipient has a history of smoking or using chewing tobacco. If "yes," continue with question 2. If "no" or "unknown" continue with question 4.

Question 2: Specify smoking or chewing use (check all that apply)

Indicate the recipient's smoking and / or chewing tobacco use from the options listed. Select "chewing tobacco" if the recipient has a history using naswar and / or paan. If "cigarettes" is selected, continue with question 3.

Question 3: Has the recipient smoked cigarettes within the past year?

Indicate if the recipient has a history of smoking cigarettes within the year prior to HCT. Do not include chewing tobacco, cigars / pipe, e-cigarettes, or marijuana.

Section Updates:

Question Number	Date of Change	Add/ Remove/ Modify	Description	Reasoning (If applicable)
Q2	5/6/ 2021	Add	Instruction added on how to report use of naswar or paan: *Indicate the recipient's smoking and / or chewing tobacco use from the options listed. Select "chewing tobacco" if the recipient has a history using naswar and / or paan. If "cigarettes" is selected, continue with question 3.*	Added for clarification

Last modified: May 06, 2021

Q4-22: Organ Function Prior to the Preparative Regimen (Conditioning)

Infusion Without a Preparative Regimen
Complete questions 4-22 based on the most recent testing prior to infusion if no preparative regimen was given.

Plasma vs Serum Samples
It is acceptable to report chemistry laboratory results based on plasma sample analysis in instances where serum sample analysis is not conducted or if it is not a standard practice at your center, even if the question text states 'serum.'

Questions 4-22: Provide last laboratory values recorded for recipient's organ function (testing done within 30 days prior to the start of the preparative regimen).

These questions are intended to determine the clinical status of the recipient prior to the start of the preparative regimen for stem cell transplantation. Testing may be performed multiple times within the pre-transplant work-up period (approximately 30 days prior to the start of the preparative regimen); report the most *recent* laboratory value obtained for each specific test. Laboratory values obtained on the first day of the preparative regimen may be reported as long as the blood was drawn **before** any radiation or systemic therapy was administered. If the assessment was not performed during the pre-transplant work-up period, report "unknown."

For each organ function test below, indicate if the value is "known" or "unknown" prior to the start of the preparative regimen. Indicate the values and units for each test, taking care to convert them to a unit available on the form, if necessary.

AST (SGOT): Aspartate aminotransferase, or serum glutamic oxalic transaminase, is an enzyme measured in serum or plasma that reflects liver function and liver cell integrity. Elevated levels of AST may indicate liver damage.

ALT (SGPT): Alanine aminotransferase, or serum glutamic pyruvic transaminase, is an enzyme measured in the blood that reflects liver function. Elevated levels of ALT indicates liver injury, minor or severe.

FEV1: Forced expiratory volume is the maximal amount of air one can forcefully exhale in one second which is then converted to a percentage of normal. FEV1 is used to assess airway obstruction.

DLCO (corrected): Corrected diffusion capacity of carbon monoxide is the extent to which oxygen travels from the alveoli of the lungs to the blood stream and is adjusted for the hemoglobin concentration. Use the Dinakara equation below to determine the corrected DLCO if only an

uncorrected value is provided.

Dinakara Equation: DLCOc = {uncorrected DLCO} / [0.06965 x {hemoglobin g/dL}]

Total serum bilirubin: Question 14 will be disabled if the total serum bilirubin is reported in question 485 on the Disease Classification (2402) Form.

Total serum bilirubin: Bilirubin is a pigment that is formed from the breakdown of hemoglobin in red blood cells. Serum bilirubin is a test of liver function that reflects the ability of the liver to take up, process, and secrete bilirubin. Total bilirubin includes the direct (conjugated) and indirect (unconjugated) bilirubin values. If your laboratory reports direct and indirect separately, add the two together to report the total serum bilirubin.

LDH: Lactate dehydrogenase is an enzyme found in the cytoplasm of almost all tissues, which converts L-lactate into pyruvate, or pyruvate into L-lactate depending on the oxygen level. For some diseases, high levels indicate active disease (e.g., lymphoma and multiple myeloma).

Serum creatinine: Creatinine is a normal metabolic waste that is primarily filtered from the blood by the kidneys and then excreted in the urine. Since it is generally produced at a constant rate, the clearance rate and the serum level are widely used as indicators of kidney function.

Upper Limit of Normal for your Institution:
Report the upper limit of normal for each assessment result. Normal values may vary by laboratory, so it is important to report the upper limit of normal for each assessment.

Section Updates:

Question Number	Date of Change	Add/Remove/ Modify	Description	Reasoning (If applicable)
Q4	4/4/2024	Add	Plasma vs Serum Samples blue box added above Q4	Added for clarification

Last modified: Apr 04, 2024

Q23-34: Hematologic Findings Prior to the Preparative Regimen (Conditioning)

Infusion Without a Preparative Regimen
Complete questions 23-34 based on the most recent testing prior to infusion if no preparative regimen was given.

Question 23: Date CBC tested: (testing within 30 days of start of preparative regimen)

These questions are intended to determine the clinical status of the recipient prior to the preparative regimen for stem cell transplantation. Testing may be performed multiple times within the pre-transplant work-up time period; report the most *recent* CBC obtained. Laboratory values obtained on the first day of the preparative regimen may be reported as long as the blood was drawn **before** any radiation or systemic therapy was administered.

Questions 24-33: Provide last laboratory values recorded just prior to preparative regimen:

For each value below, indicate if the result was “known” or “unknown” prior to the start of the preparative regimen. Indicate the units for each test, taking care to convert them to a unit available on the form, if necessary.

WBC: The white blood cell count is a value that represents all of the white blood cells in the blood. If the count is too high or too low, the ability to fight infection may be impaired.

Neutrophils: Neutrophils are a subtype of white blood cell that fights infection. The value on the laboratory report may be a percentage or an absolute value. If an absolute value is reported, divide it by the white blood cell count for a percentage. Neutrophils are also known as polymorphonuclear leukocytes (PMNs).

Lymphocytes: Lymphocytes are another subtype of white blood cell that fights infection. The value on the laboratory report may be a percentage of an absolute value. If an absolute value is reported, divide it by the white blood cell count for a percentage.

Hemoglobin: Hemoglobin is a molecule in red blood cells that delivers oxygen to tissues throughout the body. A low hemoglobin count is considered “anemia” and blood transfusions or growth factors may be required to increase the hemoglobin level. Also indicate if the recipient received a red blood cell transfusion within 30 days prior to testing.

Hematocrit: The hematocrit is the percentage (sometimes displayed as a proportion) of red blood cells relative to the total blood volume. A low hematocrit may require red blood cell transfusions or growth factors. Indicate if the recipient received a red blood cell transfusion within 30 days prior to testing.

Platelets: Platelets are formed elements within the blood that help with coagulation. A low platelet count,

called thrombocytopenia, may lead to easy bleeding or bruising. Thrombocytopenia may require platelet transfusions. Indicate if the recipient received a platelet transfusion within 7 days prior to testing.

Question 34: Was RBC transfused ≤ 30 days before date of test?

Indicate if the recipient received a red blood cell transfusion within 30 days prior to the date of the CBC reported in question 23.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
.	.	.	.	.

Last modified: Dec 22, 2020

Q35-38: Infection

Question 35: Did the recipient have a history of clinically significant fungal infection (documented or suspected) in the 6 months prior to the start of the preparative regimen?

Fungal infections play a major role in the clinical outcome of a transplant recipient. The intent of this question is to identify serious fungal infection(s) that might have an effect on the outcome of the HCT. For the purposes of this manual, the term “clinically significant” refers to conditions that are treated at the time of pre-HCT evaluation, or that have affected the recipient’s medical history, that might cause complications post-HCT.

Examples of fungal infections include, but are not limited to the following: invasive aspergillosis (infection codes 210-213, 219), zygomycosis (infection code 240) and other molds (infection codes 230, 240, 242, 261), invasive candidiasis (infection codes 200-209), cryptococcosis (infection code 220), endemic mycosis (infection code 241), other yeasts (infection code 250), and pneumocystsis (PCP/PJP) (infection code 260). Include any fungal abscesses of the lungs, sinuses, liver, or spleen.

✻ Non-invasive fungal infections such as thrush and nail fungus should not be reported.

If the recipient has a history of clinically significant fungal infection **in the 6 months** prior to this HCT event, check “yes” and continue with question 36. For a subsequent HCT, report any documented significant fungal infections in the recipient’s medical history, between the start of the preparative regimen of the previous HCT to just prior to the preparative regimen for the current HCT.

If the recipient does not have a history of clinically significant fungal infection **in the 6 months** prior to this HCT event, check “no” and continue with question 38. For assistance with reporting fungal infections, consult with a transplant physician.

✻ **Questions 36-37 Reporting Multiple Infections**
FormsNet3^{SM} application: Complete questions 36-37 to report multiple significant fungal infections by adding an additional instance in the FormsNet3^{SM} application.
Paper form submission: Copy questions 36-37 and complete for significant fungal infection.

Question 36: Select organism:

From the list of “Codes for Commonly Reported Fungal Organisms,” select the code corresponding to the identified or suspected fungus. A fungal infection form (Form 2046) must be completed for all organisms.

Question 37: Date of diagnosis

Enter the date of diagnosis of the fungal infection. For suspected fungal infections, enter the date of a

radiology test or date treatment was started as the date of diagnosis.

Fungal Infection Diagnosis Reporting Scenario
p((. A recipient has a CT scan on 4/1/2015 due to a persistent cough. The CT scan documents multiple nodules. An *Aspergillus* galactomannan was drawn in the blood on 4/2/2015 and the patient underwent a bronchoscopy on 4/3/2015. Fluid from the bronchoaveolar lavage was stained for fungal elements and submitted for culture. The stain was positive for fungal elements and the culture grew *Aspergillus* The blood galactomannan was also positive.
p((. * The date of diagnosis of infection will be **4/2/2015**. This is the date the galactomannan was obtained and positive.
p((. * If galactomannan was negative and the BAL negative, the date of infection would be **4/1/2015** (the date of the CT scan).

Question 38: Testing for evidence of prior viral exposure/infection: (check all that apply)

Indicate if the recipient was *positive* for any of the viral exposure or infections listed below. Do not select the viral exposure or infection if the test was performed and the results were negative.

If testing for evidence of prior viral exposure / infection was not performed, select “not done.”

Select “not applicable” if testing for evidence of prior viral exposure / infection was performed and *all* of the results were negative.

Serologic Tests
Serologic tests should be completed during the pre-HCT work-up phase, or approximately one month prior to the start of the preparative regimen.

If a recipient tests positive for Hepatitis B core antibody (Anti HBc), Hepatitis B surface antigen (HBsAg), Hepatitis B NAAT, Hepatitis C antibody (Anti HCV), and/or Hepatitis C NAAT serologic tests, also complete the HEP Form (Form 2047).

If a recipient tests positive for HIV antibody or HIV NAT serologic tests, also complete the HIV Form (Form 2048).

HTLV1 antibody: Human T-Lymphotropic virus I/II (HTLV I/II) is a retrovirus in the same class as HIV. HTLV I/II is associated with certain leukemias and lymphomas, as well as demyelinating diseases such as multiple sclerosis.

Anti-EBV (Epstein-Barr virus antibody): Epstein-Barr Virus (EBV) is a common virus of the herpes family. It can cause infectious mononucleosis, but in most cases is asymptomatic. EBV establishes a lifelong dormant infection in some cells of the body’s immune system. Serious post-transplant

complications related to EBV include EBV viremia (reactivation) and post-transplant lymphoproliferative disease (PTLD).

Hepatitis B surface antibody: Hepatitis B is caused by the hepatitis B virus (HBV). Infection with this virus can cause scarring of the liver, liver failure, liver cancer, and even death. Hepatitis B is spread through infected blood and other body fluids. Acute hepatitis B infection does not usually require treatment because most adults clear the infection. Treatment of chronic infection may be necessary to reduce the risk of cirrhosis and liver cancer.

The hepatitis B surface antibody test reveals the presence of hepatitis B antibodies, indicating previous exposure to HBV (or successful vaccination), but the virus is no longer present, and the person cannot pass on the virus.

A Hepatitis insert (Form 2047) is **not** required for a positive result.

Anti-HBc (hepatitis B core antibody): The enzyme-linked immunosorbent assay (ELISA) technique tests for the antibody directed against the hepatitis B virus core proteins. The hepatitis B core antibody test can indicate previous HBV infection. Currently there is no licensed confirmatory test for Anti-HBc. If the screening test is reactive, a second Anti-HBc test is performed using a different manufacturer's test kit.

If the result is "positive," a Hepatitis insert (Form 2047) is also required.

HBsAg (hepatitis B surface antigen): The ELISA or enzyme immunoassay (EIA) techniques test for the presence of proteins produced by the hepatitis B virus. Confirmatory testing is done using a neutralization test. The first marker appears approximately three weeks following infection, and disappears approximately six months later.

If the result is "positive," a Hepatitis insert (Form 2047) is also required.

Hepatitis B – NAAT: The HBV NAAT test is more sensitive than regular serologic tests and is often used in conjunction with those tests to monitor patients with chronic HBV infections. If Hepatitis B – NAAT testing was done, report the results in this section.

If the result is "positive," a Hepatitis insert (Form 2047) is also required.

Anti-HCV (hepatitis C antibody): Hepatitis C is a serious infection caused by the hepatitis C virus (HCV), which attacks the liver and may cause life-long infection. HCV is considered the most serious hepatitis infection because of its significant long-term health consequences. The infection is often asymptomatic, but once established, chronic infection can cause inflammation of the liver. This condition can progress to fibrosis and cirrhosis. In some cases, those with cirrhosis will go on to develop liver failure or liver cancer. Presence of the antibody in the blood represents exposure to HCV, which is most often spread by blood-to-blood contact. No vaccine against HCV is available.

The ELISA technique tests for antibodies to the HCV. Confirmatory testing is done using the

recombinant immunoblot assay (RIBA) test. These tests can determine past exposure to HCV, but not current viral load.

If the result is "positive," a Hepatitis insert (Form 2047) is also required.

Hepatitis C – NAAT: Nucleic acid testing (NAAT) is a combination PCR test that detects the presence of viral genes (HCV RNA) rather than antigens or antibodies. This test allows earlier detection and provides more sensitivity than previously used tests.

If the result is "positive," a Hepatitis insert (Form 2047) is also required.

HIV antibody: HIV infection is caused by exposure to one of two viruses: HIV-1 or HIV-2. HIV-2 is less virulent and has a longer incubation period than HIV-1. Both types of HIV progressively destroy lymphocytes, which are an important part of the body's immune defense. HIV can lead to acquired immunodeficiency syndrome (AIDS), a condition in which the immune system begins to fail, leading to life-threatening opportunistic infections. Infection with HIV occurs by the transfer of bodily fluids and is present as both free virus particles and virus within infected immune cells.

HIV antibody testing is done using combination ELISA which detects antibodies to the HIV-1 and HIV-2 viruses. HIV-1 is confirmed by Western Blot, which detects specific proteins using gel electrophoresis. There is currently no licensed confirmatory test for HIV-2. If the screening test is reactive, HIV-2 is confirmed by specific ELISA.

The results of HIV assessments are often kept in confidence and may not be reportable to anyone other than the patient and their physician. If HIV testing was done, but the results are not available, do not select this option.

If the result is "positive," an HIV insert (Form 2048) is also required.

HIV – NAAT: Nucleic acid testing (NAAT) is a PCR test that detects the presence of viral genes rather than antigens or antibodies. This test allows earlier detection and provides more sensitivity than previously used tests.

The results of HIV assessments are often kept in confidence and may not be reportable to anyone other than the patient and their physician. If HIV testing was done, but the results are not available, do not select this option.

If the result is "positive," an HIV insert (Form 2048) is also required.

Toxoplasmosis antibody: Toxoplasmosis is caused by the parasitic protozoan *Toxoplasma gondii*, or *T. gondii*. Toxoplasmosis is spread through ingestion of contaminated food or water or contact with infected cat feces. *T. gondii* infection is usually subclinical in healthy individuals, but infection can cause serious symptoms in pregnant women and immunocompromised individuals. Chronic, dormant *T. gondii* infection may follow initial exposure, and can then reoccur. Severe toxoplasmosis can affect the brain, eyes, and other organs and can cause permanent organ damage.

Testing for antibodies to *T. gondii* is generally done by enzyme-linked immunosorbent assay (ELISA) or chemiluminescent immunoassay (CIA). These immunoassays can be used to detect IgM and / or IgG antibodies to T. gondii. The presence of IgM antibodies indicates a recent or current infection, usually within the past four to six months. The presence of IgG antibodies indicates a previous infection and confers a long-term immune response to the virus. Results may be expressed as quantified antibody titer; in this case, the laboratory or test kit manufacturer will provide reference ranges to determine if the result is considered positive, indeterminate, or negative. Confirmatory testing is available to verify a positive serological result; this is done by Toxoplasma Serological Profile (TSP), which is a panel of multiple antibody ELISAs and agglutination testing.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Dec 22, 2020

Q39-85: Pre-HCT Preparative Regimen (Conditioning)

Question 39: Was a pre-HCT preparative regimen given?

Recipients are generally transplanted using a specific protocol that defines the radiation and / or systemic therapy the recipient is intended to receive in preparation for transplant. This protocol, which may be either a research protocol or standard of care protocol, should be referred to when completing this section.

However, there are instances when a preparative regimen may not be given. Examples may include, but are not limited to:

- Primary diagnosis of an immune deficiency.
- Subsequent allogeneic HCT due to loss of, or poor, neutrophil engraftment.

If a preparative regimen was given, select “yes” and continue with question 40. If a preparative regimen was not given, select “no” and continue with question 86.

Question 40: Specify protocol intent: (check only one)

Indicate whether “all agents given as outpatient,” “some, but not all, agents given as inpatient,” or “all agents given as inpatient.” Agents are defined as systemic therapy drugs or radiation therapy.

Question 41: Was irradiation performed as part of the pre-HCT preparative regimen?

If irradiation was performed as part of the preparative regimen, check “yes” and continue with question 42. If irradiation was not performed, check “no” and continue with question 58. Irradiation performed as previous treatment should not be reported in this section, but as previous treatment on the appropriate Disease Specific Form or in question 58, if applicable (radiation given within 21 days of the transplant).

Question 42: What was the radiation field?

Indicate if the recipient received irradiation to “total body,” “total body by intensity modulated radiation therapy (IMRT),” “total lymphoid or nodal regions,” or “thoracoabdominal region.” This information is often available on the radiation oncology summary.

If “total body by intensity modulated radiation therapy (IMRT)” is selected, continue with question 43. If not, continue with question 54.

Question 43: Average organ doses (completed only if organ has been contoured and planned as an avoidance organ)

Total marrow irradiation (TMI) is a more targeted form of TBI that became feasible with the introduction of IMRT (intensity modulated radiation therapy) technologies that allow for the delivery conformal dose distributions to the entire body. This method allows for reduction in radiation doses to organs and the

potential to escalate doses to target regions such as bone marrow better than standard TBI [1].

[1] Stein A, Palmer J, Tsai N-C, Al Malki MM, Aldoss I, Ali H, et al, Phase I trial of total marrow and lymphoid irradiation transplantation conditioning in patients with relapsed/refractory acute leukemia. Biology of Blood & Marrow Transplantation 2017;23:618-24.

Indicate if the average organ doses administered via IMRT are “known” or “unkown.” If “known” continue with questions 44-53, if “unknown” continue with question 54.

Questions 44-53: Average Organ Doses

Report the known average organ doses of IMRT for the organs listed in questions 44-53.

Question 54: Total dose: (dose per fraction X total number of fractions)

Enter the total dose of radiation given. If radiation was given as a single dose, the amount of radiation delivered in the single dose constitutes the total dose. If the radiation was given in fractionated doses, multiply the total number of fractions by the dose per fraction to determine the total dose. Enter the total dose of radiation in either grays (Gy) or centigrays (cGy).

Example:
Radiation Order: TBI, 200 cGy/day for three days (3 doses)
Total dose: 200 cGy x 3 doses = 600 cGy
Report “Total Dose” as: 600 cGy

Question 55: Date started:

Enter the date the single dose or first fraction of radiation was administered.

Question 56: Was the radiation fractionated?

Radiation is either delivered as a single dose or in several treatments (fractions). Radiation is fractionated to increase the destruction of diseased cells as they do not recover as quickly as disease-free cells.

If the radiation was fractionated, check “yes” and continue with question 57. If the radiation was not fractionated, check “no” and continue with question 58.

Question 57: Total number of fractions:

Enter the total number of fractions (treatments) of radiation that were administered. The recipient may receive more than one fraction per day (hyperfractionation).

The total number of fractions multiplied by the dose per fraction must be equal to the total dose reported in question 54.

Question 58: Was additional radiation given to other sites within 21 days of the HCT?

Additional Radiation
Additional radiation start dates may be prior to the HCT event. If additional radiation began more than 21 days prior to the HCT event, but at least one dose was received within 21 days prior to the HCT event, report the actual start date of the additional radiation in this section, even if the start date is more than 21 days prior to the start of the HCT event. Radiation treatments completed more than 21 days prior to the HCT event should be reported on the appropriate Disease Specific Form in the treatment section.

In this section, report any sites that received a “radiation boost.” Boosts are often given to smaller sites that may have residual malignant cells or to areas that were shielded (ex. chest wall or lung). Include any radiation boosts that were administered **within 21 days** prior to the HCT event.

Questions 59-75: Specify radiation field:

Indicate if the recipient received radiation to each site listed. For each site that received additional radiation, indicate the dose, units, and start date.

Questions 76-85, Reporting Multiple Drugs for Preparative Regimen
FormsNet3^{SM} application: Complete questions 76-85 for each drug given for the preparative regimen by adding an additional instance in the FormsNet3^{SM} application.
Paper form submission: Copy questions 76-85 and complete for each drug given for the preparative regimen.

Questions 76-78: Drugs (choose from list)

Preparative Regimen: Drugs
The following questions refer to the drug therapy that was actually given as part of the preparative regimen versus the prescribed drug therapy that was reported on the Pre-TED. In this section, include any intrathecal drugs the recipient received for prophylaxis or treatment of CNS disease within 21 days prior to the start date of the preparative regimen. Do **not** include drugs that are intended to offset the side effects of the systemic therapy (e.g., corticosteroids for nausea, MESNA for hemorrhagic cystitis, etc.).

Occasionally, protocols list drugs that may be given before and after day 0. If the drugs are given before and after day 0, **only the doses given before day 0 should be quantified in the preparative regimen section**. The doses given *after day 0* should be reported on the Post-HCT Disease Specific form (if applicable on that form) or GVHD Prophylaxis section of the 100 Day Post-HCT Data Form (Form 2100). For example, if bortezomib or rituximab is given on Days -2, +1, +4, and +7, report the day -2 dose in the preparative regimen section, and the post-transplant doses as planned post-HCT therapy on the disease insert.

Drugs during the Peri-Transplant Period
ATG, alemtuzumab (Campath), defibrotide, KGF, and ursodiol may be given during the peri-transplant period. Previously, if these drugs were administered prior to Day 0, they were reported in the preparative regimen section of the Baseline (2000) Form. However, the Baseline (2000) Form has been updated – if these drugs were administered prior to Day 0, report them in questions 86-103, not in questions 76-78.

Select the drugs given as part of the preparative regimen. Report the total dose of each drug that was actually given. Do not report the prescribed dose or the daily dose. The pharmacy record or Medication Administration Record (MAR) should be used for determining the exact total dose given.

Some drugs used as part of the preparative regimen are administered with guidance of serum pharmacokinetic testing to determine the recipient's metabolism of the drug. This allows for individual "customization" of the drug dosing to optimize the desired effect and minimize the toxicity. Depending upon when the drug used to monitor drug levels is administered, it can be reported in one of two different ways on the CIBMTR Pre-TED (2400) and Baseline (2000) forms.

A common example of this situation occurs in the use of busulfan. In some cases, a "test dose" of the drug is given before the actual preparative regimen is started, and this dose is used for acquiring drug levels that are used to adjust the dose that will be used in the preparative regimen. In other situations, the first dose of the drug is given in the usual fashion as part of the preparative regimen. After this first dose, serum drug levels are drawn and sent to a reference lab. The drug is continued at the starting dose until the lab results are reported and adjustment is made to later doses.

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 with a "test dose" before beginning the preparative regimen or using the first dose of the preparative regimen. The reporting of the dosing for the CIBMTR forms depends upon this distinction. This helps distinguish whether the dose is part of the therapeutic regimen, or not.

A test dose was given **> 24 hours** prior to the intended therapeutic dosing.
Example: A patient with AML underwent allogeneic HCT from a sibling; busulfan and cyclophosphamide were used as the preparative regimen. The patient presented to clinic 9 days before the HCT, where a dose of busulfan at 0.5 mg/kg was given intravenously. Blood samples were drawn for the next 6 hours, after which the patient left the clinic. His samples were sent to a lab, results were returned the next day, and an adjusted dose of busulfan was calculated. He returned to the hospital 6 days before HCT, and began to receive busulfan at the adjusted dose intravenously for 4 days, followed by cyclophosphamide, and proceeded to receive his cells. Since he received 0.5 mg/kg as a "test dose," this would not be reported in his total preparative regimen dose.

If a test dose was given, where the dose was distinct from the therapeutic dosing preparative regimen (often 1-2 or more days prior to the initiation of regular dosing), the following should be reported:

- 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.

The first dose of therapeutic dosing is used for monitoring.
Example: A patient with MDS received an allogeneic HCT from an unrelated donor; busulfan and fludarabine were used as the preparative regimen. She was admitted to the hospital 7 days before her HCT, and received a dose of busulfan at 0.8 mg/kg IV at 6:00 AM. Serum samples were drawn every 30 minutes until the next dose of Busulfan at 0.8 mg/kg IV was given at 12:00 noon. Her blood was sent to a reference lab, and she continued to receive busulfan every 6 hours. On day -6, the lab called with her drug levels, and it was determined that the current dose was correct. No adjustment was made, and she completed all 16 doses of busulfan. Since the dose of busulfan (0.8 mg/kg) that was used for drug testing was ALSO her first dose of the preparative regimen, it should be included in the amount of drug that was given for preparative regimen.

If the first dose of the preparative regimen was 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.

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.

Drug doses may be reported to the tenth decimal place. For paper submission, do not modify the number of boxes or include decimal values.

The “other drug” category should only be used if the drug is not one of the listed options. If more than one “other” drug is prescribed, list the generic name of the drugs in question 78 **and** attach a copy of the source document to the form in FormsNet3^{SM}.

Drugs given for prophylaxis of infection, GVHD, or organ toxicity should not be reported in this section. Report these drugs on the Post-HCT Follow-Up (2100) Form.

If the Baseline is completed for a subsequent HCT, do not report therapy that was given to treat the recipient’s disease (between the previous and current planned HCTs) in the preparative regimen section. Report this therapy on the appropriate Disease Specific Form.

Question 79: Date started

Enter the date when the first dose of the preparative regimen drug was administered. The pharmacy record or Medication Administration Record (MAR) should be used for determining the date the drug was started.

Question 80: Dosing weight

Report the recipient's dosing (adjusted) body weight calculated by the pharmacy / physician to determine the total dose of the drug given as part of the preparative regimen and specify the units of measurement. The dosing body weight is usually documented on the transplant preparative regimen chemotherapy orders.

Questions 81-82: Was the exposure of busulfan measured?

Indicate if the exposure of busulfan was measured. If "yes" report the overall exposure (with the appropriate unit of measure) in question 82. See below for an example on how to report the overall exposure. If "no" continue to question 83.

Example: A recipient received busulfan daily for four doses as part of the preparative regimen – the busulfan exposure was measured. The target AUC was 1000 – 1400 umol x min/L per dose. Pharmacokinetics were obtained after the first dose; the AUC was 900 umol x min/L. The busulfan dose was increased in order to meet a target AUC of 1200 umol x min/L. Pharmacokinetics were obtained again after the second dose; the AUC was 1200 umol x min/L. No additional adjustments were made to doses three and four. The overall busulfan exposure would be 900 + 1200 + 1200 + 1200 = 4500 AUC. The overall busulfan exposure should be reported as "4500 AUC (umol x min/L)."

Question 83-84: Was the busulfan dose adjusted based on pharmacokinetics?

Pharmacokinetic testing can be used to determine whether the drug concentration in the bloodstream is appropriate to the dose given. This reflects the speed of absorption and elimination of the drug. These tests are usually performed with a test dose prior to the preparative regimen, or performed after the first dose of systemic therapy, where multiple samples are drawn at specific time points following the first dose. The samples are sent to a laboratory that performs the testing to determine the drug concentration. Pharmacokinetic evaluation of busulfan dosing, as in the examples shown above, is common. If it is not known whether or not this testing was performed, consult with a transplant physician.

Indicate if the busulfan dose was adjusted based on pharmacokinetics. If "yes," specify how the dose was modified in question 84. If "no," continue with question 85.

Question 85: Specify administration (busulfan only)

Report the busulfan administration route as either "oral," "IV," or "both."

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Dec 22, 2020

Q86-103: Additional Drugs Given in the Peri-Transplant Period

Drugs may be given during the peri-transplant (before and after infusion) period to prevent transplant-related complications or facilitate engraftment.

Question 86: ALG, ALS, ATG, ATS

Anti-Lymphocyte Globulin (ALT), Anti-Lymphocyte Serum (ALS), Anti-Thymocyte Globulin (ATG), or Anti-Thymocyte Serum (ATS) are serum or gamma globulin preparations containing polyclonal immunoglobulins directed against lymphocytes. These drugs are usually prepared from animals immunized again human lymphocytes. Indicate “yes” or “no” if ALG, ALS, ATG, or ATS was administered during the peri-transplant period. If “yes,” continue with question 87. If “no,” continue with question 94.

Question 87: Total dose

Report the total dose actually given during the peri-transplant period (before and after infusion). Do not report the prescribed dose or the daily dose. The pharmacy record or Medication Administration Record (MAR) should be used for determining the exact total dose given.

Question 88-89: Absolute lymphocyte count (prior to first dose)

Indicate if the absolute lymphocyte count is “known” or “unknown” prior to the first administration dose of ALG, ALS, ATG, or ATS. If “known” report the absolute lymphocyte count and specify the units of measurement in question 89. If “unknown,” continue with question 90.

Question 90-91: Date first dose

Indicate if the date when the first dose of ALG, ALS, ATS, or ATS was administered is “known” or “unknown.” If “known,” report the date when the first dose was administered in question 91. If “unknown,” continue with question 92.

Question 92-93: Date last dose

Indicate if the date when the last dose of ALG, ALS, ATS, or ATS was administered is “known” or “unknown.” If “known,” report the date when the last dose was administered in question 93. If “unknown,” continue with question 94.

Question 94: Alemtuzumab (Campath)

Antibody preparations that are infused in the recipient. Indicate “yes” or “no” if alemtuzumab was administered during the peri-transplant period. If “yes,” continue with question 95. If “no,” continue with question 100.

Question 95: Total dose

Report the total dose actually given during the peri-transplant period (before and after infusion). Do not report the prescribed dose or the daily dose. The pharmacy record or Medication Administration Record (MAR) should be used for determining the exact total dose given.

Question 96-97: Date first dose

Indicate if the date when the first dose of alemtuzumab administered is “known” or “unknown.” If “known,” report the date when the first dose was administered in question 97. If “unknown,” continue with question 98.

Question 98-99: Date last dose

Indicate if the date when the last dose of alemtuzumab was administered is “known” or “unknown.” If “known,” report the date when the last dose was administered in question 99. If “unknown,” continue with question 100.

Question 100: Were clinically significant donor specific anti-HLA antibodies detected?

Indicate if clinically significant donor specific anti-HLA antibodies were detected. If “yes,” continue with question 101. If “no,” continue with question 104.

If testing for clinically significant donor specific anti-HLA antibodies was not performed, select “not done” and continue with question 104.

Questions 101-103: Was the recipient on a desensitization protocol?

Indicate “yes” or “no” if the recipient was on a desensitization protocol. If “yes,” check the method(s) of desensitization is question 102. If “other method” is selected, specify in question 103. If “no,” continue with question 104.

Section Updates:

Question Number	Date of Change	Add/ Remove/ Modify	Description	Reasoning (If applicable)
Q86	5/1/ 2023	Add	Instructions above Q86 updated to define peri-transplant period: *Drugs may be given during the peri-transplant (before and after infusion) period to prevent transplant-related complications or facilitate engraftment.*	Added for clarification
Q87	5/1/ 2023	Add	Instructions updated to define peri-transplant period: *Report the total dose actually given (color-red%during the peri-transplant period (before and after infusion). Do not report the prescribed dose or the daily dose. The pharmacy record or Medication*	Added for clarification

			Administration Record (MAR) should be used for determining the exact total dose given.	
Q95	5/1/ 2023	Add	Instructions updated to define peri-transplant period: *Report the total dose actually given during the peri-transplant period (before and after infusion). Do not report the prescribed dose or the daily dose. The pharmacy record or Medication Administration Record (MAR) should be used for determining the exact total dose given.*	Added for clarification

Last modified: May 01, 2023

Q104-117: Socioeconomic Information

Question 104: Is the recipient an adult (18 years of age of older) or emancipated minor?

Indicate if the recipient is 18 years of age or older, or if under 18, has been declared an emancipated minor by law. An emancipated minor is a child who has been granted the status of adulthood by a court order or other formal arrangement.

If “yes,” continue with question 105. If “no,” continue with question 106.

Question 105: Specify the recipient’s marital status:

Report the recipient’s marital status as of the date of HCT. If the recipient is in a same-sex partnership, but they are not legally married in their state, report “married or living with a partner.”

Questions 106-107: Specify the category which best describes the recipient’s current occupation: (if the recipient is not currently employed, check the box which best describes his/her last job.)

Report the recipient’s occupation category prior to illness.

If the recipient is unemployed, select the option that best describes his/her most recent job.

If the recipient is “under school age,” select this option, and continue with question 109.

The “other” category should only be used if the recipient’s occupation does not fit into one of the broad occupation categories listed. Please review the text associated with each answer to ensure that the occupation is being reported within the correct category. One common oversight is the reporting of “other” when the recipient’s occupation actually fits best in the “Professional, technical, or related occupation” category.

Question 108: What is the recipient’s most recent work status? (Within the last year)

> ✻ The question on the form currently refers to the recipient’s current or most recent work status with the last year; however, the intent of the question is to capture the recipient’s most recent work status prior to the start of the preparative regimen.

Report the recipient’s most recent work status within the last year. This refers to the employment status at the time in which they were no longer able to work due to the illness or due to preparation for their transplant. If the recipient is on medical leave other than medical disability (such as short-term or long-term medical leave), report their employment status prior to the start of their leave. If they are on medical disability, select “medical disability.”

Example 1: Patient was diagnosed with AML and had been working a full-time job. The patient was on a medical leave as the AML treatment prevented them from returning to work prior to the HCT. The

correct option to choose would be “Full time.”

Example 2: Patient was diagnosed with Multiple Myeloma and had been working a full-time job. Due to treatment related side effects, the patient had to reduce their hours and only work part-time. The correct option to choose would be “Part time, due to illness” & not “Full time”. Full time would not be chosen because the most recent status of their employment was part time. Full time would have been chosen had the recipient stopped working and was on a medical leave from their employer due to their illness.

Example 3: Patient was diagnosed with Non-Hodgkin’s Lymphoma and worked part time during her treatment. Following initial therapy, the recipient began working full time. After the recipient’s retirement, her annual scan showed relapse, treatment began again and the recipient proceeded to transplant. “Retired” would be reported on the form.

If the recipient’s occupation was reported as “student” in question 106, specify “full time,” “part time,” or “unknown” in question 108.

Question 109: What is the highest educational grade the recipient completed?

Report the recipient’s highest completed educational level as of the date of HCT. If the recipient is a student who is currently in the middle of a school year, indicate the previous education level completed.

Question 110: Is the recipient currently in school, or was enrolled prior to illness?

Indicate if the recipient is a current student, or was a student prior to illness.

Question 111: Is the recipient covered by health insurance?

Indicate if the recipient has health insurance.

If “yes,” continue with question 112. If “no,” continue with question 115.

Questions 112-114: Specify type of health insurance (check all that apply)

Report the recipient’s source of health insurance as of the date of HCT. If the recipient carries more than one source, check for all that apply. If the recipient has a government health insurance that is not listed, select “Other government program” and specify the government health insurance program in question 113. If the recipient has a health insurance that is not listed, select “Other health insurance coverage” and specify the health insurance in question 114.

! *Specify the recipient’s combined household gross annual income* is disabled. This question will be updated with the next revision of the Recipient Baseline (2000) Form.

Question 115: Specify the recipient's combined household gross annual income: (include earnings by all family members living in the household, before taxes.) (For U.S. residents only)

Indicate the sum of the before-tax annual incomes for all family members living in the recipient's household. If the recipient decides not to provide this information, select "recipient declines to provide this information." If annual income is only known for some of the income earners in the house or if it is not known what the household's gross annual income is, select "unknown."

Question 116: Number of people living in the household

Specify the total number of people who are living in the recipient's household. Include those who are both older and younger than the age of 18.

Question 117: Number of people living in the household under the age of 18

Specify the number of people who are under the age of 18 living in the recipient's household.

Section Updates:

Question Number	Date of Change	Add/ Remove/ Modify	Description	Reasoning (If applicable)
Q115	7/28/ 2023	Add	Red warning box added above Q115 to clarify question is now disabled: *Specify the recipient's combined household gross annual income is disabled. This question will be updated with the next revision of the Recipient Baseline (2000) Form.*	Due to Summer 2023 Quarterly Release

Last modified: Jul 31, 2023