DukeMedicine
Division of Cellular Therapy

ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Evaluation And Management of Patients Receiving Gene Therapy for Sickle Cell Disease

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APBMT-COMM-048
EVALUATION AND MANAGEMENT OF PATIENTS RECEIVING GENE THERAPY FOR SICKLE CELL DISEASE

1 PURPOSE

1.1 This document serves to outline the evaluation and management of patients with sickle cell disease (SCD presenting to the Adult and Pediatric Blood and Marrow Transplant (APBMT) Clinical Programs, (which includes cellular and gene therapy), for consideration of gene therapy from initial point of referral through post-gene therapy infusion management.

2 INTRODUCTION

2.1 Gene therapies are an available therapeutic option for patients with sickle cell disease with the goal of reduction in complications related to red blood cell sickling with improvement in quality of life with reduction in vaso-occlusive events (VOEs).

2.2 Current products that are FDA-approved for patients with SCD and utilized within our institution include:

2.2.1 Lyfgenia (lovotibeglogene autotemcel) is an autologous product that is FDA-approved for the treatment of patients 12 years and older with "sickle cell disease and a history of VOEs." This product works through the addition of a modified beta-globin gene that results in functional HbA, reduced HbS% and sickling of red blood cells. This product functions with the goal of reducing vaso-occlusive events (VOEs).

2.2.2 Casgevy (exagamglogene autotemcel) which is FDA-approved for the treatment of patients 12 years and older with "sickle cell disease and a history of recurrent VOEs." This autologous product works through the modification of a patient's CD34+ stem cells to reduce BCL11A expression, which ultimately increases HbF expression, reduces HbS% and sickling of red blood cells. This product functions with the goal of reducing VOEs.

3 SCOPE AND RESPONSIBILITIES

3.1 All providers caring for patients receiving gene therapy within the APBMT Clinical Program, which includes gene therapy, are responsible for the contents of this procedure.

4 DEFINITIONS/ACRONYMS

4.1 APBMT Adult and Pediatric Blood and Marrow Transplant

4.2 Acute pain crisis is defined as an acute pain event requiring an encounter with a medical facility for analgesic (opioids or IV NSAIDs) or PRBC transfusion

4.3 AML Acute myeloid leukemia

4.4 ANC Absolute neutrophil count

4.5 CBC Complete blood count

4.6 CVL Central venous line

4.7 Engraftment failure defined as failure to achieve three consecutive absolute neutrophil counts (ANC) ≥ 500 cells/microliter obtained on different days by Day 43 after infusion

4.8 GCSF Granulocyte colony stimulating factor

4.9 Hb Hemoglobin

4.10 HbA Hemoglobin A

4.11 HbF Hemoglobin F

4.12 HbS Hemoglobin S

4.13 HSCs Hematopoietic stem cells

4.14 HSCT Hematopoietic stem cell transplant

4.15 HU Hydroxyurea

4.16 MDS Myelodysplastic syndrome

4.17 MRI Magnetic resonance imaging

4.18 Neutropenia is defined as ANC < 500

4.19 PFTs Pulmonary function tests

4.20 PK Pharmacokinetics

4.21 PRBC Packed red blood cells

4.22 PTCT Pediatric transplant and cellular therapy

4.23 PTIS Pre-transplant immunosuppression

4.24 ROI Release of information

4.25 SCD Sickle cell disease

4.26 SOS Sinusoidal obstruction syndrome

4.27 TCD Transcranial doppler

4.28 VOD Venoocclusive disease

4.29 VOE Vaso-occlusive event

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 N/A

7 SAFETY

7.1 Gene therapy products may contain Black Box Warnings and other important safety considerations as outlined in the respective product prescribing information.

7.2 Prescribers will review all current product safety information prior to utilization.

7.3 All safety warnings will be explicitly reviewed with the patient and appropriate accompanying parties at the time of consent.

8 PROCEDURE

8.1 Patient Screening and Eligibility

8.1.1 Patients under consideration for gene therapy will be screened for eligibility and in comparison to other therapeutic options.

8.1.2 The applicable APBMT medical team will conduct a thorough review of the patient's sickle cell disease history, including but not limited to:

8.1.2.1 Diagnostic studies – newborn screen, genetic testing, hemoglobin electrophoresis

8.1.2.2 Family history of sickle cell disease or sickle cell trait carriers

8.1.2.3 Transfusion history

8.1.2.4 Prior and current medical management modalities

8.1.2.5 Review of previous transcranial doppler (TCD) evaluations, standardly completed through age 16

8.1.2.6 History of complications (including, but not limited to):

8.1.2.6.1 Number and frequency of VOEs

8.1.2.6.2 Hospitalizations

8.1.2.6.3 Acute chest syndrome

8.1.2.6.4 Priapism (lasting > 2 hours and requiring a visit to a medical facility)

8.1.2.6.5 Avascular necrosis

8.1.2.6.6 Stroke

8.1.2.6.7 Moya Moya

8.1.2.6.8 Cholecystectomy

8.1.2.6.9 Venous thromboembolism

8.1.2.6.10 Splenic sequestration or splenectomy

8.1.3 Patients will have an initial consult with the applicable APBMT team as part of gene therapy eligibility screening to review gene therapy process and myeloablative conditioning, available product comparison, risks and benefits of gene therapy.

8.1.3.1 All product-specific safety warnings will be explicitly reviewed with the patient and appropriate accompanying parties.

8.1.3.2 Infertility and potential preservation options will be reviewed as applicable.

8.1.3.3 Preliminary screening labs will be obtained at this point in time if the patient and/or consenting caregiver is interested in moving forward. Additional screening studies may be obtained at the discretion of the prescribing provider.

8.1.3.3.1 Infectious disease markers (as required per respective gene therapy product manufacturer guidelines).

8.1.3.3.2 Hemoglobin electrophoresis (if indicated)

8.1.3.3.3 Alpha thalassemia genetic testing when required, minimally in patients receiving Lyfgenia (lovotibeglogene autotemcel).

8.1.3.4 Preliminary psychosocial assessment will be completed by a member of the Social Work team.

8.1.4 Contraindications to Gene Therapy

8.1.4.1 Lyfgenia (lovotibeglogene autotemcel) ONLY:

8.1.4.1.1 two alpha thalassemia genetic mutations

8.1.4.2 Evidence of clonal hematopoiesis confirmed on bone marrow aspirate evaluation performed at Duke

8.1.4.3 Patient has an available and eligible matched, related HSCT donor

8.1.4.4 Positive history for overt ischemic or hemorrhagic stroke, Moya Moya, cerebral vasculopathy, or abnormal TCD

8.1.4.4.1 Subjects with radiologic evidence of silent infarction may still be eligible.

8.1.4.4.2 Patients with history of cerebral vasculopathy will be evaluated on a case-by-case basis at the discretion of the treating APBMT provider.

8.1.4.5 Infectious contraindications

8.1.4.5.1 Positive for virologic evidence of human immunodeficiency virus type 1 or 2 (HIV-1 or HIV-2), hepatitis B, hepatitis C, human T-lymphotropic virus-1 (HTLV-1), active syphilis.

8.1.4.5.2 Documented evidence of active, uncontrolled, bacterial, viral, fungal, or parasitic infection,

8.1.4.6 Presence of cirrhosis via MRI or liver biopsy

8.1.4.6.1 Liver iron concentration ≥15 mg/g unless liver biopsy shows no evidence of cirrhosis, active hepatitis or significant fibrosis,

8.1.4.7 History of prior gene therapy or HSCT

8.1.4.8 History of malignancy or clinically significant immunodeficiency

8.1.4.9 Any condition that would deem a recipient ineligible for an autologous HSCT

8.1.4.10 Evidence of a chromosomal or genetic predisposition to the development of MDS or AML, as per the treating provider's analysis

8.1.4.11 Evidence of a known or suspected Familial Cancer Syndrome

8.1.4.12 A patient that is breastfeeding, pregnant, or planning to become pregnant at any point from initial screening to at least 6 months post-gene therapy infusion

8.1.4.13 Inadequate bone marrow function, as defined by ANC of $<1\times10^9$/L ($<0.5\times10^9$/L for subjects on hydroxyurea treatment) or a platelet count $<100\times10^9$/L

8.1.4.14 Any contraindication to the use of Plerixafor

8.1.4.15 Any contraindication to the use of Busulfan

8.1.4.16 The need for therapeutic anticoagulation treatment during the period of conditioning through platelet engraftment

8.1.5 Potential patients will be evaluated to determine which therapy modality, either gene therapy or HSCT, would be considered based on the following baseline criteria:

8.1.5.1 Patients aged 12 years and younger

8.1.5.1.1 Evaluate for HSCT. Exclusion criteria to include evidence of severe end organ damage per program HSCT general eligibility criteria.

8.1.5.1.2 Donor priority:

(1) Matched Sibling Donor

(2) As defined by available well designed clinical trial.

(3) Haploidentical Familial Donor (with PTIS)

(4) Matched Unrelated Donor

8.1.5.2 Patients aged greater than or equal to 12 years

8.1.5.2.1 With SCD complicated by recurrent VOE, discuss gene therapy unless otherwise contraindicated based on criteria outlined above as well as consider HSCT as potentially curative therapy, if an appropriate donor is available.

8.1.5.2.2 With SCD complicated primarily by disease manifestations other than VOE (i.e. pulmonary hypertension, stroke), consider HSCT first line pending end organ evaluation and donor/recipient availability.

8.1.5.2.3 If patient has an available matched sibling donor, offer HSCT.

8.1.6 Following initial evaluation and preliminary screening, if a patient is deemed an eligible and appropriate candidate for gene therapy, they are presented to the Gene Therapy Review Committee, a multi-disciplinary group that includes representatives from both the adult and pediatric divisions of the APBMT Clinical Program.

8.1.6.1 Clearance by the Gene Therapy Review Committee will be obtained prior to proceeding with financial authorization.

8.1.7 Patient-specific considerations for gene therapy products

8.1.7.1 If medical management with hydroxyurea has failed to reduce number of VOEs (despite significant increase in fetal hemoglobin consider prioritizing Lyfgenia (lovotibeglogene autotemcel).

8.1.7.2 If medical management with hydroxyurea has shown some improvement with reduced number of VOEs, and/or patient cannot tolerate hydroxyurea due to adverse events, consider prioritizing Casgevy.

8.1.7.3 With presence of two alpha thalassemia genetic mutations, patient is ineligible to receive Lyfgenia (lovotibeglogene autotemcel).

8.1.7.4 Prioritization of respective products should include patient/family perceptions of risk/benefit profile and respective black box warnings.

8.2 Evaluation and Management Prior to Stem Cell Mobilization and Collection

8.2.1 Appropriate APBMT medical team to document medical clearance to proceed with gene therapy based on preliminary evaluation.

8.2.2 If the patient is not already cared for by a Duke Hematologist for SCD management, a referral will be placed to the appropriate Duke Sickle Cell team as part of comprehensive evaluation prior to gene therapy.

8.2.3 Patient and/or consenting caregiver to complete Release of Information (ROI) and pharmaceutical manufacturer consent form(s) prior to enrollment in respective manufacturer gene therapy portal, if applicable.

8.2.4 Patient is then entered into the respective gene therapy portal by nurse coordinator.

8.2.5 Collection dates for apheresis is based on availability in manufacturer portal, after patient and medical team discussion.

8.2.6 Coordination with necessary team members of APBMT apheresis team, STCL team, CHC team for pediatric patients, and any other appropriate party.

8.2.7 Apheresis procedure and consent teaching to be completed by nurse coordinator.

8.2.7.1 Patient and/or consenting caregiver to sign Duke combined pheresis/treatment consent per institutional standard.

8.2.8 Medication Management

8.2.8.1 SCD treatment medications as outlined in respective gene therapy product's prescribing information will be discontinued at least 60 days prior to the start of mobilization – i.e. hydroxyurea, Crizanlizumab, L-glutamine.

8.2.8.2 Erythropoietin will be discontinued at least 60 days prior to the start of mobilization.

8.2.8.3 Iron chelators will be discontinued at least 7 days prior to the start of mobilization.

8.2.9 Chronic Transfusions

8.2.9.1 With discontinuation of SCD medication management, patients will transition to a scheduled simple or exchange transfusion regimen for a minimum of 60 days prior to the start of mobilization.

8.2.9.2 Hemoglobin target prior to mobilization is 8-10g/dL, generally not to exceed 12.5g/dL.

8.2.9.3 The patient should receive simple or exchange transfusions for the appropriate duration to achieve a pre-transfusion HbS% target of < 20-30% to reduce the risk of SCD-related complications associated with mobilization.

8.2.9.4 Patients may receive chronic transfusions at referring institutions at the discretion of the treating APBMT provider with appropriate documentation.

8.2.10 Bone marrow evaluation

8.2.10.1 To be completed at Duke, following the first scheduled chronic transfusion, to evaluate for clonal hematopoiesis.

8.2.10.2 Standard studies to include (additional studies at the discretion of the treating provider):

8.2.10.2.1 Pathology

8.2.10.2.2 Chromosome analysis

8.2.10.2.3 FISH – MDS panel

8.2.10.2.4 Myeloid NGS panel

8.2.10.2.5 Flow cytometry leukemia/lymphoma analysis

8.3 Mobilization and Apheresis

8.3.1 Unless otherwise stated, patients managed by the pediatric services will have PTCT as the primary team from the time of mobilization and apheresis through post-gene therapy infusion.

8.3.2 Patients managed by the pediatric service may admit to the inpatient unit for pre-procedural hydration vs transfusion (whichever is indicated), CVL placement, mobilization, and stem cell collection for gene therapy product manufacturing.

8.3.3 Obtain Hemoglobin electrophoresis PRE to confirm HbS% < 20-300% prior to mobilization.

8.3.4 Prior to initiation of mobilization, patients must meet general eligibility criteria for autologous collection as defined in program SOP.

A pregnancy test is required and should be documented as negative using serologic or urinalysis is performed on females of childbearing ages within seven days of the initiation of mobilization.

Patient's IDM panel must be drawn and show no evidence of active infection within 30 days of the initiation of mobilization.

Confirm availability of appropriately cross-matched blood prior to initiation of mobilization.

8.3.5 Apheresis

8.3.5.1 Total target collections will include enough HSCs for both gene therapy product manufacture as well as cryopreservation of unmodified HSCs to store as autologous rescue if needed.

8.3.5.2 Obtain CBC with differential and peripheral CD34+ count prior to each day of collection.

8.3.5.3 Patients will standardly be mobilized with Plerixafor P prior to collection. Patients with SCD shall not receive GCSF for mobilization as this is medically contraindicated. Use of alternative mobilization agents such as motixafortide among patients who mobilize poorly may be considered on a case-by-case basis, after obtaining consent from the patient/family (if not previously obtained).

8.3.5.4 Documented platelet count will be $\geq 100 \times 10^9$ within 12 hours prior to the first apheresis procedure. Documented platelet counts will be $\geq 75 \times 10^9$ within 24 hours of subsequent apheresis sessions.

8.3.5.4.1 Patients may receive clinically appropriate transfusion support as needed.

8.4 Collection Targets

8.4.1 Lyfgenia (lovotibeglogene autotemcel)

8.4.1.1 Minimum total collection target is 16.5×10^6 CD34+ cells/kg

8.4.1.1.1 15.0 × 106 CD34+ cells/kg to be collected for manufacturing

8.4.1.1.2 1.5 × 106 CD34+ cells/kg to be collected for unmodified autologous rescue cells

8.4.2 Casgevy (exagamglogene autotemcel)

8.4.2.1 Minimum total collection target: 22.0×10^6 CD34+ cells/kg

8.4.2.1.1 20.0 x 106 CD34+ cells/kg to be collected for manufacturing

8.4.2.1.2 2.0 x 106 CD34+ cells/kg to be collected for unmodified autologous rescue cells

8.4.3 If additional mobilization and collection cycles are needed after the initial 3 days of apheresis, subsequent cycles must be separated by a minimum of 14 days.

8.5 Management after collection and while awaiting Gene Therapy Product Manufacture/Infusion

8.5.1 Patients may resume prior medication management for SCD OR continue with chronic transfusion therapy, at the discretion of the treating providers and anticipated time to cell manufacture.

8.5.1.1 HU can take 6 months to achieve peak effect, so if time to manufacture is less than 3 months, consider continuing chronic transfusion therapy instead of resuming.

8.5.1.2 HU can be resumed between collection and start of conditioning for gene therapy infusion, but must be

discontinued within the recommended time frame, as per the respective gene therapy product prescribing information.

8.5.1.3 Iron chelation may be restarted after completion of stem cell collection while awaiting product manufacturing, but must be stopped 7 days prior to start of conditioning.

8.5.1.4 Continue asplenia prophylaxis and other general sickle cell precautions/management as indicated, unless otherwise specifically prohibited.

8.5.2 Patients will undergo comprehensive autologous stem cell transplant evaluation – to be completed within 3 months of gene therapy admission. For additional details regarding donor evaluation see related SOP: APBMT-COMM-001 *Donor Selection, Evaluation and Management.*

8.5.2.1 Complete autologous stem cell donor evaluation in collaboration with the primary NC, APP, and attending physician as per applicable division procedure. (See PBMT-GEN-011 *NC Workup Checklist*).

8.5.2.2 PFTs will be repeated with development of any pulmonary complication (i.e. ACS or pneumonia) prior to initiation of conditioning chemotherapy.

8.5.2.3 The patient may proceed with gene therapy if oxygen saturation is ≥ 90% without supplemental oxygen (excluding periods of infection or SCD crisis), correct DLco ≥ 50% (absence of infection) or if not applicable due to age, patient must have a normal pulmonary exam and chest radiograph without infiltrates.

8.5.2.4 Infectious disease markers need to be collected within 30 days prior to initiation of conditioning.

8.5.2.5 Pregnancy test, as applicable, within 7 days of conditioning and mobilization.

8.6 Hospital Admission for Gene Therapy

8.6.1 Admission studies as per institutional practice for autologous stem cell recipients

8.6.2 Transfusion thresholds

8.6.2.1 Hb target prior to conditioning is 8-10 g/dL. Generally, NOT to exceed 12g/dL

8.6.2.2 Platelet transfusion threshold of at least 50K per SCD standard of care

8.7 Conditioning Regimen

8.7.1 All patients will receive myeloablative conditioning regimen with Busulfan.

8.7.2 Conditioning may not be initiated until gene therapy product has been received and stored at the treatment center, with confirmed availability of adequate dose of unmodified autologous rescue cells and confirmed availability of appropriately cross-matched blood.

8.7.3 Busulfan Dosing and Pharmacokinetics

8.7.3.1 Standard initial Busulfan dose of 3.2mg/kg/day will be administered as a 3-hour intravenous infusion daily for 4 days with subsequent dose adjustments as needed based on PK levels as per institutional standard.

8.7.3.2 PK monitoring will be obtained as per institutional standard, at minimum coinciding with the first administered dose of Busulfan.

8.7.3.3 Target AUC range: 4200 to 5500 μM*min

8.7.3.3.1 **Note:** A target AUC may be more narrow and/or fall out of this reference range in certain patient or product specific scenarios and should be taken into consideration at time of interpretation.

8.7.3.4 There must be 48 hours of rest post-Busulfan.

8.7.3.5 A final Busulfan PK level will be obtained 48 hours after completion of final Busulfan dose for retrospective confirmation of adequate washout.

8.7.3.6 Pediatric teams may refer to related SOP for additional details for Busulfan administration. (See PBMT-GEN-018 *Administration of High Dose Chemotherapy – Busulfan).*

8.7.4 Seizure Prophylaxis

8.7.4.1 All patients will receive seizure prophylaxis with first-line agent of levetiracetam starting at least 12 hours prior to the first dose of busulfan.

8.7.4.2 Seizure prophylaxis will continue at a minimum through 24 hours post-completion of the final dose of Busulfan. Extension of prophylaxis based on unique patient risk factors at the discretion of the treating provider.

8.7.4.3 Alternative anti-seizure medications may be used as clinically indicated EXCEPT phenytoin, which is contraindicated due to its induction of cytochrome P-450 and resultant increased clearance of busulfan.

8.8 Gene Therapy Product Infusion

8.8.1 Minimum post-manufacturing cell dose

8.8.1.1 Lyfgenia (lovotibeglogene autotemcel): 3.0×10^6 CD34+ cells/kg

8.8.1.2 Casgevy (exagamglogene autotemcel): 3 x 10^6 CD34+ cells/kg

8.8.2 Gene Therapy Product Administration

8.8.2.1 Standard pre-medications will be administered 30-60 minutes prior to start of infusion.

8.8.2.2 Nursing will notify appropriate provider at the start of gene therapy product infusion(s).

8.8.2.3 Standard emergency medications will be available at the bedside for the entire duration of the infusion(s).

8.8.2.4 Do NOT use an in-line blood filter or an infusion pump.

8.8.2.5 Lyfgenia (lovotibeglogene autotemcel) considerations:

8.8.2.5.1 Will arrive in one to four infusion bags.

8.8.2.5.2 Administer cells within 4 hours after thawing.

8.8.2.5.3 Administer each infusion bag via intravenous infusion over a period of less than 30 minutes.

8.8.2.5.4 If more than one infusion bag is required, administer the contents of each infusion bag completely before proceeding to thaw and infuse the contents of the next infusion bag.

8.8.2.5.5 After administration of each drug product, infusion bag and any associated tubing are flushed with at least 50mL normal saline to ensure as many cells as possible are infused into the patient.

8.8.2.6 Casgevy (exagamglogene autotemcel) considerations

8.8.2.6.1 Time to infuse per vial must be completed within 20 minutes from product thaw as per prescribing information.

8.8.2.6.2 The total volume administered within one hour must not exceed 2.6 mL/kg.

8.9 Supportive Care Management

8.9.1 Management of expected side effects as per institutional standard (including, but not limited to): chemotherapy-induced nausea and vomiting, neutropenia-associated infection prophylaxis, anorexia and malnutrition, mucositis pain, chemotherapy-induced pancytopenia.

8.9.2 Infection prophylaxis and surveillance as per applicable division policy. (see related SOP: PBMT-GEN-073 *Infection Prevention and Surveillance*).

8.9.3 Special considerations

8.9.3.1 GCSF will not be used for patients with sickle cell disease.

8.9.4 Transfusion thresholds following infusion of gene therapy product – return to standard of care for sickle cell disease.

8.9.5 VOD/SOS Prophylaxis

8.9.5.1 Refer to separate procedure for full details: (see APBMT-COMM-015 *Veno-Occlusive Disease (VOD)/Sinusoidal Obstruction Syndrome (SOS) Prophylaxis, Diagnosis and Treatment*).

8.9.5.2 Hepatotoxic medications should be avoided and/or used in caution due to risk of VOD/SOS. Provider should take into account associated risk when utilizing Parenteral Nutrition and/or avoid use when possible.

8.9.5.3 Patients will receive prophylaxis with ursodiol starting on admission through hospital discharge.

8.9.5.4 Early initiation of defibrotide therapy with concern for VOD.

8.9.6 Fever management as per applicable APBMT medical team policy. (See related SOP: PBMT-GEN-025 *Evaluation and Therapy of Neutropenic Fever).*

8.9.7 Indications for autologous stem cell rescue as per respective gene therapy product prescribing information.

8.10 Hospital or Outpatient Day Hospital Discharge Criteria

8.10.1 Patients will be monitored in the in the inpatient or outpatient day hospital setting at a minimum through neutrophil engraftment (ANC $\geq$ 0.5 x10^9/L for 3 consecutive days post infusion nadir) and complete transfusion independence.

8.11 Long-Term Monitoring

8.11.1 Hemoglobin electrophoresis within 30 days post-gene therapy infusion, then monthly through first 100 days.

8.11.2 Immune reconstitution panel at Day 45-60 and Day 90-100.

8.11.3 Patient will return to referring Hematology team for primary management at approximately 60-100 days post-gene therapy infusion, or when it is deemed medically appropriate by the Applicable APBMT team.

8.11.4 Post-gene therapy immunization recommendations per applicable division policy (See PBMT-GEN-070 *Pediatric Post Transplant Vaccination Schedule*).

8.11.5 Avoid the use of non-myelosuppressive iron chelators for at least 3 months and use of myelosuppressive iron chelators for at least 6 months after CASGEVY (exagamglogene autotemcel) infusion (consider phlebotomy if needed).

8.11.6 Obtain CBC with differential at minimum of 6 months and 12 months post-gene therapy, followed by annual evaluation for at least 15 years to monitor for development of hematologic malignancy.

8.12 Monitoring Endpoints for Clinical Function:

8.12.1 Endpoints are established and monitored as outlined in APBMT-COMM-027 *Adult and Pediatric Blood and Marrow Transplant Program Quality Management Plan.*

9 RELATED DOCUMENTS/FORMS

9.1 APBMT-COMM-001 Donor Selection, Evaluation and Management.

9.2 APBMT-COMM-027 Adult and Pediatric Blood and Marrow Transplant Program Quality Management Plan

9.3 APBMT-COMM-015 Veno-Occlusive Disease (VOD)/Sinusoidal Obstruction Syndrome (SOS) Prophylaxis, Diagnosis and Treatment

9.4 PBMT-GEN-011 NC Workup Checklist

9.5 PBMT-GEN-018 Administration of High Dose Chemotherapy – Busulfan

9.6 PBMT-GEN-025 Evaluation and Therapy of Neutropenic Fever

9.7 PBMT-GEN-073 Infection Prevention and Surveillance

9.8 PBMT-GEN-070 Pediatric Post Transplant Vaccination Schedule

9.9 Febrile Neutropenia in Patients with Cancer - Empiric Antibacterial therapy | Duke CustomID

9.10 Adult Stem Cell Transplantation Infection Prophylaxis and Vaccination Guidelines | Duke CustomID

10 REFERENCES

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11 REVISION HISTORY

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