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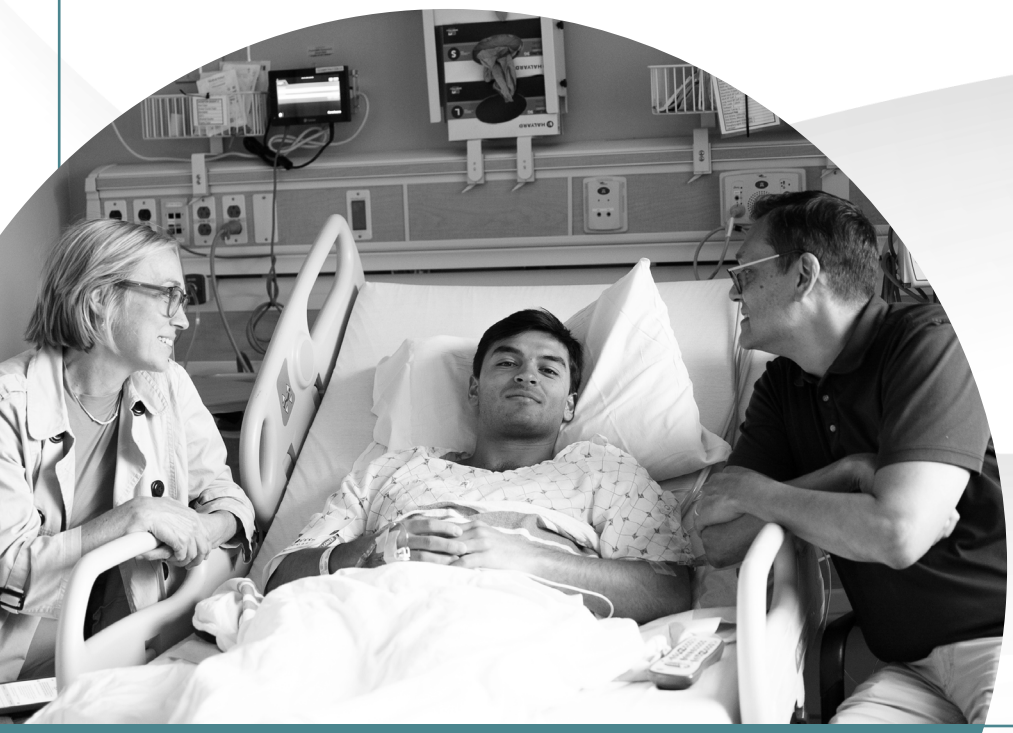
ASTCT AND NMDP℠ HEMATOPOIETIC CELL TRANSPLANTATION (HCT)

Coverage & Reimbursement Guide



Shay, blood stem cell donor. Image courtesy of NMDP.

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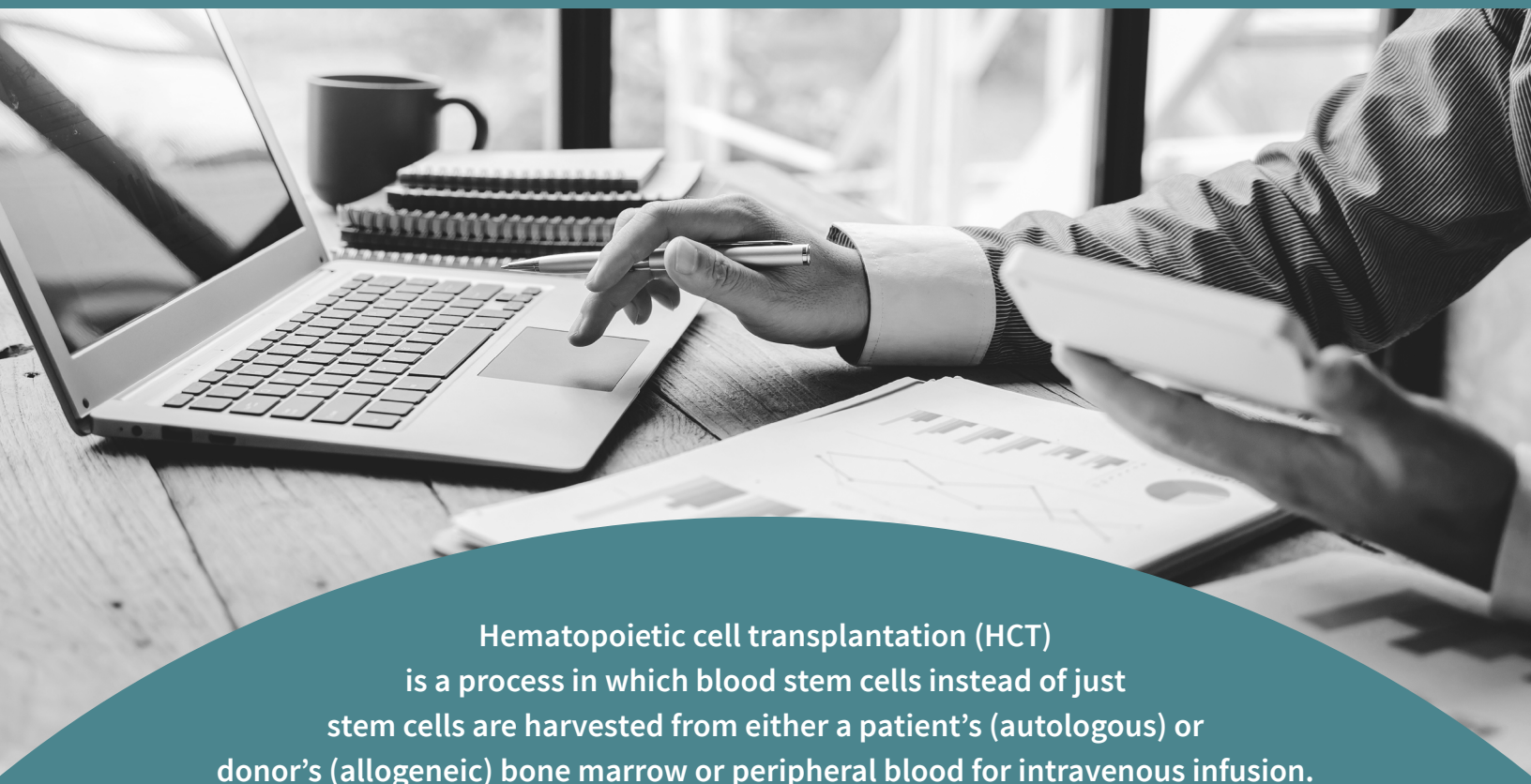

Hematopoietic cell transplantation (HCT) is a process in which blood stem cells instead of just stem cells are harvested from either a patient's (autologous) or donor's (allogeneic) bone marrow or peripheral blood for intravenous infusion.

Topics covered in this guide include a quick overview of insurance types, benefit screening, contracting, authorization workflows, and the registration and billing processes involved when an HCT case is opened. This guide is not intended to capture all payer-specific authorization requirements.

Coverage and Reimbursement Guide Authors

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I. INSURANCE TYPES AND BENEFITS

Confirming and understanding the insurance type of each patient and the benefits associated with the insurance type is key to understanding coverage, coding and billing of HCT services.

Types of Insurance:

COMMERCIAL

- Employer group health plans (EGHP)
- Individual policies
  - Affordable Care Act Exchange
  - Off-Exchange

MEDICARE FEE FOR SERVICE

- **Part A** – Hospital inpatient. Part A deductible may be applied
- **Part B** – Hospital outpatient and physician services
- **Part D** – Prescription drugs

MEDICARE ADVANTAGE (PART C)

- Patient assigns Medicare A&B benefits to a commercial insurance plan
- May be HMO, PPO or no network

MEDICARE SUPPLEMENT (MEDI-GAP)

- Coordinates with Medicare A&B benefits. Helps pay for remaining 20% of covered charges

MEDICAID

- Direct coverage under state program
- Managed Medicaid – State assigns coverage to a commercial payer

GOVERNMENT OTHER:

- Veteran's Affairs (VA) – Former military with service-related disabilities
- TriCare – Uniformed service members, retirees and their families

Commercial Insurance Benefit Screening

The first step in obtaining authorization for HCT usually starts with benefit screening to verify the following patient benefits under the specific health plan:

- Contract (Does the transplant center (TC) have a general contract in place with the health plan?)
- Transplant benefit (Does the patient have transplant benefits under the health plan?)
- Co-pay
- Co-insurance
- Deductible
- Out-of-Pocket (OOP) Maximum
- Out-of-Network Benefits
- Donor Search and Procurement Coverage
- Prescription Coverage

When verifying the above benefits, check for any restrictions. Some plans may present as PPO and appear in-network to the TC, but are in fact a type of Fixed Benefit Plan with fixed benefit rates for services. These types of plans are non-Affordable Care Act (ACA) compliant because they do not cover all the essential health benefits required under the ACA. Even if the PPO discounts are applicable, the caps on payment amount for services will mean the patient has to pick up the remaining balance (balance billing) which could be significant.

> **"OPENING A CASE TOO EARLY MAY LEAD TO DENIALS WHEN THE TEAM IS UNABLE TO PROVIDE THE CLINICAL PACKET REQUIRED BY THE HEALTH PLAN IN ORDER TO REVIEW THE CASE."**

SCREENING FOR TRANSPLANT BENEFITS

When to do a full benefit screen varies from center to center. Some TCs may opt to perform only screening for general medical insurance prior to the new patient visit to simply determine if the TC is in-network or out-of-network (OON) to the health plan. After the new patient visit, the TC staff may then perform a more in-depth benefit screen focusing on transplant benefits. Other TCs may perform a comprehensive benefit screen upfront before the new patient visit.

DOES A CASE HAVE TO BE OPENED PRIOR TO THE NEW PATIENT VISIT?

Some TCs may wait to open the transplant case until after the new patient visit has concluded, when the transplant timeline is known. Opening a case too early may lead to denials when the team is unable to provide the clinical packet required by the health plan in order to review the case.

Medicare Benefit Screening

The coverage & reimbursement process includes terms that might not be familiar to TCs. Below is a list of common terms from Centers for Medicaid & Medicare Services (CMS) that will be helpful to know when working through this process.

- **National Coverage Determinations (NCD)** – This is the published coverage determinations from the CMS that confirm coverage and non-coverage for specific treatments. The current HCT NCD is 110.23.
- **Local Coverage Determination (LCD)** – If there is no NCD for a specific treatment, a Medicare Administrative Contractor (MAC) can issue an LCD to provide coverage guidance. The LCD is only applicable in the region(s) covered by the specific MAC.
- **Coverage with Evidence Development (CED)** – In cases where Medicare may be unclear on whether to issue an NCD for a treatment due to lack of clinical information, they may issue a CED to allow for coverage if or when a Medicare recipient enrolls in a specified clinical trial. There is currently a CED for allogeneic HCT for patients with myelofibrosis, multiple myeloma or sickle cell disease.
- **No existing coverage determination (No NCD or LCD)** – When there is no applicable NCD or LCD available, such as the case for allogeneic HCT for non-Hodgkin lymphoma, the MAC will determine on a case-by-case basis if a particular service is covered. Some MACs will not provide prior review or approval for a service and will only review after a treatment is performed and a claim submitted. In those cases, the patient and/or the provider may have significant financial risk, and a Medicare Advance Beneficiary Notice (ABN) may need to be signed by the patient.
- **Medicare as Secondary Payer (MSP)** – CMS has specific rules to determine the primary payer for patients with both Medicare and a commercial insurance. The Medicare Secondary Payer Questionnaire (MSPQ) provides guidance for which plan is primary. NOTE: Special rules apply to patients who qualify for Medicare due to End Stage Renal Disease (ESRD).

II. CONTRACTING

Center of Excellence Network Processes

Many commercial insurance companies have developed Centers of Excellence (COE) for HCT. In addition, there are third-party administrators that have COE networks that other insurance plans can pay to access.

A COE network is typically narrow and TCs must meet quality and sometimes cost requirements to participate in the network. Many COE contracts use a case rate structure where financial risk is shared between the health plan and the transplant provider.

EXAMPLES:

Aetna – National Medical Excellence (NME) network

Blue Cross and/or Blue Shield – Blue Distinction Centers for Transplant (BDCT). Each state has their own Blue Cross, Blue Shield, or Blue Cross/Blue Shield companies, and the state plans may also access the BDCT network. In addition, the Blue Card system allows patients with out-of-state plans to access in-network benefits at participating out-of-state facilities. It is important to verify whether a particular out-of-state plan will access BDCT or Blue Card for transplant claims.

Cigna – LifeSOURCE Transplant Network. Two tiers: Designated and Supplemental. Some policies may only cover treatment at the Designated network level.

Optum – Owned by United Healthcare (UHC), the Transplant Centers of Excellence network is accessed by most UHC plans, as well as third-party payers and self-funded plans.

Image courtesy of NMDP.

WHAT IF YOUR CENTER IS OUT-OF-NETWORK (OON)?

Establish a process on how to handle OON cases, including differentiating OON status for medical management vs transplant benefits.

A TC is in-network with a health plan if there is a contractual agreement between the TC and the health plan regarding the payment rates for services. It is important for each TC to establish a process to address referrals for which the TC is OON with the patient's health plan. It is not uncommon for a patient to be OON under the medical benefits portion of the health plan but may be in-network for transplant or vice versa. The initial review of benefits should include transplant benefits, co-pays, co-insurance, deductible and out-of-pocket maximum, and whether the patient has OON benefits. However, even if a patient has OON benefits, it is important to note that the patient may not want to utilize OON benefits to avoid paying higher co-pays and co-insurance.

SHOULD THE CENTER OBTAIN A GAP EXCEPTION OR SINGLE CASE AGREEMENT?

This is particularly important when there are gaps in coverage, such as when there are no other TCs that can provide the transplant care in a patient's particular area. The gap exception, when approved, will allow the patient to receive a specific service or procedure under in-network rates. This may be followed by a single case agreement between the TC and the health plan establishing the payment terms. A single case agreement establishes a contractual agreement between the TC and the health plan for a specific patient and only that patient, to protect the patient from high financial liability while being treated at an OON facility. It is important for TCs to discuss these nuances with intake or access teams to ensure that a thorough review of a particular case has been completed before choosing to refer a patient to another facility due to OON status.

III. AUTHORIZATION WORKFLOW

Initiating authorization begins by submission of a formal request to open the transplant case. This typically requires, at a minimum, a letter of medical necessity indicating the type of service being requested (autologous or allogeneic HCT), a copy of the most recent progress note, and a request to perform pre-transplant workup to determine a patient's candidacy for transplant. If allogeneic HCT is being requested, this may also include a request to initiate donor search. Each TC may have their own way of opening a case, either by calling the transplant case manager (if known) for a specific health plan, by faxing the request, or by submitting the request through online portals (e.g., Availity). Review the health plan's process for initiating an authorization to determine their preferred method.

Commonly Used CPT Codes for Transplant

The below list is meant to provide the most commonly used procedural codes requested for transplant.

TYPE OF TRANSPLANT:

- Autologous HCT (38241)
- Allogeneic HCT (38240)

COLLECTION:

- Autologous PBSC Collection (38206)
- Allogeneic Donor PBSC Collection (38205)
- Allogeneic Donor Bone Marrow Harvest (38230) (may be performed in OR under anesthesia)
- NMDP Donor Search (38204)

CELL PROCESSING:

- Cryopreservation of the HPC Cells (38207)
- Thawing of Previously Cryopreserved HPC Cells without wash (38208), with wash (38209)
- T-cell depletion (38210)
- Red cell removal (38212)
- Plasma depletion (38214)
- Cell Concentration of Mononuclear Cell (38215)

Related Donor HLA Typing

Recipient HLA typing is generally covered under medical benefits. Related donor HLA typing, however, may require pre-authorization. Some of the CPT codes used to request HLA typing may include, but are not limited to, the following CPT codes: 81370, 81373, 81376, 81378, and 81382 depending on the level of HLA resolution required by the TC.

Unrelated Donor Search Authorization

Once recipient HLA typing is available, donor search coordinators may begin a preliminary search of the national donor registry, the NMDP Registry℠ for unrelated donors and cords. Unrelated donor in this guide refers to matched or mismatched unrelated donors (MUDs or MMUDs), or cord blood units. This preliminary search process can be done while typing potential related donors. Performing a preliminary search is free. Coupled with the related donor typing, a preliminary search of the national donor registry helps to provide a comprehensive view of all potential donor options so that future formal donor search and selection can be optimized. Some TCs may have algorithms which provide guidance on when to activate a formal search of the registry. A formal search includes requesting a healthy adult volunteer through NMDP to come forward as a potential donor.

This process includes the donor providing a blood sample for confirmatory HLA typing. In the case of cords, formal search means requesting confirmatory HLA typing to be performed on an attached segment of the cord blood unit. Formal search comes with a standard fee for the blood sample and the fee depends on the location of the donor (domestic or international).

How soon to activate the formal unrelated donor search depends upon a number of things, such as the recipient having older siblings, having no or only one sibling, or having siblings who live internationally. More often than not, the urgency of the transplant timeline may also dictate an earlier formal search to be conducted. Some TCs may wait 1 to 2 weeks to complete related donor typing before initiating the formal search for unrelated donors.

Some health plans may request copies of donor typing as part of the clinical packet. TCs should follow their own institutional guidelines on how to safely share information about donors while maintaining donor confidentiality.

Some plans may not cover a donor search at all. This is particularly true of some state Medicaid plans. NMDP offers financial assistance programs for eligible patients to help offset out-of-pocket costs of typing and transplant. Patient and financial navigators can also help navigate costs and other barriers.

NMDP also offers NMDP HLA Today, a free HLA typing service for newly diagnosed patients and their family members. Intended for use at hematology/oncology practices, HLA Today helps strengthen referral networks and streamline access to transplant.

Transplant Procedure Authorization

Depending on the health plan, obtaining the transplant global authorization may require a stepwise approach. A health plan may require authorization to conduct pre-transplant evaluation first before providing the global transplant authorization.

To request approval to perform pre-transplant evaluation, the TC may submit the following CPT codes: 99205, 99215, 99244. It is important to clarify with the health plan if the codes encompass all of the pre-transplant testing procedures or if individual codes will need to be submitted. Once approved by the health plan, the TC should follow their own institutional protocol for what tests to perform as part of the pre-transplant evaluation. HMO plans may require individual procedure and lab codes to be submitted for approval.

Common Tests/Procedures Requested for Insurance Approval

STANDARD:

- Physician letter of medical necessity indicating the type of procedure (auto or allo) being requested
- Most recent History and Physical (H&P) or progress note describing the treatment plan
- Pathology report (for disease identification)
- Restaging (current disease assessment and response to treatment)
- Cardiac testing (echo or MUGA, EKG)
- Pulmonary Function Test
- Chest X-ray
- Standard labs: CBC with differential and Chemistry Panel, Infectious Disease Markers (IDM)
- Psycho-social evaluation
- Some TCs may also perform chest CT and sinus CT for allogeneic candidates, if applicable

ADDITIONAL TESTS THAT MAY BE REQUIRED:

- TB screening (e.g., quantiferon gold test)
- Dental clearance
- Colonoscopy, fecal occult blood test (FOBT) or Cologuard
- Pap Smear
- Mammogram
- Prostate-Specific Antigen (PSA) test
- Toxicology screening/ETOH assessment

IV. REGISTRATION AND BILLING PROCESSES

Institutional guidelines for recipient and donor registration vary depending on the TC's electronic medical record (EMR) system used and the teams involved in the registration process.

Recipient Registration

It is important to note during registration if the recipient's health plan will access a transplant contract. The Epic EMR system allows for the use of unique Guarantor types such as a "Case Rate or Transplant Guarantor" to facilitate the following: a) alert the transplant billing team that HCT case rate will apply, b) link a recipient to their donors as the Guarantor (financially responsible party), c) attach the recipient's insurance to donor claims. Setting up the correct transplant plan code also allows the financial specialists to enter a specific claim submission address if different from address used for general services. Registration steps may be different depending on the type of electronic medical record used.

Related Donor Registration

Related, potential allogeneic HCT donors must be registered in a TC's EMR in a way that keeps their medical information separate from the recipient, as well as secure and HIPAA-compliant. While related donors may have their own personal insurance information entered usually under a Personal/Family Guarantor account type, use of the Transplant Guarantor account type as available in Epic EMR facilitates linking any potential donor to the recipient so that transplant-related donor claims are billed to the recipient's insurance. This allows donor claims to be processed with the donor named as the patient, identified by a donor ICD-10 code (Z52.001 or Z52.011), and be sent to the recipient's insurance company as either an individual claim or as part of a transplant case billing package.

A Transplant FYI Billing Flag can be used to note the recipient's name and medical record number for which the donor is being considered, and FYI flag rules with hard stops can be implemented to prevent the use of the donor's own Personal/Family Guarantor. This can prevent the billing of donor services to the donor's own personal insurance.

Transplant programs should work closely with their IT teams to develop and understand the system's capabilities to link potential related donors to recipients. It should be noted that CMS requires actual donor service charges to be reported; centers should not create an "average" search/acquisition charge as they do for solid organ transplantation.

Medicare Cost Report

Medicare requires that applicable donor search and acquisition charges be held until transplantation and submitted under revenue code 0815 on the transplant claim. These charges are excluded from the DRG payment calculation but are used to help determine interim payments for acquisition cost recovery. Applicable donor search and acquisition charges are reported on the Medicare Cost Report for donor acquisition. This includes NMDP costs excluding DLI, and donor coordinator time and effort spent searching for and identifying donors.

> **"FINANCIAL TEAMS INVOLVED IN THE SPECIALTY BILLING PROCESSES FOR HCT CASES IDEALLY SHOULD HAVE A COPY OR A SUMMARY OF THE TRANSPLANT CONTRACTS."**

Commercial Insurance HCT Case Rate Billing

Commercial insurance carriers often have their own preferred structure for HCT case rate billing, so it is important to understand your TC's various contracts. While some payers would like to see any HCT-related services included in a contract, it may be difficult to include early services such as an initial consultation/evaluation. These services may take place months prior to the start of actual transplant treatment, and holding claims for a significant time period can have a negative effect on a TC's accounts receivable balance. In addition, some diagnostic testing may be performed by a patient's local or referring physician, especially if patients live far away from the TC. These tests may also be part of standard disease tracking, making it difficult to determine if diagnostic services are truly "transplant-related."

Autologous HCT Case Rate contracts often include apheresis (PBSC collection), the transplant preparative regimen, transplant infusion, and a set follow-up period. Mobilization, the process of stimulating stem cells out of the bone marrow and into the bloodstream, may also be included in the HCT case rate, but if a patient is mobilized by self-injected granulocyte colony-stimulating factor (G-CSF) alone, it can be difficult to identify the mobilization start date in the EMR. In addition, if the TC does not have the ability to dispense G-CSF as a prescription medication, it may be difficult to include that within a case rate billing package.

HOW DO YOU IDENTIFY THE EFFECTIVE START DATE WHEN USING G-CSF OR BIOSIMILARS AND PLERIXAFOR (MOZOBIL) FOR MOBILIZATION?

Since growth factors may be prescribed to be dispensed at an outside pharmacy for home self-injection, some TCs may use the day Plerixafor (Mozobil) was administered as the start date of mobilization.

Allogeneic HCT Case Rate contracts usually include the transplant preparative regimen, the transplant infusion and a set follow-up period. Donor services may or may not be included; in some cases, related donor services performed at the TC are included but purchased services (NMDP or other donor registry charges) may be passed through outside of a case rate billing package.

IS YOUR CENTER CAPTURING THE APPROPRIATE RELATED DONOR SERVICES SUCH AS DONOR EVALUATION AND WORKUP?

Preparative or conditioning regimen is typically considered the chemotherapy and/or radiation therapy immediately preceding the stem cell infusion. If patients are admitted one day prior to the start of the preparative regimen, or a hydration day precedes the start of the regimen, both the TC and the health plan should have an agreement that clearly delineates whether this day is included or carved out from the case rate billing. The contract may stipulate that the case period begins at the start of preparative regimen or at the time of inpatient admission, whichever comes first; however, this can cause issues for patients that have been in-house for non-transplant care and then start their HCT treatment during the same admission.

HOW MUCH POST-TRANSPLANT FOLLOW-UP CARE SHOULD BE INCLUDED IN A TRANSPLANT CASE PERIOD?

If patients come from outside the local geographic or catchment area for the TC, one may look at the length of time that the TC requires these patients to stay locally, and use that as a guide for the case period follow-up length. Once patients return to their home, they typically receive most of their monitoring locally.

It is important for specialty billing teams to understand the full continuum of care for an autologous or allogeneic transplant patient. This requires a solid understanding of the clinical processes, such as mobilization and apheresis procedures, the preparative regimens used, and the actual infusion to be able to determine the global period effective and end dates. A standing meeting between the financial and clinical teams may help to clarify some of the processes, to ensure that specific procedures and services are appropriately captured as part of the global case rate. As a case in point, it will be helpful to clarify to the billing team that patients receiving total body irradiation (TBI) will have a consultation and simulation visit with the radiation oncology team but that this simulation visit does not constitute the start of the radiation treatment as usually defined in the global period.

HOW CAN BILLING TEAMS IDENTIFY CASE RATE INCLUSION/EXCLUSION OF SERVICES?

Financial teams involved in the specialty billing processes for HCT cases ideally should have a copy or a summary of the transplant contracts from the TC's Managed Care or team responsible for executing transplant contracts with payers. The contract or summary will ideally provide the working definition of the phases of care, the global case rate, stoploss and outlier provisions, per diem case rate above a certain threshold, and the length of time in each phase of care.

SHOULD THE CENTRAL LINE PLACEMENT PROCEDURE BE INCLUDED IN THE HCT CASE RATE?

A central line may need to be placed a day prior to or on the first day of collection. It is important for TCs to review the transplant contract to determine if the placement of a central line is included in the mobilization or collection phase to be reimbursed under the transplant contract.

Billing for Clinical Trial Cases

It is important to identify which group will be responsible for obtaining authorization for HCT patients participating in clinical trials, as TCs may have a clinical trial team that is distinct or separate from the larger transplant operations depending on the structure of the organization. The person obtaining the authorization should verify if the patient's health plan has a specific plan exclusion such as clinical trial participation, as coverage for most clinical trials involving HCT requires prior authorization. Additionally, TCs are encouraged to work closely with clinical trial teams responsible for reviewing the protocol schema. Reviewers assigned to review the protocol's Schedule of Assessments should be familiar with the HCT process and the existing global HCT contracts within the organization to properly distinguish labs and procedures as either billable to insurance payers (standard of care) or to trial sponsors (research-related). TCs are encouraged to set up a mechanism to review and drop specific charges to a research guarantor account when applicable, ideally before the global billing package is submitted to the health plan.

Noah, blood stem cell donor. Image courtesy of NMDP.