

Transplant Center Billing and Reporting for Allogeneic HCT: Frequently Asked Questions

Below are some common questions we’ve received from transplant centers.

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Contents

A. Types of services and items that can be charged as donor search and cell acquisition.....	1
B. Billing for donor search and cell acquisition.....	2
C. Hospital cost reporting and tracking of donor search and cell acquisition services.....	7
D. Coverage of allogeneic hematopoietic stem cell transplant (alloHCT)	10
E. Medicare Advantage (MA) payers and alloHCT.....	12
F. Miscellaneous HCT Topics	13

A. Types of services and items that can be charged as donor search and cell acquisition

1. What services are included as part of donor search and cell acquisition charges for allogeneic hematopoietic stem cell transplants (alloHCT) for Medicare beneficiaries?

Donor search and cell acquisition charges for Medicare beneficiaries are defined at 42 CFR 412.113(e) and include the following:

- Registry fees from a national donor registry described in 42 U.S.C. 274k, if applicable, for stem cells from an unrelated donor.
- Tissue typing of donor.
- Tissue typing of recipient (this is the only recipient service included in the definition of donor search and cell acquisition).
- Donor evaluation.
- Physician pre-admission/pre-procedure donor evaluation services.
- Costs associated with the collection procedure (for example, general routine and special care services, procedure/operating room and other ancillary services, apheresis services), and transportation costs of stem cells if the recipient hospital incurred or paid such costs.
- Post-operative/post-procedure evaluation of donor.
- Preparation and processing of stem cells derived from bone marrow, peripheral blood stem cells, or cord blood (but not including embryonic stem cells).

This includes services to evaluate donors that are then ruled out and services (e.g., cell collection, cell processing, medical evaluation, etc.) for the selected donor whose cells are collected and processed for the recipient’s transplant.

2. Are donor selection fees a covered benefit for the recipient?

Yes, the cost of finding a donor or a potential donor is a covered benefit for the recipient. See Medicare Claims Processing Manual Chapter 3, Section 90.3.1 and Chapter 4, Section 231.11.

3. Is the transplant recipient’s evaluation services included in the definition of donor search and cell acquisition services under Medicare Fee for Service (FFS)?

No, under Medicare Fee-For-Service (FFS), the recipient's evaluation service(s) are not included in the definition of donor search and cell acquisition. Since the recipient is the patient, all services for the recipient are considered patient benefits, and should be charged and billed to Medicare as they occur, with the exception of HLA typing of the recipient, which is included in the definition of donor search and cell acquisition as defined in 42 CFR 412.113, and is eligible for cost reimbursement. Therefore, the HLA typing of the recipient, but not other evaluation services for the recipient, is reported along with all other services for donors.

4. Do donor selection fees include professional fees (e.g., physician time reviewing human leukocyte antigen typing of potential donors)?

There are two options for receiving payment for professional fees to evaluate donors. One option is to bill the services as they occur under the recipient's name and Medicare beneficiary number for Medicare physician fee schedule (MPFS) payment. See Chapter 3 of the Medicare Claims Processing Manual, Section 90.3.B.I.a. which states: “[E]xpenses incurred by a donor are a covered benefit to the recipient/beneficiary but, except for physician services, were not paid separately.” [emphasis added] The “except for physician services were not paid separately” language means that physician services are allowed to be paid separately, but are only covered when billed on the recipient's claim. This is why the claim must be billed under the recipient's name and policy number.

The second option is to report the professional Part B physician expense as allowable cost for cost-reimbursement as stated in 42 CFR 412.113. Since separate professional fee billing occurred prior to passage of Section 108, and since many privileged professionals are not contracted or employed, many transplant centers continue to bill professional fees separately.

5. If a Transplant Center collects allogeneic hematopoietic stem cells for use by other transplant centers in alloHCT, are those costs eligible for Medicare reimbursement?

No, the transplant center collecting cells for intended recipients at other transplant centers is not eligible for cost-based reimbursement, since it did not use the cells for a recipient at its center. Rather, reimbursement should be made by whatever entity arranges for and orders the collection and has contracted for this service to occur, such as the other transplant center or NMDP. Hospitals have accounting rules to offset their expense by these type of payments.

B. Billing for donor search and cell acquisition

1. When should Transplant Centers bill for donor search and cell acquisition for allogeneic stem cell transplants where the patient is a Medicare beneficiary?

For Medicare beneficiaries, a Center must hold all donor search and cell acquisition charges (that is, do not bill these charges) until the recipient's transplant occurs (regardless of when that occurs). This means transplant centers may be holding charges for several weeks or months. These held charges are then billed on the transplant claim.

2. How are donor search and cell acquisition charges for stem cell transplants for Medicare beneficiaries supposed to be reported?

For Medicare beneficiaries, all donor search and cell acquisition charges that have been held must be reported on the transplant recipient's claim under revenue code 0815 using the transplant date as the date of service for donor charges. See Medicare Claims Processing Manual Chapter 3, Section 90.3.1 and Chapter 4, Section 231.1

For non-Medicare payers, follow each payers' billing instructions. If the non-Medicare payer accepts separate outpatient claims for donor services, the National Uniform Billing

Committee (NUBC) defined condition code 88 is to be used on these claims since the name on the claim and the insurance is the recipient's.

3. What codes should a Transplant Center report on the bill for donor search and cell acquisition services?

For reporting donor search and cell acquisition services on claims, there are different types of codes that convey related information.

An important code is revenue code 0815, which must be reported on the claim for all payers for stem cell transplant acquisition services, per National Uniform Billing Committee (NUBC) requirements, with the charges for donor search and cell acquisition services (see Medicare Claims Processing Manual Chapter 3, Section 90.3.1 and Chapter 4, Section 231.11).

The reporting of the CPT codes for procedures associated with the donor search and cell acquisition services, along with a condition code, is dependent on the recipient's payer type, and whether the transplant is provided to an outpatient or inpatient. See details in the table below.

CPT Coding	Medicare (and also payers following Medicare)	Commercial payers that allow real-time billing of related donor services
Outpatient transplant	You must report individual CPT codes for each test for each potential donor as separate line items on the recipient claim.	If a commercial payer accepts claims for NMDP services (under the recipient's name) prior to the transplant (e.g., histocompatibility testing), you must report the CPT code for each test following NUBC requirements. Also report condition code 88 (allogeneic HCT related donor charges).
Inpatient transplant	You should not report CPT codes; report the sum of all donor service charges on the transplant recipient's claim with revenue code 0815 and using the transplant procedure date as the date of service.	If a commercial payer accepts outpatient claims for the NMDP services (under the recipient's name) prior to the transplant (e.g., histocompatibility testing), you must report the CPT code for each test following NUBC requirements. If the donor service is inpatient, do not report CPT codes. Also report condition code 88 (allogeneic HCT related donor charges) on claims with donor charges.

Reporting value codes (on the recipient's transplant claim) is optional but encouraged, to ensure complete information and accurate reporting:

Value code 88: the number of related donors evaluated (zero for no related donors).

Value code 89: the total charge amount for both related and unrelated donor services, including charges submitted on separate claims.

4. Should a Transplant Center use revenue code 0815 for medical supplies used during cell acquisition (instead of revenue code 270)?

Yes, bill supplies related to cell collection services that meet donor search and cell acquisition eligibility on the recipient's account under revenue code 0815. See Medicare Claims Processing Manual Chapter 3, Section 90.3.1 and Chapter 4, Section 231.11.

5. Both CMS and NUBC instructions specify stem cell donor costs are to be reported with revenue code 0815. For all of the potential services a donor might receive (i.e., labs, EKG, etc.) are the individual CPT codes for these services to be reported with revenue 0815, or just one single CPT/HCPCS code with the costs summed together? Or, are the costs just submitted on the recipient claim with revenue code 0815 and all CPT/HCPCS codes suppressed?

The National Uniform Billing Committee (NUBC) has defined revenue code 0815 charges for HCT donor services reported on institutional claims. This is the case whether the charges will be billed on the recipient's transplant claim (as Medicare and other payers may require), or on separate claims, as some certain non-Medicare payers may require. When reported on inpatient claims, no CPT/HCPCS are included on inpatient claims pursuant to Health Insurance Portability and Accountability Act (HIPAA) requirements.

If the recipient is a non-governmental/commercial insurance patient and the payer allows real-time billing of related donor services, then NUBC manual for institutional claims has a "Y" in the HCPCS field meaning HCPCS codes on the 013x claim are required and yes, the revenue code is 0815. A center should check with their commercial payers on this matter, as they may require CPT/HCPCS codes for the different donor services or allow summation of all the charges and the reporting of a single CPT code, such as 38204. Condition code 88 should also be reported. The name on the claim is the recipient and the insurance is the recipient's insurance.

Note that when the payer requests a separate outpatient claim for donor services, do not add these donor services to a recipient's outpatient claim as this may result in inappropriate edits and condition code 88 can only be used if the entire claim is solely for stem cell donor services.

6. Why can't donor services be billed under the donor's name to the donor's insurance?

The reason the donor is not billed under their name or insurance is that the services are not medically necessary for the donor – hence, the services are not covered by donor insurance unless it explicitly has a benefit for this such as an altruism benefit to encourage donation. But for all governmental and most non-governmental insurances, a basic tenet for coverage is that the services be medically necessary for the member or that the services be a specific benefit like preventive services.

Medicare's citations come from Chapter 3, of Medicare's online manual 100-04, section 90.3, B, I, a, which states, "*Expenses incurred by a donor are a covered benefit to the recipient/beneficiary...*"

Also, Chapter 4 of the Medicare online manual 100-04, section 231.11 states, "*The Medicare contractor does not make separate payment for these [allogeneic donor] acquisition services, because hospitals may bill and receive payment only for services provided to the Medicare beneficiary who is the recipient of the stem cell transplant and whose illness is being treated with the stem cell transplant.*"

7. Should a Transplant Center bill donor-related professional fees separately?

For non-Medicare, the fees are reported on separate claims under the recipient's name and insurer but may be included in submission of all claims encompassed by a global case rate. This means the professional claims are printed and included in a packet with hospital claims for payment which is sent to the payer.

For Medicare, CMS provides two options: (1) bill professional services under the recipient's name and to Medicare real-time via the professional claim to the MAC or (2) the professional has an arrangement (i.e., a contract) with the transplant center for payment of the professional fees and the transplant center submits this cost on the cost report for reimbursement. Also see FAQ #5 Section A.

8. How should a Transplant Center bill donor visits to the transplant patient's insurance on Form CMS-1500?

Report physician and other non-physician practitioner services under the recipient's name and insurance, using the appropriate CPT, place of service, and other codes, following National Uniform Claim Committee (NUCC) reporting rules. Medicare guidance from Chapter 3, Medicare online manual 100-04, Section 90.1 - General (Rev. 486, Issued: 03-04-05, Effective Date/Implementation Date: N/A) Allogeneic Stem Cell Transplantation states:

“Allogeneic stem cell transplantation is a procedure in which a portion of a healthy donor's stem cells is obtained and prepared for intravenous infusion to restore normal hematopoietic function in recipients having an inherited or acquired hematopoietic deficiency or defect. Expenses incurred by a donor are a covered benefit to the recipient/beneficiary but, except for physician services, are not paid separately. Services to the donor include physician services, hospital care in connection with screening the stem cell and ordinary follow-up care.”

9. How should a Transplant Center bill the patient's insurance for multiple potential stem cell donors that NMDP tested?

The center will receive invoices from NMDP that include the costs of screening each potential donor. The hospital establishes charges for NMDP services based on the costs. The hospital is to bill the charges associated with evaluating all potential donors under the recipient's name and insurance. For Medicare, these charges are held and reported on the transplant recipient's claim. For commercial payers, each payer will have instructions about how to report. Charges to evaluate potential donors should be covered the same as charges for the matched donor – this is part of the donor search and once a match is made, then cell acquisition or collection occurs.

10. Which CPT procedure codes should a Transplant Center use to bill for NMDP services for Medicare beneficiaries?

Whether or not the transplant center lists CPT procedure codes on the bill depends on the patient status for Medicare beneficiaries:

- For outpatient Medicare transplant cases, use CPT code 38204 to bill and report NMDP services for donor search on the recipient's claim. For the collection of blood-derived hematopoietic progenitor cells (HPC), separately report CPT code 38205.
- Do not report CPT codes for inpatient Medicare transplant cases; rather, report the sum of all donor service charges on the transplant recipient's claim under revenue code 0815 using the date of the transplant procedure as the date of service for all donor charges.

See also FAQ #3 under this Section B.

11. What is the definition of CPT code 38204 and what can it be used to report?

The definition for CPT code 38204 is “*Management of recipient hematopoietic progenitor cell donor search and cell acquisition.*” The layman's description of this code is: The management of locating donor hematopoietic progenitor cells and the physical acquisition of the cells for the recipient's transplant. So, CPT code 38204 can be used to report any donor search such as a formal search fee or the management of searching for a matched related or unrelated donor and later the acquisition of the cells such as from NMDP.

12. Can a Transplant Center bill CPT code 38204 more than once per patient search for Medicare beneficiaries?

Yes, the definition of the 38204 CPT code is twofold, for the following:

- Management of recipient HPC donor search and
- Cell acquisition

Therefore, report the search for the recipient using CPT code 38204. Report cell acquisition from the matched donor using CPT code 38204 again. Revenue code 0815 should be reported and remember to sum all donor charges and report them with a single unit of 38204 as this is considered management of the donor search along with the collection/acquisition.

13. Why would a commercial payer not reimburse a Transplant Center for unrelated donor search and acquisition activity when billing with CPT code 38204?

Typically transplant centers either have a contract or enter into a single case agreement with a commercial payer, which specifies billing and payment information for donor costs, whether for related donor work-up or unrelated donor search. Most commercial payers with transplant networks have contracts that are episode-based with phases or zones. In this case, a center would submit the claims for donor charges as part of a packet with other recipient services with a cover letter pursuant to the correct phase.

The payer may not pay separately for the specific claim for the unrelated donor charges, but should include those charges in the payment for the phase. The correct CPT code is 38204, and should be accepted by a center's commercial payers, along with revenue code 0815.

14. Commercial payers have sometimes erroneously assumed that the use of CPT code 38204 multiple times for multiple donors represents duplicative services. How can a Transplant Center try to prevent this error?

For commercial payers that accept donor search and cell acquisition charges on separate outpatient claims, bill the recipient's insurance on the outpatient claim with the recipient's name using CPT code 38204 on a separate line for each potential donor, and list the date of service for each potential donor tested or submit a separate claim for each donor.

- Also use condition code 88 (allogeneic HCT related donor charges) on these claims.
- Do not mix donor services with recipient services as this may trigger inappropriate code and claim edits.

15. Are there separate CPT codes for cord search and acquisition charges by overseas cord blood facilities?

There is no unique CPT code for the search and acquisition of international cord blood. The CPT code for the search and for the cell acquisition for allogeneic stem cell transplants is 38204: management of recipient hematopoietic progenitor cell donor search and cell acquisition. For more information on 38204, see the latest publication of CPT codes from the American Medical Association (AMA), Current Procedural Terminology (CPT)®, Chicago (IL) at <https://www.ama-assn.org/amaone/cpt-current-procedural-terminology>.

16. Should a Transplant Center add a mark-up to the total invoice amount from NMDP?

The center should add a mark-up to the total invoice amount received from an entity that they have purchased a service from, such as NMDP, in accordance with the hospital's mark-up policy, and report that charge on the recipient's transplant claim using revenue code 0815. A best practice is to use the hospital's overall cost-to-charge ratio (CCR) as the basis of marking up purchased clinical services.

In the 2006 OPSS Final Rule (70 Federal Register 68654), CMS stated: "...*We believe that hospitals have the ability to set charges for items properly so that charges converted to costs can appropriately account fully for their acquisition and overhead costs....*"

CMS has reiterated this statement in the FY 2021 and FY 2022 IPPS final rules as well.

17. Using NMDP's crosswalk, how would a Transplant Center determine what CPT codes to use for infectious disease marker (IDM) testing services?

The transplant physician order and the performing lab's invoice should list the specific CPT code for each IDM test ordered. There would also be a venipuncture 36415 for a venous blood sample for testing. If the invoice does not list the CPT codes, the center can typically match the order by test name. The lab should be able to assist with this crosswalk. A best practice for purchased service contracts with labs and other entities, such as apheresis companies, is that the negotiated contract should list prices defined by CPT code for each service. The service definitions should be labeled with CPT codes to facilitate HIPAA-compliant billing of the hospital for the services.

18. What is the mechanism by which Medicare should be billed and made aware that patients participated in a CMS-approved study, including coverage with evidence development (CED) registries and studies?

Transplant Centers must follow the clinical trial billing requirements as outlined in the online [Medicare Claims Processing Manual Section 69](#). The document states, in summary, that all inpatient and outpatient hospital claims require the following when the claim is for a patient enrolled/under a CED study/registry:

- Condition Code 30
- Value Code D4 followed by the National Clinical Trial (NCT) number of the study/CED/registry
- Diagnosis code Z00.6

In addition, for outpatient claims, specific CPT codes require either modifier Q1 for routine services that are billed for payment for a patient in a study/CED/registry, or modifier Q0 for any investigational services/products/items covered and paid by the trial. Any CPT codes for investigational services/products/items covered by the trial would be reported with token charges because the transplant center should not incur cost.

19. What additional resources are available for HCT donor search and cell acquisition billing and tracking processes for government and commercial payers?

Please visit the [HCT Billing and Coding Resources webpage](#) on the ASTCT website for more resources.

C. Hospital cost reporting and tracking of donor search and cell acquisition services

1. Should our Medicare cost report include all allogeneic related and unrelated donor charges for all payers or just for Medicare beneficiaries?

Medicare cost reporting must include claims and expense data from all patients, not just Medicare beneficiaries. It is important to report all purchased donor services under cost center 77, for example, NMDP invoice cost and HLA typing invoice cost, and calculate related donor costs using worksheet D-6. This requires identifying all the donor charges on accounts with the charge description number of the department performing the services. The best practice is to report revenue code 0815 for donor services on the bills for all HCT recipients, regardless of payer type, so that costs for all patients are correctly included in the cost report to CMS.

2. Is Section 108 cost-based reimbursement for allogeneic HCT the same or similar to solid organ? Why or why not?

No, Medicare's Section 108 cost-based reimbursement for allogeneic hematopoietic stem cell transplant (alloHCT) is not the same as solid organ transplant, but it is similar in that there is a settlement process and that during the fiscal year, the transplant center receives bi-weekly interim payments based on an estimate of their cost which is later reconciled to the cost report at settlement.

Section 108 cost-based reimbursement differs in several important ways that transplant centers should know. First, there is no Organ Procurement Organization (OPO) involved, to whom acquisition costs are reported. Second, the transplant center is instructed to not develop a standard acquisition charge (SAC) for stem cell transplants. This is different from the instructions for solid organ transplants, where each type of organ would have a standard acquisition charge (SAC) developed. Rather, for alloHCTs, the transplant center must report actual charges for donor evaluations and cell collection/acquisition because each alloHCT is different.

With alloHCTs, there is a range of potential charges—for example, such as having charges for the evaluation of a single matched related donor to charges for several tried and non-matched related donors to a transplant with unrelated donor cells from international or cord blood, having significantly more donor costs. Reporting actual donor charges reflects this wide variation in donor costs. In the FY 2021 inpatient prospective payment system (IPPS) final rule at 85 FR 58837 CMS states: *“since we are not finalizing our proposal that hospitals bill a SAC, but instead are finalizing that hospitals must continue to bill their actual charges for Medicare allogeneic hematopoietic stem cell acquisition...”*

Many alloHCT costs are purchased clinical services by transplant centers including HLA typing, cell collection and cell acquisition from NMDP. Therefore, invoices are expected to underlie much of the expense and revenue reported in the standard allogeneic HCST cost center 77 for the Medicare cost report.

Additionally, if, in the Bone Marrow Transplant or Cell Therapy department, if there are any positions where the job description and duties mean those personnel are fully devoted to working on tasks related to donor search and acquisition, such as donor coordinators, then the salary and benefit expense is to be reported in cost center 77. For physician administrative and director, manager and other staff that work with both donors and recipients, the transplant center may request approval from their Medicare Administrative Contractor (MAC) to conduct time studies to be able to support additional staff expense associated with donor services.

3. How should a Transplant Center track their payments of fees to NMDP for its services to report to Medicare for cost-based reimbursement?

The best way to do this is to assign expenses associated with purchased donor services to a unique general ledger (GL) cost center and sub-account in the hospital’s chart of accounts and save the invoices in the clinical department and Accounts Payable files. Payments of fees to NMDP for all transplant patients are included in the cost report line 77 when it is completed after the end of each fiscal year.

4. For billing purposes, how can a Transplant Center track the non-standard (i.e., actual) donor charges for alloHCTs, which vary based on the services each patient receives?

It is important to note that the actual charges for the various services are the hospital’s standard charges from the chargemaster. What the reference to “non-standard” in this question (referring back to prior instructions from Medicare), is that the hospital should not average its standard charges into a single estimated amount for donor services: actual charges are required. In order to track actual charges which vary, it is recommended that the transplant center:

- Flag and hold HCT donor accounts.
- Use (or create) charges in the center’s chargemaster for all the different services a donor may receive, including, but not limited to:
 - The clinic visit for the evaluation.

- Ancillary lab and other tests to evaluate the donor.
- The NMDP search fee charge.
- The charge for the cells from NMDP.
- Charges for HLA typing applicable to the recipient and the donor.
- The HCT services that should have separate charges defined in the chargemaster are available at [42 CFR 412.113\(e\)](#), and are listed in Section A Question 1, in the FAQ above.

5. What should a provider do to report and track donor search and cell acquisition, if patients do not proceed to transplant?

If the commercial insurance allows payment for donor services per the contract or per network authorization, then outpatient claims under the recipient's name and insurance with donor charges reported under 0815 revenue code and individual CPT codes or 38204 per insurance instruction would be reported. Condition code 88 is also used on the claim to signal the claim is for HCT donor services billed under the recipient's name and insurance.

For Medicare, the charges cannot be billed, since there will be no recipient claim and therefore should be adjusted off (i.e., written off) the accounts receivable but must be able to be retrieved and used to complete the Medicare cost report. Medicare allows cost settlement to occur for costs incurred by the transplant center in cases when the transplant is cancelled.

To facilitate retrieval of donor charges where transplants are cancelled in the fiscal year to be reported in the cost report, a dedicated write off or adjustment code is recommended. Donor charges for cancelled transplants are to be added to related donor charges when calculating cost in worksheet D-6. See the Medicare online manual 100-04, Chapter 3, Section 90.3.1 and Chapter 4, section 231.11 where it states “[f]or allogeneic stem cell acquisition services in cases that do not result in transplant, due to death of the intended recipient or other causes, hospitals include the costs associated with the acquisition services on the Medicare cost report”.

Also, Transplant Centers should review the cost reporting instructions for worksheet D-6 (emphasis added): “*On the Worksheet D-6, the hospital reports the acquisition costs for allogeneic HSCT. The worksheet, effective from cost reporting periods beginning on or after October 1, 2020, calculates the inpatient routine, ancillary, and other costs associated with acquiring allogeneic hematopoietic stem cells for transplantation, including costs in cases that do not result in transplant due to death of the intended recipient or other causes, and reimbursed under reasonable costs as required under §1886(d)(5)(M) of the Act.*”

6. How are Transplant Centers determining the staff time devoted to donor services and cell acquisition for Medicare cost reporting purposes?

Some transplant centers obtain MAC approval to conduct time studies for reporting physician and staff time devoted to donor services. If not already in the hospital chart of accounts, transplant centers are establishing a dedicated cost center specific to donor search and cell acquisition costs. Staff in the bone marrow transplant department who work 100 percent on donor issues can have their salary and benefit expense reported in the cost center specific to donor services. For staff that split time between autologous and allogeneic donor and recipient services, they can complete time studies to allocate their expense between donor and non-donor work.

7. For Transplant Centers who pay for medical school for services provided, but the physicians do not bill for their services, should those centers conduct time studies of

physician time spent working with HCT transplant patients pre- and post-transplant, to include those expenses on the cost report?

There are two types of professional expenses: administrative expenses where professionals help manage the quality care of the program across all patients and patient-specific services. CMS refers to the former as Part A and the latter as Part B. For the hospital to claim any Part A professional expenses in the cost report, time studies are required. For professional services rendered to donors or Part B services, there are two options for HCT:

- Bill professional services under the recipient's name and to Medicare real-time via the professional claim to the MAC, or;
- The professional has an arrangement (i.e., a contract) with the transplant center for payment of the professional fees and the transplant center submits this cost on the cost report for reimbursement.

For more information, see the Medicare Claims Processing Manual, Chapter 3, Section 90.3.

D. Coverage of allogeneic hematopoietic stem cell transplant (alloHCT)

1. Does Medicare provide coverage based on the disease of the alloHCT recipient?

Coverage is always determined by the diagnosis or the disease of the recipient as documented by the treating clinician, and also by other criteria, such as failed prior conservative treatment for the diagnosis which leads to the medical necessity of the transplant. If a diagnosis is not specifically listed as covered or non-covered in the NCD or LCD, then the coverage determination is at the discretion of the center's A/B MAC.

For more information, please see NCD 110.23 at <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=366&ncdver=1&keywordtype=starts&keyword=stem%20cell&bc=0>.

For conditions covered by Medicare under Coverage with Evidence Development (CED), the patient will need to be enrolled in the clinical trial or study and have signed an appropriate consent in addition to meeting other study criteria for coverage.

2. When the transplant NCD is silent for a specific diagnosis or condition, is a Transplant Center still allowed to provide the care, and bill Medicare?

Yes. CMS' Claims Processing Manual, Publication 10-0-04 Chapter 32, Section 90.3 states, "*NOTE: Coverage for conditions other than those specifically designated as covered in 90.2 or 90.2.1 or specifically designated as non-covered in this section will be at the discretion of the individual A/B MAC.*"

This means that the transplant center would research whether their MAC has published any additional Local Coverage Determination (LCD) or guidance regarding transplant for the diagnosis/indication being considered. If no such documentation exists, the transplant center can conduct the transplant and bill. A paid or denied remittance from a MAC is also an initial coverage determination.

3. What are a Transplant Center's options if a claim is denied by their MAC for an indication for which the NCD is silent?

If a MAC denies a claim, the provider can appeal using the medical history of the patient, peer-reviewed journals regarding the efficacy of transplant for lymphoma and the language from of the NCD and associated coverage guidance in CMS' Claims Processing Manual, Chapter 32, Section 90.3 and other MAC Local Coverage Determinations (LCDs) showing coverage to appeal.

It is important to include clinical rationale such as peer-reviewed journals of the efficacy of transplant for the condition of the patient. If the MAC denies the appeal, it is strongly recommended that the provider take the case to the second appeal level with the Qualified Independent Contractor (QIC) and reference that other MACs have covered transplant for conditions not listed as covered or non-covered such as lymphoma as well as other payers.

4. What is the process for determining whether the regional MAC will cover HCT for lymphoma?

Medicare does not have a prior authorization program for most services. Rather, the process is to bill as usual after an HCT for lymphoma for a Medicare beneficiary. If the MAC denies coverage of the claim, the center may appeal using the coverage memo and other documentation for support. If the MAC then denies the appeal, the recommendation is to take the case to the second appeal level with the Qualified Independent Contractor (QIC).

While determining coverage in advance is not possible, one approach is for the treating physician to request a discussion with the MAC Medical Director.

5. Will Medicare cover a second transplant for a patient who had a transplant for acute myeloid leukemia (AML) who has relapsed with myelodysplastic syndrome (MDS)? Does the payer type for the first transplant affect Medicare coverage of the second transplant?

The NCD does not have a limitation to a single alloHCT. The payer type for the first transplant does not impact Medicare coverage of a second transplant. If the patient meets the NCD eligibility requirements for MDS, Medicare will cover the second transplant.

6. What is the process for determining whether Medicare/the regional MAC will cover a donor lymphocyte infusion (DLI)?

Medicare does not have a prior authorization program for most services. Rather, the process is to perform and bill the service. A DLI is defined by CPT code 38242; if the transplant was covered, then the DLI will be covered. Because of no prior authorization, the process is to perform the service and bill for the procedure, and appeal if the MAC denies coverage.

7. What code should be billed for the donor cell collection for a donor lymphocyte infusion (DLI)?

There is no CPT code for this type of cell collection, and CPT code 38205 is not appropriate to use, because the description of the code is for stem cell collection, and the cells collected for a DLI are not stem cells, but lymphocytes, and they are not being used for stem cell transplant. Therefore, the most appropriate CPT code to report is 38999, as “unlisted procedure, hemic or lymphatic system”.

The AMA’s instructions for the use of the CPT codes state: “Do not select a CPT code that merely approximates the service provided. If no such procedure or service exists, then report the service using the appropriate unlisted procedure or service code.”

8. Will Medicare still cover an alloHCT for Chronic Myelomonocytic Leukemia (CMML) not in remission under the CED?

CMML is included in the MDS CED decision memo that was released in March 2024. However, CMML is not covered in the final decision. Although, it is still possible to get coverage with approval from a local MAC at their discretion. Medicare’s CED coverage determination is based on the specific diagnosis codes listed in the Medicare coverage reference file applicable for the date of transplant. [CMML is listed in two of the three disease classification tables](#) in the background section of the coverage decision and is part of how CMS defines MDS.

9. Has CMS ended the CED for Myelodysplastic Syndromes (MDS)?

Yes, the CED is closed. CMS issued their final decision on March 6, 2024 with an implementation in October 2024. For more information, and to read the submitted public comments, see the tracking sheet for the NCA here: <https://www.cms.gov/medicare-coverage-database/view/ncacal-tracking-sheet.aspx?ncid=312&keyword=MDS&keywordType=starts&areaId=all&docType=NCA%2cCAL%2cNCD%2cMEDCAC%2cTA%2cMCD%2c6%2c3%2c5%2c1%2cF%2cP&contractOption=all&sortBy=relevance&bc=1>

E. Medicare Advantage (MA) payers and alloHCT

1. Is an MA Plan required to cover the same services as Medicare?

Yes, all MA plans must cover the same services that regular Medicare Part A and Part B cover. Coverage is different from payment/reimbursement, so it is very likely that the reimbursement amount will not be the same as for Medicare FFS. A review of the [CMS Medicare Managed Care manual](#) can provide further information on MA plans and Medicare FFS.

2. How does the implementation of Section 108, which provides cost reimbursement for donor search and cell acquisition costs (effective October 1, 2021) affect MA Plan reimbursement for alloHCT?

There are several scenarios involving MA plans that will have impacts on alloHCT reimbursement:

- When an MA enrollee receives an alloHCT claim from a non-contracted center, the MA plan must reimburse acquisition costs at the same amount established for Medicare FFS, less any cost sharing paid by the enrollee under the MA Plan.
- When an MA enrollee receives an HCT from a contracted provider, CMS does not set the payment amount. Rather, the MA plan and its contracted provider may negotiate payment arrangements for covered services.
- Currently, most MA contracts reimburse transplant centers based on MS-DRG 014 for Allogeneic Bone Marrow Transplant, which no longer includes payment for donor search and cell acquisition. Therefore, for MA contracts that solely base payment on MS-DRG 014, contact the MA Plan to determine whether they will re-negotiate or amend the contract. One method would be to negotiate for the MA Plan to pay a percentage of 0815 charges based on the CCR in the hospital's cost report.

3. Are the biweekly Medicare Periodic Interim Payments (PIP) made to Transplant Centers for donor search and cell acquisition costs only for Medicare FFS beneficiaries, or also the payments also made for MA plan members?

The biweekly PIPs are calculated solely based on Medicare FFS data for FFS beneficiaries, and are not calculated on MA plan data, or meant to reimburse for donor search and cell acquisition costs for MA plan members.

4. For a patient in a clinical trial who has an MA Plan, should a Transplant Center bill the Medicare Administrative Contractor (MAC) or the MA plan for an alloHCT case, and do these billing requirements apply to clinical trials in all states?

Because alloHCT is covered under a Medicare National Coverage Determination (NCD) requiring Coverage with Evidence Development (CED), Transplant Centers with this situation should bill alloHCT claims to the MA Plan. See [Section 10.7 of Chapter 4 of the Medicare Managed Care internet only manual](#) concerning clinical trials. The trial must

meet the NCD coverage requirements for HCT. These requirements are national Medicare instructions, [applicable to all MA Plans and all transplant centers](#). MA Plans are responsible for payment of items and services in CMS-approved CED studies unless CMS determines that the significant cost threshold is exceeded for that item or service See 42CFR 422.109 The approved studies are listed on [CMS' CED website](#).

If the clinical trial meets both the Medicare clinical trial policy requirements and is also not a trial approved under Coverage with Evidence Development (CED), a Transplant Center would bill the MAC/Medicare FFS. In this case, the MA plan has the option to pay the difference in out-of-pocket routine costs. See the [Routine Costs in Clinical Trials webpage](#) on the CMS.gov website for more information.

5. How does a Transplant Center submit a request for authorization for transplant under a Coverage with Evidence (CED) study? What if it is a patient enrolled with an MA plan?

Medicare does not have prior authorization for most services, and there is not prior authorization in place for CED studies or other clinical trials. CMS publishes [billing guidelines](#) regarding the submission of claims for routine costs under qualifying clinical trials.

For MA patients, per CMS policy in section 10.7.3, MA plans are required to match the coverage that is offered through Medicare's CEDs; however, it is not unheard of for an MA plan say that it will not authorize an alloHCT for a patient with an indication that is covered under a CED, because it wants the patient to enroll in FFS Medicare. If the patient qualifies for a CED and the MA plan will not authorize the alloHCT, the provider can make a complaint about the MA plan to the CMS regional office, who is required to ensure MA plans follow CMS rules. For additional information, see: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>.

F. Miscellaneous HCT Topics

1. Should a Transplant Center bill for an allogeneic CD34+ stem cell boost as a repeat allogeneic transplant?

No, an HPC boost is different from transplant and should not be reported as a second or repeat transplant. A boost is an infusion of additional HCTs to a recent HPC transplant patient who has poor graft function, graft failure, or graft rejection, with or without immunosuppression. Bill and report an allogeneic boost using CPT code 38243 – “hematopoietic progenitor cell (HPC); HPC boost”.

2. If a patient was admitted to the hospital for observation, was released, and is then admitted as an inpatient for alloHCT, would the Medicare Prospective Payment System (PPS) 3-day rule say that the observation stay would need to bundle into the transplant admission?

This rule is called the “3-day window rule” and applies to outpatient services by the same hospital or a facility wholly owned by the hospital rendered up to three days prior to the day of admission. All services on the day of admission must be added to the inpatient claim. All diagnostic services such as lab and x-ray whether related to the admission or not must be billed on the inpatient claim and only unrelated non-diagnostic services can continue to be billed separately. When a separate outpatient claim for unrelated non-diagnostic services is billed, condition code 51 must be used on the outpatient claim to attest that the outpatient services are non-diagnostic and unrelated to the inpatient

admission. See Medicare online manual 100-04, Chapter 3, Section 40.3 for additional information.

3. What should a Transplant Center who is having Medically Unlikely Edit (MUE) claim issues on their Medicare outpatient autologous transplant cases do? These edits are appearing for the conditioning preparation for an alloHCT for a covered indication.

Each of the chemotherapy drug HCPCS code units billed should be compared against the published MUE limits per HCPCS code. If the actual units administered to the patient exceed the published limits, the provider should bill the units administered, take the denial and appeal with documentation. Published MUE limits can be found on the [CMS.gov website](https://www.cms.gov) for Medicare NCCI MUE edits.

4. Do any payers require reporting of alloHCT to the CIBMTR®?

Yes, almost all major payers require reporting to CIBMTR via their Centers of Excellence requirements.

5. Should autologous HCTs have a separate C-APC (Comprehensive Ambulatory Payment Classification)?

[CMS evaluated creating a separate C-APC for autologous transplant](#), and the outcome of their evaluation was the creation of another C-APC would lower C-APC 5244 (Level 4 Blood Product Exchange and Related Services, the alloHCT C-APC) by approximately 75 percent. Therefore, CMS chose not to create a separate C-APC for autologous HCTs.

CMS stated: “after analyzing the results, we found that creating a C-APC for APC 5242 would increase the number of single claims available for rate setting for this APC by approximately 8 percent, however creating new C-APCs in the Stem Cell Transplant clinical family would decrease the geometric mean cost of C-APC 5244 - Level 4 Blood Product Exchange and Related Services by approximately 75 percent due to complexity adjustments of code combinations within the clinical family, specifically complexity adjustments from C-APC 5243 to C-APC 5244. Therefore, at this time we do not believe it is appropriate to create a C-APC for autologous hematopoietic