



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

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## Inclusion Criteria for Donor Search and Cell Acquisition Charges

- **What services are included as part of donor search and cell acquisition charges for allogeneic stem cell transplants for Medicare beneficiaries?**

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

- (i) Registry fees from a national donor registry described in 42 U.S.C. 274k, if applicable, for stem cells from an unrelated donor.
- (ii) Tissue typing of donor and recipient.
- (iii) Donor evaluation.
- (iv) Physician pre-admission/pre-procedure donor evaluation services.
- (v) 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.
- (vi) Post-operative/post-procedure evaluation of donor.
- (vii) 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 ruled out and services (cell collection, cell processing, medical evaluation etc.) for the donor whose cells are selected for the recipient’s transplant.

- **Are there separate CPT codes for cord search and acquisition charged by overseas cord blood facilities?**

There is no unique CPT code for international cord blood – the CPT code for the search and for the cell acquisition is 38204. Refer to AMA CPT® definition. American Medical Association (AMA), Current Procedural Terminology (CPT)®, Chicago (IL): AMA, 2022. Online: <https://www.ama-assn.org/amaone/cpt-current-procedural-terminology>

- **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.

- **Are recipient 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. These are considered patient benefits and should be charged out real-time. HLA typing of the recipient, however, is included in the definition of donor search and cell acquisition as defined in 42 CFR 412.113 and is eligible for cost reimbursement.

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

Yes, and there are two options for receiving payment for professional fees to evaluate donors. One option is to bill under the Medicare physician fee schedule (MPFS) under the recipient’s name and Medicare beneficiary number. See Chapter 3 of the Medicare Claims Processing Manual, Section 90.3.B.1.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 means that physician services are allowed to be paid separately but are only covered under the recipient.

The second option is to claim the professional Part B physician expense in 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 separately. Coverage of professional Part B services and AMA CPT® codes for transplant require the professional spend time with the recipient and/or donor when billing for review of HLA typing.

- **If we collect HCT donations for use by other transplant centers, 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. Rather, reimbursement should be covered 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.

## Billing for Donor Search and Cell Acquisition

- **When should we bill for donor search and cell acquisition for stem cell transplants for Medicare beneficiaries?**

For Medicare beneficiaries, you must hold (not bill for) all donor search and cell acquisition charges until the recipient’s transplant occurs regardless of when that occurs. This means transplant centers may be holding charges for several weeks or month.

- **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 O815 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.

- **What codes should we report on the bill for donor search and cell acquisition services?**

Revenue code O815 must be reported on the bill for all payers for stem cell transplant acquisition services per National Uniform Billing Committee (NUBC) requirements. See Medicare Claims Processing Manual Chapter 3, Section 90.3.1 and Chapter 4, Section 231.11. Additionally, whether procedure (CPT) codes should be reported along with a condition code depends on the recipient’s payer type and whether the transplant is provided to an outpatient or inpatient:

Coding	Medicare (& payers following Medicare)	Commercial payers that allow real-time billing of related donor services
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<p><b>Outpatient transplant</b></p>	<p>You must report individual CPT codes for each test for each potential donor as separate line items on the recipient claim.</p>	<p>If a commercial payer accepts 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. Also report condition code 88 (allogeneic HCT related donor charges).</p>
<p><b>Inpatient transplant</b></p>	<p>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.</p>	<p>If a commercial payer accepts 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. Also report condition code 88 (allogeneic HCT related donor charges).</p>

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.
- **Should we 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.

- **Please provide clarification for reporting donor acquisition costs for allogeneic transplants. 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 whether on the recipient's transplant claim as Medicare and other payers may require or on separate claims as some non-Medicare payers 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 O13x claim are required and yes, the revenue code is 0815. Check with your commercial payers 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.

- **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."

- **Should we 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 with hospital claims for payment.

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.

- **How should we 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.”

- **How should we bill the patient’s insurance company for multiple potential donors that NMDP tested?**

You will receive invoices from NMDP that include the costs of screening each potential donor. 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.

- **Which procedure codes should we use to bill the patient’s insurance for NMDP services for Medicare beneficiaries?**

Whether you list 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 the 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.

- **Should we add a mark-up to the to the total invoice amount from NMDP?**

The hospital 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



OPPS 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 in the FY 2021 and FY 2022 IPPS final rules as well.

- **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.” [underline added]. 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.

- **Can we bill CPT code 38204 more than once per patient search for Medicare beneficiaries?**

Yes, the definition of the 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 O815 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.

- **Why would a commercial payer not reimburse us 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, you would submit the claims for donor charges under 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 your commercial payer along with revenue code O815.

- **Commercial payers have sometimes erroneously assumed that the use of CPT code 38204 multiple times for multiple donors represents duplicative services. How can we 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 transplantation related donor charges) on these claims.
  - Do not mix donor services with recipient services as this may trigger inappropriate code and claim edits.
- **Using the NMDP crosswalk, how would we 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, you 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.

- **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 (see: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf>).

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.

## Cost Reporting and Internal Tracking of Donor Search and Cell Acquisition

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

ANSWER:

- Medicare cost reporting must include claims and expense data from all patients, not just Medicare beneficiaries.
  - Report all donor services under cost center 77. Current instructions for worksheet D-6 are still in draft form, but they indicate that HCT donor charges used in this worksheet are Medicare only.
  - Best practice is to report revenue code O815 for donor services on the bills for all HCT transplant recipients, regardless of payer type, so that costs for all patients are correctly included in the cost report to CMS.
- **Is Section 108 cost-based reimbursement for allo HHCT the same or similar to solid organ? Why or why not?**

No, Medicare's Section 108 cost-based reimbursement for allo HHCT is not the same as solid organ 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 with HHCT transplants as this is with solid organ transplants to whom acquisition costs are reported. Rather, for HHCT transplants, acquisition cost is paid for by the recipient's insurance.

Second, the transplant center is instructed to not develop a standard acquisition charge for stem cell transplants. This is different from what they do for each type of organ with solid transplant. Rather, for HHCTs, the transplant center must report actual charges for donor evaluations and cell collection/acquisition because each allo HHCT is different and can range from having charges from 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 allo HHCT costs are purchased clinical services by transplant centers including HLA typing, cell collection and cell acquisition from Be the Match. Therefore, invoices are expected to underlie much of the expense and revenue reported in the standard allo HCST cost center 77 for the Medicare cost report.

- **How should we track our payments of fees to NMDP for its services to report 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.

- **For billing purposes, how can we track the non-standard (i.e., actual) donor charges for stem cell transplantation (HCT) which vary based on the services each patient receives?**

Remember, the actual charges for the various services are actually the hospital’s standard charges. What the reference to “non-standard” means 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 do vary, it is recommended that the transplant center:

- Flag and track HCT donor accounts.
  - Use (or create) charges in your 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\(e\)](#).
- **What should I do if patients do not go to transplant?**

If the commercial insurance allows payment for donor services per the contract or per network authorization, then outpatient claims under the recipient name and insurance with donor charges reported under O815 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 the accounts receivable but must be able to be retrieved and used to complete the Medicare cost report since Medicare will allow cost settlement to occur for costs incurred by the transplant center in cases when the transplant is cancelled. 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."

- **How are transplant centers determining staff time devoted to donor services and cell acquisition?**

Some transplant centers have done 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 new 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 expense reported in the cost center specific to donor services. For staff that split time between autologous and allogeneic donor and recipient services, they should complete time studies to allocate their expense between donor and non-donor work.

- **Our health system pays the medical school for services provided, but the physicians do not bill for their services. Should we 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: (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. See the Medicare Claims Processing Manual, Chapter 3, Section 90.3

## Coverage of HCT Transplantation

- **Does Medicare provide coverage based on the disease of the recipient or just based on the reporting of CPT 38242?**

Coverage is always determined by the diagnosis or the disease of the recipient 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 your A/B MAC. See the Medicare online manual 100-04, Chapter 32, Section 90.3.

- **When the transplant NCD is silent for a specific diagnosis or condition, are we 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.

- **What are our options if a claim is denied by our MAC for an indication for which the NCD is silent?**

If a MAC denies a claim for example, for an allogeneic transplant for lymphoma performed for a Medicare patient, 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 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.

- **What is the process for determining whether the regional MAC will cover HCT transplant for lymphoma?**

ANSWER:

- Medicare does not have a prior authorization program for most services. Rather, the process is to bill as usual after an HCT transplant for lymphoma for a Medicare beneficiary.
  - If the MAC denies coverage of the claim, you may appeal using the coverage memo and other documentation for support.
  - If the MAC 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.
- **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 with CED does not have a limitation to a single HCT transplant. The payer type for the first transplant does not impact Medicare coverage of a second transplant. If the patient meets the eligibility requirements for the MDS CED study, Medicare will cover the second transplant. For the applicable CEDs, see <https://www.cms.gov/medicare/coverage/coverage-with-evidence-development>

- **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.

### **HCT Transplantation Under Medicare Advantage (MA) Plans**

- **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 may be useful and can be found at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019326>

- **How do the changes in donor search and cell acquisition costs (effective October 1, 2021) affect MA Plan reimbursement?**

When an MA enrollee receives an HCT transplant 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 transplant 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.<sup>1</sup>
  - 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 O815 charges based on the CCR in the hospital's cost report.
- **Are the biweekly Medicare Periodic Interim Payments (PIP) based on stem cell acquisition costs only for Medicare FFS beneficiaries or also for MA Plan members?**

The biweekly PIPs are solely based on Medicare FFS. At 85 FR 58841 – the 2021 Final IPPS Rule, CMS explains: “Under section 1852(a) of the Act, when an MA organization’s coverage responsibilities include payment for services furnished to an MA enrollee by a hospital with which the MA organization does not have a contract that establishes a payment amount, the MA organization’s payment to the hospital must be equal to the total dollar amount that would have been authorized for such services under the Medicare FFS program, less any cost sharing paid by the enrollee under the MA plan. In addition, section 1866(a)(1)(O) of the Act provides that a hospital that does not have a contract establishing payment amounts for services furnished to an MA enrollee must accept as payment in full the amount that the hospital would be paid if the MA enrollee had instead been enrolled in Medicare FFS.”

The payment amount established in this rule for the Medicare FFS program would therefore apply in cases where an MA organization must cover allogeneic hematopoietic stem cell acquisition costs when the MA enrollee receives the relevant services from a non-contracted hospital. CMS does not interfere in the contracts between an MA organization and its



contracted providers to require either the MA organization to contract with a specific provider or to require a specific payment or pricing arrangement; an MA organization and its contracted providers may negotiate payment arrangements for covered services furnished to MA enrollees.

For in-network services and services furnished by contracted providers to MA enrollees, this rule and the amendments to section 1886(d) of the Act by section 108 of the Further Consolidated Appropriations Act, 2020, do not impose or set the payment amount from an MA organization for these services. CMS will consider whether additional guidance specific to payment for allogeneic hematopoietic stem cell acquisition by MA organizations is necessary.

- **For a patient in a clinical trial who has an MA Plan, should we bill the Medicare Administrative Contractor (MAC) or the MA Plan for an HCT case and do these billing requirements apply to clinical trials in all states?**

Because HCT is approved under a national coverage determination (NCD) requiring CED, bill HCT claims to the MA Plan. See Section 10.7 of Chapter 4 of the Medicare Managed Care internet only manual concerning clinical trials at

<https://www.cms.gov/RegulationsandGuidance/Guidance/Manuals/Downloads/mc86c04.pdf>

and <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>. 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. <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=238>

- 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:
  - <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index>
  - Bill the MAC/regular Medicare if the clinical trial meets Medicare clinical trial policy requirements and is not a trial approved under coverage with evidence determination (CED). In this case, the MA Plan has the option to pay the difference in out-of-pocket routine costs. See <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=1&ncdver=2&bc=BAABAAAAAAA>
- **How do we submit a request for authorization for transplant under a Coverage with Evidence (CED) study? What if it is a Medicare Advantage patient?**

Medicare does not have prior authorization for most services and not CED or other

clinical trials. CMS publishes billing guidelines regarding submission of claims for routine costs under qualifying clinical trials at

<https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Downloads/Mandatory-Clinical-Trial-Identifier-Number-QsAs.pdf>

For Medicare Advantage patients, per CMS policy, section 10.7.3, MA plans are required to cover CEDs; however, it would not be surprising if the MA plan says it will not “authorize” because it wants the patient to enroll in FFS Medicare – this is a tactic we’ve heard some plans use. If the patient qualifies for a CED and the MA plan will not authorize, 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 reference: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>

## Miscellaneous HCT Transplantation Topics

- **How should we code for a DLI for a Medicare beneficiary four years after HCT transplant?**

The outpatient procedure (CPT) code is 38242 (allogeneic lymphocyte infusions). No policies are in the Medicare Coverage Database for CPT code 38242, but MACs may have local edits to also question coverage for diagnoses for this procedure. The diagnosis coding therefore should indicate the condition or signs/symptoms and that the patient is post-transplant.

See <https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?hcpcsOption=code&hcpcsStartCode=38242&hcpcsEndCode=38242&sortBy=title&areald=all&docType=6,3,5,1,F,P&contractOption=all>

- **Should we bill for an autologous CD 34+ boost as a repeat 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 a boost using CPT code 38243.

- **If a patient was admitted to the hospital for observation, was released, and is then admitted as an inpatient for transplant 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.

- **Can you provide assistance concerning Medically Unlikely Edit (MUE) claim issues on our Medicare outpatient autologous transplant cases, specifically as it relates to the conditioning preparation for multiple myeloma. Our claims for Melphalan are being denied for MUE. Are the denials the result of billing or coding errors on our end?**

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 at: <https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/MUE>

- **A prospective Medicare allogeneic transplant patient’s original diagnosis is CLL. His disease has transformed to Hodgkin’s Lymphoma, DLBCL, and now possibly prolymphocytic leukemia. Is a diagnosis of CLL allowed?**

When CLL/SLL are both applicable diagnoses, correct coding is to report codes for both diagnoses. If applicable, code transformed lymphomas so those that transform from one type to the other. If the documentation is not clear, query the physician to determine which diagnosis he is treating with stem cell transplant and whether all of the other conditions are also currently present and should be coded. This would help ensure the correct principal diagnosis is assigned along and other diagnoses reported as secondary diagnoses.

### Do any payers require reporting to CIBMTR?

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

- **On the CIBMTR CED consent form, do I indicate patient diagnosis as CMML 2 or as MDS or as both? Will Medicare still cover under CED an allogeneic for CMML not in**

## remission?

The CIBMTR form question would be best directed to CIBMTR staff. With respect to the CMML remission status, 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. See <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=366&ncdver=1&keywordtype=starts&keyword=stem&bc=0>

Neither the table nor the decision specify anything further about remission status. CMS states that “Allogeneic HHCT for MDS is covered by Medicare only for beneficiaries with MDS participating in an approved clinical study.” If the patient qualifies for enrollment in the CIBMTR study, it will meet that definition.

Any denial by Medicare should be challenged given the explicit inclusion of CMML and nothing that explicitly excludes this diagnosis based on remission status. The AML coverage language does differentiate in this way; and this is an indication that CMS could have chosen to specify the CMML remission status but did not choose to do so.

- **Should autologous HHCTs have a separate C-APC (comprehensive Ambulatory Payment Classification)?**

CMS evaluated doing this and the outcome of their evaluation was that it lowered another C-APC’s payment (C-APC 5244—Level 4 Blood Product Exchange and Related Services) by approximately 75 percent, so CMS chose not to create a separate C-APC for autologous HHCTs. <https://www.govinfo.gov/content/pkg/FR-2019-11-12/pdf/2019-24138.pdf> 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 stem cell transplant.”