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To: Centers participating in Part I MDS Study for CED

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Re: Medicare Billing Clarifications for CIBMTR Part I Study of MDS for CMS CED

As the HCT for MDS Medicare Study continues to accrue patients and transplant centers begin submitting billing claims, we have received a number of questions in regards to processing these claims or in dealing with denials. CIBMTR recently had a telephone call with CMS to clarify procedures for a few of these situations.

In general, the best initial course of action is to work with your local Medicare contractor to understand the reason for the denial and the possible course of action or appeal. If the issue is something that cannot be resolved in this manner or is in relation to what your center believes to be a misinterpretation of the Coverage with Evidence Determination guidelines, please contact Anne Dircks at 612-884-8209 or adircks@nmdp.org

Two issues that warrant specific clarification are as follows:

- **MDS patients participating in Medicare Advantage plans:** CMS guidance specifies that costs related to a Medicare approved clinical trial, such as the MDS CED, should be paid through traditional fee-for-service Medicare, even when a patient has enrolled in a Medicare Advantage plan. In the case of the MDS study, this includes the transplant hospitalization and any associated follow-up care or hospitalizations attributable to the transplant. This would apply for as long as care is related to the original transplant for MDS. Centers are asked to treat this on a patient-by-patient basis and use their clinical judgment and integrity in discerning which claims are transplant-associated. All such claims should be marked with the 8 digit clinical trial number: NCT #01166009

  See Section L of the attached reference: **2011 Combined Call Letter** for more information about Medicare Advantage plans and clinical trials administration.

- **Post-transplant follow-up care or hospitalizations:** Similar to the instructions above, CMS clarified that all traditional FFS Medicare beneficiaries should also have their transplant-associated subsequent care and hospitalizations marked with the clinical trial number. As per above, the length of time during which subsequent care is related to the transplant will vary by patient and is up to the medical determination of the provider. This **will not affect reimbursement**; it is for tracking purposes only. Transplant centers should remember that proper documentation of subsequent admissions or care and attribution of association with transplantation is very important as these claims are subject to the usual auditing practices.

All study information, including general CMS-MDS Study and Billing FAQ’s can be found at [www.cibmtr.org/HCTforMDS](http://www.cibmtr.org/HCTforMDS).

We hope that these clarifications are helpful. Please contact us with any additional questions or concerns.