

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C1-09-06
Baltimore, Maryland 21244-1850



Office of Clinical Standards and Quality

J. Douglas Rizzo, MD, MS, CIBMTR, FMLH & MCW Clinical Cancer Center
9200 West Wisconsin Avenue, STE C5500
Milwaukee, WI 53226

Ehab Atallah, MD, CIBMTR, FMLH & MCW Clinical Cancer Center
9200 West Wisconsin Avenue, STE C5500
Milwaukee, WI 53226

Protocol Number: CAG-00415N(CIBMTR)

DEC 13 2010

Dear Drs. Rizzo and Atallah,

After careful review, the Centers for Medicare & Medicaid Services (CMS) has approved the proposal entitled, "Assessment of allogeneic hematopoietic stem cell transplantation in Medicare Beneficiaries with myelodysplastic syndrome and related disorders" under Coverage with Evidence Development and will cover the items and services required for studying this procedure.

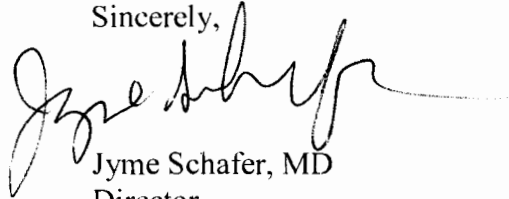
We understand that this study is a sub-study of the National Marrow Donor Program® and Center for International Blood and Marrow Transplantation Research® Research Database for Hematopoietic Stem Cell Transplantation and Marrow Toxic Injuries. The Research Database is registered on ClinicalTrials.gov as: NCT01166009. We will place the title, participating sites of this approved study and the NCT identifier on the CMS Coverage website under the name of the national coverage decision. (<http://www.cms.gov/MedicareApprovedFacilitie/06>)

You stated in the protocol that the International Prognostic Scoring System (IPSS) data elements will be collected for all Medicare beneficiaries for this study. Since this information is collected on a form that is completed on a voluntary basis for the Research Database we asked you to confirm that the IPSS data elements will be mandatory for all study subjects. In your subsequent letter, dated November 24, 2010, you provided a confirmation that stated in part "the data elements outlined in our protocol (including the IPSS)will be considered required reporting for purposes of participation in the protocol for CED for MDS." This satisfies our previous concern related to mandated collection of the IPSS score.

Page 2

CMS appreciates your commitment to research and evidentiary development in order to improve care for Medicare beneficiaries. Please direct any questions to Roya.Lotfi@cms.hhs.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Jyme Schafer". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Jyme Schafer, MD

Director

Division of Medical and Surgical Services

Coverage and Analysis Group

Office of Clinical Standards and Quality