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President

Armand Keating, MD
Princess Margaret Hospital
610 University Avenue, Suite 5-303
Toronto, ON M5G 2M9
CANADA
phone 416-946-4595
fax 416-946-4530
armand.keating@uhn.on.ca

President-Elect

Janis L. Abkowitz, MD
University of Washington
Box 357710
Seattle, WA 98195-0001
phone 206-685-7877
fax 206-684-3530
janabl@u.washington.edu

Vice President

Linda J. Burns, MD
Division of Hematology, Oncology,
and Transplantation
420 Delaware Street, SE
MMC 490/Room 14-154A Moos Tower
Minneapolis, MN 55455-0341
phone 612-624-8144
fax 612-625-9988
burns019@umn.edu

Secretary

Charles S. Abrams, MD
University of Pennsylvania
School of Medicine
421 Curie Boulevard, #912
Philadelphia, PA 19104-6140
phone 215-673-3288
fax 215-673-7400
abrams@mail.med.upenn.edu

Treasurer

Richard A. Larson, MD
University of Chicago
5841 S. Maryland Avenue, MC-2115
Chicago, IL 60637-1470
phone 773-702-6783
fax 773-702-3002
rlarson@medicine.bsdc.uchicago.edu

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Charles Parker, MD, *The Hematologist*

Executive Director

Martha L. Liggett, Esq.
mliggett@hematology.org

Dear Hemophilia Treatment Center Director:

The American Society of Hematology (ASH) was recently contacted by the National Correct Coding Initiative (NCCI) staff regarding a proposal to set limits on the number of units of specific clotting factor replacement therapies that Medicare will allow reimbursement for on a given day. NCCI advises the Centers for Medicare and Medicaid Services (CMS) on coding and other issues related to Medicare claims.

The proposed limits, known as Medically Unlikely Edits or MUE's, will apply to clotting factor replacement therapies when they are provided in the hospital outpatient and ambulatory/physician office settings. The edits were derived by CMS and its contractors by examining the "typical" number of units of service provided to individuals over the past six months and subsequently establishing a maximum limit above that level. CMS institutes these limits as a measure of what it considers to be medically necessary usage and believes that imposing such limits will prevent fraud and abuse when Medicare is billed for a volume of services exceeding the edit.

Unfortunately, for a number of the MUE edits, including those proposed for clotting factor replacement concentrates, the specific limit (i.e., how many units) cannot be disclosed to providers, as per the policies of the CMS. CMS believes that if the edits were disclosed, some providers would routinely bill at the established threshold.

ASH was told by NCCI that the limits for clotting factor replacement therapies that are being set are well above the number of units in clotting factor claims for Medicare patients over the past six months. In addition, the MUE's will not apply to clotting factor provided to inpatients nor will it apply to Medicaid patients.

The purpose of this notice is to inform you of the actions you might consider to avoid experiencing a denial or to pursue if reimbursement is denied by Medicare, based on a MUE edit. The following strategies were provided by the NCCI staff:

- If an unusually large quantity of clotting factor replacement concentrate is provided more than once during the day, you can bill for the services on separate line items using a -59 modifier with the appropriate J Code to indicate that it is a distinct procedural service. Thus, if you provide 20,000 units of a particular product initially and then an additional 20,000 units later in the day, you can report the second service as a separate line item with a -59 modifier.
- If you do experience a denial that the units billed are in excess of the maximum allowable level, you can appeal the denial with your local Medicare contractor explaining your rationale as to why the number of units billed was medically necessary for that patient. In this event, please also inform ASH of the circumstances and the disposition of the appeal. You should direct this information to Ellen Riker, ASH's consultant on reimbursement policy at eriker@dc-crd.com.

- Please note that if there seems to be a pattern of inappropriate denials for medically necessary services, ASH will bring this to the attention of NCCI and CMS leadership and work towards getting the MUE threshold revised.

ASH consulted Drs. Craig Kessler and Margaret Ragni on this policy. Please contact Ellen Riker at 202-484-1100 or eriker@dc-crd.com with any questions or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "Sam M. Silver". The signature is written in a cursive, flowing style.

Samuel M. Silver, MD, PhD
Chair, ASH Subcommittee on Reimbursement