



Conquering Blood Diseases –
From Research to Patient Care

AMERICAN SOCIETY OF HEMATOLOGY

1900 M Street, NW, Suite 200, Washington, DC 20036 phone 202-776-0544 fax 202-776-0545 e-mail ASH@hematology.org

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President

Kenneth Kaushansky, MD
Department of Medicine
University of California, San Diego
402 Dickinson Street, Suite 380
San Diego, CA 92103-8811

phone 619-543-2259
fax 619-543-3931
kkaushansky@ucsd.edu

President-Elect

Nancy Berliner, MD
Chief, Hematology Division
Brigham & Women's Hospital
75 Francis Street
Boston, MA 02115-6110

phone 617-732-5840
fax 617-264-5215
nberliner@partners.org

Vice President

Hal E. Broxmeyer, PhD
Walther Oncology Center
Indiana University School of Medicine
950 W. Walnut Street, Room 302
Indianapolis, IN 46202

phone 317-274-7510
fax 317-274-7592
hbroxmey@iupui.edu

Secretary

Armand Keating, MD
Princess Margaret Hospital
610 University Avenue, Suite 5-303
Toronto, Ontario M5G 2M9
CANADA

phone 416-946-4595
fax 416-946-4530
armand.keating@uhn.on.ca

Treasurer

Linda J. Burns, MD
Division of Hematology,
Oncology, and Transplantation
University of Minnesota
420 Delaware Street, SE
Mayo MC 286/Room 14-154A Moos Tower
Minneapolis, MN 55455-0341

phone 612-624-8144
fax 612-625-9988
burns019@umn.edu

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Executive Director

Martha L. Liggett, Esq.
American Society of Hematology
1900 M Street, NW, Suite 200
Washington, DC 20036

phone 202-776-0544
fax 202-776-0545
mliggett@hematology.org

Mr. Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Attention: CAG-00400N
7500 Security Boulevard
Baltimore, MD 21244-8018

Re: Pharmacogenomic Testing for Warfarin Response

Dear Mr. Weems:

The American Society of Hematology (ASH) is pleased to have the opportunity to comment on the national coverage analysis for pharmacogenomic testing for warfarin response. ASH represents over 16,000 hematologists in the United States who are committed to the treatment of blood and blood-related diseases. ASH members include hematologists and hematologist/oncologists who regularly render services to Medicare beneficiaries.

Because bleeding is the primary adverse event associated with warfarin use, ASH understands that there has been scientific interest in the potential of pharmacogenomic testing to predict patients' response to the drug. *While the Society finds the scientific developments in this area very interesting, at this time significant uncertainty remains regarding this new and emerging technology and ASH does not support the use of pharmacogenomic testing to guide initial dosing or ongoing treatment of warfarin.*

The society strongly believes that it is much too premature for the implementation of such a coverage policy in the general Medicare population based on currently available evidence. ASH does, however, support the use of pharmacogenomic testing for warfarin responsiveness in the context of randomized prospective clinical trials to establish the efficacy and safety of this approach.

Thank you for the opportunity to submit these comments. Please do not hesitate to have your staff contact Carol Schwartz, Senior Manager, Policy & Practice at ASH (202) 292-0258 or cschwartz@hematology.org for any additional information.

Sincerely,

Kenneth Kaushansky, M.D.
President

cc: J. Roche, MD; CMS