American Society of Hematology
Carrier Advisory Committee (CAC) Meeting
June 24, 2022

Annual Meeting
ASH Headquarters
Washington, DC
8:00 a.m. – 3:00 p.m. ET
https://hematology.zoom.us/j/95194292531

American Society of Hematology

Helping hematologists conquer blood diseases worldwide

Hematology Carrier Advisory Committee (CAC) Meeting
June 24, 2022

Agenda

8:00 a.m.	Breakfast		
8:30 a.m.	Welcome and Introductions	Dr. Diana Howard	
	• Speaker List		3
	• ASH Staff List		6
	• Medical Director List and Jurisdiction Map		7
8:45 a.m.	Hematology's Impact on the CAC Process		
	• ASH's Role in the National and Local Coverage Process	Dr. Chancellor Donald	
	• Proposed Local Coverage Determination - Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin	Dr. Howard	10
	• Reconsideration of the National Coverage Determination - Removal of Coverage with Evidence Development for Stem Cell Transplantation for Myelodysplastic Syndromes	Ellen Riker	12
	• Von Willebrand Disease ICD-10 Codes	Ms. Riker	21
9:15 a.m.	Clinical Trials: Design and Medicare Coverage	Dr. Meredith Loveless Dr. Alan Mast	
10:15 a.m.	Break		
10:45 a.m.	Medicare Coverage of Vaccinations Post-Transplant	Leslie Brady Dr. Steven Devine	
11:30 a.m.	Networking Lunch		
1:00 p.m.	ASH Clinical Practice Guidelines	Dr. Robert Plovnick	29
1:45 p.m.	Coverage of COVID-19 Therapies under the Public Health Emergency	Andrew Leboeuf Dr. Jennifer Brown	
2:30 p.m.	Closing Remarks and Reference Materials	Dr. Howard	
	• CMS Resources		37
	• ASH Practice Resources		38
	• ASH Choosing Wisely		40
	• Meeting Reimbursement Policy		46
	• Meeting Reimbursement Form		49
3:00 p.m.	Adjourn		

Speaker List

Chancellor Donald, MD

Chancellor Donald, MD is the Chief Medical Officer of the Taking Aim at Cancer in Louisiana initiative. He currently holds the position of Assistant Professor of Clinical Medicine at Tulane University School of Medicine. His academic focus is advocacy and health disparities regarding patients with hematologic disorders and malignancy. He previously cared for patients in a community practice at Lourdes Oncology Associates in Lafayette, Louisiana. The Taking Aim at Cancer in Louisiana initiative aims to improve the cancer outcomes of citizens of the state. As a lead, Dr. Donald engages and builds consensus with key stakeholders. In this role he guides and aligns strategies and champions policies aimed at improving measurable cancer care metrics in Louisiana.

Originally from Gretna, Florida, Dr. Donald attended Florida A&M University for undergraduate studies and graduated magna cum laude. He then attended the University of Miami School of Medicine for his medical degree. He completed his internship, residency and fellowship at Tulane University. He was selected as Chief Resident and Chief Fellow during his training. In 2010 he joined Louisiana Oncology Associates, PMC and became President of the practice in 2014. Dr. Donald would subsequently serve as a lead in crafting a professional services agreement with Our Lady of Lourdes Regional Medical Center. While at Our Lady of Lourdes Regional Medical Center, he functioned as Medical Director of the oncology service line, a Member of the Medical Executive Committee and as a Trustee on the Board of Directors at that institution. In 2013, he was given the Spirit of Hope Award by the American Cancer Society.

Dr. Donald has extended himself beyond his practice to advocate for patients and the appropriate delivery of care. He is the immediate past President of the Louisiana Oncology Society. The American Society of Hematology granted him selection as Chair of the Committee on Practice. He also holds the position of the American Society of Hematology's delegate to the American Medical Association's House of Delegates and alternate to the AMA CPT Editorial Advisory Committee. Since 2012 he has served as the Hematology Representative for Louisiana for the Medicare Carrier Advisory Committee (CAC). In December, Dr. Donald participated in the plenary session of the annual American Society of Hematology meeting by introducing work on health disparities involving Black patients with acute myeloid leukemia. He also serves on the Hematology Examination Committee of the American Board of Internal Medicine.

Dianna Howard, MD

Dianna Howard, MD has been the director of a bone marrow transplant (BMT) program for 15 years, first at the University of Kentucky, and now at Wake Forest. Both programs provide care to a swath of the Appalachian region and a subset of patients for whom barriers to access either because of co-morbidities, distance, or delay in referral remain a challenge. Dr. Howard has a special interest in the adolescent and young adult (AYA) population as she is trained in both pediatric and internal medicine. When Dr. Howard joined Wake Forest, her priorities included improving data management and quality reporting to Center for International Blood and Marrow Transplant Research (CIBMTR); transitioning autologous transplant care to outpatient; starting a transplant survivorship program; and positioning Wake as a center of excellence with insurers so patients would have access to transplant without having to travel. BMT programs are evaluated on volume and outcomes - accomplishing both at the same time is an imperative with greater challenges in modest sized transplant programs. Dr. Howard has been involved in efforts focused on expanding regional access for patients who need transplant. Her team was awarded an ASHP Best Practice Award in 2017 for our Autologous SCT outpatient program, recognizing our inclusion of clinical practice pharmacists. Consistent with her interest in patient access to health care, she has participated in advocacy campaigns with LLS, ACP, ASH and ASTCT. Dr. Howard completed the ASH Advocacy Leadership Institute and serves on ASH Committee of Government Affairs. Dr. Howard also serves on ASTCT Outcomes Committee, as faculty for the inaugural ASTCT Leadership Course, Co-Chair the ASTCT Leadership course for 2020, Chair ASTCT Government Relations Committee, and represents ASTCT on ASH Committee on Practice and ACP Council of Subspecialists, where she has co-chaired a health policy subcommittee. Through this level of committee engagement Dr. Howard has been able to work with colleagues to advocate for access to transplant and cell therapy - advancing health policy that impacts patient barriers. At Wake Forest she has worked with the government policy office to respond to the

call for comments to CMS on issues important to our transplant program and led a regional effort to influence insurer policy with regard to transplant reimbursement practices.

Ellen Riker
Ellen Riker is a Principal with the Artemis Policy Group, an association management and lobbying firm she established in April 2020 in Washington, DC. She has advised the American Society of Hematology on government affairs, health policy and practice issues for nearly twenty years. As a federal policy advisor and lobbyist since 1989, Ellen has managed federal strategies for corporate and non-profit organizations, specializing in public and private insurance reimbursement and coverage policies, biomedical and health services research, and public health programs. Ellen has worked with the many agencies of the Department of Health and Human Services and has been involved in the development of legislation coming out of the House and Senate committees with jurisdiction over Medicare, Medicaid, and public health service programs. Ellen served on the professional staff of the House Energy and Commerce Committee from 1983 - 1988, with particular focus on health policy. Before coming to Washington, Ellen worked as assistant to the president of a major multi-hospital system in Cincinnati, Ohio. Ellen received her master's degree in Health Administration from Xavier University and a B.A. with honors from the University of Cincinnati.

Meredith Loveless, MD
Meredith Loveless, MD is a Chief Medical Officer for CGS Administrators J15 Part A/B and focuses on policy. She was a teaching physician in ob/gyn at Johns Hopkins and University of Louisville prior to transitioning to Medicare. She has multiple academic papers and presentations, chaired several committees for the American College of Ob/Gyn and is an enthusiastic supporter of evidence-based medicine.

Alan E. Mast, MD, PhD
Alan E. Mast, MD, PhD is a Senior Investigator at the Versiti Blood Research Institute in Milwaukee Wisconsin where he holds the Walter A. Schroeder Endowed Chair for Blood Research. Dr. Mast received a BS in biochemistry at the University of Illinois and MD and PhD degrees from Duke University. He performed residency training in Laboratory Medicine at Washington University in St. Louis.

Steven Devine, MD
Steven Devine MD is currently Chief Medical Officer at the National Marrow Donor Program (NMDP)/Be The Match and Associate Scientific Director at the Center for International Blood and Marrow Transplant Research (CIBMTR). Prior to joining the NMDP, he was the Director of the BMT Program at The Ohio State University Comprehensive Cancer Center. He served for eight years as Chair of the National Cancer Institute funded Alliance Transplant Committee as well as a 2-year term as Chair of the NIH-funded Blood and Marrow Transplant Clinical Trials Network (BMT CTN) Steering Committee. He is currently one of the three Co-PIs for the BMT CTN Data Coordinating Center. He has a major research interest in the application of stem cell transplantation for patients with acute leukemia and myelodysplastic syndrome and has been Chair of two multi-center NIH-supported clinical transplantation trials in AML. He has authored more than 200 peer-reviewed papers and more than 400 abstracts as well as several reviews and book chapters in the field of stem cell transplantation, leukemia, and hematology. He is an Associate Editor for the ASTCT journal Transplantation and Cellular Therapy.

Andrew A. LeBoeuf, JD, MS
Andrew LeBoeuf is an Associate Director for Policy (Acting) in the Office of New Drug Policy in FDA's Center for Drug Evaluation and Research. In his role, Andrew is responsible for developing new or analyzing current regulatory policies impacting the review and approval of new drug products, including drug-device combination products. Since March 2020, Andrew has been providing substantial regulatory support to the Office of New Drugs' clinical offices on the review and issuance of Emergency Use Authorizations (EUAs) for CDER-regulated therapeutics for COVID-19. Prior to joining CDER's Office of New Drug Policy, Andrew spent several years working in CDER's Office of Generic Drug Policy as well as FDA's Center for Devices and Radiological Health and the Office of Regulatory Affairs. Andrew received a Juris Doctor from the John Marshall Law School-Chicago, a Master's of Science in Applied Physiology from the Rosalind Franklin University of Medicine and Science, and a Bachelor's of Science in Biology from Loyola University of Chicago. He is a member of the Illinois Bar.

Jennifer R. Brown, MD, PhD

Jennifer R. Brown, MD, PhD is the Director of the CLL Center of the Division of Hematologic Malignancies at Dana-Farber Cancer Institute and the Worthington and Margaret Collette Professor of Medicine in the Field of Hematologic Oncology at Harvard Medical School in Boston, Massachusetts. Dr. Brown completed a B.S. and M.S. simultaneously in molecular biophysics and biochemistry (MB&B) at Yale, graduating summa cum laude with distinction. She proceeded to Harvard Medical School where she received her MD and PhD in molecular genetics in 1998 and was awarded the James Tolbert Shipley Prize. She then served as an intern and resident in Internal Medicine at Massachusetts General Hospital followed by fellowship in Hematology and Medical Oncology at DFCI. Dr. Brown joined the faculty of DFCI and Harvard Medical School in 2004, where she has an active clinical-translational research program in CLL.

Her interests include the development of novel targeted therapeutics for CLL, as well as CLL genomics. She has been instrumental in the clinical development of idelalisib and ibrutinib, leading to their regulatory approvals in CLL. Her genomics work has characterized the somatic mutation profile of CLL, and she is now particularly interested in the implementation of genomic technology in the clinic. She also has a longstanding research interest in the inherited predisposition to CLL. To date she has published about 250 papers in the scientific literature, predominantly in CLL. In 2014 she was the recipient of two awards from DFCI, the Clinical Innovation Award, as well as the George Canellos Award. She is a member of the International Workshop on CLL (iwCLL) and enjoys a worldwide reputation as a CLL expert having made the Highly Cited Researchers list by Clarivate, with multiple papers ranking in the top 1% by citations for their field and year of publication.

Staff Information

SUZANNE M. LEOUS, MPA
Chief Policy Officer
American Society of Hematology
Phone: 202-292-0258
sleous@hematology.org

KATHERINE STARK
Policy and Practice Manger
American Society of Hematology
Phone: 202-292-0252
kstark@hematology.org

~

LESLIE BRADY, MPH
ASH Policy Consultant
Senior Policy Advisor, Artemis Policy Group
Phone: 202-800-7072
eriker@artemispolicygroup.com

ELLEN RIKER
ASH Policy Consultant
Principal, Artemis Policy Group
Phone: 202-800-7072
eriker@artemispolicygroup.com

Contractor Medical Directors

OLATOKUNBO AWODELE, MD, MPH
CMD: J-6
National Government Services
Olatokunbo.awodele@anthem.com

LISA BANKER, MD, FACP
CMD: JJ/JM
Palmetto GBA
lisa.banker@palmettogba.com

EARL BERMAN FACP, MALPS-L
CMD: J15 Part B
CGS Administrators, LLC
earl.berman@cgsadmin.com

GABRIEL BIEN-WILLNER, MD
CMD: MOLDX
Palmetto GBA
gabriel.bien-willner@palmettogba.com

ANDRE BLOSCHICHAK, MD, MBA
CMD: JH/JL
Novitas Solutions, Inc
andrew.bloschichak@novitas-solutions.com

STEPHEN BOREN MD, MBA
CMD: JK
National Government Services
stephen.boren@anthem.com

MIGUEL BRITO, MD
CMD: JM
Palmetto GBA
miguel.brito@palmettogba.com

ALICIA CAMPBELL, MD
CMD: JN
First Choice Service Options, Inc.
alicia.campbell@fcso.com

RAEANN CAPEHART, MD
CMD: JE/JF
Noridian Healthcare Solutions
raeann.capehart@noridian.com

ANGELLA AHARNOT-KATSIKAS, MD
CMD: MOLDX
Palmetto GBA
angella.charnot-katsikas@palmettogba.com

LAURENCE CLARK, MD, FACP
CMD: JE/JF
Noridian Healthcare Solutions
laurence.clark@noridian.com

CAROLYN CUNNINGHAM, MD
CMD: J-6
National Government Services
Carolyn.cunningham@anthem.com

MARC DUERDEN, MD
CMD: JK
National Government Services
marc.duerden@anthem.com

HARRY FELICIANO, MD, MPH
CMD: J11 MAC
Palmetto GBA
harry.feliciano@palmettogba.com

LELAND GARRETT, MD, FACP, FASN, CPC
CMD: J11 MAC
Palmetto GBA
leland.garrett@palmettogba.com

CRAIG HAUG, MD
CMD: J-K MAC
NHIC, Corp
Craig.haug@dcx.com

ROBERT KETTLER, MD
CMD: J-5, ALJ
Wisconsin Physician Services Corp.
robert.kettler@wpsic.com

JANET LAWRENCE, MD
CMD: JE/JF
Noridian Healthcare Solutions
janet.lawrence@noridian.com

MARIA LENAZ, MD
CMD: JM/JJ
Palmetto GBA
maria.lenaz@palmettogba.com

MEREDITH LOVELESS, MD, FACOG
CMD: J15
CGS Administrators, LLS
meredith.loveless@cgsadmin.com

ARTHUR LURVEY, MD, FACP, FACE
CMD: JE A/B MAC
Noridian Healthcare Solutions
Arthur.lurvey@noridian.com

PATRICK MANN, MD
CMD: JH/JL
Novitas Solutions, Inc
patrick.mann@novitas-solutions.com

GREG MCKINNEY, MD, MBA
CMD: Pending
National Government Services
greg.mckinney@anthem.com

EILEEN MOYNIHAN, MD, FACR, FACP
CMD: JE/JF A/B MAC
Noridian Healthcare Solutions
eileen.moynihan@noridian.com

SHANE MULL, MD, MHA, FAAFP, FACHE
CMD: JM
Palmetto GBA
shane.mull@palmettogba.com

DENISE NACHODSKY, MD
CMD: J5, J8, ALJ
Wisconsin Physician Services Corp
denise.nachodsky@wpsic.com

ELLA NOEL, DO, FACIO
CMD: J-8
Wisconsin Physician Services Corp
ella.noel@wpsic.com

GARY OAKES, MD, FAAFP
CMD: JF A/B MAC
Noridian Healthcare Solutions
gary.oakes@noridian.com

NEIL SANDLER, MD
CMD: J15 MAC
CGS Administrators, LLC
neil.sandler@cgsadmin.com

JUAN SCHAENING, MD
CMD: JN
Triple S Salud, Inc.
jschaening@triples-med.org

JYME SCHAFER, MD
CMD: JH/JL
Novitas Solutions, Inc
jyme.schafer@novitas-solutions.com

LESLIE STEVENS, MD
CMD: JN
First Coast Service Options, Inc.
leslie.stevens@fcso.com

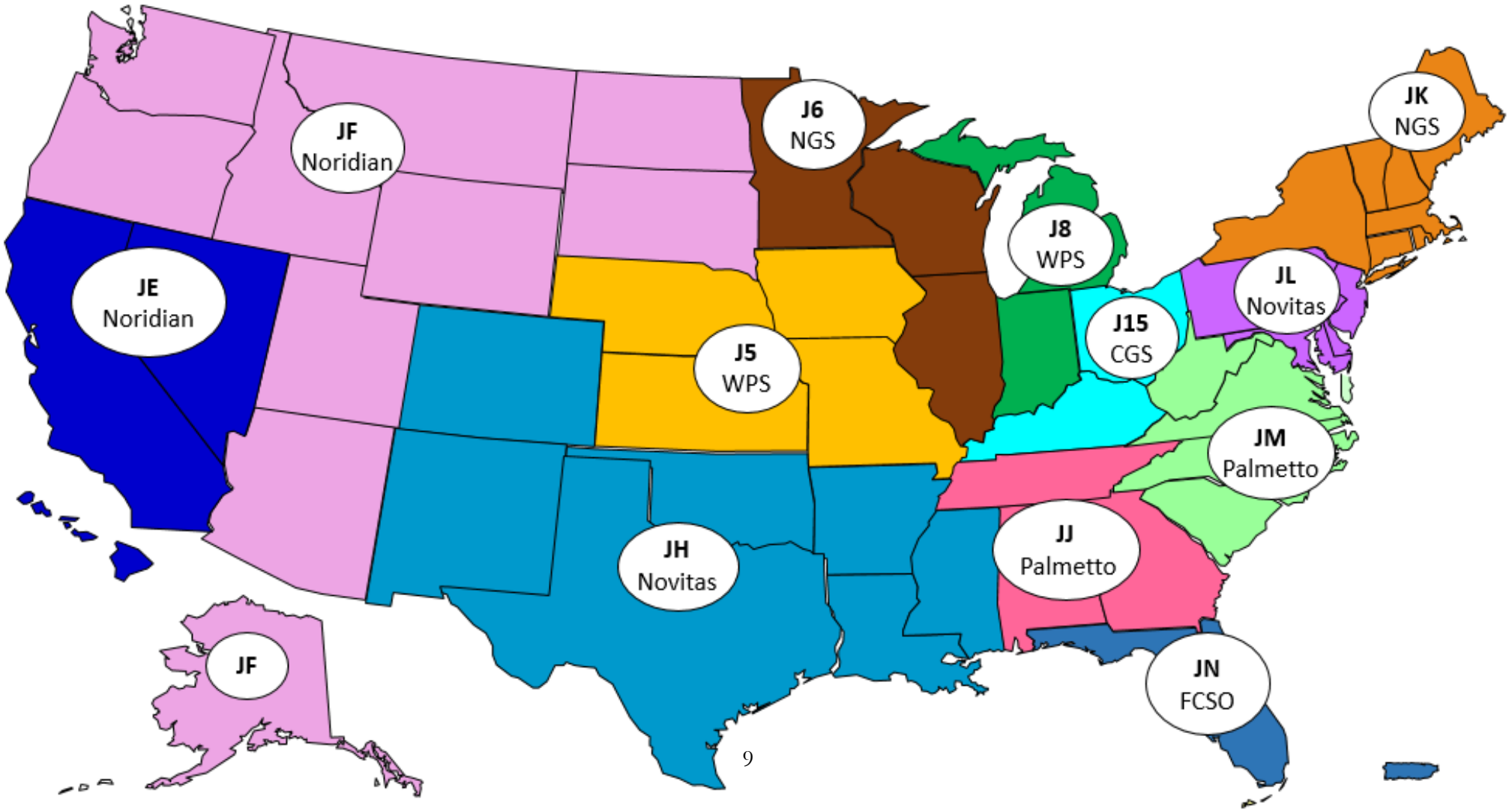
JASON STROUD, MD, MS
CMD: JJ, JM
Palmetto GBA
jason.stroud@palmettogba.com

ANNMARIE SUN, MD
CMD: JE/JF
Noridian Healthcare Solutions
annmarie.sun@noridian.com

JUDITH VOLKAR, MD, FACOG, MBA
CMD: JJ/JM
Palmetto GBA
judith.volkar@palmettogba.com

BARRY WHITES, MD, FCCP, MSHA, CHCQM
CMD: JH, JL
Novitas Solutions, Inc
barry.whites@novitas-solutions.com

A/B MAC Jurisdictions
as of June 2019



May 12, 2022

Leland E. Garrett MD FACP FASN CPC
Chief Medical Officer
Contractor Medical Director
Medicare Jurisdictions RRB, JM, JJ
Palmetto GBA

Lisa Banker, MD, CPE, FACP, CCS, CCDS
Chief Medical Officer
Contractor Medical Director
Medicare Jurisdictions J & M
Palmetto GBA

RE: Proposed Local Coverage Determination (LCD): Palmetto GBA: Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin (DL39270)

Dr. Garrett and Dr. Banker,

The American Society of Hematology (ASH) and the American Society for Transplantation and Cellular Therapy (ASTCT) are very appreciative of Palmetto GBA's leadership in drafting the local coverage determination (LCD), DL39279, Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin. Our Societies support this LCD, as written, and believe it will have a positive impact on the health of Medicare beneficiaries living with certain types of lymphoma by providing access to allogeneic hematopoietic cell transplantation (allo-HCT).

ASH represents more than 18,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy.

The ASTCT is a professional membership association of more than 3,000 physicians, scientists and other health care professionals promoting blood and marrow transplantation and cellular therapy through research, education, scholarly publication, and clinical standards. The clinical teams in our society have been instrumental in developing and implementing clinical care standards and advancing

cellular therapy science, including participation in trials that led to current FDA approvals for chimeric antigen receptor T-cell (CAR-T) therapy.

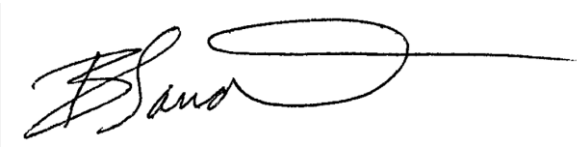
Our Societies understand that the LCD will expand coverage for allogeneic stem cell transplant for Medicare beneficiaries with primary refractory or relapsed Hodgkin and non-Hodgkin lymphomas with B-cell or T-cell origin, for whom there are no other curative intent options when it is deemed medically necessary. The scientific evidence referenced in the draft LCD is recognized by our Societies as demonstrating the effectiveness in general and the comparable success of the procedure regardless of age, providing the justification for this coverage decision. The Medicare National Coverage Determination (NCD) for Allogeneic Stem Cell Transplantation (110.23) does not specifically include lymphoma as a covered indication, leaving Medicare beneficiaries with lymphoma without nationally consistent access to this potentially curative treatment and creating a different standard of care under Medicare than what is afforded to patients with commercial insurance. For the subset of lymphoma patients who need it, allo-HCT is their only option for curative intent therapy, making this LCD critically important.

ASH and ASTCT strongly support this LCD and are grateful to Palmetto GBA for addressing this gap in coverage and allowing our patients to access this life-altering treatment.

Should you have questions, please contact Suzy Leous (sleous@hematology.org), ASH's Chief Policy Officer, or Alycia Maloney (amaloney@astct.org), ASTCT's Director of Government Relations.

Sincerely,

Jane N. Winter, MD
ASH President



Brenda M. Sandmaier, MD
ASTCT President

October 12, 2021

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD

RE: A Formal Request for the Reconsideration of the National Coverage Determination for Stem Cell Transplantation (110.23)

Dear Ms. Syrek Jensen:

The American Society of Hematology (ASH), the American Society for Transplantation and Cellular Therapy (ASTCT), the National Marrow Donor Program (NMDP), and the Center for International Blood and Marrow Transplant Research (CIBMTR) submit this letter as a formal request for reconsideration of the National Coverage Determination (NCD) for Stem Cell Transplantation (110.23). Specifically, the above organizations are asking for full coverage of allogeneic hematopoietic stem cell transplantation (HSCT) for individuals with myelodysplastic syndromes (MDS) and the removal of the Coverage with Evidence Development (CED) requirement currently tied to coverage for HSCT for Medicare beneficiaries with MDS.

Allogeneic HSCT remains the only curative therapy for patients with MDS, a group of blood disorders in which the bone marrow does not produce enough healthy, functioning blood cells. MDS primarily impacts older adults: the median age at diagnosis is 70 years, making Medicare coverage for HSCT essential for patients to access this life-saving treatment. Because of the importance of maintaining patient access, our organizations ask that the CED for HSCT remain in place until the full coverage policy requested becomes effective.

Background Information and Current Status of Medicare Coverage of HSCT for MDS

In 2009, the organizations listed above joined other medical societies to request a NCD for allogeneic HSCT for MDS for the Medicare population. On August 4, 2010, CMS established coverage for HSCT for MDS through CED. In December 2010, a CIBMTR study comparing outcomes of patients 55-64 vs. 65 and older was approved by CMS for transplant centers to participate in the CED.

The CED has allowed for coverage of HSCT for Medicare patients with MDS. Currently, there are more than 140 U.S. transplant centers providing Medicare covered HSCT and participating in the CED study of HSCT for MDS in patients over 65. Since approval of the CED, the number of allogeneic HSCTs in the U.S. for patients 65 years and older more than quadrupled, demonstrating that insurance coverage in this population is an essential factor in providing access to HSCT.

The NMDP, operated by Be The Match ®, runs the federally authorized bone marrow program that matches living unrelated adult donors with patients in need of a life-saving transplant. For over three decades, through a competitively bid contract with the Health Resources and Services Administration (HRSA), NMDP has been entrusted to operate the federal registry designated by Congress as part of the C.W. Bill Young Cell Transplantation Program (Program). The CIBMTR is a research

collaboration between the NMDP/Be The Match® and the Medical College of Wisconsin (MCW). The CIBMTR runs the Stem Cell Therapeutics Outcomes Database (SCTOD) as part of the Program since 2006. The CIBMTR is charged with collecting data on all allogeneic (related and unrelated) HSCTs performed in the U.S. (from approximately 180 transplant centers), and on all HSCTs done with products procured through the Program but performed outside of the U.S.. In sum, the SCTOD collects and uses data about cellular transplants for research that refines transplantation to help more patients live longer, healthier lives.

Both the NMDP and the Foundation for the Accreditation of Cellular Therapy and the Joint Accreditation Committee – ISCT and EBMT (FACT-JACIE) have established provider and facility standards directly related to providing HSCT for MDS and the other clinical indications covered by Medicare. These established standards will ensure that the appropriately selected Medicare beneficiaries who receive this service will receive care by qualified providers in a safe environment

Formal Request

With the publication of recent studies strong evidence now exists to motivate our organizations to formally request the reconsideration of the NCD 110.23 for HSCT for patients with MDS and seek the removal of the CED requirements and the inclusion of a statement of full coverage, as suggested here:

> B. Nationally Covered Indications
>
> I. Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)
>
> c) Effective for services performed on or after (effective date), for the treatment of Myelodysplastic Syndrome (MDS), when it is reasonable and necessary. (New language to be inserted in place of the existing language in NCD 110.23, B. I. c.)

Required Information for Reconsideration

Per the Federal Register Notice: Medicare Program; Revised Process for Making National Coverage Determinations, below is the information as requested for a formal reconsideration.

Proposed use of service

HSCT is a procedure in which stem cells are taken from a person's bone marrow or blood and then administered to the patient by intravenous infusion. When the stem cells come from a donor, the procedure is called an allogeneic HSCT. The only treatment providing or leading to or yielding long-term, progression-free survival for MDS is allogeneic HSCT.

Target Medicare population & Medical indications

Medicare beneficiaries with a diagnosis of MDS regardless of age should have access to HSCT. The services provided to Medicare beneficiaries diagnosed with MDS, and who require a transplant, include, but are not limited to, the statutorily defined benefit categories of inpatient hospital services and the physician services benefit categories (1861(b) and 1861(q), respectively).

MDS refers to a group of diverse blood disorders in which the bone marrow does not produce enough healthy, functioning blood cells. These disorders are varied with regard to clinical characteristics, cytologic and pathologic features, and chromosome analysis. The abnormal production of blood cells in the bone marrow leads to low blood cell counts, referred to as cytopenias, which are a hallmark feature of MDS along with a dysplastic and hypercellular-appearing bone marrow. Patients may die as a result of complications of cytopenias, or after progression to Acute Myelogenous Leukemia. Please see Appendix A for a list of the diagnosis codes for MDS.

Relevance, usefulness, or the medical benefits of the service to the Medicare population

Allogeneic HSCT remains the only curative therapy for patients with MDS. The recent studies summarized below met CMS' criteria for its CED and further substantiate the effectiveness of allogeneic HSCT for MDS among Medicare aged beneficiaries and provide the full response to the request for this information.

Summary of Recent Scientific Evidence to Justify the Request

Summary of Biologic Assignment Trial of Reduced-Intensity Hematopoietic Cell Transplantation Based on Donor Availability in Patients 50-75 Years of Age With Advanced Myelodysplastic Syndrome

Nakamura R, Saber W, Martens MJ, et al. Biologic Assignment Trial of Reduced-Intensity Hematopoietic Cell Transplantation Based on Donor Availability in Patients 50-75 Years of Age With Advanced Myelodysplastic Syndrome. J Clin Onc 2021, online ahead of print.

Allogeneic HSCT, widely used in younger MDS patients, is the only curative therapy for MDS. While transplantation outcomes among selected older patients with MDS are similar to younger patients with MDS, early transplantation for older patients is infrequently offered since the relative benefits of HSCT over non-HSCT therapy have not been well defined in this patient group. The goal of this multi-center, biologic assignment study in older individuals with high-risk MDS was to define the benefit of HSCT over non-HSCT therapy. Specifically, the study compared allogeneic HSCT with DNA hypomethylating therapy or best supportive care in individuals aged 50-75 years with advanced MDS.

To summarize, the study found that overall survival and leukemia-free survival was significantly improved for individuals who had a suitably matched donor in comparison with those who did not have a donor. Nearly half of subjects with a donor were alive 3 years after trial entry when compared with only one quarter when a donor was unavailable.

Biologic assignment was to the donor or no donor group based on the identification of a suitable, HLA-matched related or unrelated donor within 90 days of trial entry. Subjects with an identified donor were expected to undergo transplantation within 6 months, while those without a suitable donor were expected to receive DNA hypomethylating therapy or best supportive care. The primary endpoint of the study was a point comparison of adjusted overall survival at 3 years from study registration. Secondary endpoints included disease-free survival at 3 years from study registration, quality of life measured at 6 timepoints, and a cost-effectiveness comparison. Additionally, pre-specified as-treated analyses were performed, analyzing only subjects who received their biologically-assigned therapy.

384 subjects in total were accrued at 34 participating centers, with enrollment ending at the end of 2018, when sufficient subjects had been accrued to the no donor arm. Of the 384 subjects, a suitable donor was identified in 260 while no donor was found for 124. Seven subjects died during the 90-day search window and were included in the no donor arm. The donor and no donor arms were well balanced for age, gender, duration of MDS, disease risk and response to prior DNA hypomethylating therapy.

At three years from trial enrollment, overall survival was significantly higher in the donor vs. no donor group, with an absolute improvement of 21.3% (47.9% vs. 26.6%, p=0.0001). In a sensitivity analysis, excluding subjects who died or withdrew prior to the end of the search window, no effect on outcomes was noted (48.0% vs. 28.1%, p=0.0004). **The effect of age on the primary outcome was specifically analyzed, with no difference in the odds ratio for outcomes when stratified by Medicare age eligibility (age < 65 [OR for survival with donor vs no donor, 2.44] vs age > 65 [OR for survival, 2.962]).** Similar to overall survival, 3-year leukemia-free survival was significantly better in the donor arm (35.8% vs. 20.6%, p=0.003), without a measurable difference in the sensitivity analyses (35.9% vs. 21.8%, p=0.0074). **Moreover, no effect of age was noted when stratified by Medicare age eligibility (OR for leukemia-free survival, 2.396 vs 2.206).**

In as-treated analyses, only subjects who underwent matched donor transplantation were included in the donor arm, and only those subjects who did not undergo transplantation in the no donor arm. The differences in outcome in this analysis were greater for both 3-year overall survival (47.4 % vs 16%, p<0.0001) and 3-year leukemia-free survival (39.3% vs 10.9%, p<0.0001).

In preliminary quality of life analyses, no clinically significant differences were noted between donor and no donor groups at several time points up to 3 years from trial entry using the FACT-G, SF-36 physical, SF-36 mental and EQ-5D scores. In contrast to commonly held beliefs that transplantation is associated with poor quality of life, our analysis suggested that there was no decrement in quality of life in transplant recipients.

Summary of Comparison of patient age groups in transplantation for myelodysplastic syndrome: the Medicare Coverage with Evidence Development study

Atallah E, Logan B, Chen M, et al. Comparison of patient age groups in transplantation for myelodysplastic syndrome: the Medicare Coverage with Evidence Development study. JAMA Oncol. 2020;6(4):486-493. Doi:10.100/jamaoncol.2019.5140. Published online Dec 12, 2019.

The CIBMTR developed an observational study that met CMS' criteria for CED in response to the August 4, 2010 Decision Memo for Allogeneic HSCT for Myelodysplastic Syndrome (CAG-00415N). This prospective, multicenter observational study compared the outcomes of patients aged 55-64 years with patients 65 years and older who received allogeneic HSCT performed in the United States. The primary outcome was overall survival. Other outcomes included non-relapse mortality, relapse, relapse-free survival, and acute and chronic graft-versus-host disease (GVHD). CIBMTR collected data from all participating HSCT centers and performed the analysis.

From December 2010 to May 2014, 688 patients aged 65 years or older were enrolled in the study, and their outcomes were compared with 592 patients aged 55 to 64 years randomly selected from the population of United States patients treated during the same time period. There was no difference in the outcome of the randomly selected sample of patients included in this study compared with the

rest of patients aged 55 to 64 years treated during the study period. Twenty-four percent of the patients in 65 and older group were 70 years or older. The median follow up was 47 months. Other than age, there were no significant differences in patient and disease characteristics between the two age cohorts. About 50% of patients in both groups had an Hemopoietic Cell Therapy-Comorbidity Index (HCT-CI) score of 3 or greater, about 25% had therapy related MDS; nearly 25% were intermediate risk by the Revised-International Prognostic Scoring System (R-IPSS) and around 30% were high or very high risk by R-IPSS at diagnosis.

Multivariate analysis of overall survival identified high/very high R-IPSS, blasts in bone marrow (bBM) > 11% before HSCT, non-age-adjusted HCT-CI of 4 or greater, and GVHD prophylaxis with calcineurin inhibitor + methotrexate as independently associated with inferior outcome. Age group 65 years or older vs those aged 55 to 64 years had no statistically significant association with mortality with (hazard ratio [HR], 1.09; 95% confidence interval [CI], 0.94-1.27; p=0.23) or without (HR, 1.13; 95% CI, 0.98-1.3; p=0.08) adjustment for excess population-based risk of mortality in the older group.

Multivariate analysis of relapse-free survival demonstrated no significant difference between patients in the 65 years and older age group compared to those 55 to 64 years (HR, 1.14; 95% CI, 0.99-1.31; p=0.07). R-IPSS high/very high, in-vivo T depletion, bBM > 11% before HSCT, conditioning regimen, not being in remission before HSCT and HCT-CI of 4 or greater were associated with worse relapse-free survival.

At 3 years, non-relapse mortality was 28% vs 25% for the patients 65 years and older vs. the 55 to 64 years age group. After adjusting for excess risk of mortality in the general older population in multivariate analysis, there was no statistically significant difference in non-relapse mortality between the 65 years or older group compared to 55 to 64 years group (HR, 1.19; 95% CI, 0.93-1.52; p=0.16). There were no differences in the rates of grades II to IV acute GVHD or chronic GVHD between the two groups.

The authors conclude older patients with MDS undergoing allogeneic HSCT have similar overall survival compared with younger patients. The strongest factors associated with survival after allogeneic HSCT were HCT-CI comorbidity score, IPSS-R score and other disease related factors, and GVHD prophylaxis regimen. Chronologic age alone should not be an appropriate selection factor for allogeneic HSCT in patients with MDS.

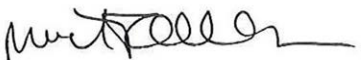
Please see Appendix B for a list of additional literature outlining new clinical evidence which supports this request.

Conclusion

ASH, ASTCT, NMDP, and CIBMTR submit this letter as a formal request for reconsideration of the NCD for Stem Cell Transplantation (110.23). Specifically, the above organizations are asking for full coverage of allogeneic HSCT for individuals with myelodysplastic syndromes and the removal of the CED requirement currently tied to coverage for HSCT for individuals with MDS. As the agency works to address this reconsideration, the organizations ask that the current CED remains in place to allow for undisrupted coverage for HSCT for Medicare beneficiaries with MDS.

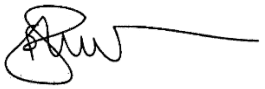
Thank you for your consideration of this request. For any questions, please contact Leslie Brady, ASH Policy and Practice Manager, at lbrady@hematology.org.

Sincerely,



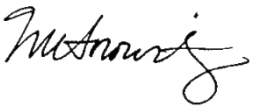
Martin S. Tallman, M.D.
President, ASH

Stella M. Davies, MBBS, PhD, MRCP
President, ASTCT

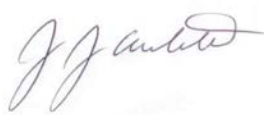


Bronwen Shaw, MD, PhD
Chief Scientific Director, CIBMTR-MCW

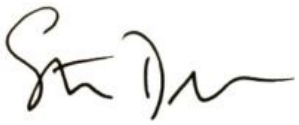
J. Douglas Rizzo, MD, MS
Senior Scientific Director and Principal Investigator, Stem Cell Therapeutic Outcomes Database, CIBMTR-MCW



Mary Horowitz, MD, MS, MACP
Principal Investigator, BMT CTN Data and Coordinating Center, MCW



Jeffery J. Auletta, M.D.
Senior Vice President, Patient Outcomes and Experience, NMDP
Chief Scientific Director, CIBMTR, NMDP



Steven Devine, M.D.
Chief Medical Officer, NMDP/Be The Match

Appendix A: International Classification of Diseases, Tenth Revision, Clinical Modification, ICD-10-CM

D46 Myelodysplastic syndromes

Use additional code for adverse effect, if applicable, to identify drug (T36-T50 with fifth or sixth character 5)

Excludes2: drug-induced aplastic anemia (D61.1)

D46.0 Refractory anemia without ring sideroblasts, so stated
Refractory anemia without sideroblasts, without excess of blasts

D46.1 Refractory anemia with ring sideroblasts
RARS

D46.2 Refractory anemia with excess of blasts [RAEB]

D46.20 Refractory anemia with excess of blasts, unspecified
RAEB NOS

D46.21 Refractory anemia with excess of blasts 1
RAEB 1

D46.22 Refractory anemia with excess of blasts 2
RAEB 2

D46.A Refractory cytopenia with multilineage dysplasia

D46.B Refractory cytopenia with multilineage dysplasia and ring sideroblasts
RCMD RS

D46.C Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality
Myelodysplastic syndrome with 5q deletion
5q minus syndrome NOS

D46.4 Refractory anemia, unspecified

D46.Z Other myelodysplastic syndromes

Excludes1: chronic myelomonocytic leukemia (C93.1-)

D46.9 Myelodysplastic syndrome, unspecified
Myelodysplasia NOS

Appendix B: Additional literature outlining new clinical evidence which supports this request

Atallah E, Logan B, Chen M, et al. Comparison of patient age groups in transplantation for myelodysplastic syndrome: the Medicare Coverage with Evidence Development study. *JAMA Oncol.* 2020;6(4):486-493. Doi:10.100/jamaoncol.2019.5140. Published online Dec 12, 2019.

Nakamura R, Saber W, Martens MJ, et al. Biologic Assignment Trial of Reduced-Intensity Hematopoietic Cell Transplantation Based on Donor Availability in Patients 50-75 Years of Age With Advanced Myelodysplastic Syndrome. *J Clin Onc* 2021, online ahead of print.

Kroger N, Sockel K, Christine W, et al. Comparison Between 5-Azacytidine Treatment and Allogeneic Stem-Cell Transplantation in Elderly Patients With Advanced MDS According to Donor Availability (VidazaAllo Study). *J Clin Onc* 2021.

Gooley T. Two Biologic-Assignment Studies Evaluating the Efficacy of Hematopoietic Cell Transplant Among Older Patients With High-Risk Myelodysplastic Syndrome. *J Clin Onc* 2021.

Warlick E, Ustun C, Andreescu, A, et al. Blood and Marrow Transplant Clinical Trials Network Study 1102 Heralds a New Era in Hematopoietic Cell Transplantation in High-Risk Myelodysplastic Syndromes: Challenges and Opportunities in Implementation. *Cancer* 2021.

Robin M, Porcher R, Ades L, HLA-matched allogeneic stem cell transplantation improves outcome of higher risk myelodysplastic syndrome A prospective study on behalf of SFGM-TC and GFM. *Leukemia* (2015) 29, 1496 – 1501.

Abel G, Kim H, Hantel A, et al. Fit Older Adults with Advanced Myelodysplastic Syndromes: Who is Most Likely to Benefit from Transplant? *Leukemia* 2021; 35(4): 1166-1175.

Von Willebrand Disease Types

The American Society of Hematology (ASH) has proposed to establish new ICD-10-CM diagnosis codes for types of von Willebrand disease (VWD). ASH represents more than 18,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases.

Von Willebrand disease is the most common inherited bleeding disorder, in which the blood does not clot properly, with wide variability in clinical phenotype. According to the Centers for Disease Control and Prevention, about 3.2 million (or about 1 in every 100) people in the US have the disease.[1,2] More recent epidemiologic studies reference a prevalence of 1 in 1000.[3] People with VWD either have a low level of von Willebrand factor (VWF), a protein that helps the blood to clot, or the VWF protein does not work the way it should. Although VWD occurs among men and women equally, women are more likely to notice the symptoms because of heavy or abnormal bleeding during their menstrual periods and after childbirth.[1]

In 2006, the International Society of Thrombosis and Haemostasias (ISTH) classified VWD into six categories or subtypes, based on the difference in clinical features and therapeutic requirements. Recently, ASH in partnership with ISTH, the National Hemophilia Foundation (NHF) and the World Federation of Hemophilia (WFH), has developed clinical practice guidelines for the diagnosis and management of VWD. The guidelines were published in *Blood Advances* in Jan. 2021.[6] With these guidelines now available, it is critically important to update the ICD-10-CM classification for VWD to allow for the adoption of the guideline recommendations and to improve best practices for clinical care.

Currently, all the types of von Willebrand disease are coded to one ICD-10-CM code, D68.0 (Von Willebrand's disease). According to ASH, this makes making it difficult to accurately document, track, and in turn, appropriately treat the different subtypes of VWD. For this reason, ASH has requested the addition of new ICD-10-CM diagnosis codes for VWD to better track the disease and its subtypes.

Type 1 von Willebrand disease (VWD) is characterized by decreased levels (qualitative deficiency) of von Willebrand factor (VWF). The VWF that is made is functionally normal; however, lower circulating levels lead to an increased risk of bleeding. Options for treatment including VWF concentrate, desmopressin to stimulate release of stored VWF, and antifibrinolytic therapy.

Type 1C von Willebrand disease (VWD) is characterized by increased clearance of VWF, leading to decreased levels. As is the case with other type 1 VWD, the circulating VWF in type 1C is functionally normal, however the protein is degraded quickly and not available to participate in hemostasis, leading to increased risk of bleeding. Options for treatment include VWF concentrate in

conjunction with antifibrinolytic therapy. While desmopressin will lead to a transient release of stored endogenous VWF, the effect is transient with quick return to baseline levels and increased risk of bleeding if not maintained in high risk situations such as surgery.

All forms of type 2 VWD are characterized by functional defects in VWF with subtyping based on the specific functional defect. Treatment may involve desmopressin for most subtypes (except type 2B) along with VWF concentrate and adjunctive therapy with antifibrinolytics.

Type 2A von Willebrand disease (VWD) is characterized by abnormal platelet-dependent VWF function with loss of the most hemostatically active high-molecular weight multimers of VWF.

Type 2B von Willebrand disease (VWD) is characterized by abnormal function of VWF due to a gain of function mutation that increases binding of VWF to platelet glycoprotein 1b-alpha, often leading to thrombocytopenia. Desmopressin is contraindicated due to paradoxically worsened bleeding due to increased thrombocytopenia.

Type 2M von Willebrand disease (VWD) is characterized by abnormal platelet-dependent VWF function, however multimers are preserved, a major difference between type 2A and type 2M.

Type 2N von Willebrand disease (VWD) is characterized by abnormal factor VIII binding by VWF, leading to decreased factor VIII levels and varying degree of bleeding similar to hemophilia A.

Type 3 von Willebrand disease (VWD) is a qualitative form of VWD with near complete absence of circulating VWF. This is the most severe subtype, requiring use of VWF concentrate as desmopressin is not effective.[4,5,6,7]

Acquired von Willebrand disease syndrome (AVWS) is a deficiency in the amount or function of von Willebrand factor (VWF) that is due to acquired rather than inherited causes. Examples of causes for AVWS include shearing and subsequent degradation of VWF across stenotic heart valves or through mechanical circulatory support circuits such as left-ventricular assist devices or via extracorporeal membrane oxygenation. AVWS may arise due to autoantibody formation such as that seen in immune dysregulation disorders or VWF may be directly adsorbed onto malignant cells as observed in patients with Wilms tumors or Waldenstrom macroglobulinemia. Treatment consists of supportive therapy with VWF concentrate, desmopressin, and/or antifibrinolytic therapy along with correction of the underlying cause (e.g. valve replacement therapy or immunosuppression).[8,9]
Platelet-type von Willebrand disease is due to a functional defect in the platelet receptor for von Willebrand factor. Often misdiagnosed as type 2B von Willebrand disease, treatment consists of platelet transfusions in addition to standard VWD therapies such as VWF concentrate or antifibrinolytic therapy.[10]

This proposal is based on the original ASH request, but differs in proposing to combine type 1C VWD with other type 1 VWD, and also in proposing to include platelet-type von Willebrand disease within another VWD code. ASH has recommended the deletion of several terms currently listed under D68.0, which are no longer used in clinical practice. It is proposed that these and all index entries related to von Willebrand disease be directed to the entry at Disease, von Willebrand, with the types to be identified as subentries there (not shown). ASH has also proposed to add the term "Low von Willebrand factor" as an inclusion term for code R79.1, Abnormal Coagulation Profile. In addition, it has been recommended the apostrophe "s" be deleted (consistent with WHO ICD-10 updates), and also that the "v" in von Willebrand be made lowercase (consistent with the medical literature and usual practice).

References

1 Centers for Disease Control and Prevention. October 2020. What is von Willebrand Disease? November 23, 2020. https://www.cdc.gov/ncbddd/vwd/facts.html

2 Rodeghiero, F, Castaman, G, Dini, E. Epidemiological Investigation of the Prevalence of von Willebrand's Disease. Blood, Vol 69, No 2, 1987: pp 454-459.

3 Bowman, M, et al. The Prevalence of symptomatic von Willebrand disease in primary care practice. J Thromb Haemost 2010; 8: 213-6.

4 Sadler JE, et al. Update on the pathophysiology and classification of von Willebrand disease: a report of the Subcommittee on von Willebrand Factor. J Thromb Haemost. 2006 Oct;4(10):2103-14.

5 Ng C, Motto DG, Di Paola J. Diagnostic approach to von Willebrand disease. Blood. 2015 Mar 26;125(13):2029-37.

6 James P, et al. ASH ISTH NHF WFH 2021 Guidelines on the Diagnosis of von Willebrand Disease. Blood Adv. 2021 Jan 12;5(1):280-300. https://doi.org/10.1182/bloodadvances.2020003265.

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8 Franchini M, Mannucci PM. The acquired von Willebrand syndrome focused for hematologists. Haematologica. 2020.

9 Nascimbene, A. et al. Acquired von Willebrand syndrome associated with left ventricular assist device. Blood, 23 June 2016, Vol 127 (25).

10 Othman M, Gresele P. Guidance on the diagnosis and management of Platelet- type von Willebrand Disease: a communication from the platelet physiology subcommittee of the ISTH. J Thromb Haemost. 2020.

TABULAR MODIFICATIONS

D68 Other coagulation defects

Revise Excludes1: abnormal coagulation profile NOS (R79.1)

Delete		~~coagulation defects complicating abortion or ectopic or molar pregnancy (O00-O07, O08.1)~~
Delete		~~coagulation defects complicating pregnancy, childbirth and the puerperium (O45.0, O46.0, O67.0, O72.3)~~
Add	Excludes2:	coagulation defects complicating abortion or ectopic or molar pregnancy (O00-O07, O08.1)
Add		coagulation defects complicating pregnancy, childbirth and the puerperium (O45.0, O46.0, O67.0, O72.3)

Revise	D68.0	Von Willebrand~~'s~~ disease
Delete		~~Angiohemophilia~~
Delete		~~Factor VIII deficiency with vascular defect~~
Delete		~~Vascular hemophilia~~

New code	D68.00	Von Willebrand disease, unspecified
New code	D68.01	Von Willebrand disease, type 1
Add		Partial quantitative deficiency of von Willebrand factor
Add		Type 1C von Willebrand disease
New subcategory	D68.02	Von Willebrand disease, type 2
Add		Qualitative defects of von Willebrand factor
New code	D68.020	Von Willebrand disease, type 2A
Add		Qualitative defects of von Willebrand factor with decreased platelet adhesion and selective deficiency of high-molecular-weight multimers
New code	D68.021	Von Willebrand disease, type 2B
Add		Qualitative defects of von Willebrand factor with hyper-adhesive forms

Add		Qualitative defects of von Willebrand factor with high-molecular-weight von Willebrand factor loss
Add		Qualitative defects of von Willebrand factor with increased affinity for platelet glycoprotein lb
New code		D68.022 Von Willebrand disease, type 2M
Add		Qualitative defects of von Willebrand factor with defective platelet adhesion with a normal size distribution of von Willebrand factor multimers
New code		D68.023 Von Willebrand disease, type 2N
Add		Qualitative defects of von Willebrand factor with markedly decreased affinity for factor VIII
Add		Qualitative defects of von Willebrand factor with defective von Willebrand factor to factor VIII binding
New code		D68.029 Von Willebrand disease, type 2, unspecified
Add		Qualitative defect in von Willebrand factor function, with no further subtyping
New code	D68.03	Von Willebrand disease, type 3
Add		(Near) complete absence of von Willebrand factor
Add		Total quantitative deficiency of von Willebrand factor
New code	D68.04	Acquired von Willebrand disease
Add		Acquired von Willebrand syndrome
New code	D68.09	Other von Willebrand disease
Add		Platelet-type von Willebrand disease
Add		Pseudo-von Willebrand disease
Add		Code also, if applicable, qualitative platelet defects (D69.1)

R79 Other abnormal findings of blood chemistry

R79.1 Abnormal coagulation profile

Add Low von Willebrand factor

INDEX MODIFICATIONS

Revise Angiohemophilia (A) (B) ~~D68.0~~ – see Disease, von Willebrand

Defect, defective Q89.9
- platelets, qualitative D69.1
Revise - - constitutional ~~D68.0~~ – see Disease, von Willebrand

Deficiency, deficient
- factor -see also Deficiency, coagulation
- - VIII (congenital) (functional) (hereditary) (with functional defect) D66
Revise - - - with vascular defect ~~D68.0~~ – see Disease, von Willebrand
- platelet NEC D69.1
Revise - - constitutional ~~D68.0~~ – see Disease, von Willebrand

Disease
Revise - Minot-von Willebrand-Jürgens (angiohemophilia) D68.0

Hemophilia (classical) (familial) (hereditary) D66
Revise - vascular ~~D68.0~~ – see Disease, von Willebrand

Revise Minot-von Willebrand-Jurgens disease or syndrome (angiohemophilia) ~~D68.0~~ – see Disease, von Willebrand

Revise Pseudohemophilia (Bernuth's) (hereditary) (type B) ~~D68.0~~ – see Disease, von Willebrand

Syndrome -see also Disease
Revise - von Willebrand (-Jürgen) ~~D68.0~~ – see Disease, von Willebrand
Revise - Willebrand (-Jürgens) ~~D68.0~~ – see Disease, von Willebrand

Thrombopathy (Bernard-Soulier) D69.1
Revise - constitutional ~~D68.0~~ – see Disease, von Willebrand
Revise - Willebrand-Jurgens ~~D68.0~~ – see Disease, von Willebrand

Revise Von Willebrand (-Jurgens)(-Minot) disease or syndrome ~~D68.0~~ – see Disease, von Willebrand

Revise Willebrand (-Jürgens) thrombopathy ~~D68.0~~ – see Disease, von Willebrand

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- Von Willebrand Disease (VWD)
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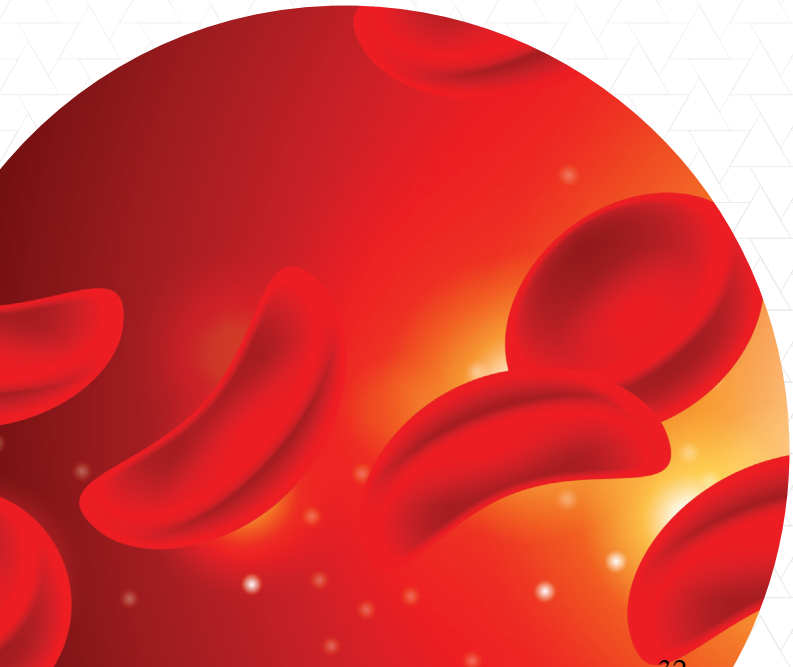
- ROBERT LIEM, MD
CO-CHAIR, ASH GUIDELINES ON SCD: CARDIOPULMONARY AND KIDNEY DISEASE



Venous Thromboembolism (VTE)

Venous thromboembolism (VTE) is a common and serious blood clotting condition that includes both deep-vein thrombosis (DVT) and pulmonary embolism (PE). VTE is an important public health problem, with an estimated 60,000 to 100,000 patient deaths in the U.S. each year.

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"These guidelines address questions that we thought were relevant for the Latin American region that differed from other parts of the world. Our goal was to ensure that these guidelines **were practical to help clinicians in Latin America make decisions in different scenarios**, but also addressed feasibility regarding the availability and affordability of each recommendation."

– **Patricia Casais, MD, PhD, MSc, Grupo** COOPERATIVO LATINOAMERICANO DE HEMOSTASIA Y TROMBOSIS, GRUPO COOPERATIVO ARGENTINO DE HEMOSTASIA Y TROMBOSIS

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- Immune Thrombocytopenia

"A big difference between these guidelines and [previous guidelines] is our **balanced composition between practitioners, methodologists, and patients**–who were not included in the 2011 guidelines. We considered past questions, in addition to brainstorming new ones. From that list, we prioritized what we thought were the most important questions to address, recognizing that this will be an iterative process that will continue."

- CINDY NEUNERT, MD
CO-CHAIR, ASH GUIDELINES ON ITP

Von Willebrand Disease (VWD)

Von Willebrand Disease (VWD) is a genetic disease caused by missing or defective von Willebrand factor (VWF), a clotting protein. Though considered a rare disease, VWD is one of the most common bleeding disorders in the U.S.–affecting up to 1% of the general population.

The guidelines on Diagnosis and Management of von Willebrand Disease were the result of a collaboration between ASH and the International Society on Thrombosis and Haemostasis (ISTH), the National Hemophilia Foundation (NHF) and the World Federation of Hemophilia (WFH).

Now Available:

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- Management of von Willebrand Disease

"We are delighted to have **patient representatives** on our panels, in addition to an **international group of clinicians and scientists with broad experience in VWD diagnosis and management**. We were guided by an expert group of methodologists and collaborated with a number partner organizations."

- **PAULA JAMES, MD**
  CO-CHAIR, ASH GUIDELINES
  ON VWD: DIAGNOSIS

Acute Myeloid Leukemia (AML)

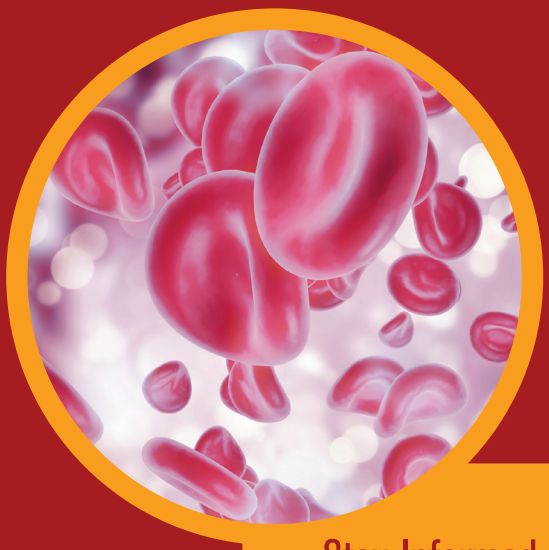
Acute myeloid leukemia (AML) is a type of cancer in which the bone marrow makes abnormal myeloblasts, red blood cells, or platelets. AML affects 61,000 new patients each year. Most of these patients are adults, with an average age of 67 years.

Now available:

- Treating Newly Diagnosed Acute Myeloid Leukemia in Older Adults

"With these guidelines, we take practitioners and patients through **every step of therapy and answer the basic questions**: from whether older adults should be treated with chemotherapy at all, to the intensity of therapy, duration of treatment, and end-oflife issues such as transfusion support in palliative and hospice settings. These guidelines are intended to be practical, rigorous, and informative."

- **MIKKAEL SEKERES, MD, MS**
  CO-CHAIR, ASH GUIDELINES
  ON AML IN OLDER ADULTS



Stay Informed

Stay up to date on newly published ASH Guidelines, plus tools and resources to support your practice. Visit *www.hematology.org/guidelines*

American Society of Hematology
2021 L Street NW, Suite 900
Washington, DC 20036
Phone: 202-776-0544
Email: *customerservice@hematology.org*
Website: www.hematology.org

CMS Resources

- Medicare's Program Integrity Manual, Chapter 13 (*Revised 2/12/19: outlines the local coverage determinations the Carrier Advisory Committee (CAC) and contractor responsibilities surrounding CACs*)
- General Information on CMS' Contracting Reform
- Medicare Administrative Contractors (MAC) Regions and Updates
- Map of Current Jurisdictions
- Map of Consolidated Regions (*what CMS is moving toward*)
- Durable Medical Equipment MACs
- Medicare Coverage
- Medicare Coverage Centers
- Patients over Paperwork: 9th Issue - Modernization Update: Local Coverage Determination (LCD)

American Society of Hematology Practice-Related Resources

ASH offers a wide range of practice-related resources on its website . Below, please find a list of resources that may be of interest to you.

ASH Carrier Advisory Committee Meeting (CAC) Website

- View resources such as the Medicare Program Integrity Manual, MAC regions, and previous Committee Notebooks.
    - If you are an ASH Member interested in being a subject matter expert, please complete this form.
    - If you are a Medical Director seeking a hematology expert, please download and complete this form, and return via email to Katherine Stark.

Resources for Clinicians

- COVID-19 Resources for Hematologists – In an effort to serve its members, ASH is maintaining this webpage as a medium to exchange information to assist hematologists in navigating the COVID-19 public health crisis.
    - COVID-19 Policy Resources – These resources, including practice webinars and reimbursement fact sheets, are intended to help navigate the complex and fast-changing COVID-19 policy landscape.
- ASH Practice Partnership – The ASH Practice Partnership (APP) is a group within the Society that was formed to better represent the interests of practicing hematologists. The APP is comprised of practicing hematologists from across the nation; participants must be board-certified in hematology and active members of ASH. Ideal candidates should be interested in malignant and classical hematology.
- Drug Resources - This page provides links to patient assistance programs and sample letters of appeal for high-cost drugs, links to Risk Evaluation and Mitigation Strategies (REMS) resources, an up-to-date list of hematologic drug shortages, resources for physicians dealing with shortages, and links to ASH/FDA webinars featuring an unbiased discussion of newly approved drugs and their uses.
- Consult a Colleague - A member service designed to help facilitate the exchange of information between hematologists and their peers.
- ASH Choosing Wisely List - Evidence-based recommendations about the necessity and potential harm of certain practices developed as part of Choosing Wisely®, an initiative of the ABIM Foundation.
- ASH Clinical Guidelines, ASH Pocket Guides, and Hematology Quality Metrics - Access guidelines on Venous Thromboembolism (VTE), Immune Thrombocytopenia (ITP), von Willebrand Disease, Sickle Cell Disease, Anticoagulation Therapy, and others. Access the full guidelines, along with other tools and resources, including pocket guides, apps, teaching slides, webinars, and podcasts.
- Well-Being and Resilience - Well-being is a critical factor in the strength of the workforce, and the Society is committed to helping hematologists address the myriad factors impacting well-being through interventions such as openly addressing burnout in live meetings and in publications, advocating on behalf of hematologists to streamline administrative work, and sharing approaches to building resilience among hematologists.

Advocacy Resources

ASH's Advocacy Center houses all of the Society's policy positions, advocacy efforts, and campaigns. Hematologists and their patients can follow the latest national policy news and directly influence their representatives through ASH Action Alerts. The Center also displays ASH's official policy statements along with Testimony and Correspondence related to federal regulation and private insurance developments.

- ASH's online advocacy toolkit provides members with the information and guidance necessary to communicate with elected officials in support of hematology. The toolkit clearly and concisely explains how members can undertake a number of actions to support ASH's advocacy efforts.

Clinical ASH Publications

- Practice Update – The Practice Update is the Society's bimonthly e-newsletter reporting on breaking news and activities of interest to the practice community.
- *ASH Clinical News* – *ASH Clinical News* is a magazine for ASH members and non-members alike – offering news and views for the broader hematology/oncology community.
- *The Hematologist*: ASH News and Reports - An award-winning, bimonthly publication that updates readers about important developments in the field of hematology and highlights what ASH is doing for its members.

Meeting Information for Clinicians

- Meeting on Hematologic Malignancies - The ASH Meeting on Hematologic Malignancies (MHM) features the top experts in the field, comprehensive clinical content, and the opportunity to interact with colleagues in an intimate, small group setting with no competing sessions. The 2022 meeting is scheduled to take place September 2 - 3, 2022 in Chicago, IL, and on the meeting's virtual platform. Participants will have an opportunity to hear experts present cutting-edge scientific data, provide out-of-the-box treatment approaches, and answer challenging patient care questions during topic-based panel discussions.
- ASH Annual Meeting and Exposition – The 64th ASH Annual Meeting and Exposition is scheduled to take place December 10-13, 2022 in New Orleans, Louisiana and as a virtual meeting. The Society's Annual Meeting and Exposition is designed to provide hematologists from around the world a forum for discussing critical issues in the field. Abstracts presented at the meeting also contain the latest and most exciting developments in hematology research.
- Highlights of ASH - This meeting is designed to provide the highlights of the top presentations from ASH's annual meeting.

Other ASH Activities and Resources

- The ASH Academy on Demand – The ASH Academy on Demand provides hematologists with easy-to-use options for knowledge testing (for both MOC and CME purposes), completing practice improvement modules, as well as evaluating ASH meetings you attend and claiming CME credit for participating. The sixth edition of the ASH Self- Assessment Program (ASH-SAP) is also available on the ASH Academy on Demand.
- ASH FDA New Drug and Therapy Alerts – ASH partners with the Food and Drug Administration to alert members on newly approved hematologic therapies.
- ASH and the American Medical Association – ASH is an engaged participant and member of the American Medical Association's (AMA) House of Delegates (HOD), AMA Current Procedural Terminology (CPT) Committee, and Relative Value Scale Update Committee (RUC).
- ASH Committee on Practice - The Committee on Practice is concerned with all issues affecting the practice of hematology. The Committee communicates with other organizations that have programs and policies that affect hematology practice. With appropriate review and approval by the Executive Committee, the Committee on Practice responds to practice-related issues by formulating positions on pending federal legislation, regulatory issues, and private insurance developments. The Committee also responds to matters of importance at the regional, state, and local levels, and to Society member requests.

If you have any questions on this list or any of the programs, please contact Katherine Stark, Policy and Practice Manager at kstark@hematology.org.

Choosing Wisely®

An initiative of the ABIM Foundation

American Society of Hematology

Ten Things Physicians and Patients Should Question

1 Don't transfuse more than the minimum number of red blood cell (RBC) units necessary to relieve symptoms of anemia or to return a patient to a safe hemoglobin range (7 to 8 g/dL in stable, non-cardiac in-patients).

Transfusion of the smallest effective dose of RBCs is recommended because liberal transfusion strategies do not improve outcomes when compared to restrictive strategies. Unnecessary transfusion generates costs and exposes patients to potential adverse effects without any likelihood of benefit. Clinicians are urged to avoid the routine administration of 2 units of RBCs if 1 unit is sufficient and to use appropriate weight-based dosing of RBCs in children.

2 Don't test for thrombophilia in adult patients with venous thromboembolism (VTE) occurring in the setting of major transient risk factors (surgery, trauma or prolonged immobility).

Thrombophilia testing is costly and can result in harm to patients if the duration of anticoagulation is inappropriately prolonged or if patients are incorrectly labeled as thrombophilic. Thrombophilia testing does not change the management of VTEs occurring in the setting of major transient VTE risk factors. When VTE occurs in the setting of pregnancy or hormonal therapy, or when there is a strong family history plus a major transient risk factor, the role of thrombophilia testing is complex and patients and clinicians are advised to seek guidance from an expert in VTE.

3 Don't use inferior vena cava (IVC) filters routinely in patients with acute VTE.

IVC filters are costly, can cause harm and do not have a strong evidentiary basis. The main indication for IVC filters is patients with acute VTE and a contraindication to anticoagulation such as active bleeding or a high risk of anticoagulant-associated bleeding. Lesser indications that may be reasonable in some cases include patients experiencing pulmonary embolism (PE) despite appropriate, therapeutic anticoagulation, or patients with massive PE and poor cardiopulmonary reserve. Retrievable filters are recommended over permanent filters with removal of the filter when the risk for PE has resolved and/or when anticoagulation can be safely resumed.

4 Don't administer plasma or prothrombin complex concentrates for non-emergent reversal of vitamin K antagonists (i.e. outside of the setting of major bleeding, intracranial hemorrhage or anticipated emergent surgery).

Blood products can cause serious harm to patients, are costly and are rarely indicated in the reversal of vitamin K antagonists. In non-emergent situations, elevations in the international normalized ratio are best addressed by holding the vitamin K antagonist and/or by administering vitamin K.

5 Limit surveillance computed tomography (CT) scans in asymptomatic patients following curative-intent treatment for aggressive lymphoma.

CT surveillance in asymptomatic patients in remission from aggressive non-Hodgkin lymphoma may be harmful through a small but cumulative risk of radiation-induced malignancy. It is also costly and has not been demonstrated to improve survival. Physicians are encouraged to carefully weigh the anticipated benefits of post-treatment CT scans against the potential harm of radiation exposure. Due to a decreasing probability of relapse with the passage of time and a lack of proven benefit, CT scans in asymptomatic patients more than 2 years beyond the completion of treatment are rarely advisable.

Choosing Wisely®

An initiative of the ABIM Foundation

American Society of Hematology

Ten Things Physicians and Patients Should Question

6 Don't treat with an anticoagulant for more than three months in a patient with a first venous thromboembolism (VTE) occurring in the setting of a major transient risk factor.

Anticoagulation is potentially harmful and costly. Patients with a first VTE triggered by a major, transient risk factor such as surgery, trauma or an intravascular catheter are at low risk for recurrence once the risk factor has resolved and an adequate treatment regimen with anticoagulation has been completed. Evidence-based and consensus guidelines recommend three months of anticoagulation over shorter or longer periods of anticoagulation in patients with VTE in the setting of a reversible provoking factor. By ensuring a patient receives an appropriate regimen of anticoagulation, clinicians may avoid unnecessary harm, reduce health care expenses and improve quality of life. This *Choosing Wisely*® recommendation is not intended to apply to VTE associated with non-major risk factors (e.g., hormonal therapy, pregnancy, travel-associated immobility, etc.), as the risk of recurrent VTE in these groups is either intermediate or poorly defined.

7 Don't routinely transfuse patients with sickle cell disease (SCD) for chronic anemia or uncomplicated pain crisis without an appropriate clinical indication.

Patients with SCD are especially vulnerable to potential harms from unnecessary red blood cell transfusion. In particular, they experience an increased risk of alloimmunization to minor blood group antigens and a high risk of iron overload from repeated transfusions. Patients with the most severe genotypes of SCD with baseline hemoglobin (Hb) values in the 7-10 g/dl range can usually tolerate further temporary reductions in Hb without developing symptoms of anemia. Many patients with SCD receive intravenous fluids to improve hydration when hospitalized for management of pain crisis, which may contribute to a decrease in Hb by 1-2 g/dL. Routine administration of red cells in this setting should be avoided. Moreover, there is no evidence that transfusion reduces pain due to vaso-occlusive crises. For a discussion of when transfusion is indicated in SCD, readers are referred to recent evidence-based guidelines from the National Heart, Lung, and Blood Institute (NHLBI) (see reference below).

8 Don't perform baseline or routine surveillance computed tomography (CT) scans in patients with asymptomatic, early-stage chronic lymphocytic leukemia (CLL).

In patients with asymptomatic, early-stage CLL, baseline and routine surveillance CT scans do not improve survival and are not necessary to stage or prognosticate patients. CT scans expose patients to small doses of radiation, can detect incidental findings that are not clinically relevant but lead to further investigations and are costly. For asymptomatic patients with early-stage CLL, clinical staging and blood monitoring is recommended over CT scans.

9 Don't test or treat for suspected heparin-induced thrombocytopenia (HIT) in patients with a low pre-test probability of HIT.

In patients with suspected HIT, use the "4T's" score to calculate the pre-test probability of HIT. This scoring system uses the timing and degree of thrombocytopenia, the presence or absence of thrombosis, and the existence of other causes of thrombocytopenia to assess the pre-test probability of HIT. HIT can be excluded by a low pre-test probability score (4T's score of 0-3) without the need for laboratory investigation. Do not discontinue heparin or start a non-heparin anticoagulant in these low-risk patients because presumptive treatment often involves an increased risk of bleeding, and because alternative anticoagulants are costly.

10 Don't treat patients with immune thrombocytopenic purpura (ITP) in the absence of bleeding or a very low platelet count.

Treatment for ITP should be aimed at treating and preventing bleeding episodes and improving quality of life. Unnecessary treatment exposes patients to potentially serious treatment side effects and can be costly, with little expectation of clinical benefit. The decision to treat ITP should be based on an individual patient's symptoms, bleeding risk (as determined by prior bleeding episodes and risk factors for bleeding such as use of anticoagulants, advanced age, high-risk activities, etc.), social factors (distance from the hospital/travel concerns), side effects of possible treatments, upcoming procedures, and patient preferences. In the pediatric setting, treatment is usually not indicated in the absence of mucosal bleeding regardless of platelet count. In the adult setting, treatment may be indicated in the absence of bleeding if the platelet count is very low. However, ITP treatment is rarely indicated in adult patients with platelet counts greater than 30,000/microL unless they are preparing for surgery or an invasive procedure, or have a significant additional risk factor for bleeding. In patients preparing for surgery or other invasive procedures, short-term treatment may be indicated to increase the platelet count prior to the planned intervention and during the immediate post-operative period.

How This List Was Created (1–5)

The American Society of Hematology (ASH) *Choosing Wisely*® Task Force utilized a modified Delphi technique to collect suggestions from committee members and recipients of its clinically focused newsletter, the *ASH Practice Update*. Respondents were asked to consider the core values of harm, cost, strength of evidence, frequency and control. Fifty-nine of 167 ASH committee members (35%) and 2 recipients of the *ASH Practice Update* submitted 81 unique suggestions. The Task Force used a nominal group technique (NGT) to identify the top 20 items, which were scored by ASH committee and practice community members, with a 46 percent participation rate. ASH's Task Force reviewed all scores to develop a 10-item list. A professional methodologist conducted a systematic literature review on each of the 10 items; the Task Force chair served as the second reviewer. Evidence reviews and source material for the 10 items were shared with ASH's Task Force, which ranked the items according to the core values. The Task Force then identified the top 5 items plus 1 alternate. ASH member content experts provided external validation for the veracity and clarity of the items.

How this List was Created (6–10)

Suggestions for the second ASH *Choosing Wisely* list were solicited from members of the ASH Committee on Practice, the ASH Committee on Quality, the ASH *Choosing Wisely* Task Force, ASH Consult-a-Colleague volunteers and members of the ASH Practice Partnership. Six principles were used to prioritize items: avoiding harm to patients, producing evidence-based recommendations, considering both the cost and frequency of tests and treatments, making recommendations in the clinical purview of the hematologist, and considering the potential impact of recommendations. Harm avoidance was established as the campaign's preeminent guiding principle. Guided by the 6 principles, the ASH *Choosing Wisely* Task Force scored all suggestions. Modified group technique was used to select 10 semi-finalist items. Systematic reviews of the literature were then completed for each of the 10 semi-finalist items. Guided by the 6 core principles outlined above, and by the systematic reviews of the evidence, the ASH *Choosing Wisely* Task Force selected 5 recommendations for inclusion in ASH's second *Choosing Wisely* Campaign.

ASH's disclosure and conflict of interest policy can be found at www.hematology.org.

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About the ABIM Foundation

The mission of the ABIM Foundation is to advance medical professionalism to improve the health care system. We achieve this by collaborating with physicians and physician leaders, medical trainees, health care delivery systems, payers, policymakers, consumer organizations and patients to foster a shared understanding of professionalism and how they can adopt the tenets of professionalism in practice.

To learn more about the ABIM Foundation, visit www.abimfoundation.org.

About the American Society of Hematology

The American Society of Hematology (ASH) is the world's largest professional society of hematologists, serving more than 14,000 clinicians and scientists from around the world who are dedicated to furthering the understanding, diagnosis, treatment and prevention of disorders affecting the blood.

For more than 50 years, the Society has led the development of hematology as a discipline by promoting research, patient care, education, training and advocacy in hematology. By providing a forum for clinicians and scientists to share the latest discoveries in the field, ASH is helping to improve care and possibly lead to cures for diseases that affect millions of people, including leukemia, lymphoma, myeloma, anemias and various bleeding and clotting disorders.

For more information, visit www.hematology.org.

Non-ASH Choosing Wisely® Recommendations of Relevance to Hematology

Choosing Wisely®

An initiative of the ABIM Foundation

American Society of Hematology

ACR

Don't image for suspected PE without moderate or high pre-test probability of PE.

While deep vein thrombosis (DVT) and PE are relatively common clinically, they are rare in the absence of elevated blood D-Dimer levels and certain specific risk factors. Imaging, particularly computed tomography (CT) pulmonary angiography, is a rapid, accurate, and widely available test, but has limited value in patients who are very unlikely, based on serum and clinical criteria, to have significant value. Imaging is helpful to confirm or exclude PE only for such patients, not for patients with low pre-test probability of PE. *Source: American College of Radiology (ACR). Wording reflects that of the Radiology recommendation, other societies have similar recommendations, some explicitly recommended D-Dimer testing prior to imaging.*

ASRM

Don't routinely order thrombophilia testing on patients undergoing a routine infertility evaluation.

There is no indication to order these tests, and there is no benefit to be derived in obtaining them in someone that does not have any history of bleeding or abnormal clotting and in the absence of any family history. This testing is not a part of the infertility workup. Furthermore, the testing is costly, and there are risks associated with the proposed treatments, which would also not be indicated in this routine population. *Source: American Society for Reproductive Medicine (ASRM).*

SHM

Don't perform repetitive CBC and chemistry testing in the face of clinical and lab stability.

Hospitalized patients frequently have considerable volumes of blood drawn (phlebotomy) for diagnostic testing during short periods of time. Phlebotomy is highly associated with changes in hemoglobin and hematocrit levels for patients and can contribute to anemia. This anemia, in turn, may have significant consequences, especially for patients with cardiorespiratory diseases. Additionally, reducing the frequency of daily unnecessary phlebotomy can result in significant cost savings for hospitals. *Source: Society for Hospital Medicine – Adult Hospital Medicine (SHM). Wording reflects that of the Adult Hospital Medicine recommendation; other societies have similar recommendations.*

AABB

Don't transfuse red blood cells for iron deficiency without hemodynamic instability.

Blood transfusion has become a routine medical response despite cheaper and safer alternatives in some settings. Pre-operative patients with iron deficiency and patients with chronic iron deficiency without hemodynamic instability (even with low hemoglobin levels) should be given oral and/or intravenous iron. *Source: American Association of Blood Banks (AABB).*

ASCO

Avoid using positron emission tomography (PET) or PET-CT scanning as part of routine follow-up care to monitor for a cancer recurrence in asymptomatic patients who have finished initial treatment to eliminate the cancer unless there is high-level evidence that such imaging will change the outcome.

PET and PET-CT are used to diagnose, stage and monitor how well treatment is working. Available evidence from clinical studies suggests that using these tests to monitor for recurrence does not improve outcomes and therefore generally is not recommended for this purpose. False positive tests can lead to unnecessary and invasive procedures, overtreatment, unnecessary radiation exposure and incorrect diagnoses. Until high level evidence demonstrates that routine surveillance with PET or PET-CT scans helps prolong life or promote well-being after treatment for a specific type of cancer, this practice should not be done. *Source: American Society of Clinical Oncology (ASCO).*

The Purpose of This List

Starting in early 2015, the ASH Choosing Wisely Task Force launched a review of all existing Choosing Wisely items to identify recommendations published by other professional societies that are highly relevant and important to the practice of hematology. Using a carefully administered methodology, items were scored for relevance and importance over a series of iterations, resulting in a list of items that were deemed to be especially useful to hematologists. The items in this list represent the top five highest-scoring items. The full list of items is available on the ASH website at ***www.hematology.org/choosingwisely***.

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How this List Was Created (Non-ASH Recommendations)

A two-phase process was developed to identify and rank non-ASH Choosing Wisely recommendations of relevance to hematologists. First, the ASH Choosing Wisely Task Force independently scored all published ABIM Foundation Choosing Wisely recommendations on the MORE reliability scale, a validated seven-point Likert scale used to assess medical relevance. Modified group technique was used to identify the top 50 unique non-ASH Choosing Wisely recommendations with regard to relevance. Overlapping recommendations from different societies were grouped together as one recommendation. Taking into consideration the core values of harm, cost, strength of evidence, frequency, relevance, and impact, the ASH Choosing Wisely Task Force was asked to score each of the remaining 50 Choosing Wisely recommendations between 1 and 10 for prioritization for inclusion on ASH's top 10 list of non-ASH Choosing Wisely recommendations. Harm avoidance was established as the campaign's preeminent guiding principle. Modified group technique was used to select the top 10 non-ASH Choosing Wisely recommendations of relevance and importance to hematologists and their patients, with the top five highest-ranked items presented in this list.

ASH's disclosure and conflict of interest policy can be found at ***www.hematology.org***.

These items are provided solely for informational purposes and are not intended as a substitute for consultation with a medical professional. Patients with any specific questions about the items on this list or their individual situation should consult their physician.

Released December 2, 2015.

For more information or to see other lists of Five Things Physicians and Patients Should Question, visit *www.choosingwisely.org*.

AMERICAN SOCIETY OF HEMATOLOGY
Travel Reimbursement Policy

The ASH Travel Reimbursement Policy, as approved by the ASH Executive Committee, is provided to travelers (i.e. committee members, staff, etc.) regarding payment and/or reimbursement for costs incurred to participate in an ASH committee meeting or activity. ***(Special rules apply for speakers at the annual meeting and small meetings* which will be specified in the relevant invitation letters.)*** *It is expected that the policy will be adhered to explicitly. Any exceptions or appeals with a cost impact of $500 or less will be directed to the relevant member of Senior Staff; however, any exceptions or appeals with a cost impact over $500 will be directed to the ASH Treasurer.*

Coverage of allowable and reimbursable expenses begins at the actual start of a trip, whether it is from the traveler's regular place of employment, home, or other location, and terminates when the traveler reaches his/her original destination. Expenses for spouses and/or dependents are personal expenses and are not reimbursable.

Receipts for all expenditures (including E-ticket passenger receipts, taxis, and parking) of **$25.00 or more** should be provided with the ASH Expense Reimbursement Form if reimbursement is to be made. Requests for reimbursement must be submitted within **thirty (30) days** of the meeting or activity for which reimbursable expenses were incurred.

Guiding Principle

It is impossible to delineate every possible travel scenario in this policy. In general, travelers are asked to consider options that utilize ASH resources most effectively. Unique situations should be reviewed and approved in advance of the travel to avoid misunderstandings when reimbursement is requested after travel has been completed.

Air Travel

Air travel must be booked through the ASH travel agent. ASH will pay for non-stop, coach class (not business or first class) airline tickets when the flight is in North America. When the flight is outside of North America AND at least one segment of the flight is longer than six hours (as indicated on the official flight itinerary), ASH will pay for upgradable coach class airline tickets, or premium seating options within coach class (Economy Plus, aisle seats, etc.). When the flight is outside of North America AND the total travel time (as indicated on the official flight itinerary) is 10 hours or more, ASH will pay for business class airline tickets. **It is required that tickets be purchased through the ASH travel agent.**

Domestic (including Canadian) airline reservations must be made at least 30 days in advance and international airline reservations at least 60 days in advance. The ASH travel agent will record the coach roundtrip fare for all destinations 30 days (for domestic travel including Canada) or 60 days (for international travel including Mexico) prior to each meeting or activity, and this amount will be the maximum that ASH will pay. If a traveler fails to make reservations at least 30 days (for domestic travel including Canada) or 60 days (for international travel including Mexico) in advance, ASH will pay the allowable amount and the ASH travel agent will charge the traveler (via his/her own credit card) for any amount that exceeds the allowable amount.

ASH will pay the most economical non-refundable coach fares available on a major airline carrier (American, Delta, Southwest, United, U.S. Airways, etc.). When a significantly less expensive option is available, reservations made at the request of the traveler with a particular carrier to benefit the traveler will not be paid in full; rather, the amount paid will equal the amount of the equivalent ticket on the most economical carrier. ASH will not reimburse a traveler with cash for tickets that were obtained using frequent flier points.

If an approved traveler wants to bring a guest, they must provide the ASH travel agent with a personal credit card for the guest's travel.

When flying into Washington, DC to attend a meeting at ASH Headquarters or nearby hotel, there are three possible airports (Baltimore-Washington International, Dulles International, and Reagan Washington National) to consider. Sometimes a flight into Baltimore-Washington International (BWI) airport is less expensive, but ground transportation can be more expensive and time-consuming. In this case, the traveler may select the airport that is more reasonable. If a traveler does not want to use taxi or shuttle service from BWI, arrangements can be made by the ASH Meetings department for other ground transportation. Also, in some instances, staying over a Saturday night will result in a fare that is considerably less than the hotel night and meals; if a traveler is willing to stay for the extra night, ASH will reimburse him/her for those associated costs.

Train Travel

Train travel must be booked through the ASH travel agent. ASH will pay for business class seats on Amtrak regional trains. Where Amtrak's Acela Express trains are available, ASH will pay for business class seats since this is the most economical option on Acela Express. **It is required that tickets be purchased through the ASH travel agent.**

Train reservations must be made at least 30 days in advance. The ASH travel agent will record the fare for all destinations 30 days prior to each meeting or activity, and this amount will be the maximum that ASH will reimburse. If a traveler fails to make reservations at least 30 days in advance, ASH will pay the allowable amount and the ASH travel agent will charge the traveler (via his/her own credit card) for any amount that exceeds the allowable amount.

If an approved traveler wants to bring a guest, he/she must provide the ASH travel agent with a personal credit card for the guest's travel.

Ground Transportation

ASH encourages use of the most economical ground transportation to and from the airport or train station and will reimburse such expenses. Examples of acceptable options include taxis, airport shuttle services, and ride-sharing services (i.e. Uber and Lyft) provided that the most economical option of these services (i.e. UberX or UberXL or equivalent) is utilized. Upgraded options called Uber Black, Uber Select, Lyft Plus, and Lyft Premier are not reimbursable. Travelers should be aware of any surge pricing that is in effect with these services and select more economical options during these peak demand periods.

Use of a personal or university vehicle will be reimbursed at the mileage rate consistent with IRS rules and regulations (**58 cents per mile as of 1/1/2022, a rate that considers the cost of gasoline**) plus toll and parking charges. (ASH will reimburse parking charges and mileage if this amount is not greater than the cost of roundtrip taxi or shuttle service.)

Use of a rental car must be approved in advance and should represent the most economical ground transportation option. If ASH approves the use of a rental car, limits will be set and communicated to the traveler by the appropriate ASH representative. The maximum rates set by ASH consider the cost of the rental, mileage, gasoline, parking, tolls, and any other expenses related to the use of the rental to attend the meeting.

Local attendees who wish to drive to ASH Headquarters can do so and park in the garage located next to the 2021 L Street building; parking charges will be reimbursed.

Hotel

The traveler is responsible for requesting a hotel room via the ASH registration system by the deadline indicated. If an attendee wishes to extend his/her reservation before or after the ASH meeting or activity, he/she must indicate this when registering and present his/her own credit card at check-in to pay for the nights not covered by ASH.

For safety and risk reasons, travelers are not permitted to stay in home-sharing type accommodations (i.e. Airbnb, HomeAway, VRBO, etc.) even if the rate is lower than available hotels.

Meals

ASH will reimburse reasonable actual expenses of the traveler's meals plus tips up to $100 per day; however, receipts must be provided. **When ASH schedules a meal for which it must guarantee a number of attendees and for which it assumes the cost, meals taken elsewhere are not reimbursable.**

Cancellations and Changes

When a traveler needs to change or cancel an airline reservation, he/she must contact the issuing agent and notify the appropriate ASH representative **immediately.** The traveler is responsible for all penalty fees and any other charges incurred due to such changes or cancellations more than $150. If the traveler does not inform the travel agency or airline of the cancellation prior to the scheduled departure time, and ticket is thereby rendered unusable for future travel, then the traveler will be held responsible for the cost of the original ticket.

If a traveler needs to change or cancel a hotel reservation, he/she must contact the appropriate ASH representative at least 72 hours prior to his/her originally scheduled arrival. The traveler is responsible for reimbursing ASH for expenses incurred due to last-minute changes, cancellations, no-shows, and early departures.

Miscellaneous Expenses

- Airline baggage fees are reimbursable with receipts.
- Baggage service (e.g. sky-cap or hotel bellman) and similar expenses are reimbursable up to a maximum of $10 dollars per day.
- Early board fees and onboard airline WiFi access fees are reimbursable with receipts.
- Tips not included with meals or cab fare should be listed separately on the ASH Expense Reimbursement Form.
- ASH will reimburse reasonable phone and Internet usage.
- When a trip involves traveling for both ASH and other purposes, the traveler must reasonably allocate the costs between ASH and other activity.

If a traveler has any questions concerning any other reimbursable expenses, he/she should contact the appropriate ASH representative in advance of travel.

**Highlights of ASH; Clinical Research Training Institute; Translational Research Training in Hematology; ASH Meeting on Lymphoma Biology; ASH Meeting on Hematologic Malignancies, or any other meeting designated by ASH.*

ASH EXPENSE REIMBURSEMENT FORM

Please fill out the information below and attach <u>original receipts</u> to the following receipt pages.

Make reimbursement payable to: _____

Address: _____

Meeting(s) Attended ASH CAC Meeting – June 23-24, 2022

<u>Signature:</u> _____ Date: _____

Itemized Expenses:

Date	Description of Expense	Account Code (*internal use only*)	Amount
_____	_____	_____	$ _____
_____	_____	_____	$ _____
_____	_____	_____	$ _____
_____	_____	_____	$ _____
_____	_____	_____	$ _____
_____	_____	_____	$ _____
_____	_____	_____	$ _____
_____	_____	_____	$ _____
_____	_____	_____	$ _____

☐ **I decline some / all of this reimbursement as a donation to the ASH Foundation to benefit the following program(s)**

Greatest Needs Fund $ _____
Career Development and Training Fund $ _____
Clinical Research Training Institute Fund $ _____
COVID-19 Fund $ _____
Global Programs Fund $ _____
Minority Recruitment Initiative Fund $ _____
Quality Care and Education Fund $ _____
Research Awards Fund $ _____
(*ASH Scholar Awards, Global Research Award, Bridge Grant Program, etc.)*
Sickle Cell Disease Initiative Fund $ _____

☐ **I accept this reimbursement**

<u>SUMMARY:</u>

Total of itemized expenses: **$**_____
Total amount declined as a donation to the ASH Foundation per above designation: **$** _____
Total amount to be reimbursed to signatory herein: **$** _____

Under U.S. Internal Revenue Service guidelines, the estimated value of benefits you have received, if any, in consideration for your gift, is not substantial and will not affect the deductibility of your gift as a charitable contribution.

Please return this completed form to ASH at invoices@hematology.org or via fax at: 888-783-2183 c/o Foster Curry.

<u>For Internal Purposes</u>

Approver Suzanne Leous
Account Code 5510-115-351-120-00