American Society of Hematology

Carrier Advisory Committee (CAC) Meeting

June 27, 2025

Annual Meeting

10:00 a.m. – 2:00 p.m. Eastern time

Zoom Link:
https://hematology.zoom.us/j/99597468185?pwd=TTYWEA4T2aySXxDYdIvuhRWFXQCWiS.1

American Society of Hematology

Helping hematologists conquer blood diseases worldwide

Carrier Advisory Committee (CAC) Network Meeting
Friday, June 27, 2025
10:00 a.m. – 2:00 p.m. ET

AGENDA

9:45 a.m.	ZOOM – Waiting Room Will Be Open		
10:00 a.m.	Welcome and Introductions	Dianna Howard, MD	
	• Attendees		4
	• Speakers		7
	• ASH Staff		10
	• CMD List and Jurisdiction Map		11
10:20 a.m.	Integrating Artificial Intelligence Tools in Healthcare Systems	Amar Kelkar, MD Olivier Elemento, MD	14
11:10 a.m.	Next Generation Sequencing and Molecular Testing for Lymphoid Malignancies	Rena Xian, MD	16
12:00 p.m.	LUNCH		
12:30 p.m.	Implementation of the National Coverage Determination for Myelodysplastic Syndromes	Dianna Howard, MD Corey Cutler, MD	17
1:00 p.m.	Fireside Chat with the MAC Medical Directors	Panel	18
	• FAQs with the MAC Medical Directors • What's going on in your Jurisdiction?	*Moderator* Dr. Howard *Panelists* Gina Mullen, NGS Meredith Loveless, CGS Joelle Vlahakis, WPS	
1:45 p.m.	Closing Remarks and Reference Materials	Dr. Howard	
	• CMS Resources		19
	• ASH Practice Resources		20
	• Meeting Reimbursement Policy and Form		22
2:00 p.m.	ADJOURN		

Appendix A: AI Presentation Slides
Appendix B: Precision Medicine in Hematology: Lymphoid Malignancies Slides
Appendix C: Implementation of the NCD for MDS Slides
Appendix D: Fireside Chat Slides

CAC 101

The Carrier Advisory Committee is established by a Medicare Administrative Contractor (MAC) to share valuable clinical insight to inform coverage decisions across the 13 MAC Jurisdictions. MACs are private health insurers contracted with the Centers for Medicare and Medicaid Services (CMS) to process Medicare claims for a specific geographic region.

CAC members include physicians (limited to one per specialty or provider type), a beneficiary representative, and representatives of other medical organizations. CAC members are a valuable asset to policy development serve as a mechanism for physicians to be made aware of and participate in the development of new Local Coverage Determinations (LCD), to discuss and amend administrative policies, and to serve as a link between Medicare and the local provider community. Often, MACs include a summary of the CAC members' recommendations with the final Local Coverage Determinations (LCDs).

ASH sponsors the Hematology CAC Network Meeting as an opportunity for CAC representatives to meet, network, and strengthen relationships with the Medical Directors from the MAC and provide input on trending topics, as well as receive information which may help your members understand Medicare policy and reimbursement. The meeting allows participants to discuss Medicare-related coverage and policy issues, draft policies, and the relationship between Medicare and the provider community. This diverse group of stakeholders also has an opportunity to discuss possible solutions to real-world issues.

Registered Attendee List

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Speaker Biographies

Dianna Howard, MD

Dianna Howard, MD is the Director of the Stem Cell Transplant and Cell Therapy (SCTCT) program at Atrium Health Wake Forest Baptist Comprehensive Cancer Center. Dr Howard has led a SCTCT program for the past 18 years – becoming deeply engaged in operations, payer relations, and quality outcomes. With that background she is now also functioning in the role of Chief Clinical Officer for the Atrium Health Levine Cancer service line, the Wake Forest market – the academic hub of Advocate Health, a large healthcare system. The comprehensive cancer center catchment area includes part of Appalachia, rural western North Carolina, and a large population of under-represented populations – attempting to meet the needs of many patients for whom barriers to access either because of co-morbidities, distance, or delay in referral remain a challenge. While Dr Howard is trained in both pediatric and internal medicine, she specializes in the care of adult patients with myeloid malignancies, especially those needing allogeneic transplant. Dr. Howard's research is currently in the areas of population health and implementation science.

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 as a member on the ASH Committee of Government Affairs. Dr. Howard also serves on ASTCT Outcomes Committee, co-chairs the ASTCT Leadership course, previously chaired the ASTCT Government Relations Committee, and represents ASTCT on the 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.

Amar Kelkar, MD, MPH

Dr. Amar Kelkar is a stem cell transplant physician at the Dana-Farber Cancer Institute and an Instructor in Medicine at Harvard Medical School. Dr. Kelkar specializes in allogeneic transplantation and gene therapy for blood disorders, including leukemia and sickle cell disease. He also directs the bone marrow transplant survivorship clinic and co-leads Dana-Farber's gene therapy program.

Beyond his clinical work, Dr. Kelkar's research bridges oncology, ethics, and health technology. He completed a Master of Public Health in Clinical Effectiveness at the Harvard T.H. Chan School of Public Health and was awarded the ASTCT New Investigator Award in 2024. His research spans cost-effectiveness of novel therapies and digital health innovation, including the development of AI-powered supportive care tools for transplant patients.

Dr. Kelkar also serves in several leadership positions with the American Society of Hematology, including as a member on the Committee on Practice as well as the Reimbursement Subcommittee. In addition, Dr. Kelkar serves as the Primary RUC Advisor for ASH and as one of the ASH Delegates to the AMA House of Delegates. Across his roles with the Society, Dr. Kelkar advocates for patient access to care, focusing his efforts on coverage and reimbursement policy.

Today, he'll be sharing an overview of patient-facing AI in clinical care, focusing on its applications, Medicare coverage considerations, and the ethical guardrails needed to protect patient dignity, drawing on his team's recent work evaluating AI avatars in transplant recovery and broader ethical frameworks for oncology AI.

Olivier Elemento, PhD

Dr. Olivier Elemento is a professor of physiology and biophysics at Weill Cornell Medicine (WCM) and Cornell University. Since 2017, he has been the Director of the Caryl and Israel Englander Institute for Precision Medicine. The Englander Institute is a multidisciplinary institute that draws over 100 faculty members from nearly all basic and clinical departments at Cornell University. The Englander Institute's mission is to use genomics, artificial intelligence

(AI), patient-derived models and other technologies to develop and bring highly personalized medicine to patients at Weill Cornell's affiliated hospital, NewYork Presbyterian Hospital (NYPH) and elsewhere. The Institute also fosters patient-centered basic and clinical research in the areas of genomics, systems biology, AI and data science. Dr. Elemento is funded by numerous NIH grants, foundation grants, NIH contracts and industry alliances. He has published over 450 papers in the area of precision medicine, genomics, computational biology, artificial intelligence, systems biology and drug discovery. He has led the development of novel clinical (CLIA) genomics assays including whole-exome sequencing offered to patients at WCM/NYPH and is currently leading a large multi-disease effort to bring whole-genome sequencing into clinical practice at WCM/NYPH. Dr. Elemento co-founded two venture capital-funded companies: Volastra Therapeutics (with Lew Cantley, Sam Bakhoum) and OneThree Biotech (with Neel Madhukar). He serves on the scientific advisory board of Volastra, OneThree Biotech as well as of Owkin, Freenome, and several other companies.

Rena Xian, MD

Dr. Xian is an Associate Professor of Pathology and Oncology where she directs the Molecular Diagnostics Laboratory and leads the division of Molecular Pathology. Dr. Xian completed her bachelor's degree at Johns Hopkins before attending medical school at Northwestern. She completed post-graduate training at the University of Pennsylvania, Johns Hopkin and UCLA and was a junior faculty at UCLA until 2018. In 2018, Dr. Xian returned to Hopkins as faculty where she has developed an active translational research program focused on cancer genomics and liquid biopsy approaches to diagnose and monitor aggressive B cell lymphomas. Besides her research, Dr. Xian is a leader in national pathology societies, such as the Association of Molecular Pathology and the College of American Pathologists. She is also an active member in several guideline development committees focused on hematologic malignancies (ASH and CLSI) and liquid biopsies (ASCO and CLSI).

Corey Cutler, MD, MPH

Corey Cutler, MD, MPH, FRCP(C) is the Director of the Stem Cell Transplantation Program at the Dana-Farber Cancer Institute and a Professor of Medicine at Harvard Medical School. Dr. Cutler's research is in the prevention and treatment of acute and chronic graft-vs.-host disease. Dr. Cutler also studies the role and timing of transplantation for the myelodysplastic syndromes and is a contributing author on more than 300 peer-reviewed publications. In 2024, Dr. Cutler served as the President of the American Society for Transplantation and Cellular Therapy.

Dr. Cutler graduated from McGill University's Faculty of Medicine, completed a residency in Internal Medicine at the McGill University Health Science Center, and completed fellowship training in hematology, medical oncology, and stem cell transplantation at the Dana-Farber Cancer Institute. Dr. Cutler earned an MPH degree at the Harvard School of Public Health.

Gina Mullen, NGS

Dr. Gina Mullen is a board-certified Emergency Medicine physician and serves as a Contract Medical Director for National Government Services. She brings a strong background in clinical leadership and operations, with a deep commitment to improving systems of care. In her current role, she works closely with teams to align medical policy with real-world practice and support high-quality, evidence-based care.

She chairs the Multijurisdictional CAC Engagement Workgroup, where she leads efforts to strengthen collaboration with all the Medicare Administrative Contractors among stakeholders, CAC members, as well as specialty and state societies. Her work focuses on practical solutions, innovation, and building strong partnerships across the medical community.

Dr. Mullen is especially honored to participate as a speaker in this year's ASH meeting. Her mother's journey with having sickle cell disease has given her a deep, personal appreciation for the life-changing impact of hematology and the amazing hematologists who have left a lasting impression. She is profoundly grateful for the work the society

continues to lead. She looks forward to learning from others, sharing insights, and continuing to support ASH's mission to improve care and advance the field.

Meredith Loveless, CGS

Meredith Loveless, a board-certified ob/gyn and pediatric and adolescent gynecologist, is passionate about evidence-based medicine and medical policy. She was faculty at Johns Hopkins and University of Louisville where she received multiple awards for clinical care and teaching. She has extensive publications and has training as a methodologist with focus on GRADE methodology. She has had >20 years of service to the American College of Ob/Gyn, where she was chairman of several committees. As a Chief Medical Officer in the J15 A/B MAC administered by CGS Administrators, her focus is medical policy serving the 48,500 physicians and 2 million Medicare beneficiaries in the jurisdiction.

Joelle Vlahakis, WPS

Dr. Joelle Vlahakis is a Contractor Medical Director at WPS Health Services who believes in the quintuple aim of medicine. We can and must deliver high-value care that both improves outcomes and lowers costs, elevates the experience of that care for beneficiaries and providers alike and does so in a way that affords everyone opportunities to enhance their health regardless of their zip code. In 2023, she completed an Innovations Challenge Project via a CMS Grant to improve both Chronic Care Management and Depression Screening for patients living in two jurisdictions which achieved those aims.

Dr. Vlahakis is Board Certified by the American Board of Internal Medicine and is a Diplomat in Hospice and Palliative Medicine. She graduated from Cornell University with a Bachelor of Arts Degree in Biology with concentration in Neurobiology and Behavior. Dr. Vlahakis received her Doctor of Medicine in 1995 at the University of Miami School of Medicine. Her residency was performed at Michigan State University College of Human Medicine where she received the Resident Teaching Excellence Award. She is a member of the American College of Physicians, a Fellow in the American Academy of Pediatrics, and a Fellow in the American Academy of Hospice and Palliative Medicine. Dr. Vlahakis is also a Clinical Assistant Professor of Internal Medicine and Pediatrics at Florida State University College of Medicine, Sarasota Regional Campus and an Affiliate Physician at H. Lee Moffitt Cancer Center & Research Institute.

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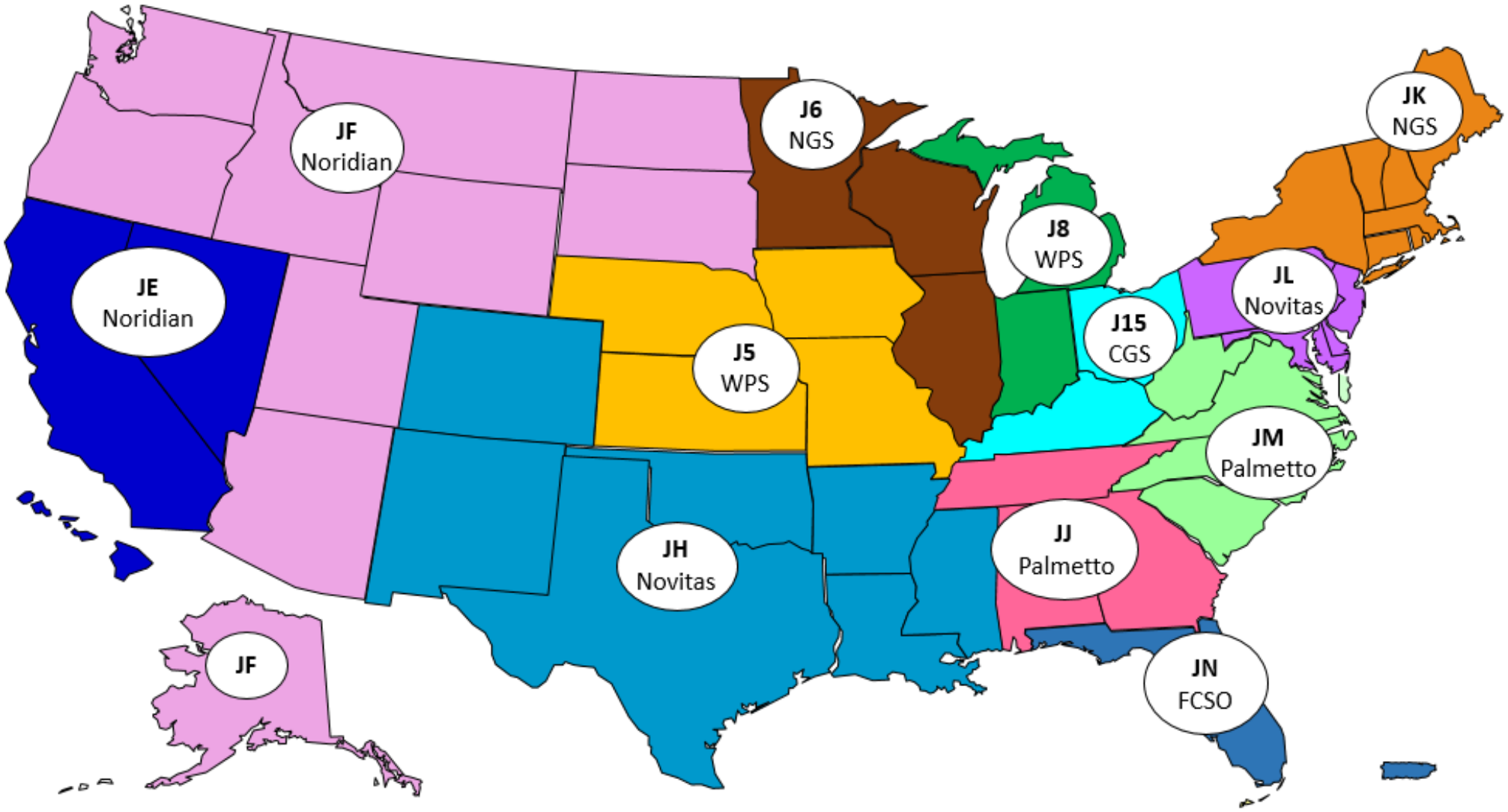


Integrating Artificial Intelligence Tools in Health Care Systems

Artificial Intelligence in Diagnostics and Clinical Practice

This presentation will examine the state of Artificial Intelligence in hematology, focusing on the critical gap between its technological promise and the evidence required for its safe and effective integration into clinical care.

AI is already enhancing hematologic diagnostics and beginning to inform high-stakes therapeutic decisions for conditions like MDS and in complex treatments like stem cell transplants and CAR-T therapy. However, there are significant hurdles to the integration of AI in clinical practice that are relevant to coverage policy. These hurdles include lack of validation from robust clinical trials, inherent risks of algorithmic bias impacting health equity, and an unclear regulatory path for these novel technologies.

The central theme highlighted throughout this presentation is the need for rigorous evaluation standards, asserting that reimbursement for AI tools in hematology must be contingent on clear evidence of improved and equitable patient outcomes.

Patient-Facing Artificial Intelligence in Cancer and Hematologic Care

As artificial intelligence (AI) technologies rapidly evolve, they are increasingly being used not only by clinicians but directly by patients. This presentation provides a high-level, clinically grounded overview of patient-facing AI, with special relevance to patients with cancer and hematologic diseases.

1. **What Is Patient-Facing AI?**
   Patient-facing AI refers to tools that interact directly with patients—via apps, chatbots, avatars, or remote monitoring platforms—to provide education, symptom support, behavioral coaching, or triage. Unlike *clinician-facing AI*, which supports medical professionals behind the scenes (e.g., diagnostics or workflow tools), patient-facing AI aims to engage, empower, and extend care access to patients themselves.

2. **Examples of Patient-Facing AI Tools**
   These tools are increasingly accessible to patients, including those undergoing intensive or prolonged treatments:

   - **AI Chatbots** (e.g., "Vik" for cancer, Woebot for mental health): Provide condition-specific guidance, support, and education.
   - **EMR-integrated bots** (e.g., Epic's MyChart GPT tools): Help answer patient questions or guide post-discharge care.
   - **Social media-based tools** (e.g., Facebook Messenger bots): Offer reminders and triage capabilities through familiar platforms.
   - **Digital health companions** (e.g., *care.coach*): Tablet-based avatars offering support to patients recovering from stem cell transplant or experiencing prolonged isolation.
   - **Wearables and AI symptom monitors**: Detect vital sign abnormalities or symptom patterns and prompt action.

3. **CMS Coverage & Medicare Payment Landscape**
   AI coverage in Medicare remains fragmented but evolving:

   - **CPT Code 92229**: Medicare pays for autonomous AI analysis of diabetic eye exams.
   - **NTAP Payments**: CMS has granted add-on payments for select AI tools (e.g., Viz.ai for stroke).
   - **Local Coverage Determinations (LCDs)**: Some Medicare Administrative Contractors (MACs) have issued LCDs for AI-enabled cardiac CT interpretation.
   - **Medicare Advantage Plans**: Permitted to use AI for utilization management with human review.

- No broad **National Coverage Determination** exists for AI—policies are currently case-by-case.

4. **Ethical Considerations in Patient-Facing AI**
   Ethical use of patient-facing AI is essential to preserve trust and equity:
   - **Human dignity and compassion**: Risk of depersonalized care if AI substitutes for human interaction.
   - Transparency and disclosure: Patients must know when they're engaging with AI and what it can and cannot do.
   - **Privacy and data use**: AI tools must safeguard patient data and comply with HIPAA.
   - **Bias and equity**: Algorithms must be trained on diverse datasets to avoid reinforcing health disparities.
   - **Accountability**: Clear responsibility for outcomes must be established between providers, developers, and institutions.

   A recent study led by Dana Farber demonstrated that a patient-facing avatar can enhance recovery and engagement for patients with hematologic or oncologic diseases undergoing allogeneic stem cell transplantation—highlighting both the potential and complexity of AI-human hybrid support systems in practice.

Conclusion

Patient-facing AI offers promising solutions for supporting patients with cancer and blood disorders—especially those requiring complex, prolonged care. As MACs and clinicians consider reimbursement and deployment, balancing innovation with ethical oversight and patient-centered design is critical. This talk aims to foster shared understanding and informed dialogue as these technologies continue to integrate into everyday care.

Next Generation Sequencing and Molecular Testing for Lymphoid Malignancies

Many diseases in classical and malignant hematology are caused by germline or somatic mutations. Therefore, accurate diagnosis now often relies on genetic testing results in patients presenting with a particular phenotype. Our understanding of the genetic basis of lymphoma, lymphoblastic leukemia, and multiple myeloma has expanded in the past decades with the use of next-generation sequencing (NGS) technology. The utility of NGS in the diagnosis, prognosis, treatment, and monitoring of patients with lymphoid malignancies is evident by the incorporation of somatic gene mutation testing, sequencing-based fusion detection, and immunoglobulin and T-cell receptor sequencing in recommendations from national and international guideline committees, including the World Health Organization (WHO), International Consensus Classification (ICC), and The National Comprehensive Cancer Network (NCCN). The genomic abnormalities detected by various sequencing-based technologies serve to inform diagnosis, such as peripheral T-cell lymphoma with a T-follicular-helper phenotype, risk-stratification, such as poor-risk fusions in B lymphoblastic leukemia, minimal residual disease monitoring for lymphoblastic leukemia and multiple myeloma, and therapy selection and resistance mutation detection for patients treated with BTK inhibitors. However, despite evidence in the literature supporting the impact of NGS on the diagnosis, treatment, and outcomes of patients with lymphoid malignancies, there remains inconsistent reimbursement for testing of patients across national centers. Therefore, the ASH Subcommittee on Precision Medicine has organized an initiative to summarize the existing evidence to support the use and reimbursement of NGS testing for patients suspected hematologic malignancies, including patients harboring germline mutations that predispose them to hematologic malignancies, patients suspected of having a myeloid neoplasm, and patients suspected of having a lymphoid malignancy, such as lymphoblastic leukemia, lymphoma or myeloma. We are currently assembling a comprehensive set of published studies that address the impact of NGS on patient diagnosis, management, prognosis, and outcomes, with a prioritization of those studies showing the potential of NGS to reduce the time and cost of patient evaluation both at diagnosis and in disease monitoring.

To address this unmet need of consistent NGS reimbursement and provide guidance on NGS testing for ASH members and the community, the Subcommittee on Precision medicine has assembled three working groups to address the impact of NGS for germline and somatic testing. The working groups include individuals with national and international expertise in germline, myeloid, and lymphoid testing. Leadership within these working groups have presented at the annual Carier Advisory Committee (CAC) Network Meeting. In 2023, Dr. Lucy Godley presented a discussion on testing for suspected germline predisposition to hematologic malignancies. In 2024, Drs. Annette Kim and Jonathan M. Gerber presented a discussion on the utility of NGS for patients with myeloid neoplasms, such as myelodysplastic syndrome and acute myeloid leukemia. At the upcoming CAC meeting, the Subcommittee on Precision medicine will present an update from the lymphoid working group on the utility of NGS testing for patients suspected of having a lymphoid malignancy. Dr. Rena Xian will highlight the importance of multigene NGS testing for the diagnosis, prognosis, treatment decisions, and monitoring of patients with lymphoid malignancies. Finally, a special report manuscript will be submitted from the three working groups (e.g., germline, myeloid, lymphoid) summarizing our findings that can serve as a resource both for ASH practitioners as well as the various agencies involved in NGS coverage and reimbursement.

National Coverage Determination for Allogeneic Hematopoietic Stem Cell Transplantation for Myelodysplastic Syndromes

On March 6, 2024, CMS released a final decision memo on the national coverage determination (NCD) for Allogenic Hematopoietic Stem Cell Transplantation for Myelodysplastic Syndromes (MDS), effective immediately. ASH, along with the American Society for Transplantation and Cellular Therapy (ASTCT), the Blood and Marrow Transplant Clinical Trials Network, the Center for International Blood and Marrow Transplantation, and the National Marrow Donor Program (NMDP), had submitted comments after the proposed decision memo was released in December 2023. The comment letter included supporting evidence for the use of cord blood stem cell products as a donor source and the use of additional recognized scoring systems and risk designations.

Since the initial decision memo, two important corrections have been made: (1) Coverage of ambulatory transplantation is permitted and (2) the use of umbilical cord blood transplantation is no longer limited to MDS transplantation (Pub 100-20, Transmittal 13097, Change Request 13939.4). However, requests to broaden coverage beyond the current IPSS-based coverage guidelines as submitted by ASH, ASTCT, BMT CTN, CIBMTR and NMDP have unfortunately not led to the improvements in access that the decision memo was aiming to address.

At this time, substantial discretion is given to the MACs regarding coverage of services that fall outside the narrow definitions as detailed in the Decision Memo. Additionally, there are several unknowns faced by the community of physicians and centers providing care to MDS patients. The number of denied cases, both within a MAC jurisdiction and nationally, are not known, as are the clinical outcomes of patients who are denied coverage. Knowing that case denials might change case submission behavior, it is imperative that this information is collated to understand the gaps and outcomes. For those cases where discretionary coverage is allowed, an agreement on the standardized minimum data requirements to be provided to the MAC would aid other transplant centers who may be facing challenges to support coverage. ASH, ASTCT, NMDP and other partner organizations are interested in developing a robust cooperation with the MACs to ensure equitable and broad access to transplantation for patients with MDS.

Fireside Chat with Medicare Administrative Contractor (MAC) Medical Directors

The goal of the **American Society of Hematology Contractor Advisory Committee Network** meeting is for hematology CAC representatives and practicing hematologists to meet, network, and strengthen relationships with the MAC medical directors. To help facilitate these relationships, ASH has dedicated a session for an informal Fireside Chat with three Contractor Medical Directors (CMDs), each from different MACs and jurisdictions.

The MAC panel will provide background about their role and function as it relates to coverage policies and share insights to **Demystify the Local Coverage Determination (LCD) process** and turn the spotlight on **CAC Member Impact**. How is the LCD process different from the National Coverage Determination (NCD) process, for example? We will discuss the lifecycle of the LCD process and where CAC members and subject matter experts can have the greatest impact. We will then discuss how the MACs weigh the evidence when writing, drafting, finalizing and reconsidering LCDs. The basic elements of a new LCD request and a reconsideration request will be discussed with specific attention paid to how MACs are instructed to evaluate the strength of the evidence. The process can be very complex, but partnership throughout is important.

Vital to this partnership is the ability of the MACs (CMDs) to engage with CAC members, society representatives and subject matter experts. CAC Engagement is another important component of our work together. The panel will highlight opportunities for CAC members to engage with their CMDs and strengthen the lines of communication to support coverage and subsequently support clinicians in their practice. One of the most important functions of the CAC is to disseminate important updates about Medicare from the MACs. Physicians depend upon this communication so that they can take care of both beneficiaries and their practices.

We hope to answer the following ***frequently asked questions*** *during the discussion:*

1. Is there guidance for how a CAC representative or other interested party may initiate an update request for a current LCD?
2. What information is helpful for a CAC representative or practicing clinician to include when identifying a coverage gap or a coverage challenge if there is not a specific LCD or NCD related to coverage for a service?
    a. Is this information similarly necessary for a reconsideration request?
3. How frequently are LCDs typically updated?
    a. What are the criteria that would prompt an LCD review?
    b. If they are done cyclically, how is this determined?
4. If there is not a distinct NCD or LCD available to support coverage for a current or new service, what is the recommended course of action to request coverage?
    a. Are there specific steps, such as an email request or an online form, to engage with the CMD to discuss the necessity and importance of coverage?
5. Are there recommendations for how CAC representatives can better engage with their MAC?
    a. Are there quarterly webinars that stakeholders can attend to stay up to date on the latest coverage issues or reconsiderations?
    b. Are there recommendations for building a relationship between the hematologists, the hematology CAC representatives, and the Contractor Medicare Administrator (CMD)?
    c. Are there points of contact who would be best to engage with?
6. Hematologists often treat patients with unique or rare conditions that might not fit neatly under a Local Coverage Determination or National Coverage Determination.
    a. What is the best procedure to follow in these cases?
    b. How can a strong line of communication between the hematology CAC representative or practicing hematologist and the Contractor Medical Director can help support clinicians to treat their patients?

The CMDs from the MACs welcome the opportunity to clarify items and address any additional lingering questions.

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*)
- Medicare Coverage
- Medicare Coverage Centers
- Patients over Paperwork: 9th Issue - Modernization Update: Local Coverage Determination (LCD)
- LCD Process Modernization Qs & As

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 ASH at CACnetworkmeeting@hematology.org.

Clinician Resources

- ASH Clinicians in Practice – The ASH Clinicians in Practice (formerly the ASH Practice Partnership (APP)) is a group within the Society that was formed to better represent the interests of practicing hematologists. The ACIP 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 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.
- In 2025, ASH has reinstated the Fight 4 Hematology advocacy campaign, highlighting the importance of hematologic research and, ultimately, the care of patients. ASH has created a new #Fight4Hematology Action Hub to keep members up-to-date on ASH's efforts and provide four easy ways to get involved and protect the future of hematology research and advances in patient care.

- 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 Advocacy News Roundup – Read the latest news and updates on legislation and regulatory matters.
- *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

- ASH Annual Meeting and Exposition – The 67th ASH Annual Meeting and Exposition is scheduled to take place December 6-9, 2025 in Orlando, Florida 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 for participants to learn about rapidly evolving developments in hematology-oncology with leading faculty in the field. Discover new treatments for patients and improve overall practice methods.

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.
- 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.
- ASH Reimbursement Subcommittee – The Reimbursement Subcommittee ensures that ASH addresses federal legislation and regulation affecting reimbursement for practicing clinical hematologists. The subcommittee advises the Committee on Practice on all reimbursement-related issues by formulating positions on pending federal legislation, regulatory, local Medicare coverage, and occasionally, private insurance developments.

If you have any questions on this list or any of the programs, please contact Carina Smith, Manager for Health Care Access Policy at casmith@hematology.org or the CAC Network Meeting inbox at CACnetworkmeeting@hematology.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 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.). ASH will pay for business class airline tickets when either of the following two travel scenario exists:

1. the flight is between North America and Europe, or
2. the flight is outside of North America AND the total travel time (as indicated on the official flight itinerary) is 10 hours or more.

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. **(This requirement has been modified to 30 days for all travelers due to the variety of COVID-19 pandemic re-opening milestones.)** 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 a nearby hotel, there are three 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 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 (**67 cents per mile as of 1/1/2024, 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.**

ASH offers to reimburse members and staff for a meal if they attend a virtual committee meeting that exceeds three hours and is held during mealtime. Attendees can use their preferred meal provider (e.g., Uber Eats, Door Dash, etc.) and can be reimbursed for up to $50 per meal, not to exceed one meal per day; the reimbursement could be declined and instead donated to the ASH Foundation. In either case, a completed ASH Expense Reimbursement Form along with a receipt must be submitted within 30 days of the meeting.

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., skycap or hotel bellman) and similar expenses are reimbursable up to a maximum of $10 dollars per day.
- Early board fees and onboard airline Wi-Fi 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.*

This is a payable invoice eligible for Concur processing.

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 _____

<u>Signature:</u>* _____ Date: _____
***Form will not be processed Without a Signature**

Itemized Expenses:

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

☐ **I decline $_____ of this reimbursement as a Pledge Payment towards my Pledge with the ASH Foundation.**

☐ **I decline some or all of this reimbursement as a one-time donation to the ASH Foundation to benefit the following program(s):**

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

☐ **I accept this reimbursement.**

<u>SUMMARY:</u>
Total of itemized expenses: **$**_____
Total amount declined as a donation/pledge payment to the ASH Foundation per above designation: **$** _____
Total amount to be reimbursed to signatory herein: **$** _____

For more information about any of these ASH programs, please refer to the ASH website at *www.hematology.org/foundation/supported-programs*.
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.

<u>Revision Date: 2/16/2023</u>

Receipts Page

When scanning your receipts, please arrange your receipts in date order, without laying one on top of another.

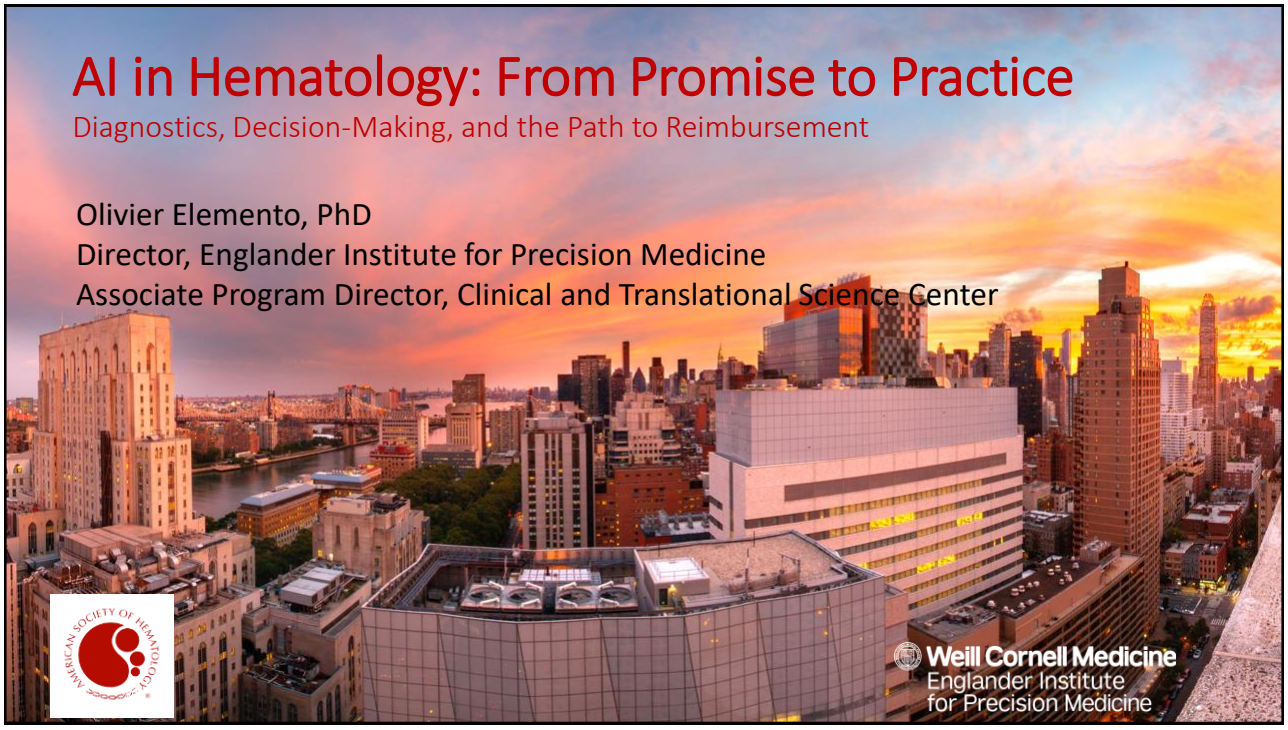
Revision Date: 8/24/2022

For Internal Purposes

Approver _____ Date_____

Account Code _____

Appendix A: AI Presentation Slides



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Disclosures

Volastra Pharmaceuticals (co-founder and equity holder)

Owkin (SAB member and equity holder)
Freenome (Equity holder)
Harmonic Discovery (SAB member and equity holder)
Exai (SAB member and equity holder)
Canary Biosciences (SAB member)

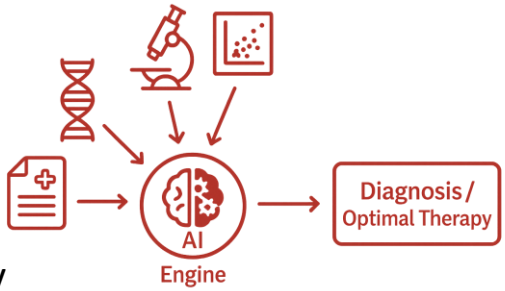
Eli Lilly, J&J/Janssen, Sanofi, AstraZeneca, Volastra (funding)

2

2

The Data Deluge in Hematology

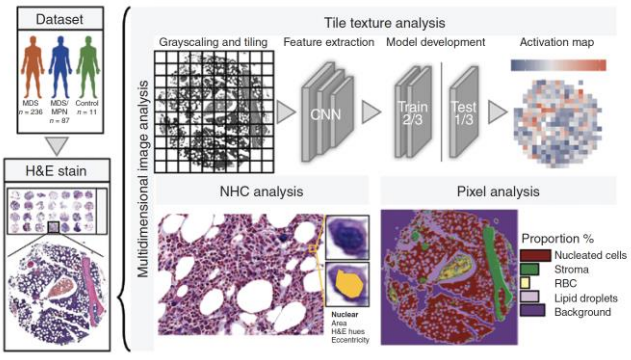
- **The Challenge:** Hematology is a data-intensive field.
- **The Need:** AI is becoming essential to integrate complex data streams:
  - Genomics (Whole Genome/Transcriptome)
  - Digital Pathology & Flow Cytometry
  - Clinical Data from EHRs
  - Lab Parameters



3

AI-Powered Histopathology

- **Application:** AI analysis of bone marrow histopathology.
- **What it does:** Extracts thousands of deep morphological features from a standard H&E biopsy slide to predict the underlying genetics of the tumor.
- **The Impact:**
  - Reveals hidden links between tissue morphology and specific gene mutations (e.g., TET2, ASXL1).
  - Can predict a patient's prognosis (IPSS-R) directly from the image.
  - Moves beyond human-level assessment to link the visual to the molecular.

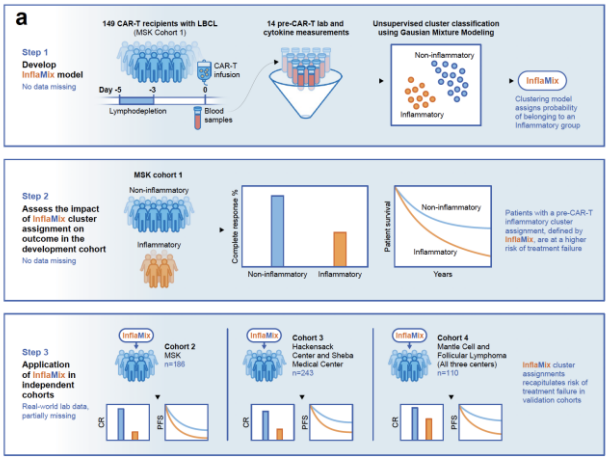


Bruck et al, 2021, Blood Cancer Discovery

4

AI Guiding High-Stakes Decisions

- **Application:** Predicting CAR-T failure risk with the "InflaMix" model.
- **What it does:** Integrates up to 14 routine pre-infusion blood tests (or a simple 6-lab panel) to identify a high-risk "inflammatory signature."
- **The Impact:**
  - Identifies patients at high risk of relapse or death *before* treatment.
  - Provides more predictive value than standard markers like tumor burden.
  - Importantly, a patient's inflammatory state is **modifiable**. Those who transition from "inflammatory" to "non-inflammatory" before infusion have significantly better outcomes.



Raj et al, Nature Medicine, 2025

5

The Sobering Reality: A Critical Evidence Gap

- The promise is clear. **But the proof is not.**
- **The Core Problem:** A significant lack of prospective, randomized clinical trials (RCTs).
- Without RCTs, we cannot confirm that these tools:
  - Actually improve patient outcomes.
  - Are safe and effective in diverse, real-world settings.
- This evidence gap is the primary barrier to widespread adoption and coverage.

6

NEJM AI

NEJM AI 2024;1(11)
DOI: 10.1056/AIe2400881

EDITORIAL

We Need More Randomized Clinical Trials of AI

David Ouyang, M.D.,[1] and Joseph Hogan, Sc.D.[2]

Received: September 5, 2024; Accepted: September 10, 2024; Published: October 18, 2024

Abstract

In the first prospective clinical trial of artificial intelligence (AI) assistance in stress echocardiography, there was no difference in diagnostic accuracy between AI assistance and standard-of-care assessment. There is significant value in conducting prospective clinical trials of AI, and there are lessons on implementation to be learned from this study.

With more than 950 U.S. Food and Drug Administration (FDA)–cleared artificial intelligence (AI) software-as-a-medical-device products on the market,[1] clinicians have many potential software products available to assist in disease detection, diagnosis, and screening. At the same time, the vast majority of FDA-cleared AI algorithms have not undergone prospective evaluation.[2] The pillars of rigorous evidence generation, such as randomization, blinding, and unbiased clinical event adjudication in clinical studies, are infrequently used in the assessment of efficacy and clinical impact for medical AI products.

7

Key Hurdles for Coverage & Reimbursement

- **Algorithmic Bias:** Models trained on limited data can fail on underrepresented populations, worsening health inequities.
- **Reliability & 'Data Drift':** A model that works today may not work tomorrow. Its performance can degrade as tests, treatments, and populations change.
- **Workflow Integration:** Most AI tools are not integrated into EHRs, creating a major barrier to practical use by clinicians.
- **Evolving Regulations:** The FDA is still building the framework to regulate this rapidly evolving class of medical software.

8

A Path Forward: Considerations for Payers

1. Demand Robust Validation: Coverage should be contingent on high-quality evidence from prospective trials or rigorous real-world studies demonstrating improved and equitable patient outcomes.

2. Promote Standardized Evaluation: Support initiatives—led by groups like ASH—to establish clear benchmarks for model accuracy, fairness, and transparency.

3. Develop Aligned Reimbursement Models: Create reimbursement pathways that incentivize evidence-based innovation, not just technological novelty.

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Conclusion

- AI is poised to transform hematology, offering the potential to enhance diagnosis and truly personalize care.
- However, realizing this potential requires us to move from *promise* to *proof*.
- A partnership between innovators, clinicians, and payers is essential to set high standards for evidence, safety, and equity.

10

American Society of Hematology Carrier Advisory Committee Meeting
June 26-27, 2025 | Washington, D.C.

Patient-Facing Artificial Intelligence

Opportunities, Coverage, and Ethical Considerations in Hematology

Amar Kelkar, MD, MPH, FACP

Dana-Farber Cancer Institute | HARVARD MEDICAL SCHOOL

1

Disclosures

Co-PI on care.coach AI avatar RCT for BMT supportive care

Career Development Award from ASTCT

2

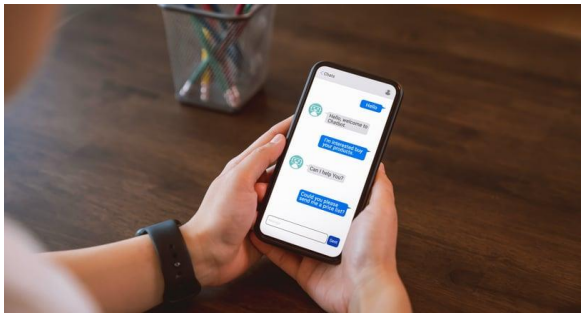
Framing the Problem

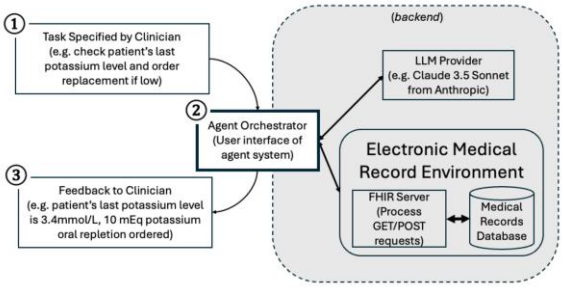
- Growing demand for supportive, scalable tools in cancer and blood disorders
- Patients increasingly engage with AI, often before we see them
- Medicare stakeholders must assess not just safety, but value and dignity in implementation

3

Definitions: What is Patient-Facing AI

- **Patient-facing AI:** Tools that engage directly with patients (e.g., chatbots, virtual agents, symptom apps)
- **Clinician-facing AI:** Tools designed to support providers (e.g., image-interpretation AI, clinical decision-support tools)



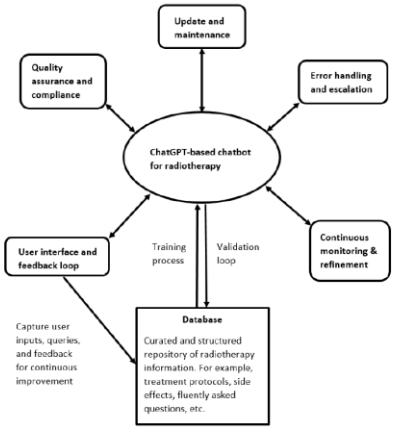


Jiang Y et al, *Qeios Preprint* 2025

4

Examples of Patient-Facing AI

- Chatbots (e.g., Vik for cancer, Woebot for mental health)
- EMR-integrated bots (e.g., MyChart GPT tools)
- Social media bots (e.g., Florence on Messenger)
- Virtual avatars (e.g., *care.coach*)
- Wearables + voice assistants (e.g., Alexa health skills)
- Remote symptom trackers (AI-driven apps)



Chow JCL et al, *JMIR Bioinformatics and Biotechnology* 2024

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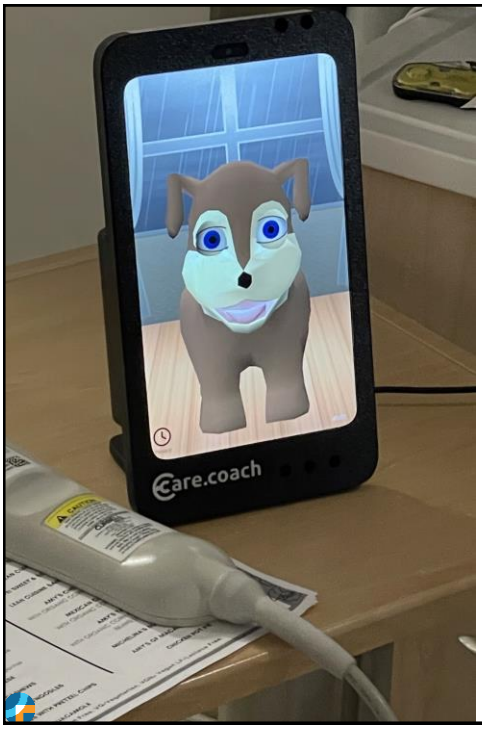


Case Example: care.coach in BMT

- Tablet-based avatar with human-in-the-loop AI
- Delivered education, reminders, and emotional support
- Used in allogeneic transplant pilot at DFCI

Kelkar AH et al, *Bone Marrow Transplant* 2024

6

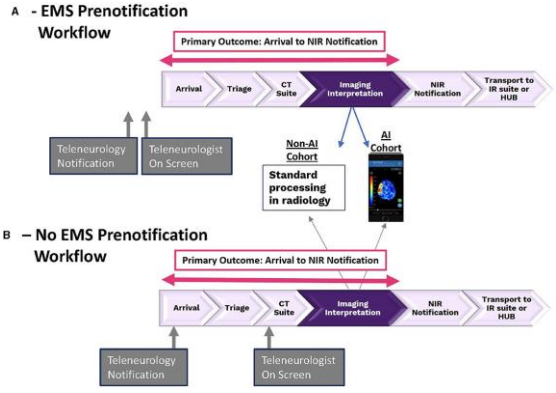
Why It Matters for Medicare

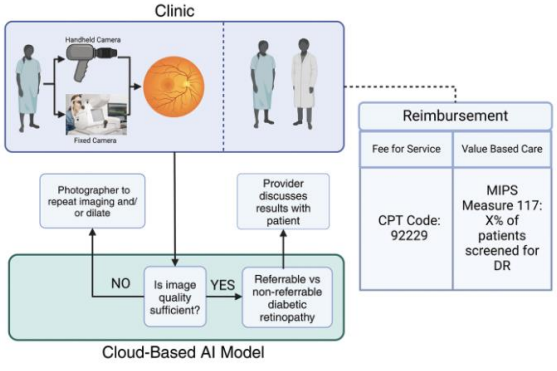
- Increasing interest in digital-first care
- AI may help reduce disparities in access
- But only if **safe and effective** (and reimbursable)

7

Current CMS Coverage Landscape

- CPT 92229: AI diabetic retinopathy screening
- Viz.ai NTAP for stroke triage
- Local Coverage for AI cardiac CT (MAC-specific)
- MA plans may use AI for UM—**must adhere to Medicare rules**
- No National Coverage Determination (NCD) for AI tools broadly





Devlin T et al, *Frontiers in Stroke* 2024

8

Table 1 Selected AI devices that are reimbursed by US Medicare.

From: Paying for artificial intelligence in medicine

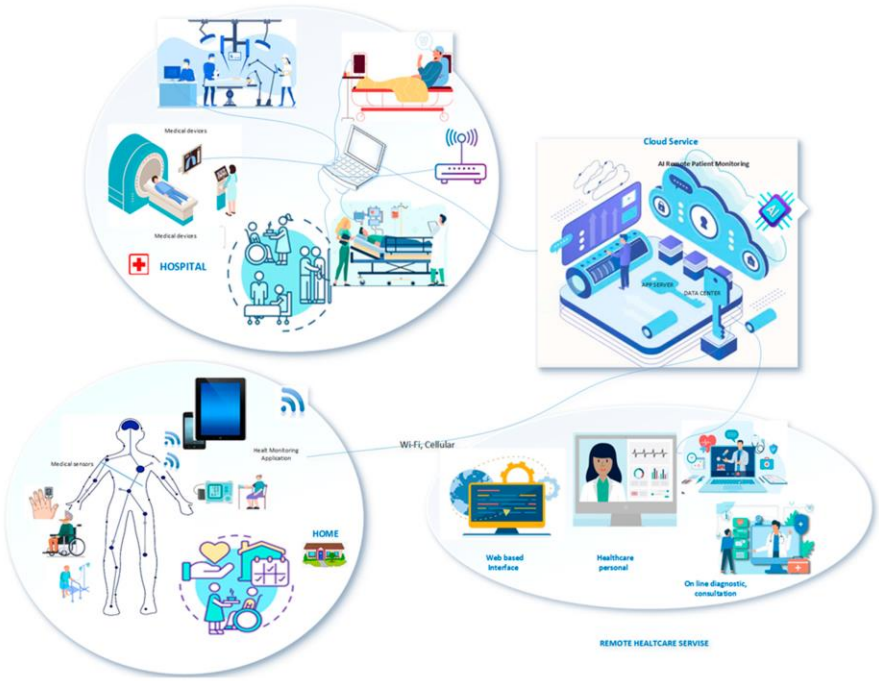
Manufacturer	Technology	Description	Payment mechanism	Year reimbursement granted
Digital diagnostics	IDX-DR	Deep learning algorithm to diagnose diabetic retinopathy from fundoscopic images in the outpatient setting	CPT	2020
viz.ai	Viz LVO	Radiological computer-assisted triage and notification software that analyzes CT images of the brain and notifies hospital staff when a suspected large-vessel occlusion (LVO) is identified	NTAP	2020
Rapid AI	Rapid LVO	AI-guided medical imaging acquisition system intended to assist medical professionals in the acquisition of cardiac ultrasound images.	NTAP	2020
Caption health	Caption guidance		NTAP	2021
viz.ai	Viz SDH	Radiological computer-assisted triage and notification software that analyzes CT images of the brain and notifies hospital staff when a suspected subdural hematoma is identified	NTAP	2022 (candidate)
Rapid AI	Rapid aspects	Computer-aided diagnostic device characterizing brain tissue abnormalities on brain CT images	NTAP	2022 (candidate)
AIDoc	Briefcase for PE	Radiological computer-assisted triage and notification software that analyzes CT images of the chest and notifies hospital staff when a suspected pulmonary embolism is identified	NTAP	2022 (candidate)
PROCEPT BioRobotics Corporation	The AQUABEAM system	Autonomous tissue removal robot for the treatment of lower urinary tract symptoms due to benign prostatic hyperplasia (BPH).	NTAP	2020

Parikh R et al, *npj digital medicine* 2022

9

Opportunities for Hematology

- Remote symptom tracking or vital sign monitoring during chemotherapy, cell therapy, transplant, or vaso-occlusive crises
- Psychosocial support during transplant and cell therapy (including support for anxiety, depression, and social isolation)
- Discharge planning & survivorship guidance
- Medication reminders & hydration nudges



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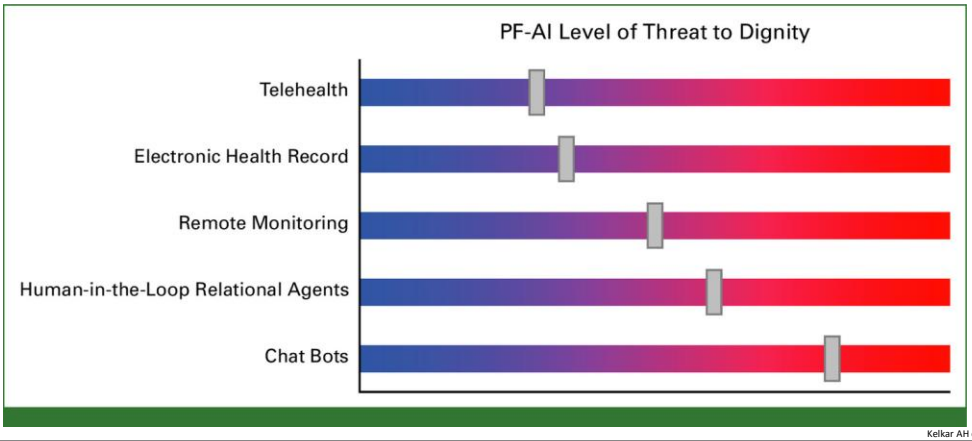
Ethical Considerations

- **Transparency** – patients must know it's AI
- **Bias & Equity** – must reflect diverse data
- **Privacy** – sensitive inputs require safeguards
- **Trust** – patients may mistake bots for clinicians
- **Dignity** – human-guided care should be prioritized
- **Oversight** – human-in-the-loop is key

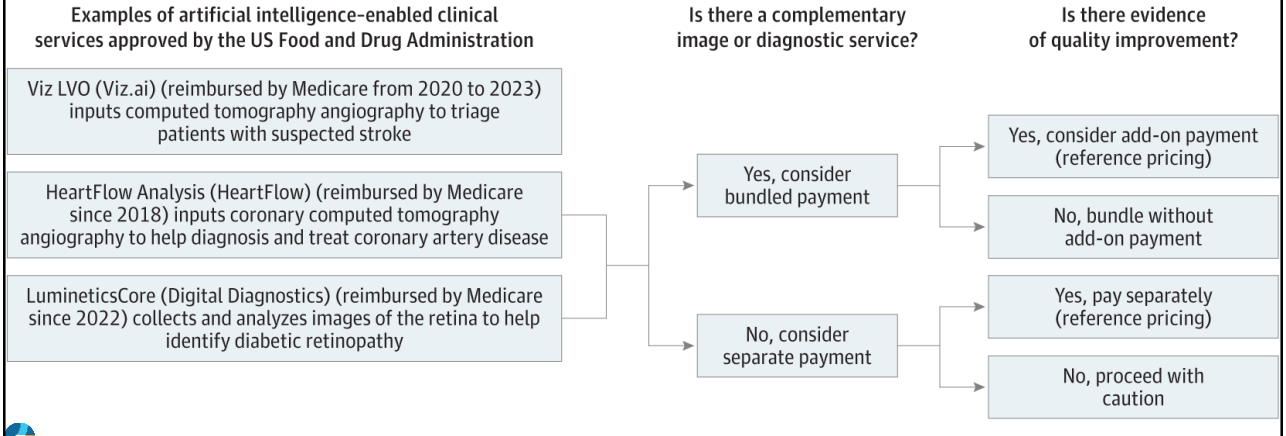


Kelkar AH et al, *JCO Oncology Practice* 2023

11

From Concept to Coverage

- FDA clearance
- Validated clinical outcomes
- Reimbursement mechanisms (CPT/RVU, NTAP, LCD/NCD, etc.)
- Equity and ethics addressed



Zink A et al, *JAMA Internal Medicine* 2024

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Thanks to …

- Goyo Abel, MD, MPH
- Medicare Administrative Contractors
- American Society of Hematology
- ASH Staff

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Appendix B: Precision Medicine in Hematology: Lymphoid Malignancies Slides

American Society *of* Hematology
Helping hematologists conquer blood diseases worldwide

Precision Medicine in Hematology
Lymphoid Malignancies

Rena R. Xian, MD
Associate Professor of Pathology and Oncology
Johns Hopkins University School of Medicine
Director, Division of Molecular Pathology
Director, Molecular Diagnostics Laboratory

1

Disclosures

The committee members and staff who are in position to control the content of this activity are required to disclose to ASH and to learners any financial relationships that have occurred within the last 24 months with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

Rena R. Xian reports the following financial relationships:

- Invivoscribe – Honorarium
- nRichDx – Research Support, honorarium
- Roche Diagnosics – Advisory Board

American Society *of* Hematology

2

Outline

- Diagnostic Classifications
- Therapeutic Strategies
- Risk Stratification Systems
- Measurable Disease Monitoring
- Current Practice and Future Opportunities

3

Main Classes of Clinical Biomarkers

	Diagnostic	Risk Stratification	Predictive
Definition	Aids in the initial recognition of the disease	Informs about a likely outcome independent of treatment (natural history)	Identifies the probability of response to a specific therapeutic agent or modality
Application	Symptomatic cancer evaluation Asymptomatic cancer screening	Baseline risk stratification Measurable residual disease	Sensitizing/resistance abnormalities for targeted therapy selection

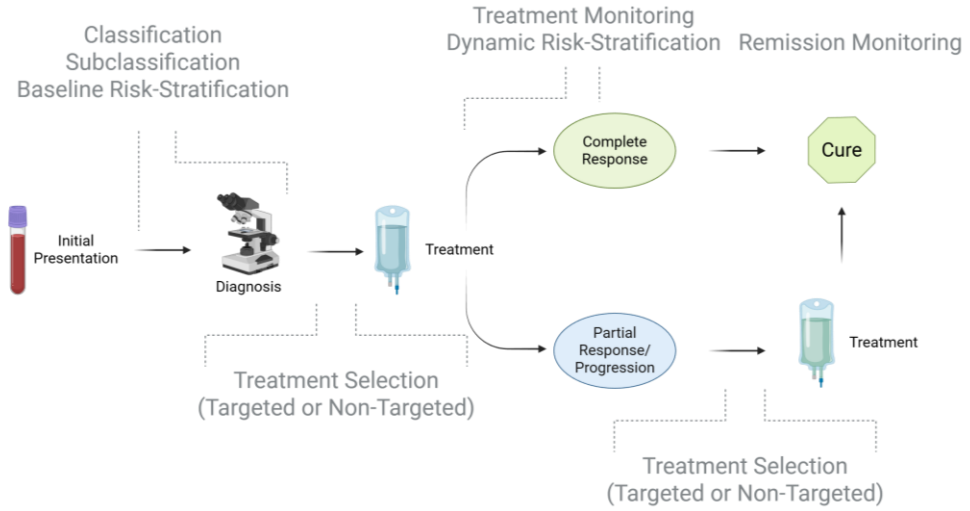
(Ballman KV, *JCO*, 2015, PMID: 26392104)
(Polley MY *et al*, *JNCI*, 2013,PMID: 24136891)

IGH gene rearrangement (clonotype) in lymphoid malignancies

BCR::ABL1 rearrangement in chronic myeloid leukemia

4

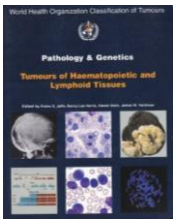
Clinical Impact of NGS in Lymphoid Malignancies



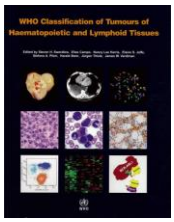
5

Evolution of Disease Classifications in Lymphoma

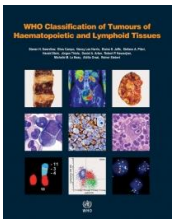
- Rappaport system (1966)
- Lukes-Collins (1974) and Kiel (1974)
- NCI Working Formulation (1982)
- Revised European and American Lymphoma (REAL) (1994)



WHO 3rd
2001



WHO 4th
2008



WHO Revised 4th
2017

ICC
2022
WHO 5th

<10 Lymphoma Diagnoses in 1966

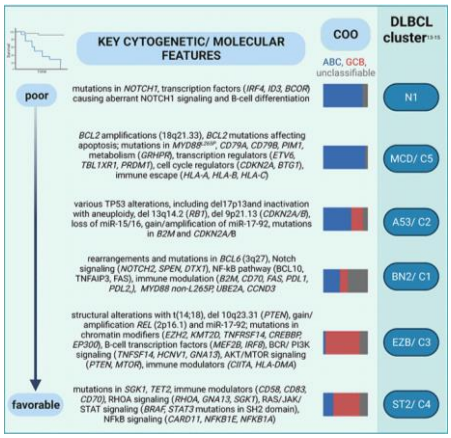
>100 Lymphoma Diagnoses in 2022

6

Mature B-cell Neoplasms with Defined Rearrangements

ICC	WHO 5th
Mature B-cell lymphoma	**Mature B-cell lymphoma**
Aggressive	
Large B-cell lymphoma with *IRF4* rearrangement	Large B-cell lymphoma with *IRF4* rearrangement
Large B-cell lymphoma with 11q aberration	High-grade B-cell lymphoma with 11q aberrations
High-grade B-cell lymphoma, with *MYC* and *BCL2* rearrangements	Diffuse large B-cell lymphoma/high grade B-cell lymphoma with *MYC* and *BCL2* rearrangements
High-grade B-cell lymphoma with *MYC* and *BCL6* rearrangements	
Indolent	
Follicular lymphoma	
BCL2-R–negative, CD23-positive follicle center lymphoma	
Plasma cell myeloma	
Multiple myeloma with *CCND* family translocation	
Multiple myeloma with *MAF* family translocation	
Multiple myeloma with *NSD2* translocation	
Multiple myeloma with hyperdiploidy	

Diffuse Large B-cell Lymphoma (DLBCL) Subclassification Relies on NGS



NOTCH1

MYD88, CD79B, PIM1

TP53

BCL6, NOTCH2

EZH2, KTM2D, TNFRSF14, CREBBP, EP300

SGK1, TET2, RHOA

(Adapted from Lucas and Kim, College of American Pathologists)

Case 1

- 69 yo man presents with one-year history of leg swelling
- Biopsy: *Crushed atypical lymphohistiocytic infiltrate, non-diagnostic*
- Molecular Studies: IGH PCR insufficient/no amplification
- NGS: Multiple mutations involving *B2M, CREBBP, EZH2, KMT2D, MYC, PAX5, PIM1, SGK1, SMARCA4, SOCS1, TNFRSF14, TP53*

- **Final Diagnosis: Extranodal DLBCL, EZB subtype; Stage IVA, IPI 3**
- Clinical treatment: Pola-R-CHP

9

NCCN Recommended NGS Testing in (D)LBCL

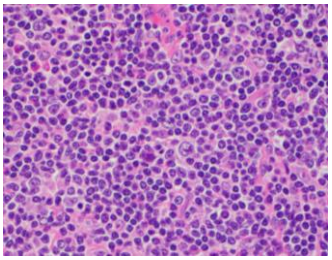
Gene	Disease	Diagnosis	Subclassification	Therapy	Risk
B2M	DLBCL				
BCL2	DLBCL				
BTK	DLBCL				
CARD11	DLBCL				
CD79B	DLBCL				
CREBBP	DLBCL				
EZH2	DLBCL				
KMT2D	DLBCL				
TP53	DLBCL				
MYD88	DLBCL				
NOTCH2	DLBCL				
PDL1	DLBCL				
PDL2	DLBCL				
SOCS1	DLBCL and PMBL				
TNFRSF14	DLBCL				
PLCG2	Richter transformation				
SMARCB1	DLBCL				

Gene	Disease	Diagnosis	Subclassification	Therapy	Risk
ACTB	DLBCL				
ATM	Mantle Cell Lymphoma				
BIRC3	Mantle Cell Lymphoma				
CCND3	Burkitt Lymphoma				
ID3	Burkitt Lymphoma				
IL4R	PMBL				
ITPKB	PMBL				
MEF2B	DLBCL				
NFKBIE	PMBL				
NSD2	Mantle Cell Lymphoma				
PIM1	DLBCL				
SMARCA4	Burkitt Lymphoma				
STAT6	PMBL				
TCF3	Burkitt Lymphoma				
UBR5	Mantle Cell Lymphoma				
XPO1	PMBL				

10

Cases 2a and 2b

	2a	2b
Clinical Presentation	52 yo man presents with an enlarged inguinal lymph node	64 yo man presents with an enlarged cervical lymph node
Biopsy	Reed-Sternberg cells with atypical T follicular helper T cells	
Molecular Studies	*IGH* PCR: Polyclonal TCR PCR: Indeterminate	IGH PCR: Polyclonal TCR PCR: Polyclonal



Final Diagnosis

Follicular helper T-cell Lymphoma

Classical Hodgkin Lymphoma

2a

Category (See below)	Chr:Pos	Base Change	Reference Database ID	Gene	AA_change	%VAF
1	chr4:106162586	G>A	COSM4766169	TET2	p.R1167K	13.46
1	chr3:49412973	C>A	COSM78415	RHOA	p.G17V	13.38
2a	chr4:106196884	AT>A	COSM10113004	TET2	p.L1740fs	24.02

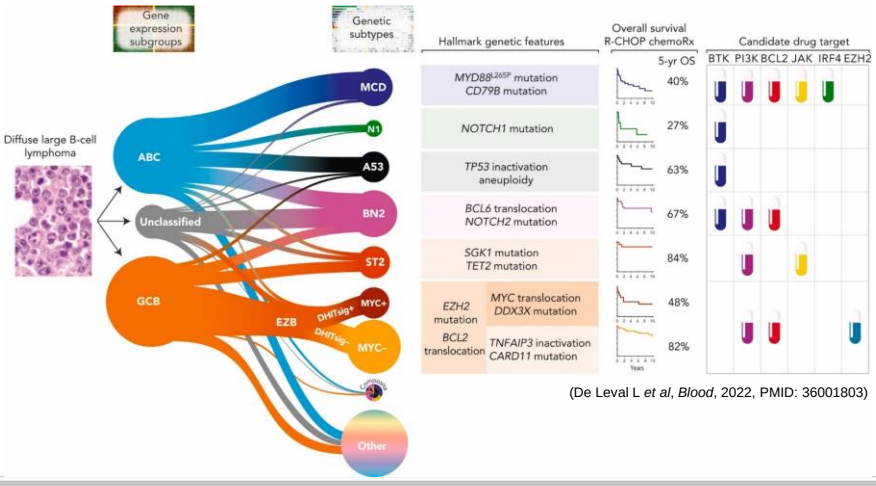
2b

Category	Chr:Pos	Base Change	Reference Database ID	Gene	AA_change	%VAF
1	chr16:11349289	GCTGTGGAGACTGCATTGT CGGCTGC >GGTGTGGAGACTGCATTG TCGA		SOCS1	p.A8fs	6.17

Outline

- Diagnostic Classifications
- Therapeutic Strategies
- Risk Stratification Systems
- Measurable Disease Monitoring
- Current Practice and Future Opportunities

Molecular Subtypes of DLBCL and Therapeutic Implications



(De Leval L *et al*, *Blood*, 2022, PMID: 36001803)

Case 3

- 73 yo woman with a 10-year history of Waldenström's Macroglobulinemia and multiple prior lines of therapy presents with Bing-Neel
- Bone marrow biopsy: *Residual Lymphoplasmacytic Lymphoma*
- Bone marrow NGS:

Category (See below)	Chr:Pos	Base Change	Reference Database ID	Gene	AA_change	%VAF
1	chrX:100611164	C>G	COSM6053938	BTK	p.C481S	2.36
1	chr3:38182641	T>C	COSM85940	MYD88	p.L265P	2.06

- Treatment: Failed two additional lines of chemotherapy with final consideration for compassionate use Pirtobrutinib

BTK Inhibitor Approvals
- CLL/SLL
- Mantle cell lymphoma
- Waldentsröm's macroglobulinemia/LPL
- Marginal zone lymphoma
- Follicular lymphoma

Resistance mutations involve *BTK* (p. C481X) and downstream activating mutations of *PLCG2* (PLCγ2)

Case 4

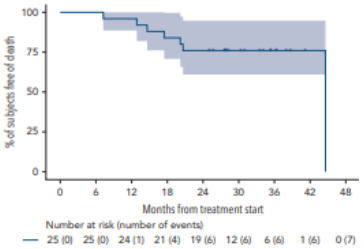
- 70 yo man with 1-year history of enlarging inguinal lymph node
- Biopsy: *Mantle Cell Lymphoma*
- Treatment plan: Bendamustine, rituximab, and acalabrutinib
- Tissue NGS was performed to guide treatment

Variants Reported

Category (See below)	Chr:Pos	Base Change	Reference Database ID	Gene	AA_change	%VAF
2a	chr17:7579470	C>CG	rs730882018;COSM128714	TP53	p.V73fs	70.47

- Given bi-allelic *TP53* mutation BR-Acala stopped after 1 cycle in favor of BOVen (Zanubrutinib, Obinutuzumab, Venetoclax)

Overall Survival with frontline BOVen in MCL



(Kumar A, *et al*, *Blood*. 2025. PMID: 39437708)

Outline

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Case 5

- 25 yo man presents with leukocytosis
- PB flow cytometry: 71% B lymphoblasts
- FISH: 5' deletion of *CRLF2* suggestive of "cryptic" *P2RY8::CRLF2* fusion
- RNA fusion sequencing: *P2RY8::CRLF2*
- NGS: JAK2 p.R683S 6.7% VAF

Abnormal Normal

- **Final Diagnosis: B-ALL with *P2RY8::CRLF2* fusion (Philadelphia-like ALL)**

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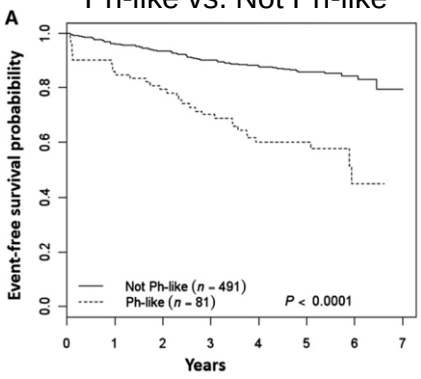
Lymphoblastic Leukemia with Defined Rearrangements

ICC	WHO 5th
B-ALL (B lymphoblastic leukemia/lymphoma)	**B lymphoblastic leukaemia/lymphoma**
Near haploid	
BCR::ABL1 with lymphoid only involvement with multilineage involvement	*BCR::ABL1*
BCR::ABL1–like, *ABL1* class rearranged	*BCR::ABL1*–like
BCR::ABL1–like, *JAK-STAT* activated	
BCR::ABL1–like, NOS	
	With other defined genetic abnormalities
DUX4 rearrangement	*DUX4*
MEF2D rearrangement	*MEF2D*
ZNF384 (or *ZNF362*) rearrangement	*ZNF384*
NUTM1 rearrangement	*NUTM1*
MYC rearrangement	*IG::MYC*
Provisional entity: *PAX5* alteration	*PAX5* alteration
Mutated *PAX5* P80R	*PAX5* P80R
UBTF::ATXN7L3/PAN3,CDX2	
Mutated *IKZF1* N159Y	
T-ALL (T lymphoblastic leukemia/lymphoma)	**T lymphoblastic leukemia/lymphoma**
ETP-ALL with *BCL11B* rearrangement	
	Acute leukaemia of ambiguous lineage
	With other defined genetic abnormalities
	ZNF384 rearrangement
	BCL11B rearrangement

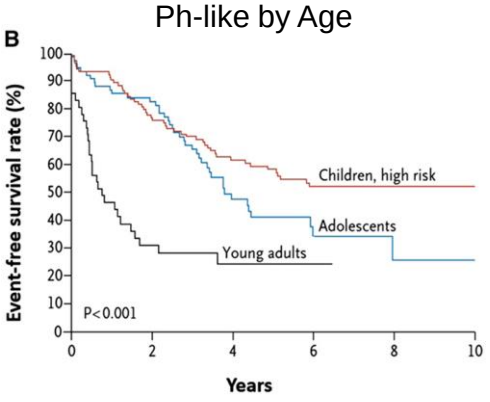
18

Ph-like ALL has Inferior Outcomes

Ph-like vs. Not Ph-like



Ph-like by Age



(Tran and Loh, The ASH Education Program Book. 2016. PMID: 27913529)

19

Risk Stratification Systems in Lymphoid Malignancies

Index	Disease	Sequencing Recommended	Marker/Gene
CLL-IPI	Chronic Lymphocytic Leukemia	Yes	*IGHV* hypermutation, *TP53*
ELN Expert Panel	Adult ALL	Maybe	*IGH* rearrangement for MRD assessment
PICOG	Pediatric ALL	Maybe	Various fusion events *ETV6::RUNX1*, *CRLF2*, *JAK*
MIPI	Mantle Cell Lymphoma	No	
MALT-IPI	MALT Lymphoma	No	
FLIPI	Follicular Lymphoma	No	
IPI	Diffuse Large B-cell Lymphoma	No	
IPS	Hodgkin lymphoma	No	
R-ISS	Multiple Myeloma	No	

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Outline

- Diagnostic Classifications
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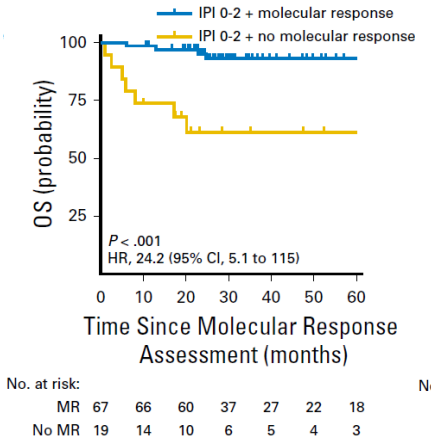
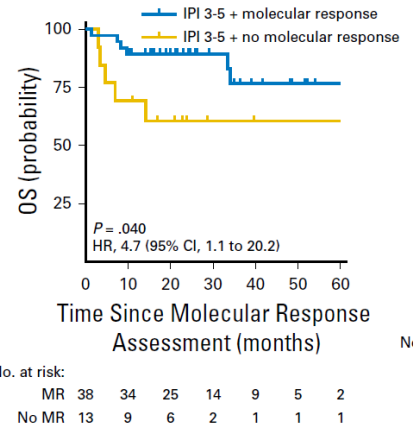
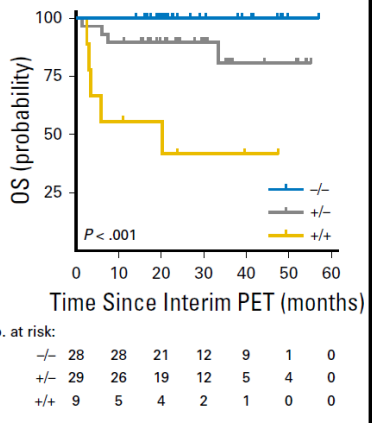
NGS of Immunoglobulin Rearrangements Informs Disease Monitoring

ALL	CLL	Myeloma
Flow MRD: 10^{-4} NGS MRD: 10^{-6}	NGS MRD: 10^{-6}	Flow MRD: 10^{-5} NGS MRD: 10^{-6}
MRD+ Guides Maintenance and BMT Decisions	Poor Outcomes if MRD+	Poor Outcomes if MRD+

Persistence of ctDNA Correlates With Poor Outcomes in DLBCL







(Kurtz DM *et al*, *JCO*, 2018, PMID: 30125215)

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Outline

- Diagnostic Classifications
- Therapeutic Strategies
- Risk Stratification Systems
- Measurable Disease Monitoring
- Current Practice and Future Opportunities

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NCCN Recommended Genetic Testing in Lymphoid Malignancies

Disease	RNA Fusion	Gene Mutations	Examples	IGH(V)/TCR
Adult ALL	Yes	Yes	*PAX5, TP53*	Yes
Pediatric ALL	Yes	Yes	*PAX5*	Yes
T-cell Lymphoma	Maybe	Yes	*DNMT3A, IDH2, RHOA, STAT3, STAT5B, TET2*	Yes
Multiple Myeloma	No	Yes	*TP53*	Yes
B-cell Lymphoma	No	Yes	*BRAF, IRF4, MYD88* and NGS for clonality*	Yes
Mantle Cell Lymphoma	No	Yes	*TP53*	No
Follicular Lymphoma	No	Yes	*CREBBP, EZH2, MAP2K1, TNFRSF14* and *STAT6*	No
CLL/SLL	No	Yes	*TP53*	Yes
Waldenström's	No	Maybe	*CXCR4, MYD88*	Yes
Hodgkin Lymphoma	No	No	NA	No

*If clonality cannot be demonstrated by another means

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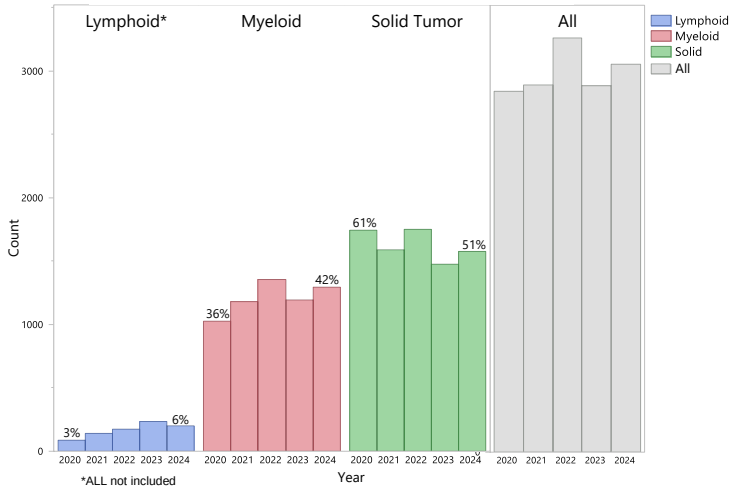
NGS Testing at Johns Hopkins



Observations

- Proportion of lymphoid testing is increasing
- Major increase is in blood and marrow studies
- Necessary tissue-based testing is not currently pursued due to coverage
- Pre-authorization remains an issues

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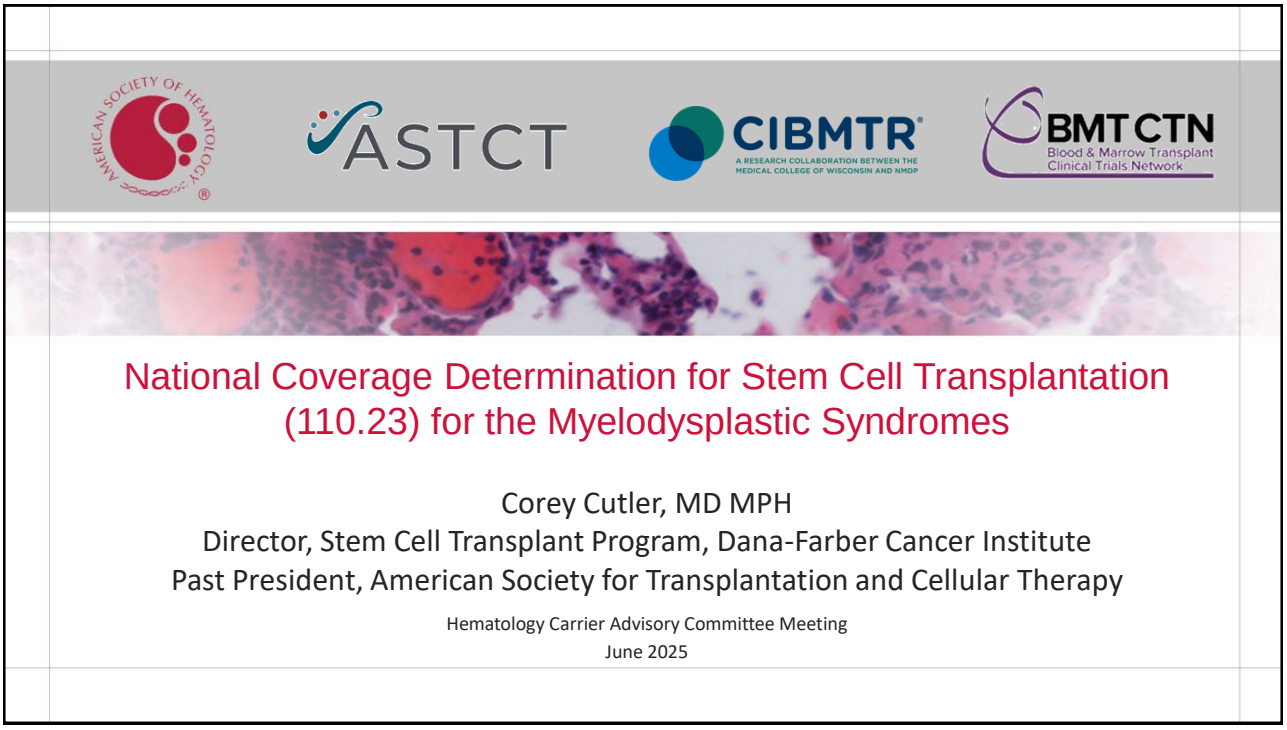
Summary

- There is increasing need for genomic testing in lymphoid malignancies
- NGS has the potential to simplify and expedite ancillary studies maximizing informative results in limited biopsy specimens
- Absence of these results can reduce the accuracy and completeness of pathologic diagnoses needed for treatment selection
- NGS can determine therapy and identify therapy resistance
- NGS is becoming important for base-line risk-stratification
- NGS is already important for dynamic risk-stratification via MRD monitoring
- Future sequencing technologies could assess karyotypic, genotypic, and microenvironment data into a single assay

Thank you.
Questions?

Appendix C: Implementation of the NCD for MDS Slides



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Disclosures for Corey Cutler, MD MPH

In compliance with ASH policy, the following disclosure is made to the assembled group:

No relevant relationships to disclose

Conflicts related to research work in GVHD:

Consulting Fees/Honoraria: Sanofi, CSL Behring, Syndax, Incyte, CareDx

Consulting Fees/Equity: Cimeio, Oxford Immune Algorithmics, OrcaBio

American Society of Hematology

2

Background – CED for MDS

- Allogeneic hematopoietic stem cell transplantation (HCT) remains the only curative therapy for patients with MDS.
- Historically, patients 65 and older with Medicare did not have coverage for HCT.
- On August 4th 2010 the Centers for Medicare and Medicaid services (CMS) established coverage for HCT for MDS through coverage with evidence development (CED).

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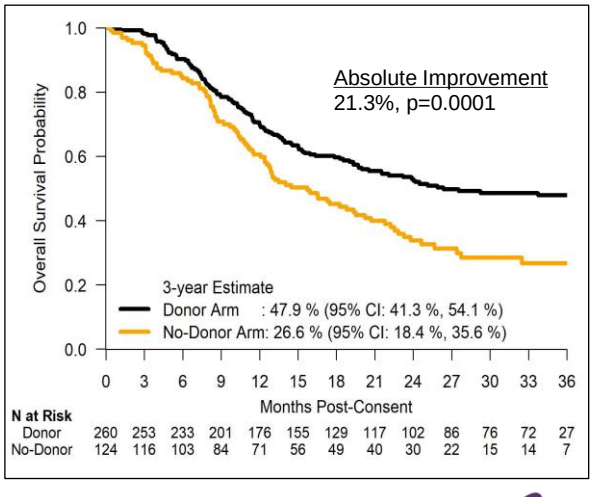
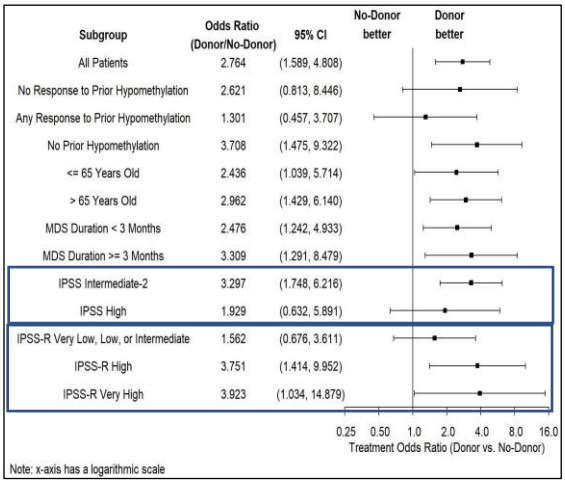
Significant Overall Survival Advantage in the Donor arm





BMT CTN Blood & Marrow Transplant Clinical Trials Network

Nakamura *et al,* J Clin Onc 2021 4

4

DATE: March 6, 2024

National Coverage Analysis (NCA)	Decision Memo

NCA - Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndromes (MDS) (CAG-00415R) - Decision Memo

Final Decision: We are expanding Medicare coverage for allogeneic hematopoietic stem cell transplant using bone marrow, peripheral blood or umbilical cord blood stem cell products for Medicare patients with myelodysplastic syndromes who have prognostic risk scores of:

- ≥ 1.5 (Intermediate-2 or high) using the International Prognostic Scoring System (IPSS), or
- ≥ 4.5 (high or very high) using the International Prognostic Scoring System - Revised (IPSS-R), or
- ≥ 0.5 (high or very high) using the Molecular International Prognostic Scoring System (IPSS-M).

In addition, coverage of all other indications for stem cell transplantation not otherwise specified will be made by local Medicare Administrative Contractors (MACs) under section 1862(a)(1)(A) of the Act.

5

NCD updates had inadvertent coding errors; Later corrected by CMS

1. The coverage spreadsheet associated with NCD 110.23 limited use of cord blood as a donor source to myelodysplastic syndromes (MDS) only
2. CMS limited use of transplants for MDS to the inpatient setting only
   - Transmittal 12948, CR 13604, issued November 6, 2024

Meeting with CAG team in February 2025 resulted in resolution of coding issues

JoAnna Baldwin, MS; Acting Deputy Director, Coverage and Analysis Group (CAG)
Laura Findeiss, MD, MHA; Director, Division of Policy and Evidence Review (DPER)
James Rollins, MD; Medical Officer, DPER
Kimberly Long, Policy Analyst, DPER

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 13097	Date: March 20, 2025
	Change Request 13939

IMPACT
Resubmission of claims erroneously denied

National Coverage Determination 110.23: Allogeneic Hematopoietic Stem Cell Transplantation
Transmittal 13097 - www.cms.gov/files/document/r13097otn.pdf

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DFCI Denial Data

- 11 MDS patients transplanted at DFCI since 3/2024 (NCD)
- **1 Claim paid without issue**
- Outpatient: 5/5 claims denied (ambulatory vs inpatient issue)
  - 4 submitted for Level 2 appeal
  - 1 paid after Level 1 appeal
- Inpatient: 5/6 claims denied (cord blood issue)
  - 3 paid/set to pay with appeal
  - 1 appeal under review
  - 1 ALJ appeal underway

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Today's Discussion

- The Decision memo stands with current limitations
  - No risk scoring system is perfect
  - Treatment gaps exist
- DISCRETION at the MAC level is allowed for all patients who do not meet strict inclusion criteria – We do not understand how best to partner within that discretionary zone.

> In addition, coverage of all other indications for stem cell transplantation not otherwise specified will be made by local Medicare Administrative Contractors (MACs) under section 1862(a)(1)(A) of the Act.

- We do not have a grasp on the denial process, frequency, patterns
- **Goal**: Develop a joint strategy to ensure access for patients in need of BMT

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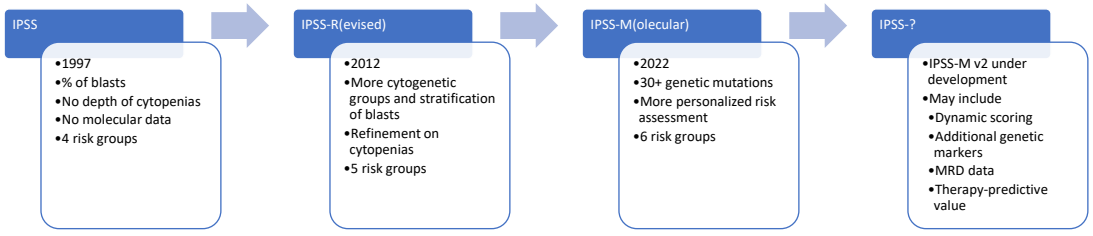
Evolution of IPSS scoring will continue; limitations based on any version will exclude some patients



- Use of outdated scoring systems forces clinician to evaluate patients based on outdated standards
- Some patients are high-risk and need transplant due to life-threatening cytopenias or TP53 status, but will not be initially scored as Int-2 or high-risk in these scoring systems
- A subset of patient patients have to wait for their disease to worsen under the current NCD limitations, increasing the risk of poor outcomes and death

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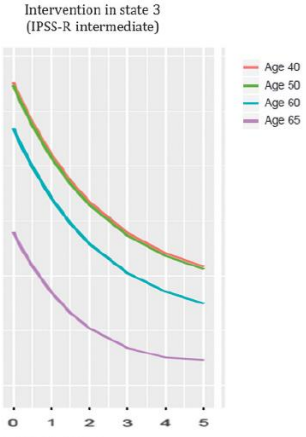
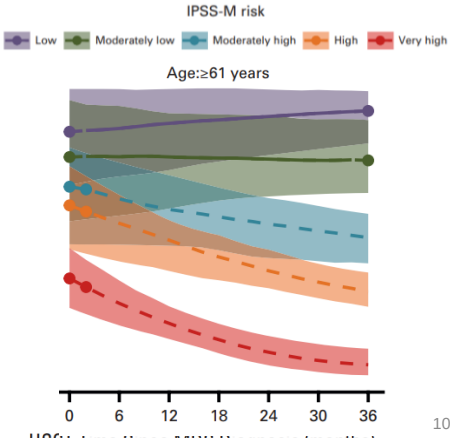
Decision Memo: Clinical Treatment Gaps

- ≥ 1.5 (Intermediate-2 or high) using the International Prognostic Scoring System (IPSS), or
- ≥ 4.5 (high or very high) using the International Prognostic Scoring System - Revised (IPSS-R), or
- ≥ 0.5 (high or very high) using the Molecular International Prognostic Scoring System (IPSS-M).





Della Porta, Leukemia 2017; Tentori J Clin Onc 2025

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Time Is Of The Essence

- Pattern of Denials at a Center Will Change Behavior
  - Fewer patients will be referred for transplantation
  - Artificial reduction in denial rate over time as behavior shifts
- Can we collect information on the Frequency of Denial
  - 12 MACs
  - ~250 Transplant Centers
  - Challenge: Develop methodology to collect this data prospectively as an academic exercise

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Approval Outside IPSS-M Criteria

- Some patients who are outside the automatic approval are being transplanted
  - What is a common process to obtain approval?
  - Are these cases being approved upfront, or after a denial/resubmission?
  - What is the level of evidence that is required to overturn a decision?

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Is There Appetite To Try to Alter the NCD

- LCD process is cumbersome
- Is it needed?

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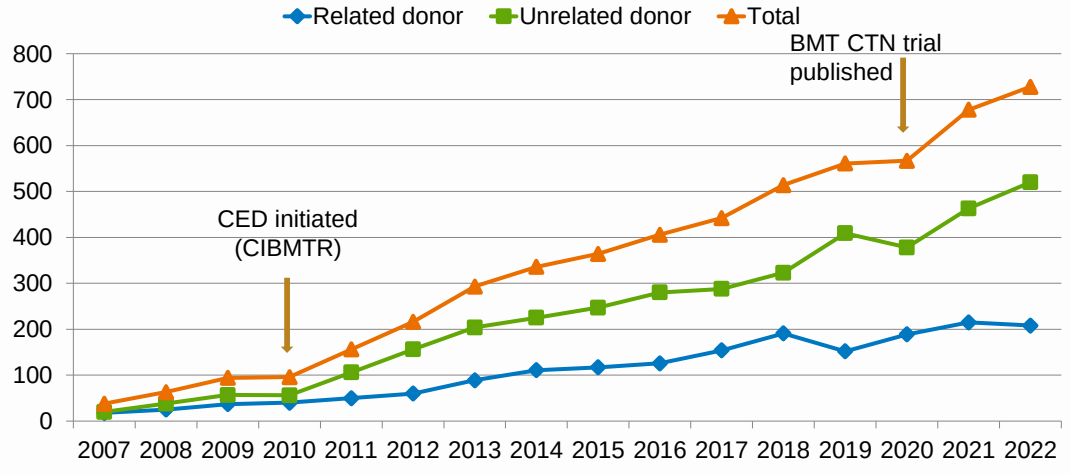
US Allogeneic Transplants for MDS in Patients Older than 65 y, 2007-2022 – What if barriers are removed?



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CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

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Credit and Appreciation to:

- Doug Rizzo, Ehab Atallah, Wael Saber, Mary Horowitz, CIBMTR
- Ryotaro Nakamura, BMT CTN
- Suzanne Leous, ASH
- Kay Moyer, CRD Associates
- Ellie Beaver, Jessica Knudson, NMDP
- Alycia Maloney, ASTCT
- Stephanie Farnia, Nimitt

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Appendix D: Fireside Chat Slides

Demystifying Local Coverage Determinations (LCD) and Contractor Advisory Committee Impact

Points of Entry & Opportunities for Physician Leaders

1

Disclaimer

The views and opinions expressed during this presentation are those of the individual speakers and do not represent the positions of their affiliated organizations or of the Medicare program. The presentation is provided for informational purposes only and is not intended to grant rights, impose obligations, or serve as official guidance. Medicare policies are subject to change, and the authoritative sources remain the applicable statutes, regulations, and official guidance documents.

2

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No conflicts of interest by any presenter to disclose.

3

3

What is a Local Coverage Determination (LCD)?

A Medicare Administrative Contractor (MAC) decides whether an LCD should cover an item or service.

The Medicare Program Integrity Manual (PIM) is part of the Internet Only Manual (IOM) and identifies the LCD development and process requirements MACs are to follow.

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Purpose of an LCD

An LCD ensures that the beneficiary has access to life saving and medically necessary products or procedures.

An LCD defines:

- If a service is covered
- Under what specific clinical circumstances a service is "reasonable and necessary"

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Section 1862(2)(a)(1)(A) of the Social Security Act

The MAC will determine if an item or service is "reasonable and necessary" under §1862(a) (1)(A) of the Act and if the service is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency in terms of whether the service or item is:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or *treatment of the beneficiary's condition or to improve the function of a malformed body member*;
  - Furnished in a setting appropriate to the beneficiary's medical needs and condition;
  - Ordered and furnished by qualified personnel; and
  - One that meets, but does not exceed, the beneficiary's medical need

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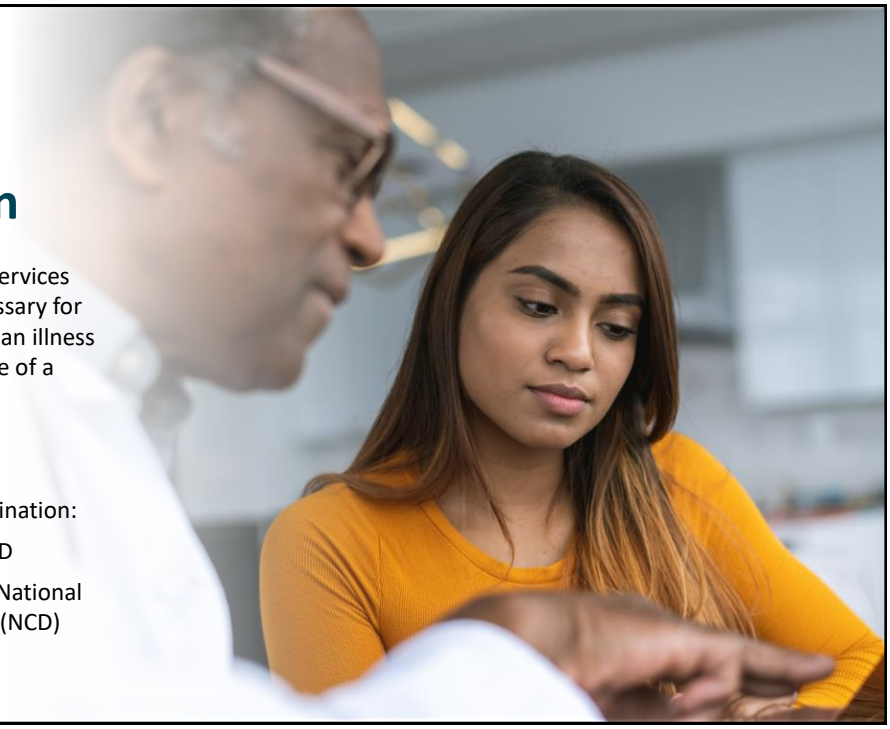
Medicare Coverage Determination



Coverage is limited to items/services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare
benefit category).

Pathways to coverage determination:

- Local level through an LCD
- National level through a National Coverage Determination (NCD)

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LCD vs. NCD

NCDs are national policies granting, limiting or excluding Medicare coverage for a specific medical item or service.

LCDs

- MAC makes the determination
- May vary between jurisdictions
- Can take 6 months to 2 years to develop
- Based on clinical evidence
- MACs can make changes

NCDs

- CMS makes the determination
- Supersedes LCDs
- Applies to all jurisdictions
- Can take years to develop
- Based on clinical evidence
- CMS can make changes

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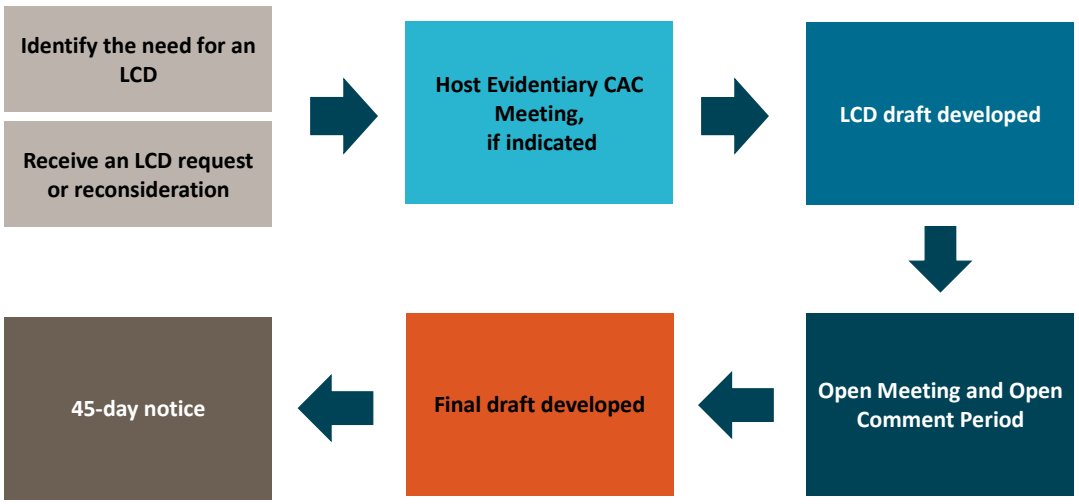
Lifecycle of LCD



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Is An LCD Needed?

Different sources may identify the need for an LCD.

Identify the need for an LCD

Timeline: ~2 months

Internal Sources

- Data analysis
- Claim review

External Sources

- Providers
- Stakeholders
- CMS
- Patient advocacy groups
- Specialty societies
- Professional organizations
- Other MACs
- Other entities

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New LCD Requests: *Insider Tip*

A MAC may consider a new LCD request complete if it:

Identify the need for an LCD

- Fully explains the design, purpose, and/or method of using the item or service, as appropriate
- Is submitted in writing
- Identifies the Medicare benefit category to which the requestor believes the item or service falls under and provides a rationale
- Includes language that the requestor wants in an LCD
- Has justification supported by peer-reviewed evidence
- Addresses the relevance, usefulness, clinical health outcomes, or the medical benefits of the item or service

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LCD Development Process

The local coverage process provides decisions related to items and
services that benefit Medicare beneficiaries.

LCD draft developed

Timeline:
3 months - years

Many components contribute to the development of a policy:

- Evidence review
- CAC input (Subject matter experts)
- Definitions
- Determining coverage criteria
- Rationale
- Only applies to the MACs jurisdiction

LCD Reconsideration Process

A beneficiary or stakeholder (including a medical professional society or physician) can utilize the LCD reconsideration request process in the MAC's jurisdiction to request a revision to an existing LCD.

Receive an LCD request or reconsideration

Timeline:
up to 60 days

The LCD reconsideration may apply under the following criteria, the:

- Reconsideration process is available for final, effective LCDs only
- Entire LCD or any part of it is subject to reconsideration
- Reconsideration process is the stakeholder's pathway to change an existing policy

MACs will review LCD reconsideration requests from the following stakeholders:

- Beneficiaries residing or receiving care in its contractual jurisdiction
- Providers doing business in its contractual jurisdiction
- Any interested party doing business in its contractual jurisdiction

LCD Reconsideration Process

Insider Tips

Interested parties can ask us to reconsider an entire LCD or just a part of it. A valid LCD reconsideration request must include:

- The specific language that the requestor proposes added to or deleted from an LCD. For example, "We request coverage of X condition due to new evidence for the surgical management described in this LCD."
- A description of the statutorily defined benefit category under which the requestor believes the item or service falls. The request must include a rationale justifying the assignment within that benefit category. The CMS IOM, Publication 100-02, Medicare Benefit Policy Manual, defines the benefit categories.
- Justification for the proposed change supported by new evidence in the medical literature that may materially affect the LCD's content or basis. The level of evidence required for LCD reconsideration is the same as that required for a new LCD development.

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LCD Reconsideration Process

Insider Tips

•Electronic copies of supporting medical literature as email attachments. Medical literature must be currently published, include the full text (not abstracts), and be published in English. Due to security restrictions, we are **not able to open links in emails**.

•Information that addresses the relevance, usefulness, clinical health outcomes, or the medical benefits of the item or service.

•Information that fully explains the design, purpose, and/or method, as appropriate, of using the item or service for which you are making the request.

How to submit an LCD Reconsideration Request and what to expect after submission

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Using evidence for policy decision making

Meredith Loveless, MD, FACOG | Chief Medical Officer | CGS Administrators | A/B MAC Jurisdiction 15

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Coverage Determination

Questions to consider when determining coverage:

- Is the service medically reasonable and necessary?
- How is the proper diagnosis made?
- Is the treatment supported by evidence to be effective?
- What are the acceptable standards of care for this condition?
- What are the risks and benefits?
- What are the alternatives?
- Is it experimental/investigational?
- Has this been investigated in a Medicare population?

Identify the need for an LCD

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Evidence Review

LCD draft developed

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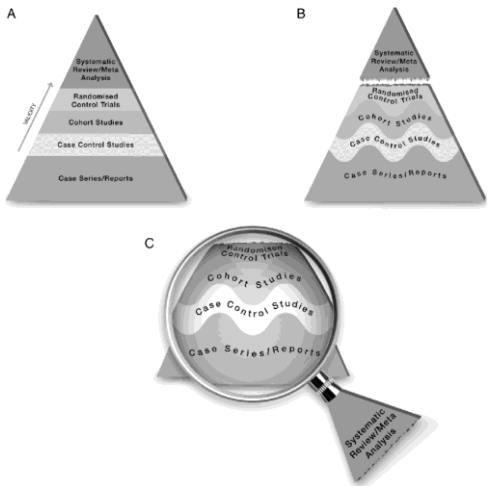
Updated Hierarchy of Study Design



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Meta-Analysis: Advantages

- Power enhanced by larger sample size available from the combined studies
- Improve applicability
- Resolve questions from conflicting studies
- Can provide important results when several smaller studies are not sufficient to demonstrate meaningful outcomes
- Useful for practice guideline development

Meta-Analysis: Disadvantages

- Investigator has no control over the existing data
  - Limited to quality of existing data
  - Important confounders or outcomes may not have been measured
- Results can be misleading if the studies are not appropriately combined
- Garbage in, Garbage out

What is Real World Evidence/ Real World Data?

- **Real World Data** collects information from electronic health records, medical claims data, patient registries, data from wearable devices, questionnaires.
- **Real world evidence** is evidence derived from real world data.
- Provides information on diverse populations outside a controlled environment.
- Limited by lack of controls, heterogenicity, bias, data quality, privacy and ethical concerns.

Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin

- *What if RCTs not feasible?*

- Not covered under NCD 110.23 Stem Cell Transplantation
- Need for policy communicated at ASH meeting
- Policy developed and adopted by most MACs

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Introduction to GRADE

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Why Guidelines?

- Intended to assist in making informed decisions
- Ideal tools to support delivery of best health care
- Summarize what is known on a topic
- Suggest recommendations for best management

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Why do we need a universal grading system?

- Increase transparency
- Increase methodological accuracy
- Better define certainty of evidence
- Reduce confusion from use of multiple systems for grading
- Increases well-informed decisions
- Limits health care disparities

GRADE Guidelines- Quality of Evidence

- Classifies overall certainty of evidence quality into one of four levels:
  - **High**- further research unlikely to change our confidence in the estimate of effect
  - **Moderate**- further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
  - **Low**- further research is very likely to have an important impact on our confidence in the estimate of effect and likely to change the estimate
  - **Very low-** Any estimate of effect is very uncertain

GRADE Guidelines- Recommendations

Classifies recommendation:

STRONG

WEAK/CONDITIONAL

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GRADE System

- Pros:
  - Quality of evidence based on totality of evidence (not individual studies)
  - Focus on patient-important outcomes
  - Quality of evidence may differ by outcomes
  - Strength of recommendation based on more than just quality of evidence
  - User-friendly, Updated tools, Available online
- Cons:
  - Requires training
  - Requires clinical and methodological skills
  - Subjectivity can be present (influence of panel members)
  - Takes time (frequently not available for new technologies)

*material supplemented from GRADE workshop presentations

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Entry Points for Subject Matter Experts/ CAC members

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Top 10 Ways Providers can Engage with their MAC

1. LCD request/reconsiderations
2. Research! Producing high quality literature to answer questions in evidence-based way.
3. Sharing pertinent literature with your MAC.
4. Serving as CAC member or as subject matter expert.
5. Participating in societies/ providing input for societies.

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Top 10 Ways Providers can Engage with their MAC

6. Societies/panels to produce evidence-based guidelines – encourage use of GRADE or systematic evidence review process.
7. Present at open meetings or submit comments if concerns – back it up with evidence.
8. Full disclosure of potential bias.
9. Understand that we are fulfilling requirements determined by law when we follow the policy process.
10. Participate in education.

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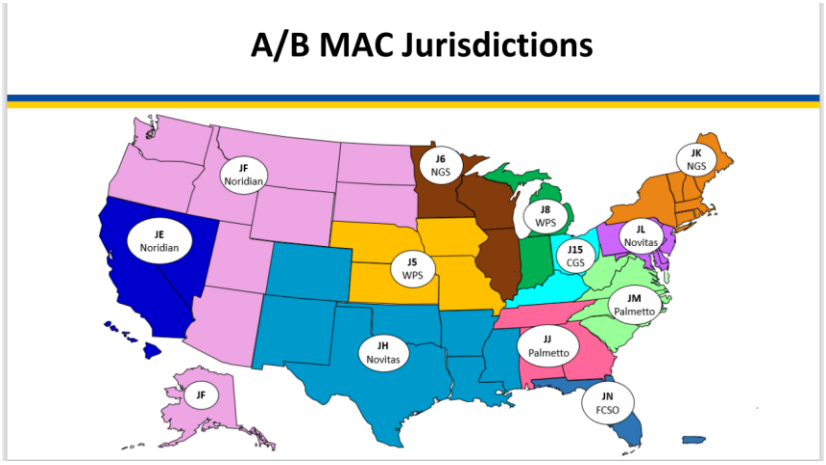
Medicare Administrative Contractors (MACs)



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Noridian

Jurisdiction F: Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming

Jurisdiction E: California, Hawaii, Nevada, American Samoa, Guam, and Northern Mariana Islands

DME Jurisdiction A: Connecticut, Delaware, Massachusetts, Maryland, Maine, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Washington D.C.

DME Jurisdiction D: Alaska, American Samoa, Arizona, California, Guam, Hawaii, Idaho, Iowa, Kansas, N. Mariana Islands, Missouri, Montana, Nebraska, Nevada, North Dakota, Oregon, South Dakota,Utah, Washington, and Wyoming

https://med.noridianmedicare.com/web/jea/policies/lcd/cac#membership

Individuals who are interested in being on our IMPAC list or who would like to identify themselves as a

SME on a particular topic can email Krista Babbit at Krista.Babbitt@noridian.com.

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WPS

Jurisdictions 5: Iowa, Kansas, Missouri, Nebraska

Jurisdictions 8: Indiana, Michigan

CAC recruitment webpage: Volunteer as a J5 or J8 CAC Member. (https://www.wpsgha.com/guides-resources/view/572)

For a list of openings, to nominate a CAC member, or for further questions on CAC meetings and engagement, email LCDCAC@wpsic.com

Potential candidates or their State/National Societies must provide the following documentation:

A Nomination Letter from the appropriate State or National Society

Name and title,

Email address,

Phone number,

Area of specialty and

Curriculum Vitae.

Candidates are vetted after nomination. If approved, WPS will reach out with details regarding upcoming meetings.

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WPS

- Produced a brief analysis of the physician work force in response to a CAC member's concern that there may be a shortage in their region.
- This analysis was shared at the October 2024 CAC Engagement meeting and generated some good discussion.

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Jurisdiction 15: Ohio and Kentucky

DME Jurisdiction B: Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, and Wisconsin

DME Jurisdiction C: Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, U.S. Virgin Islands,Virginia and West Virginia

CAC members are nominated by state medical societies or standing CAC members. Self-nominations are considered. Candidates are asked to send their contact information and CV to:

CMD.inquiry@cgsadmin.com and are vetted after nomination.

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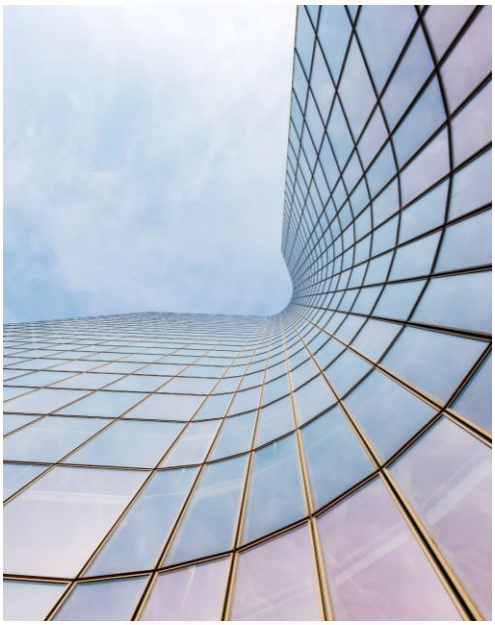
- Provider Touch Point Meetings- a meeting for CAC members only to discuss Medicare updates, questions, and topics of interest.
- CAC Newsletter- quarterly newsletter to provide CAC members timely updates and be able to share with societies and providers.
- ListServe- to communicate with CAC members, share Open and CAC meeting dates and timely updates.
- Policy Webinars- for education on new policies for J15



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Novitas

Jurisdiction H: Arkansas, Colorado, Louisiana, Mississippi, New Mexico, Oklahoma, Texas, Indian Health Service (IHS) and Veterans Affairs (VA) nationally

Jurisdiction L: Delaware, Maryland, New Jersey, Pennsylvania, District of Columbia, Arlington and Fairfax counties in Virginia, The city of Alexandria, Virginia

Clinical healthcare professionals interested in serving as a CAC member should submit the following via email to: MedicalAffairs@guidewellsource.com

Nomination letter from their affiliated National or State Society/Specialty Organization

Their contact information (Name, email address, phone number, etc.)

Their area of specialty

Name of medical practice, if applicable

Individual NPI number and, if applicable, group NPI number

https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00196701

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Palmetto

Jurisdiction J: Alabama, Georgia, and Tennessee

Jurisdiction M: North Carolina, South Carolina, Virginia, and West Virginia

Please submit their request with the specialty they wish to fill and their CV to B.Policy@PalmettoGBA.com for Palmetto.

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FCSO

Jurisdiction N: Florida, Puerto Rico, and the U.S. Virgin Islands

https://medicare.fcso.com/CAC/0489835.asp

Assist us in developing local coverage determinations (LCDs) – Volunteer as a CAC member!

The Centers for Medicare & Medicaid Services (CMS) released Change Request 10901 and the companion MLN Matters article to expand the parameters of who may serve as a Medicare Contractor Advisory Committee (CAC) member. The purpose of the CAC is to provide a formal mechanism for healthcare professionals to be informed of the evidence used in consideration of a proposed LCD and to promote communications between the Medicare Administrative Contractor (MAC) and the healthcare community. CAC members serve in an advisory capacity as representatives of their constituency to review the quality of the evidence regarding a topic under consideration for development of a proposed LCD.

FCSO Solutions invites you to volunteer as a CAC primary or alternate member to represent your organization during our CAC meetings.

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NGS

Jurisdiction 6 – Illinois, Minnesota and Wisconsin

Jurisdiction K – Maine, New Hampshire, Vermont, Massachusetts, Rhode Island, Connecticut and New York

https://www.ngsmedicare.com/web/ngs/contractor-advisory-committee-cac?selectedArticleId=11936180&lob=96664&state=97178&rgion=93623

NGS invites healthcare professionals from each state within our jurisdictions (JK and J6) to volunteer as Medicare Contractor Advisory Committee (CAC) members, or alternates, to represent your specialties or organizations. An important role of a CAC member is to serve as a Subject Matter Expert or to recommend a Subject Matter Expert to serve on a Jurisdictional or Multijurisdictional CAC Panel.

If you would like to volunteer as a representative or alternate, please request your affiliated National or State Society to provide you with a nomination letter.

Next, potential candidates must provide the following documentation to NGSCAC@elevancehealth.com:

- A Nomination Letter from the appropriate State or National Society
- Name and title
- Email address
- Phone number
- Area of specialty
- Curriculum Vitae.

Candidates are vetted after nomination. Once the vetting process has been completed, approved candidates will be notified of their official acceptance.

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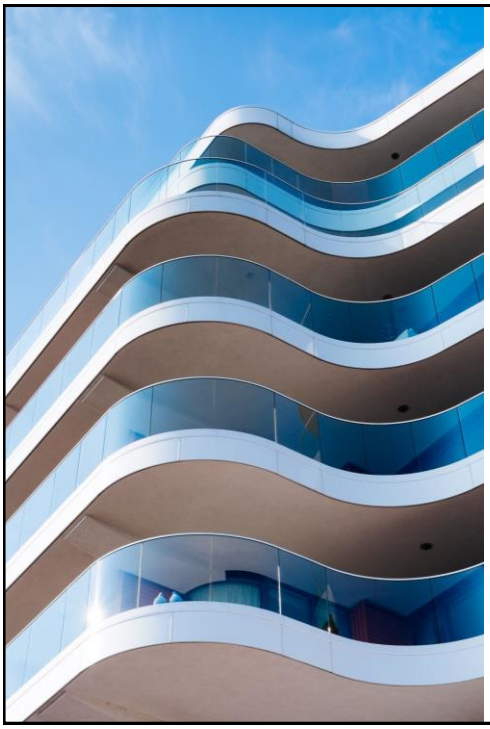

NGS

- Monthly stakeholder meetings within our jurisdiction
- Provider Engagement Meeting quarterly

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Thank you!

Questions?

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Helpful Resources

LCDs and NCDs

- The Medicare Coverage Database
- The CMS Internet Only Manual, Publication 100-02, Medicare Benefit Policy Manual, defines the benefit categories.
- Meeting Schedules

Evidence

- Cochrane Training
- GRADE Working Group

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Acronyms

ALJ: Administrative Law Judge
BFL: Business Function Lead
BIPA: Benefits Improvement and Protection Act
CAC: Contractor Advisory Committee
CCTA: Coronary Computed Tomographic Angiography
CERT: Comprehensive Error Rate Testing
CFR: Code of Federal Regulation
COR: Contracting Officer Representative
CMS: Centers for Medicare & Medicaid Services
DAB: Department of Appeals Board
FR: Federal Register
FFR: Fractional Flow Reserve Computed Tomography
IOM: Internet Only Manual
LCD: Local Coverage Determination
LCBE: Local Coverage Backend Database
MAC: Medicare Administrative Contractor
MCD: Medicare Coverage Database
MLM: Medicare Learning Network
OIG: Office of Inspector General
PIM: Program Integrity Manual
PFS: Physician Fee Schedule
RAC: Recovery Audit Contractor
RTC: Response to Comments
SMRC: Supplemental Medical Review Contractor
SSA: Social Security Act
UPIC: Unified Program Integrity Contractor