



2023

President

Robert Brodsky, MD
Johns Hopkins University
Ross Building, Room 1025
720 Rutland Avenue
Baltimore, MD 21205
Phone 410-502-2546

President-Elect

Mohandas Narla, DSc
New York Blood Center
310 E 67th Street
New York, NY 10065
Phone 212-670-3056

Vice President

Belinda Avalos, MD
Atrium Health
215 N. Pine Street, Unit 4703
Charlotte, NC 28202
Phone 980-442-2000

Secretary

Cynthia Dunbar, MD
NHLBI/NIH
Translational Stem Cell Biology Branch
Building 10-CRC, Room 5E-3332
10 Center Drive
Bethesda, MD 20892
Phone 301-402-1363

Treasurer

Joseph Mikhael, MD, FRCPC, MEd
Translational Genomics Research Institute,
City of Hope Cancer Center
445 N. Fifth Street
Phoenix, AZ 85004
Phone 602-343-8445

Councillors

Christopher Flowers, MD, MS
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Executive Director

Martha Liggett, Esq.

December 28, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-8016

RE: Sickle Cell Disease Action Plan

Dear Administrator Brooks-LaSure:

The American Society of Hematology (ASH) commends the Centers for Medicare & Medicaid Services (CMS) for recognizing the challenges that individuals living with sickle cell disease (SCD) face and releasing an SCD Action Plan outlining the Agency's efforts to eliminate barriers, reduce health disparities, and improve health outcomes for these individuals. ASH has a longstanding commitment to combating inequities in healthcare and research, and the Society is committed to improving SCD care. We look forward to working with you to implement this action plan and other policies, including supporting access to comprehensive care for those living with SCD, to advance this goal.

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

In 2015, ASH launched a transformative, multi-faceted, patient-centric [initiative](#) spanning practice, research, and policy to improve outcomes for individuals living with the disease, both in the United States and globally. Through our work, the Society has recognized that access to comprehensive care is critical to improving the health of individuals living with SCD. Outcomes improve when patients have access to a multidisciplinary care team; together patients and their physicians select clinical protocols that range from disease management to hematopoietic stem cell transplantation (HSCT) and gene therapy as part of a care plan that best supports the patient's health and quality of life. Access to comprehensive care must also include wrap-around services such as transportation and dental and vision care. ASH believes that CMS' SCD Action Plan should include expanding access to the full scope of comprehensive care.

CMS Should Support Access to Comprehensive Care for SCD Patients

Today, many patients face barriers accessing experienced care teams and therapies, and receive uncoordinated care outside of a medical home, leading to poor clinical outcomes, avoidable complications, low quality of life, and increased costs to the healthcare system. It is important for people with SCD to have access to the range of treatment options currently available. What might be the right treatment option for one individual may not be appropriate for another. Physicians and patients must determine the most appropriate course of care

together, taking a patient's unique circumstances into account. To make the most appropriate determination, it is important that each patient have access to multi-disciplinary care teams that may include hematologists, obstetricians and gynecologists, reproductive health specialists, urologists, ophthalmologists, neurologists, nephrologists, psychologists, psychiatrists, orthopedists, cardiologists, pulmonologists, care coordinators, and social workers to adequately treat an individual for SCD and its many complications.

Furthermore, ASH continues to call for CMS to support access to comprehensive care for SCD in both the Medicaid and Medicare programs. We commend the agency for the progress it has made in expanding coverage for Medicare beneficiaries with SCD through national coverage determinations. However, according to a CMS report, approximately 50% of individuals in the United States with SCD are covered by Medicaid. Given the proportion of individuals with SCD who rely on Medicaid, ASH encourages CMS to consider innovative solutions to ensure consistent coverage for all individuals who qualify and are interested in transplant, cell and gene therapy (CGT), or other available treatment options – regardless of which state they live in or where they travel to for care. It is important that CMS target coverage decisions for both Medicare *and* Medicaid programs to capture the broader SCD population.

ASH applauds the CMS Innovation Center for developing the Cell & Gene Therapy Access Model, which will support access to the newly approved gene therapies for SCD in the Medicaid program. As noted in ASH's [recent letter](#) to the Innovation Center, we appreciate the agency's willingness to collaborate with ASH and stakeholders to ensure this model captures the full scope of services—ranging from pain management to mental health services—required for those individuals with SCD who are eligible for and elect to receive gene therapy. The approvals of these therapies represent a significant breakthrough, offering a new and potentially curative treatment option for many individuals affected by SCD. However, only a fraction of patients will be eligible for this therapy and will elect to pursue this treatment protocol. Those who are not good candidates for gene therapy or choose not to pursue this rigorous treatment regime deserve to have the Medicaid and Medicare programs' support to access other appropriate services and therapies.

Specifically, autologous and allogeneic HSCT are supported by a growing body of research and are viable options for an increasing pool of eligible candidates. In addition, the recent ASH Annual Meeting & Exposition highlighted [research](#) on reduced intensity haploidentical bone marrow transplantation for severe SCD cases, demonstrating curative potential at 2-years with event free survival and overall survival rates comparable to matched sibling donor transplantation. Progress in HSCT, including the expansion of the donor pool to a half- or partial- matches, increase the accessibility of this treatment option. Additionally, the treatment plan for HSCT is like CGT in that they both require significant pre- and post- treatment care. ASH encourages CMS to ensure coverage of HSCT for Medicaid and Medicare beneficiaries.

Components of the Action Plan

ASH applauds CMS' efforts to improve SCD care as outlined in the Action Plan. Specifically, we believe that the promotion of access to non-emergency medical transportation (NEMT) for this population is critically important. This is essential for ensuring that individuals with SCD can access the medical care and support they need to manage their disease effectively to encourage better health outcomes and improved quality of life. ASH appreciates the release of CMS' state coverage guidance and believes that NEMT is a required element of comprehensive care for individuals living with SCD.

ASH recognizes that CMS is working diligently across its programs to advance policies to improve access, quality, and the experience of health care for individuals with SCD as outlined in the Action Plan. We believe the expansion of chronic pain management and treatment services, access to multidisciplinary teams, and new services, including Community Health Integration and Principal Illness Navigation services, in the Medicare Physician Fee Schedule (MPFS) will support better care for individuals with SCD. However, this expansion in services still falls short of the comprehensive care and wrap-around services that ASH believes is necessary to meaningfully improve the lives of individuals living with SCD.

Finally, ASH urges CMS to improve access to covered dental services for people with SCD. We have submitted several comment letters to CMS on this topic and were disappointed that the agency did not recognize dental care as inextricably linked to the care delivered to patients being treated for SCD. As we have stated in the past, people with SCD experience increased dental caries and periodontal disease, resulting in the loss of teeth, which greatly limits

nutrition, general well-being, and overall quality of life. We believe it is crucial for the agency to provide comprehensive coverage of dental services, including regular checkups (prophylactic services) and treatment of dental caries and periodontal disease. ASH recognizes that many state Medicaid programs provide dental care, yet there is no Medicare coverage. Dental services are a key component of comprehensive care for SCD regardless of, and ASH will be following up with the agency on this topic with the goal of providing appropriate dental coverage for SCD in the Calendar Year 2025 MPFS.

Conclusion

ASH thanks you for your commitment to improving the health of individuals with SCD. While we did not address ASH's SCD efforts related to equity, quality metrics, and data analysis, we have numerous resources that we would be pleased to make available to the agency. We stand ready to work with you to improve the health and quality of life for patients living with SCD. We strongly urge CMS to support the delivery of comprehensive care to individuals living with SCD across Medicaid and Medicare. While the agency has made significant investments in this area, additional SCD-specific policies are necessary to overcome the longstanding disparities and barriers to comprehensive care this population faces. We welcome the opportunity to meet with you to discuss the recommendations outlined in this letter. Please contact ASH Manager for Health Care Access Policy, Carina Smith at casmith@hematology.org or 202-292-0264 to arrange a meeting and/or if you have any questions.

Sincerely,



Robert A. Brodsky, MD
President, 2023



Mohandas Narla, DSc
President, 2024