Action Plan

CMS Sickle Cell Disease



Introduction

CMS strives to improve access, quality, and experience of health care for individuals living with Sickle Cell Disease (SCD), a lifelong inherited blood disorder that affects over 100,000 individuals in the United States, the majority of whom are from Black or African American and Hispanic or Latino populations.[i] While medical advancements, such as newborn screening and therapeutics, have transitioned SCD from a fatal childhood disease to a chronic condition, patients with SCD still have a significantly shorter life expectancy, more than 20 years shorter than the general population.[ii] Additionally, many long-term health complications – including stroke, acute chest syndrome, and chronic end-organ damage – persist. Compared to individuals without SCD, individuals with SCD have higher rates of asthma, fibromyalgia and chronic pain and fatigue, hypertension, depression, chronic kidney disease, heart failure, liver disease, stroke, and epilepsy.[iii]

Approximately half of people affected by SCD are enrolled in Medicaid[iv] and 11% are enrolled in Medicare[v,vi] - often as dually eligible enrollees in both Medicaid and Medicare - underscoring the burden of disease among people enrolled in CMS programs and the importance of CMS action. Individuals with SCD often face challenges along their care journeys, including:

- Significant pain and other serious medical problems, including higher infection risks, lung problems, stroke, and pregnancy-related complications[vii]
- Higher rates of emergency department visits and hospitalizations, at an estimated cost of $2.4B per year[viii]
- Gaps in receiving clinically recommended standard of care, such as ultrasound screenings for primary stroke prevention[ix]
- Vulnerability in the transition from pediatric to adult care, with many falling out of care during this transition[x,xi]
- Obstetric considerations, such as more frequent or more severe pain episodes and higher risk of preterm labor and of having a low birthweight baby
- Stigma that contributes to negative health care interactions and decreased physiological and psychological well-being[xii]

The CMS Sickle Cell Disease Action Plan addresses these challenges specific to CMS programs and is designed to improve health outcomes and reduce health disparities for individuals with SCD. The Action Plan builds on the Health Equity pillar of the **CMS Strategic Plan** and the goals under the **CMS Health Equity Framework** and aligns with the mission and vision of the **CMS National Quality Strategy** and the **CMS Behavioral Health Strategy's** goal to ensure effective pain treatment and management.

CMS Actions

Coverage and Access

- **Improving access to chronic pain management services**: Individuals with SCD often have chronic pain that can be debilitating. In the **2023 Medicare Physician Fee Schedule**, CMS created new payment and codes describing services for chronic pain management and treatment (CPM). These new services can help Medicare enrollees with SCD and chronic pain to receive holistic chronic pain care within a trusting, supportive, and ongoing care relationship.

- **Promoting access to innovative therapies**: The Secretary has selected for testing, the Cell & Gene Therapy (CGT) Access Model, which would be a Medicaid-focused Innovation Center model. The CGT Access Model would establish a partnership among CMS, manufacturers, and state Medicaid agencies, and would test a new approach for administering outcomes-based agreements (OBAs) to help Medicaid beneficiaries gain access to potentially life changing, high-cost specialty drugs. In lieu of state Medicaid agencies pursuing manufacturer agreements individually, the Innovation Center would structure and coordinate multi-state OBAs with participating manufacturers on behalf of states. CMS would also take on the responsibility of implementing, monitoring, reconciling, and evaluating the financial and clinical outcomes outlined in the OBAs. This Model would target gene therapies for illnesses like SCD and cancer. Participation would be optional for both manufacturers and states.

- **Strengthening access in Medicaid**: Released in April 2023, the ***Ensuring Access to Medicaid Services and Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality*** **notices of proposed rulemaking** proposed historic advancements in access to care, quality of care, and improved health outcomes for Medicaid and CHIP enrollees. Medicaid and CHIP are the nation's largest health coverage programs. If adopted as proposed, these rules would build on Medicaid's already strong foundation as an essential program for millions of families and individuals, including thousands of people living with SCD.

- **Covering Allogeneic Stem Cell Transplantation for Medicare beneficiaries**: In 2016, CMS released a **National Coverage Determination** stating that Stem Cell Transplantation for Sickle Cell Disease under Medicare would cover allogeneic hematopoietic stem cell transplantation for beneficiaries with severe, symptomatic Sickle Cell Disease who participate in an approved prospective clinical study, subject to certain requirements.

- **Promoting access to non-emergency medical transportation (NEMT)**: State Medicaid plans are required to ensure that eligible Medicaid beneficiaries have necessary transportation to and from providers. In June 2023, HHS submitted an expanded **Report to Congress** that provided a more extensive analysis of Medicaid coverage of NEMT. The report reflects data for calendar years 2018 to 2021. CMS also plans to issue a transportation coverage guide at the end of 2023 that updates NEMT guidance for states.

- **Enhancing access to dental services**: CMS is committed to improving access to covered dental services. Individuals with SCD are at risk for oral health complications, including infections; these complications can also put people who are immunocompromised with SCD at risk for a sickle cell crisis. CMS finalized a public process in the Calendar Year 2023 (CY2023) Medicare Physician Fee

Schedule (PFS) to allow stakeholders to share recommendations for CMS consideration, review, and analysis to potentially be included as analogous clinical scenarios under which Medicare payment could be made for dental services. Per the CY2023 PFS final rule and 42 CFR 411.15(i)(3)(i)(A), stem cell transplantation for SCD would be a scenario under which Medicare payment could be made for inextricably linked dental services.

- **Leveraging Multidisciplinary Teams to Promote Whole-Person Care**: Individuals with SCD experience a multitude of medical complications and associated unmet health-related social needs and behavioral health ramifications. In the Calendar Year 2024 Proposed Medicare Physician Fee Schedule, CMS has proposed new codes and payment for Community Health Integration and Principal Illness Navigation services, which are the first codes that are specifically designed to describe services involving certain types of auxiliary personnel such as community health workers, care navigators, and peer support specialists. These proposed services involve a patient-centered assessment to understand the patient's lived experiences care coordination, contextualizing health education, building patient self-advocacy skills, health system navigation, behavior change, providing social and emotional support, and facilitating access to community-based social services to address social determinants of health needs.

Quality of Care

- **Improving the Continuum of Care**: CMS released its **National Quality Strategy**, a long-term initiative that aims to promote the highest quality outcomes and safest care for all individuals. The Strategy focuses on a person-centric approach across an individual's life span and the continuum of care, from home or community-based settings to hospital to post-acute care, and across all payer types. CMS plans to use the framework of the National Quality Strategy to assess the quality-of-care issues related to sickle cell treatment within the Medicare and Medicaid populations. Specifically, CMS plans to conduct a series of listening sessions over the coming year to learn from key stakeholders about the gaps in quality related to Sickle Cell Disease, examine the landscape of quality measures or need for new measures, and identify opportunities to improve overall health care quality for this population.

- **Supporting Pediatric SCD Quality Measurement**: In 2022, the Core Quality Measures Collaborative (CQMC), a public-private partnership of which CMS is a member, added two quality measures for children with Sickle Cell Disease to the Consensus Core Set for pediatrics. CMS supported the development of these two pediatric SCD quality measures through the Medicaid and CHIP Pediatric Quality Measures Program (PQMP).

- **Standardizing Quality Measures**: CMS also released a **final rule** in August 2023 to establish requirements for mandatory annual State reporting of standardized quality measures in Medicaid and CHIP, including the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP; the behavioral health measures on the Core Set of Adult Health Care Quality Measures for Medicaid; and the Core Sets of Health Home Quality Measures for Medicaid. States will be required to report stratified data for an increasing number of measures over time, with potential stratification factors including geography and race/ethnicity. These quality measures help identify gaps and health disparities among the millions of people enrolled in Medicaid and CHIP.

Equity and engagement

- **Engaging Individuals and Communities with Lived Experience**: CMS is committed to listening to the needs of individuals with SCD and identifying and addressing barriers to high-quality care. In Fall 2023, CMS plans to host dedicated roundtables to hear directly from individuals, caregivers, and providers about SCD, including support and tools that are needed for improve access to care and realize better health outcomes and experience of care.

- **Developing SCD Toolkit**: In conjunction with the aforementioned roundtables, CMS plans to develop an SCD Toolkit that aims to strengthen the infrastructure for primary care and other care settings to care for people with SCD, improve care management, and assist providers with supporting the needs of people with SCD and other chronic conditions. Building on HRSA's portfolio of SCD programs, the toolkit will include provider-focused content as well as educational materials geared towards individuals with SCD and other community partners who serve them.

- **Connecting individuals through Coverage to Care (C2C)**: **Coverage to Care** offers health insurance literacy resources with consumer-friendly information in multiple languages that community partners and providers can use to help any person understand how to make the most of their health coverage and use it to stay healthy. Coverage to Care offers general information, as well as information about preventive care, telehealth, and behavioral health, Coverage to Care is currently expanding its care management portfolio to chronic care management, prescriptions, and other potential topics. These C2C resources can help people with SCD and other chronic conditions to understand health coverage, stay connected to care, and be an active part of their care plan.

- **Sharing educational resources**: CMS Office of Minority Health (OMH) will share information and resources – such as this **video** – about SCD through its website, listserv, partner emails, and social media to help providers deliver quality care to individuals with SCD.

Data and Analytics

- **Analyzing care trends in Medicaid and Medicare**: CMS published data highlights on the prevalence of SCD among **Medicare** FFS beneficiaries and **Medicaid** beneficiaries. These data highlights also look at utilization of care across settings, burden of chronic disease, and geographic and other demographics of individuals with SCD.

- **Examining state-level demographic, health characteristic, and utilization patterns**: Using Medicaid data from the United States, Puerto Rico, and the U.S. Virgin Islands (USVI), CMS released the **At a Glance: Medicaid and CHIP Beneficiaries with Sickle Cell Disease (SCD), T-MSIS Analytic Files (TAF) 2017** infographic, as well as the companion report - **Medicaid and CHIP Sickle Cell Disease Report, T-MSIS Analytic Files (TAF) 2017** to improve understanding of the diverse populations served by state Medicaid and CHIP programs and highlight opportunities for quality improvement.



CMS looks forward to working with partners across the health care system to increase access to services and improve the quality of care for people with SCD. More information may be found at go.cms.gov/omh.

i. Centers for Disease Control and Prevention. Data & Statistics on Sickle Cell Disease, July 2023. **https://www.cdc.gov/ncbddd/sicklecell/data.html**.

ii. **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10336259/**

iii. Center for Medicaid and CHIP Services, Division of Quality and Health Outcomes. At a Glance: Medicaid and CHIP Beneficiaries with Sickle Cell Disease (SCD), T-MSIS Analytic Files (TAF) 2017. Centers for Medicare & Medicaid Services. September 2020. **https://www.medicaid.gov/medicaid/quality-of-care/downloads/sickle-cell-disease-infographic.pdf**

iv. Cells S, Mpa E, Jalowsky M, et al. Medicaid Access & Landscape Review For Prescription Drugs Treating Sickle Cell Disease Opportunities To Improve Access For Sickle Cell Disease Therapies. 2022. **https://sickcells.org/wp-content/uploads/2022/08/Sick-Cells_Medicaid-Access-and-Landscape-Review_Final-Report.pdf**

v. Jiao B, Johnson KM, Ramsey SD, Bender MA, Devine B, Basu A. Long-term survival with sickle cell disease: a nationwide cohort study of Medicare and Medicaid beneficiaries. Blood Adv. 2023;7(13):3276-3283. **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10336259/**

vi. Prevalence of Sickle Cell Disease among Medicare Fee-For-Service Beneficiaries, Age 18-75 Years, in 2016. **https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-15-Sickle-Cell-Disease.pdf**

vii. Center for Medicaid and CHIP Services, Division of Quality and Health Outcomes. At a Glance: Medicaid and CHIP Beneficiaries with Sickle Cell Disease (SCD), T-MSIS Analytic Files (TAF) 2017. Centers for Medicare & Medicaid Services. September 2020. **https://www.medicaid.gov/medicaid/quality-of-care/downloads/sickle-cell-disease-infographic.pdf**

viii. Huo J, Xiao H, Garg M, Shah C, Wilkie D, Mainous III A. The Economic Burden of Sickle Cell Disease in the United States. Value in Health. 2018;21:S108. doi: **https://doi.org/10.1016/j.jval.2018.07.826**

ix. American Society of Hematology 2020 guidelines for sickle cell disease: prevention, diagnosis, and treatment of cerebrovascular disease in children and adults: **https://ashpublications.org/bloodadvances/article/4/8/1554/454384/American-Society-of-Hematology-2020-guidelines-for**

x. Johnson KM, Jiao B, Ramsey SD, et al. Lifetime medical costs attributable to sickle cell disease among nonelderly individuals with commercial insurance. Blood Adv. 2023; 7(3): 365-374. doi:10.1182/bloodadvances.2021006281

xi. Assistant Secretary for Health (ASH). Sickle Cell Disease. U.S. Department of Health and Human Services. November, 2020. **https://www.hhs.gov/ash/osm/innovationx/human-centered-design/sickle-cell-disease/index.html**

xii. Assistant Secretary for Health (ASH). Sickle Cell Disease. U.S. Department of Health and Human Services. November, 2020. **https://www.hhs.gov/ash/osm/innovationx/human-centered-design/sickle-cell-disease/index.html**