

Submitted electronically to: [NCDRequest@cms.hhs.gov](mailto:NCDRequest@cms.hhs.gov)

June 9, 2025

Tamara Syrek Jensen  
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Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

RE: Formal Request for Reconsideration of National Coverage Determination 110.23, “Stem Cell Transplantation,” to Utilize the International Staging System for Autologous Stem Cell Transplantation

Dear Ms. Jensen,

On behalf of the undersigned organizations, we respectfully request that CMS amend §110.23 of the National Coverage Determinations (NCD) Manual, (Pub. 100-03, Chapter 1, Part 2) regarding coverage of autologous stem cell transplantation (AuSCT) to include a disease staging system for multiple myeloma supported by current clinical guidelines.<sup>1</sup> Unfortunately, NCD 110.23, “Stem Cell Transplantation,” only references the Durie-Salmon staging system, rather than the International Staging System (ISS) and its revisions, when identifying covered indications of multiple myeloma.<sup>2</sup> This oversight severely restricts Medicare beneficiaries’ access to AuSCT. We urge CMS to adopt a revised NCD to better reflect clinical practice and ensure all eligible Medicare beneficiaries can receive this type of care.

We are requesting this reconsideration because there is additional scientific evidence regarding the use of ISS and its revisions when identifying covered indications of multiple myeloma. This evidence was not considered during the most recent review of NCD §110.23, and if it had been considered, it would have warranted a change to the NCD decision for AuSCT. The adoption of ISS as a preferred staging system for multiple myeloma is well supported in the medical literature, which we include as a list of citations in the appendix. Durie-Salmon was developed in 1975 and utilized clinical parameters that were “commonly available” at that time, but clinical advances have led to more contemporary prognostic staging systems.<sup>3</sup> For example, the National Comprehensive Cancer Network (NCCN) references ISS and the two ISS revisions in its version 4.2024 guidelines

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<sup>1</sup> AuSCT is part of “the standard treatment for eligible patients” and often preferred to allogeneic stem cell transplant. Dhakal, B. et al (2022). ASTCT Clinical Practice Recommendations for Transplantation and Cellular Therapies in Multiple Myeloma. *Transplantation and Cellular Therapy*, 28(6), 284–293.

<sup>2</sup> National Coverage Determination: Stem Cell Transplantation (Formerly 110.8.1). *Centers for Medicare & Medicaid Services*, vol. 2, 3 (Mar. 2024). *Medicare Coverage Database*, <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=366>.

<sup>3</sup> Scott, E. C. et al (2018). Staging Systems for Newly Diagnosed Myeloma Patients Undergoing Autologous Hematopoietic Cell Transplantation: The Revised International Staging System Shows the Most Differentiation between Groups. *Biology of Blood and Marrow Transplantation: Journal of the American Society for Blood and Marrow Transplantation*, 24(12), 2443, 2444.

for multiple myeloma but does not include Durie-Salmon.<sup>4</sup> Similarly, an expert panel convened by the American Society of Clinical Oncology recommended that an oncologist should assess the risk status using R-ISS, a revised version of ISS, for patients at the time of diagnosis.<sup>5</sup> The European Hematology Association (EHA) and European Society for Medical Oncology (ESMO) reference R-ISS for staging in their clinical practice guidelines,<sup>6</sup> and the International Myeloma Working Group similarly recommends “ISS should always be used at diagnosis.”<sup>7</sup> In sum, staging a patient with multiple myeloma using ISS or revised versions of ISS is the current standard of care. Of note, the ISS prognostic system more accurately predicts progression free survival following AuSCT in the ASTCT Clinical Practice Recommendations.<sup>8</sup>

We also note that the adoption of ISS in clinical practice is not a recent phenomenon,<sup>9</sup> but unfortunately, NCD 110.23 for Medicare fee-for-service has not similarly been updated to reflect the new staging systems in relation to AuSCT. The last national coverage analysis decision memo for AuSCT for multiple myeloma was published in 2001, prior to the widespread adoption of ISS in clinical practice two decades ago.<sup>10</sup> Notably, other payers (examples provided in Appendix II) do not use Durie-Salmon staging when considering eligibility for AuSCT, causing considerable disparities for patients covered under Medicare fee-for-service versus those with other sources of coverage.

Given this long-standing and well-documented shift in clinical practice, we urge CMS to include the ISS and consider subsequent revisions as an appropriate staging system for AuSCT and to ensure flexibility to recognize its revisions as an alternative pathway for AuSCT coverage, in addition to the existing reference to Durie-Salmon staging. Unfortunately, the lack of timely review for AuSCT has resulted in this standard being outdated as staging systems become more accurate with continued revisions. We would propose the following language in addition to existing language for *Indications and Limitations of Coverage* of AuSCT under NCD 110.23:

Effective [the date of revision], single AuSCT is covered for Stage II or Stage III patients using International Staging System (ISS) and its revisions who fit the following requirements:

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<sup>4</sup>Kumar, S. et al (2024). NCCN Clinical Practice Guidelines in Oncology. *National Comprehensive Cancer Network*, 4.2024, 1- 121), MYEL-B, MS-6. In contrast, Durie-Salmon is only mentioned once in the section on supportive care. Id. at MS-46.

<sup>5</sup> Mikhael, J. et al (2019). Treatment of Multiple Myeloma: ASCO and CCO Joint Clinical Practice Guideline. *Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology*, 37(14), 1228, 1250.

<sup>6</sup> Dimopoulos, M. A. et al (2021). Multiple myeloma: EHA-ESMO Clinical Practice Guidelines for Diagnosis, Treatment and Follow-up. *Annals of Oncology*, 32(3), 309, 311.

<sup>7</sup>Palumbo, A. et al (2014). International Myeloma Working Group Consensus Statement for the Management, Treatment, and Supportive Care of Patients with Myeloma Not Eligible for Standard Autologous Stem-Cell Transplantation. *Journal of Clinical Oncology*, 32(6), 587, 588-89.

<sup>8</sup> Dhakal, B. et al (2022). ASTCT Clinical Practice Recommendations for Transplantation and Cellular Therapies in Multiple Myeloma. *Transplantation and Cellular Therapy*, 28(6), 287.

<sup>9</sup> ISS was developed in 2005 and continues to be revised to become a more sophisticated and useful tool for staging patients. Palumbo, A. et al (2015). Revised International Staging System for Multiple Myeloma: A Report from International Myeloma Working Group. *Journal of Clinical Oncology*, 33(26), 2863–2869.

<sup>10</sup> National Coverage Analysis: First reconsideration for Autologous Stem Cell Transplantation (AuSCT) for Multiple Myeloma (CAG-00011R). *Centers for Medicare & Medicaid Services*, Feb. 2001. *Medicare Coverage Database*, <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=11>.

- Newly diagnosed or responsive multiple myeloma. This includes those patients with previously untreated disease, those with at least a partial response to prior chemotherapy (defined as a 50% decrease either in measurable paraprotein [serum and/or urine] or in bone marrow infiltration, sustained for at least 1 month), and those in responsive relapse; and
- Adequate cardiac, renal, pulmonary, and hepatic function.

Thank you for your attention to this important matter, and we look forward to working with you on adopting this proposed NCD revision to provide the best and most up-to-date care for our patients. Should you have questions, please contact Oliver Kim, Senior Director, Public Policy, Corewell Health ([oliver.kim@corewellhealth.org](mailto:oliver.kim@corewellhealth.org)).

Sincerely,

American Society of Hematology  
Association of Cancer Care Centers  
Corewell Health  
International Myeloma Foundation  
Medical University of South Carolina, Hollings Cancer Center