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May 29, 2015

Cheryl Gilbreath, PharmD, MBA, RPh  
Lead Analyst  
Centers for Medicare and Medicaid Services  
Mail Stop C1-09-06  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

**BY ELECTRONIC DELIVERY**

**Re: National Coverage Analysis (NCA) Tracking Sheet for Stem Cell  
Transplantation (Sickle Cell Disease and Myelofibrosis) (CAG-  
00444R)**

Dear Dr. Gilbreath:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the recent National Coverage Analysis (NCA) request for public comments on expanding coverage of stem cell transplantation for sickle cell disease and myelofibrosis.<sup>1</sup> ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC represents more than 20,000 cancer care professionals from approximately 1,100 hospitals and more than 1,000 private practices nationwide. These include Cancer Program Members, Individual Members, and members from 32 state oncology societies. It is estimated that 60 percent of cancer patients nationwide are treated by a member of ACCC. ACCC believes that stem cell transplantation serves as an important treatment not only for a variety of blood cancers, but also for inherited genetic disorders, immunodeficiency syndromes, and aplastic anemia. We urge the Centers for Medicare & Medicaid Services (CMS) to expand coverage to explicitly include sickle cell disease, myelofibrosis, lymphoma, and multiple myeloma.

<sup>1</sup> CMS, *National Coverage Analysis (NCA) Tracking Sheet for Stem Cell Transplantation (Sickle Cell Disease and Myelofibrosis) (CAG-00444R)* (Apr. 30, 2015), <http://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=280&bc=gIAAAAAAAAAgAAAA%3d%3d&>.

ACCC is committed to ensuring that Medicare beneficiaries have access to high quality cancer care, including the innovative and cutting-edge therapies our patients need to win their battles against this deadly disease. ACCC supports the requestors, the American Society for Blood and Marrow Transplantation (ASBMT) and the National Marrow Donor Program (NMDP), request for expansion of coverage of stem cell transplantation to sickle cell disease, myelofibrosis, lymphoma, and multiple myeloma. Stem cell transplantation is the only therapy offering the potential for cure for patients with blood cancers who relapse after initial chemotherapy. ACCC is particularly supportive of explicit coverage for myelofibrosis, an uncommon type of chronic leukemia that disrupts the body's normal production of blood cells. Although there a few other treatment options for myelofibrosis, allogeneic stem cell transplantation remains the only curative therapy for this serious bone marrow disorder.<sup>2</sup>

Currently, the stem cell transplantation National Coverage Determination<sup>3</sup> (NCD) explicitly covers allogeneic transplantation for patients with leukemia/aplastic anemia, severe combined immunodeficiency disease (SCID), Wiskott-Aldrich, and, under Coverage with Evidence Development (CED), Myelodysplastic Syndromes (MDS). The NCD explicitly denies coverage for multiple myeloma, however, and is silent on coverage for sickle cell disease, lymphoma, and myelofibrosis. Seeking coverage locally from individual Medicare Administrative Contractors (MAC) is burdensome and time consuming. Many patients receive stem cell transplantation as a final option, and waiting can mean the difference between life and death. Furthermore, an NCD with explicit coverage for sickle cell disease, myelofibrosis, lymphoma, and multiple myeloma will lead to even, national coverage of this important treatment among all Medicare beneficiaries.

We agree with ASBMT and NMDP that the Medicare beneficiary population appears to be underutilizing stem cell transplantation as a treatment option. Many private insurance companies cover stem cell transplantation for additional indications such as myelofibrosis, but patients are unable to access the treatment once they become a Medicare beneficiary at the age of 65. ASBMT and NMDP estimate that more than 2,000 Medicare beneficiaries who need a transplant are unable to access one each year because of the lack of clarity in the national coverage policy.<sup>4</sup> ACCC believes that national coverage clarity is absolutely vital for Medicare access to stem cell transplantation for indications such as sickle cell disease, myelofibrosis, lymphoma, and multiple myeloma. Further, the lack of CMS coverage impedes the enrollment

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<sup>2</sup> K. Ballen, *How to manage the transplant question in myelofibrosis*, 2 Blood Cancer J. 3 (2012), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3317522/>.

<sup>3</sup> CMS, *National Coverage Determination (NCD) for Stem Cell Transplantation (110.8.1)* (Aug. 4, 2010), [http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=45&ncdver=5&NCAId=10&ver=8&NcaName=Autologous+Stem+Cell+Transplantation+\(Autologous+Stem+Cell+Transplantation\)+for+Multiple+Myeloma&bc=ACAAAAAIAAA&](http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=45&ncdver=5&NCAId=10&ver=8&NcaName=Autologous+Stem+Cell+Transplantation+(Autologous+Stem+Cell+Transplantation)+for+Multiple+Myeloma&bc=ACAAAAAIAAA&).

<sup>4</sup> *Id.* at 1.

Cheryl Gilbreath  
May 29, 2015  
Page 3 of 3

of patients in clinical trials evaluating innovative approaches to perform stem cell transplantation. These clinical trials are crucial to develop new treatments and further science in this important field.

For these reasons, ACCC urges CMS to issue an NCD for stem cell transplantation with explicit coverage for sickle cell disease, myelofibrosis, lymphoma, and multiple myeloma. We firmly believe that stem cell transplantation can improve – and even save – the lives of Medicare beneficiaries with these life-threatening diseases. Please contact Leah Ralph, Manager, Provider Economics and Public Policy, at (301) 984-5071 if you have any questions regarding these comments or need any additional information. Thank you for your attention to this very important matter.

Respectfully submitted,



Steven D'Amato, BPharm, BCOP  
President  
Association of Community Cancer Centers