



June 13, 2017

**2017**

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Ms. Seema Verma  
Administrator  
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Attention: CMS-1677-P  
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RE: CMS-1677-P; Medicare Program; Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2018 Rates

Dear Ms. Verma:

I am writing on behalf of the American Society of Hematology (ASH) to provide the following comments to the Centers for Medicare and Medicaid Services (CMS) on the CY 2018 Hospital Inpatient Prospective Payment System proposed rule.

ASH represents over 17,000 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 sick cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists were pioneers in demonstrating the potential of treating various hematologic diseases; and we continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians are providing care to patients in diverse settings including teaching and community hospitals, as well as private practice.

The Society looks forward to working closely with the agency as these proposals are implemented and offers the following comments on issues of particular importance to our members and the patients they serve:

1. CY 2018 Payment Rate for Hematopoietic Cell Transplantation
2. Autologous & Allogenic Transfusion Coding
3. New Technology Add-on Payments
  - a. VYXEOS
  - b. KTE-C19
4. Request for Information on Reducing Administrative Burden

### CY 2018 Payment Rate for Hematopoietic Cell Transplantation

Each year CMS calculates a weight for each MS-DRG by reviewing the resources required for the service. For CY 2018, the agency has proposed that the weight for hematopoietic

cell transplantation (HCT) be 11.5318 with standard cost per weight of \$5,436.51 for base-level hospitals. This results in a payment rate for the MS-DRG of \$69,844.

HCT is the standard of care for more than 70 diseases, including blood cancers, such as leukemia and lymphoma. Cell acquisition cost varies and is dependent on clinical factors as well as cell source. In 2016, adult donor cells from marrow and peripheral blood stem cells (PBSC) had an average cost of \$48,436 while the average cost of cord blood was \$65,117. The average inpatient hospital stay for this transplant averages 27.45 days. With these acquisition costs and average of length of stay, the Medicare reimbursement does not cover the hospitals' costs of providing the service. It is not sustainable for hospitals to continue performing this service at this reimbursement rate and may negatively impact patient access.

ASH requests that CMS take action to avoid this patient access issue by using existing authority to reimburse the cell acquisition costs for HCT in the same way it reimburses for solid organ donors. Solid organ transplant programs receive a payment separate from the MS-DRG for the cost of locating and purchasing the organ used for transplant. If the acquisition cost for donor cells and cord blood was reimbursed on reasonable cost basis, hospitals would be able to cover their costs under the MS-DRG for HCTs, eliminating the threat to patient access.

### **Autologous & Allogenic Transfusion Coding**

In the proposed rule, CMS shifts 26 ICD-10 procedural classification system (PCS) transfusion codes for HCT from operating room to non-operating room status. ASH believes this change is clinically appropriate. However, it has resulted in the inappropriate reassignment of these ICD-10 PCS HCT transfusion codes into 70 different MS-DRGs. These codes should be included in one of three MS-DRGs, 014/016/017, depending on the type of transplant and associated complications or comorbidities. We respectfully request that CMS reassign these ICD-10 PCS transplant transfusion codes back to the three appropriate MS-DRGs.

### **New Technology Add-on Payments**

#### VYXEOS

In the proposed rule, CMS invites public comment on the VYXEOS New Technology Add-on Payment (NTAP) application. VYXEOS, a liposomal formulation containing a fixed combination of cytarabine and daunorubicin in a 5:1 molar ratio, was developed to treat patients with high-risk (secondary) acute myeloid leukemia (AML). The current standard of care regimen of cytarabine and daunorubicin is known as 7+3. After consulting with ASH members who treat patients with high-risk acute AML and have used VYXEOS therapy, ASH recommends CMS approve the VYXEOS NTAP application.

Specifically, CMS asked if VYXEOS is substantially similar to existing technology, including whether the mechanism of action of VYXEOS differs from the mechanism of action of the current treatment regiment, specifically the 5:1 molar ratio of VYXEOS compared to the free-drug dosing of cytarabine and daunorubicin.

- No, VYXEOS is not substantially similar to existing technology, it is a unique drug combination.

- The mechanism of action of VYXEOS differs from the mechanism of action of the current treatment regimen. The increased ratio of drug is facilitated by the liposomal formulation, which is a substantial improvement for patients.

CMS also asked if the clinical results of the VYXEOS Phase III Study 301 represent substantial clinical improvement, specifically with respect to overall survival rate, lower risk of early death, improved response rates, better outcomes following transplant, increased response rate and overall survival in patients diagnosed with FLT3 mutation, and higher response rates versus conventional “salvage” chemotherapy in younger patients diagnosed with poor-risk first relapse.

- The clinical results of the VYXEOS Phase III Study 301 represent substantial clinical improvement, specifically overall survival rate, lower risk of early death, and improved response rates.
  - The median overall survival for patients treated with VYXEOS in the study was 9.56 months compared to 5.95 months for patients receiving 7+3.
  - The percentage of patients alive 12 months after randomization was 41.5% on the VYXEOS arm compared to 27.6% on the 7+3 arm.
  - The percentage of patients alive 24 months after randomization was 31.1% on the VYXEOS arm compared to 12.3% on the 7+3 arm.
- There is data showing that patients who go to transplant have a two-year survival in the 65% range.

Finally, CMS asked if the overall improvement in survival from 5.95 months (7+3 free-drug dosing) to 9.56 months (VYXEOS) represent a substantial clinical improvement.

- Yes, four months of difference is a substantial clinical improvement.

Based on these responses from ASH members who treat patients with high-risk acute AML and have used VYXEOS therapy, ASH recommends CMS approve the VYXEOS NTAP application.

#### KTE-C19

In the proposed rule, CMS invites public comment on Kite Pharma, Inc.’s application for a NTAP for KTE-C19 (axicabtagene ciloleucel) for FY 2018. KTE-C19 is an engineered autologous T-cell immunotherapy used for the treatment of adult patients with relapsed/refractory aggressive B-cell non-Hodgkin lymphoma (NHL) who are ineligible for autologous stem cell transplant (ASCT). With KTE-C19 treatment, a patient’s own T-cells are harvested and engineered ex vivo by retroviral transduction of a chimeric antigen receptor (CAR) construct encoding an anti-CD19 CD28/CD3-zeta. The anti CD-19 CAR T-cells are expanded and infused back into the patient. The new anti-CD19 CAR T-cells can recognize and eliminate CD19 antigen expressing target cells, an antigen also expressed on the cell surface of B-cell lymphomas and leukemias.

After consulting with ASH members who treat patients with chemotherapy-refractory diffuse large B-cell lymphoma and have used CD19-CAR therapies, ASH recommends CMS approve the NTAP application for KTE-C19.

Specifically, CMS is inviting public comments on whether KTE-C19 meets the substantial similarity criteria and the newness criterion.

Genetically engineered immune cells have never previously been utilized as part of standard cancer therapy. Chimeric antigen receptors represent an entirely novel class of therapeutics, incorporating a synthetic receptor that endows the immune cell with the capacity to recognize and become activated in response to any cell surface receptor. In the case of CD19-CARs, the genetically engineered receptor endows the immune system with the capacity to recognize and attack CD19 expressing cells. There is no precedent for using a synthetic, engineered receptor and thus it is clear that this technology is without a question, new.

Additionally, CMS is inviting public comment on whether KTE-C19 meets the substantial clinical improvement criterion.

CD19-CAR T cells have demonstrated unprecedented complete response rates in Phase I trials for patients who are refractory to all standard therapies. This is true for B cell acute lymphoblastic leukemia where complete response rates are 70-90% and where a large fraction of the patients show durable clinical benefit. In many cases, patients with incurable leukemia are now rendered disease free without any additional therapy beyond one infusion of CD19-CAR T cells. Similarly, in diffuse large B cell lymphoma, patients that have been enrolled on CD19-CAR T cell trials are refractory to all chemotherapy available. One infusion of CD19-CAR T cells has induced complete responses in approximately 50% of patients with a sizable fraction of these patients experiencing durable remission beyond 6 months. Substantial clinical improvement of existing services or technologies is evidence based upon the following:

- a. CD19-CAR T cells kill chemoresistant cancer cells. Because chemoresistance to one agent over time ultimately results in broad based chemoresistance, there are NO CHEMOTHERAPIES AVAILABLE capable of inducing remission in relapsed/refractory B cell leukemia and diffuse large B cell lymphoma. In contrast, immune based killing via CD19-CAR T cells is capable of complete eradication of all cancer in 70-90% of B-ALL and 50% of diffuse large B cell lymphoma. No other therapeutic demonstrates response rates of this magnitude in these refractory cancers.
- b. Chimeric antigen receptor based therapies provide a durability of effect that cannot be accomplished with any other therapeutic modality available today. While bispecific antibodies incorporating CD19 can also mediate benefit in some patients with chemorefractory B cell leukemia, their effect is short lived and there is no evidence that a durable antileukemic effect can be induced by these therapeutics. Furthermore, the response rate in B-ALL for CD19-directed bispecific antibodies is well below that for CD19- CAR T cells. Finally, there is no evidence that CD19-directed bispecific antibodies have any efficacy against diffuse large B cell lymphoma.

In summary, the data speaks clearly and a careful and objective review of the data available cannot lead to any conclusion other than: a) CD19-CAR T cells are new b) the costs to generate and administer CD19-CAR T cells are beyond that for standard cytotoxic chemotherapy and c) CD19-CAR T cells represent a substantial clinical improvement based upon their capacity to kill chemoresistant cancer cells and their capacity to induce durable clinical benefits which last months beyond the date of administration of the therapeutic. Based on this information, ASH is confident the substantial clinical criterion is met and the NTAP application should be approved to treat patients with chemotherapy-refractory diffuse large B-cell lymphoma and have used CD19-CAR therapies.

## **Request for Information on Reducing Administrative Burden**

### *E/M Documentation Requirements*

Revising the current medical documentation guidelines for Medicare's evaluation and management (E/M) codes offers an opportunity for CMS to provide an immediate and substantial reduction of administrative burden for all practicing physicians.

The guidelines for E/M documentation were last updated in 1997, before the widespread adoption of electronic health records (EHRs). The conventional auditing tools used for patient EHR design were originally developed to distinguish between the work intensity levels for the E/M service codes. EHRs evolved to become electronic versions of the paper based office notes of the 1990s with enhancements specifically designed to fulfill auditing requirements. In order to optimize billing, software institutionalized the various information categories used for chart audit. Unfortunately, EHR documentation for face-to-face E/M clinical care is now driven by the need to fill these required data fields in order to finalize a visit. EHRs have been created that automatically add information to the documentation merely to increase the likelihood of a claim being processed successfully at the highest billing level, leading to "coding creep."

Physician and provider interaction studies have consistently shown that EHRs have led to a decline in physician satisfaction, time with patients, and patient satisfaction, as well as increases in burnout. Current EHRs are often filled with extraneous information that does not accurately describe the care of the patient or provide a meaningful summary of clinical thinking.

Existing E/M documentation expectations fail to capture the cognitively intense work of services delivered by hematologists and other cognitive physicians. The linear nature of the current coding/auditing mandate means that "elements" (inputs and outputs) count once, if they count at all. There is no accounting for the interactivity of elements and the complexity that emerges as elements accumulate. Additionally, there is no recognition of the clinical expertise achieved with years of training and experience that creates the ability to instantly recognize a pattern and make a diagnosis of enormous clinical value in a matter of moments.

ASH is concerned about the profound deficiencies of the E/M codes as well as the associated documentation requirements. These codes do not accurately define discrete levels of cognitive service, do not capture the broad range of services, and undervalue the critical role that complexity and physician-patient interaction demand in ensuring the safe provision of high quality healthcare services to patients. Last year, Medicare spending on E/M services totaled \$47.455 billion; a \$1.473 billion increase over the previous year. This high level of spending on E/M services and major increase in cost across just one year illustrates the urgent need to address the accuracy of the physician fee schedule, resulting in more accurately valued E/M codes and a continued stabilization of the physician workforce.

We believe that improving the documentation expectations for E/M services must be linked to correcting the legacy deficiencies in both definition and valuation of these services. There has been no adjustment in the definitions, and only incremental changes in their valuations, since the development of the Resource Based Relative Value Scale (RBRVS), despite the increasingly complex and interacting medications and health care conditions presented by Medicare beneficiaries. There is demonstrably more work involved with intense E/M services delivered by our members than 25 years ago. Despite their best efforts, CMS has not been able to address this issue. While the agency has

failed to act, we are concerned about a potential for a significant workforce shortage in hematology because of the burnout, low work satisfaction, and the undervaluation of the services our members provide.

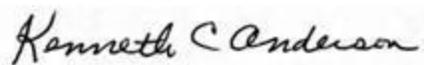
Addressing the unnecessary administrative burden created by the existing E/M documentation guidelines offers an opportunity to substantially improve the face-to-face experience of care, from both patient and physician perspectives. Revising and improving the documentation expectations allows the existing service codes to be reworked in ways that match the current content of E/M service delivery. ASH believes that this process should begin with the development of a representative knowledge-base that will then lead to a better definition of the discrete levels of E/M services. We urge CMS to conduct the research necessary to redefine and revalue cognitive E/M services, as we believe that this will not only improve the accuracy and precision of the fee schedule, but will also reduce the burden on cognitive physicians.

#### Prior Authorization

The American Medical Association (AMA) conducted a survey of 1000 practicing physicians and found a medical practice completes an average of 37 prior authorization requirements each week per physician. The processing of these requests takes a physician and their staff an average of 16 hours to complete, diverting time and resources from patient care. ASH is a supporter of the 21 [Prior Authorization and Utilization Management Reform Principles](#) developed and released by the AMA and 16 other organizations earlier this year. These principles are divided into the following 5 broad categories: clinical validity; continuity of care; transparency and fairness; timely access and administration; and alternatives and exemptions. We urge CMS to implement reasonable reforms as recommended by these principles. Doing so will significantly relieve the administrative burden these requirements place on physicians.

Thank you for the opportunity to provide these comments. We welcome the opportunity to discuss these proposals, and others being considered with you and your team. If you have any questions or require further clarification, please contact Leslie Brady, ASH Policy and Practice Manager at [lbrady@hematology.org](mailto:lbrady@hematology.org) or 202-292-0264.

Sincerely,



Kenneth C. Anderson, MD  
President