September 27, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1717-P
P.O. Box 8016
Baltimore, Maryland 21244-8016

SUBMITTED ELECTRONICALLY VIA http://www.regulations.gov

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children’s Hospitals-Within-Hospitals

Dear Administrator Verma,

The American Society of Hematology (ASH) is pleased to offer comments on the proposed rule outlining revisions to the Hospital Outpatient Prospective Payment System.

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 sickle cell disease, 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 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 providing care to patients in diverse settings including teaching and community hospitals, as well as private practice.

ASH offers comments on the following areas of the proposed rule, which are of particular importance to the Society’s members:

1. Status Indicator Assignment for CAR-T Category III CPT Codes 0537T-0539T
2. Proposed Revisions to the Laboratory Date of Service Policy

**Status Indicator Assignment for CAR-T Category III CPT Codes 0537T-0539T**

Last year, ASH submitted comments requesting that the Centers for Medicare and Medicaid Services (CMS) change the status indicators for the Category III chimeric antigen receptor T-cell (CAR-T) CPT codes 0537T (cell collection), 0538T (cell processing), 0539T (cell processing), and 0540T (cell infusion) from “B” to “S” as recommended by the CMS.
Advisory Panel on Hospital Outpatient Payment (HOP). The agency only made the change for 0540T.

Given that the entire family of Category III CPT codes was effective January 1, 2019, providers are not able to report codes 0537T-0539T because of their status indicator of “B” which requires CMS to reject the claim upon receipt. CMS has released specific coding and billing guidance to providers instructing them to hold any outpatient claims with codes 0537T-0539T until the infusion code 0540T is reported on the patient’s inpatient claim. This allows these outpatient services to be counted towards the patient’s total covered billed charges, deviating significantly from standard coding and billing practice.

This year, ASH requests that CMS change the status indicators for codes 0537T-0539T to “Q1” which would allow these services to be eligible for payment on the condition that no other procedures or visits were provided on the same claim. Providers could then report these services in a manner consistent with normal practice. The Society believes CMS can do this because it is how the agency is treating a similar new Category III CPT code 05X3T (autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; tissue harvesting and cellular impact creation). The HOP panel recommended the same status indicator change.

ASH also requests that CMS work with the Healthcare Common Procedure Coding System (HCPCS) group to modify the description of the two CAR-T Q codes, Q2041 and Q2042, to separate the cell collection and cell processing services from the product itself. This will allow these physician services to be reported consistent with coding and billing practices and will make the data available to the agency as it sets future payment rates.

ASH understands that CMS has not changed the status indicator for the CPT codes because the descriptions of the two CAR-T Q codes, Q2041 and Q2042, both include “leukapheresis and other dose preparation services.” The agency believes that reimbursement for these physician services is provided through the Q codes and therefore, is not needed through CPT codes 0537T-0539T. However, neither the providers nor the manufacturers consider the cell collection and processing services (represented by codes 0537T-0539T) to be part of the manufacturing process for CAR-T, and consequently, the manufacturers do not reimburse physicians for these services from the payment provided when either Q code is billed. ASH requests that CMS point out the specific statutory language in the Public Health Service Act that is guiding these coding and billing decisions.

Proposed Revisions to the Laboratory Date of Service Policy

CMS requested comments on potential changes to the laboratory date of service (DOS) exception. In order to preserve patient access, we recommend that the agency refrain from making any changes to this policy at this time.

Changing the Test Results Requirement

The agency asked stakeholders whether a test should be considered part of a hospital service and be excluded from the DOS policy. This would make the hospital responsible for billing for the test through the “under arrangements” regulations, if the ordering physician determines that the test results are intended to guide treatment during a hospital outpatient encounter, including a future hospital outpatient encounter. ASH is concerned this proposal will impose an additional administrative burden on providers and potentially delay patient access to care and therefore, we urge CMS not to implement this policy.

While in theory this proposed revision could put the decision back in the hands of the care team, in practice it would be difficult to implement, particularly because physicians should not be asked to determine if and how testing will guide treatment related to any potential future outpatient encounters. Physicians cannot predict all of a patient’s future care needs at the time a test is being ordered. The level of innovation in care of blood cancers is advancing at such a rapid pace that physicians cannot always know the future value of a lab test at the time of the hospitalization. Furthermore, care teams are not always unified, and it may be
difficult to assign responsibility for making the determination of whether the test is included or separate from the current and future hospital encounters. Therefore, ASH urges CMS to keep this testing separate from the hospital outpatient encounter without requiring the ordering physician to attest to this at the time the testing is ordered.

CMS has implemented a number of policies to reduce administrative burden for providers and this policy runs counter to those efforts. Besides creating additional provider burden, ASH cannot support any policy that would jeopardize timely patient access to care.

Limiting the DOS Exception at 42 CFR 414.510(b)(5) to Advanced Diagnostic Laboratory Tests

CMS is also requesting comments on limiting the laboratory DOS provisions in Social Security Act § 414.510(b)(5) to tests designated by CMS as an Advanced Diagnostic Laboratory Tests (ADLTs) under paragraph (1) of the definition of an ADLT in § 414.502. The agency is no longer convinced that molecular pathology tests present the same concerns of delayed access to medically necessary care as ADLTs, and therefore, is proposing to exclude these tests from the laboratory DOS provisions. ASH strongly opposes this proposed limitation as this would limit patient access to clinically appropriate molecular testing and the treatment decisions that result from it. If this change is finalized, some hospitals would choose to wait until 14-days after the hospital encounter to perform and bill this testing so they could bill CMS directly for it. But for many patients with acute leukemia, for example, time is of the essence in determining any relevant genomic mutations that might exist in that patient’s leukemia cells that could impact therapy. As more effective, targeted treatments that address driver gene mutations are developed, hematologists will need rapid access to relevant genomic/genetic test results. When it comes to patients with blood cancers, waiting weeks could mean the difference between life and death. Therefore, ASH supports the existing DOS policy that allows laboratories to bill Medicare directly for certain laboratory tests.

Furthermore, CMS should not distinguish between ADLTs and molecular testing, as ADLTs are a type of molecular pathology testing with similar patterns of clinical use. The distinguishing characteristic of ADLTs is that they are offered by a single laboratory. This is a distinction that was made to establish Medicare pricing. There is no difference in patients’ needs for molecular pathology testing and ADLTs to be accurate and delivered in a timely fashion. Therefore, all molecular testing should remain separate from the preceding hospital stay and should have a DOS that is the date of performance rather than the date of collection.

Thank you for the opportunity to provide comments on the proposed rule for revisions to payment policies under the Hospital Outpatient Prospective Payment System for 2020. We welcome the opportunity to discuss these comments with you and your team at any time. If you have any questions or require further clarification, please contact Leslie Brady, ASH Policy and Practice Manager at lbrady@hematology.org or 202-292-0264.

Sincerely,

Roy L. Silverstein, MD
President