CY 2020 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM FINAL RULE SUMMARY

On November 1, 2019, the Centers for Medicare and Medicaid Services (CMS) published the CY 2020 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System final rule outlining payment rates and policy changes for the upcoming year. The final rule and addendums can be found here. The provisions of the final rule will take effect on January 1, 2020, unless stated otherwise.

In general, the rule provides for a 2.6 percent update in the hospital outpatient payment rates in 2020. Hospitals that fail to meet the hospital outpatient quality reporting requirements will continue to receive a 2 percent reduction in payments.

The payments made under OPPS cover facility resources including equipment, supplies, and hospital staff, but do not include the services of physicians or non-physician practitioners paid separately under the Medicare Physician Fee Schedule. Services under OPPS, which are clinically similar and require similar resources are classified into payment groups called Ambulatory Payment Classifications (APCs) which all have an individual payment rate. The APC payment rates are adjusted for geographic cost differences, and payment rates and policies are updated annually through rulemaking.

Impact on Hematology/Oncology Services

<u>Linked</u> to this summary is a set of charts showing the APC assignments for Hematology/Oncology services. In summary, the APC payment rates for 2020 are stable or increasing for most services. More significant changes are occurring in the blood/blood product APCs and for specific services in other APC categories.

CAR T-Cell Therapy Q Codes

Although ASH had requested that CMS change the status indicators for codes 0537T – 0539T, CMS is continuing to assign the status indicator "B" (non-allowed item or service for OPPS) to the Category III CPT codes:

- 0537T (Chimeric antigen receptor T-cell (CAR-T) therapy, harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day);
- 0538T (Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage));
- 0539T (Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration).

These codes, if billed, will not be recognized under the APC rate-setting system. CMS maintains that the costs to hospital outpatient departments for cell collection and cell processing are included in the payment for the Q-codes for the two approved products, Yescarta and Kymriah.

Separately Payable 340B Drug Policy

CMS is proposing to continue its policy to pay ASP minus 22.5 percent for separately payable non-pass-through drugs acquired with a 340B discount, including when furnished in nonexcepted off-campus provider based departments. Hospitals subject to the reduction must report claim level modifiers to signify when 340B vs. non-340B drugs are used. Critical access hospitals, rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals are not subject to the payment reduction.

The agency acknowledges the ongoing litigation related to the lower 340B payments and plans on continuing to apply the reduction until the court decision. CMS plans to survey hospitals on actual acquisition costs for 340B drugs soon

and states that it will use the survey data to establish an alternative to ASP-22.5 or determine another option, if the court rules in favor of the hospitals.

Site Neutral Payment Policy for Excepted Off-Campus Provider-Based Departments

CMS is finalizing its proposal to complete the implementation of the two-year phase-in of applying the Medicare Physician Fee Schedule (MPFS) rate for the clinic visit service (G0463 – Hospital outpatient clinic visit for assessment and management of a patient) when provided at an off-campus provider-based department (departments that bill the "PO" modifier on claims lines). The agency is striving to control the volume growth of these visits by implementing this site neutral payment policy as this clinic visit is the most common service billed under OPPS that also billed in the physician office. These visits will be paid at 40 percent of their OPPS rate.

<u>Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services</u> CMS finalized its proposal to require prior authorization for the five following services to assure that they are billed only when medically necessary: 1) blepharoplasty, 2) botulinum toxin injections, 3) panniculectomy, 4) rhinoplasty and 5) vein ablation.

While none of these services are delivered by Society members, it should be noted that CMS is proposing to use prior authorization in the outpatient setting to control volume growth noting it has already been applied to certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) to control improper payments. It merits monitoring this policy as it CMS may expand the application of prior authorization to additional services in future rulemaking.

Clinical Laboratory Fee Schedule: Revisions to the Laboratory Date of Service Policy

CMS is finalizing its proposal to exclude blood banks and blood centers from the laboratory DOS exception at 42 CFR 414.510(b)(5). This results in the date of service for those tests to be the date that the specimen was collected. CMS recognizes blood banks and centers perform molecular pathology test for a different clinical purpose: to identify the most compatible blood product for a patient, whereas other laboratories typically provide molecular pathology testing for diagnostic purposes. This "is inherently tied to a hospital service because hospitals receive payment for and/or use the blood and/or blood products provided by blood banks and blood centers to treat patients in the hospital setting."

CMS did not finalize its proposals related to changing the Test Results Requirement at 42 CFR 414.510(b)(5)(iv) or limiting the Laboratory DOS Exception at 42 CFR 414.510(b) (5) to advanced diagnostic laboratory test (ADLT). ASH had opposed the proposals because it would have jeopardized timely patient access to care.

Background on Laboratory Date of Service Policy

CMS' laboratory date of service (DOS) policy determines whether a hospital or the performing laboratory bills Medicare for a clinical diagnostic laboratory test (CDLT) or an advanced diagnostic laboratory test (ADLT). Generally, if the DOS falls during a hospital inpatient or outpatient stay payment for the test is typically bundled with the hospital service.

CMS conditionally packages most CDLTs and only pays separately when: (1) it is the only service provided to the beneficiary on a claim; (2) it is considered a preventive service; (3) it is a molecular pathology test; or (4) an ADLT. However, CMS has created exceptions to this policy. The agency has excluded molecular pathology tests and ADLTs because they may have a different pattern of clinical use that is separate from a primary service delivered in the outpatient setting.

In 2018, CMS finalized another exception to the packaging policy for molecular pathology tests and ADLTs such that the DOS must be the date the test was performed only if the following conditions outlined at 42 CFR 414.510(b)(5) are met:

- (i) The test is performed following a hospital outpatient's discharge from the hospital outpatient department;
- (ii) The specimen was collected from a hospital outpatient during an encounter;

- (iii) It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
- (iv) The results of the test do not guide treatment provided during the hospital outpatient encounter; and
- (v) The test was reasonable and medically necessary for the treatment of an illness.

In these instances, the test is essentially separated from the hospital outpatient encounter requiring the laboratory billing the test to bill Medicare directly rather than seeking payment from the hospital outpatient department. Otherwise, the DOS is the date of specimen collection. These changes were made to provide greater consistency between the laboratory DOS rules and the packaging policy to reduce administrative and billing issues. However, CMS has been exercising its enforcement discretion since July 2018 allowing either the hospital or the laboratory to bill for the test to address the administrative challenges they were experiencing in making changes to their systems needed to implement the new exception.