



## **CY 2020 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM PROPOSED RULE SUMMARY**

On July 29, 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 proposed rule outlining payment rates and policy changes for the upcoming year. The final rule is expected to be released in early November with an effective date of January 1, 2020.

In general, the rule provides for a 2.7 percent update in 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**

Attached 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, with more significant increases in the blood/blood product APCs and for some chemo therapy services.

### **CAR T-Cell Therapy Q Codes**

CMS maintains that the costs for cell collection and cell processing, two hospital outpatient department services, are included in the payment for the Q-codes for the two approved products, Yescarta and Kymriah. Therefore, they do not recognize 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)); or 0539T (Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration) and have assigned them a status indicator of "B" (non-allowed item or service for OPPS). These codes if billed are rejected by CMS and will not be recognized in charges for the APC rate-setting system.

The agency did not make any changes in the proposed rule to the status indicator for these services despite advocacy to request it be changed to N (no additional payment, payment included in line times with APCs for incidental service) for these services. A status indicator of N would have allowed hospitals to report these codes, allowing CMS to collect the data on their utilization, but would not provide separate payment.

### **Separately Payable Drugs in the Outpatient Setting**

CMS is proposing to continue their policy to pay ASP plus 6 percent for separately payable drugs and biologicals and to continue pay ASP minus 22.5 percent for separately payable non-pass-through drugs acquired with a 340B discount.

The agency acknowledges the ongoing litigation related to the lower 340B payments and requests comments on the following regarding these payments:

- The appropriate payment rate for 340B-acquired drugs, including whether a rate of ASP plus 3 percent would be an appropriate payment amount for these drugs in CY 2020
- How best to provide a remedy for hospitals for reduced payments in CYs 2018 and 2019.

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

CMS is proposing 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 OPSS that also billed in the physician office. These visits will be paid at 40 percent of their OPSS rate. This reduction will not be applied in a budget neutral manner, and CMS projects this will save the Medicare program \$810 million and lower the average beneficiary copayments from \$23 to \$9 in 2020.

### **Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services**

CMS reviewed claims data and identified the five following services as having unnecessary increases in volume: 1) blepharoplasty, 2) botulinum toxin injections, 3) panniculectomy, 4) rhinoplasty and 5) vein ablation. The agency proposes to require prior authorization for these services to ensure they are billed only when medically necessary as they are often cosmetic procedures.

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.

### **Increasing Price Transparency of Hospital Standard Charges**

CMS is proposing to implement the President’s Executive Order on Improving Price and Quality Transparency and Section 2718(e) of the Public Health Service Act, which requires hospitals to provide a public list of standard charges for all items and services provided by the hospital. Hospitals would be required to update this information annually. CMS is defining items and services as any individual item and service or service package, that could be provided by a hospital to a patient in connection with an inpatient admission or an outpatient department visit for which the hospital has established a standard charge and is defining standard charges as “gross charges and payer-specific negotiated charges” for all items and services.

#### *Requirements for Display of the Payer-Specific Negotiated Charges for Selected Shoppable Services*

CMS wants to ensure that the information provided is meaningful and easily accessible to consumers, and therefore, is proposing that hospitals be required to publish the standard charge data for at least 300 “shoppable services”, a subset of hospital items and services, and any ancillary services typically provided by the hospital with those services. The agency is proposing to define “shoppable services” as a service package that can be scheduled by a consumer in advance. These are typically services that are not provided in urgent situations, allowing patients to price shop and schedule a service at their

convenience. They consider ancillary items and services to include laboratory, radiology, drugs, delivery room (including maternity labor room), operating room (including post-anesthesia and postoperative recovery rooms), therapy services (physical, speech, occupational), hospital fees, room and board charges, and charges for employed professional services.

While CMS is requiring data be reported on 300 “shoppable services”, CMS is identifying 70 “shoppable services” in Table 37 (See Appendix A for the full list.) for which hospitals must report if they deliver these services to patients. Hospitals must report on as many of these 70 services as they provide and as many additional services as necessary to reach the required 300. For example, if a hospital delivers all 70 “shoppable services” included on the list they must report an additional 230 services. The agency is requesting comment on whether it should require more or less than 300 total services and specifically wants to know whether a list of 100 specific services or less would be a reasonable starting point. They also request comment on the 70 services they have identified for inclusion and other services should be added to this list.

Several of the consult and new patient outpatient visits and blood cell count codes (85025, 85027) and clotting time/coagulation assessment codes (85610, 85730) are included on the list of reportable services.

#### *Proposed Monitoring and Enforcement*

CMS has the authority to monitor hospital compliance by evaluating complaints made to CMS, reviewing analysis of noncompliance, and auditing hospitals’ websites. The agency may assess a monetary penalty of not more than \$300 per day after providing a warning to the hospitals or requesting a corrective action plan from the hospital if it is deemed to be noncompliant. They will publicize any penalties assessed on a CMS website. The agency proposes to establish an appeals process. Hospitals can request a hearing before an Administrative Law Judge (ALJ) to appeal the penalty, and the CMS Administrator may review the ALJ’s decision.

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

#### *Background*

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.

#### *Potential Revisions to Laboratory DOS Policy and Request for Comments*

CMS is now seeking comment on three options for potential changes to the laboratory DOS exception:

- Changing the Test Results Requirement at 42 CFR 414.510(b)(5)(iv): CMS is no longer convinced that whether the results of a test guides treatment during the hospital outpatient encounter in which the specimen was collected should determine whether a molecular pathology test or ADLT should be separated from the hospital service. The agency believes there are a number of factors that should be evaluated to determine the test's relationship to the hospital encounter.

CMS is considering a revision to the policy that would specify that the ordering physician would determine whether the results of the ADLT or molecular pathology test are intended to guide treatment provided during a hospital outpatient encounter, if the other four requirements under § 414.510(b)(5) are met. Under this approach, the test would be considered a hospital service unless the ordering physician determines that the test does not guide treatment during a hospital outpatient encounter. CMS requests comments on the potential change. The agency notes that they are only requesting comment on potential changes to the laboratory DOS exception and not the 14-day rule or the chemotherapy sensitivity test exception. Any changes to these two other exceptions would be addressed in future rulemaking.

- Limiting the Laboratory DOS Exception at 42 CFR 414.510(b) (5) to ADLT: CMS is requesting comments on limiting the laboratory DOS provisions of § 414.510(b) (5) to tests designated by CMS as an ADLT 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, which by definition must be performed by single lab. CMS recognizes this change, if implemented, would not be consistent with the OPPI packaging policy and stresses this change is only related to the DOS policy included in §414.510(b)(5).

- Excluding Blood Banks and Blood Centers from the Laboratory DOS Exception at 42 CFR 414.510(b)(5): CMS is proposing to exclude blood banks and centers from the laboratory DOS exception at § 414.510(b)(5), resulting 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."

**APPENDIX A**

**TABLE 37.—PROPOSED LIST OF 70 CMS-SPECIFIED SHOPPABLE SERVICES**

<b>Evaluation &amp; Management Services</b>	<b>2020 CPT/HCPCS Primary Code</b>
Psychotherapy, 30 min	90832
Psychotherapy, 45 min	90834
Psychotherapy, 60 min	90837
Family psychotherapy, not including patient, 50 min	90846
Family psychotherapy, including patient, 50 min	90847
Group psychotherapy	90853
New patient office or other outpatient visit, typically 30 min	99203
New patient office or other outpatient visit, typically 45 min	99204
New patient office or other outpatient visit, typically 60 min	99205
Patient office consultation, typically 40 min	99243
Patient office consultation, typically 60 min	99244
Initial new patient preventive medicine evaluation (18-39 years)	99385
Initial new patient preventive medicine evaluation (40-64 years)	99386
<b>Laboratory &amp; Pathology Services</b>	<b>2020 CPT/HCPCS Primary Code</b>
Basic metabolic panel	80048
Blood test, comprehensive group of blood chemicals	80053
Obstetric blood test panel	80055
Blood test, lipids (cholesterol and triglycerides)	80061
Kidney function panel test	80069
Liver function blood test panel	80076
Manual urinalysis test with examination using microscope	81000 or 81001
Automated urinalysis test	81002 or 81003
PSA (prostate specific antigen)	84153-84154
Blood test, thyroid stimulating hormone (TSH)	84443
Complete blood cell count, with differential white blood cells, automated	85025
Complete blood count, automated	85027
Blood test, clotting time	85610
Coagulation assessment blood test	85730
<b>Radiology Services</b>	<b>2020 CPT/HCPCS Primary Code</b>
CT scan, head or brain, without contrast	70450
MRI scan of brain before and after contrast	70553

X-Ray, lower back, minimum four views	72110
MRI scan of lower spinal canal	72148
CT scan, pelvis, with contrast	72193
MRI scan of leg joint	73721
CT scan of abdomen and pelvis with contrast	74177
Ultrasound of abdomen	76700
Abdominal ultrasound of pregnant uterus (greater or equal to 14 weeks 0 days) single or first fetus	76805
Ultrasound pelvis through vagina	76830
Mammography of one breast	77065
Mammography of both breasts	77066
Mammography, screening, bilateral	77067
<b>Medicine and Surgery Services</b>	<b>2020 CPT/HCPCS/DRG Primary Code</b>
Cardiac valve and other major cardiothoracic procedures with cardiac catheterization with major complications or comorbidities	216
Spinal fusion except cervical without major comorbid conditions or complications (MCC)	460
Major joint replacement or reattachment of lower extremity without major comorbid conditions or complications (MCC)	470
Cervical spinal fusion without comorbid conditions (CC) or major comorbid conditions or complications (MCC)	473
Uterine and adnexa procedures for non-malignancy without comorbid conditions (CC) or major comorbid conditions or complications (MCC)	743
Removal of 1 or more breast growth, open procedure	19120
Shaving of shoulder bone using an endoscope	29826
Removal of one knee cartilage using an endoscope	29881
Removal of tonsils and adenoid glands patient younger than age 12	42820
Diagnostic examination of esophagus, stomach, and/or upper small bowel using an endoscope	43235
Biopsy of the esophagus, stomach, and/or upper small bowel using an endoscope	43239
Diagnostic examination of large bowel using an endoscope	45378
Biopsy of large bowel using an endoscope	45380
Removal of polyps or growths of large bowel using an endoscope	45385
Ultrasound examination of lower large bowel using an endoscope	45391
Removal of gallbladder using an endoscope	47562
Repair of groin hernia patient age 5 years or older	49305
Biopsy of prostate gland	55700
Surgical removal of prostate and surrounding lymph nodes using an endoscope	55866
Routine obstetric care for vaginal delivery, including pre-and post-	59400

delivery care	
Routine obstetric care for cesarean delivery, including pre-and post-delivery care	59510
Routine obstetric care for vaginal delivery after prior cesarean delivery including pre-and post-delivery care	59610
Injection of substance into spinal canal of lower back or sacrum using imaging guidance	62322-62323
Injections of anesthetic and/or steroid drug into lower or sacral spine nerve root using imaging guidance	64483
Removal of recurring cataract in lens capsule using laser	66821
Removal of cataract with insertion of lens	66984
Electrocardiogram, routine, with interpretation and report	93000
Insertion of catheter into left heart for diagnosis	93452
Sleep study	95810
Physical therapy, therapeutic exercise	97110