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2018 FINAL MEDICARE RULES ISSUED:
No MPFS Payment Changes for Nuclear Medicine

In early November, the Centers for Medicare & Medicaid Services (CMS) issued several final rules, including ones for the:

- Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs
- Medicare Physician Fee Schedule (MPFS).

Both of these contain changes of interest to radiology providers as well as a few status-quo provisions and the usual payment updates.

Payment Rates to Increase

After considering all other policy changes under the final rule, including estimated spending for pass-through payments, CMS expects an overall 1.4 percent payment increase for providers paid under the OPPS in 2018. It also finalized its proposal to increase the OPPS conversion factor (CF) by 1.75 percent bringing it up to $76.483 for 2018. Additionally, CMS finalized its proposal to set the reduced CF for hospitals failing to meet the Hospital Outpatient Quality Reporting (OQR) Program requirements at $74.953 or a 2 percent reduction.

The overall update to payments under the MPFS based on the finalized 2018 rates will be +0.41 percent with an estimated 2018 conversion factor of $35.9996, which is a slight increase from the current conversion factor of $35.8887.

In Table 50 of the MPFS, CMS lists estimates of the overall impact of the MPFS proposed changes by specialty. There will be no payment changes for nuclear medicine, interventional radiology, and diagnostic radiology. Payments for radiation oncology and radiation therapy centers will increase by an estimated 1 percent. However, independent diagnostic testing facilities are not so lucky, and the estimated impact is minus 4 percent, which is less than the proposed 6 percent decrease.

CMS will continue to make separate payments for the 10 planning and preparation services adjunctive to the delivery of stereotactic radio surgery (SRS) treatments using Cobalt-60-based or LINAC-based technology when these services are furnished to beneficiaries within 30 days of SRS treatment. Note too that the data-collection period for SRS claims with modifier "CP" is set to conclude on December 31, 2017, so CMS will delete this modifier and discontinue its required use.

Pass-Through Payment Status

The pass-through payment status of 19 drugs and biologicals will expire on December 31, 2017. Included in that list of expiring drugs is the following radiopharmaceutical:

A9586 Florbetapir F18, diagnostic, per study dose, up to 10 millicuries (brand name: Amyvid®)

This FDA-approved radioactive diagnostic agent is used for positron emission tomography (PET) imaging of the brain to estimate beta-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline.

Instead of the separate payment of $2,756 (as of October 2017) that providers received for A9586 (as of October 2017), when it had pass-through status, its payment will be packaged into the rate for other services performed (status indicator "N") beginning January 1, 2018.

As per Medicare policy, codes with pass-through status receive OPPS separate payment for at least two years. Some drugs do get extensions for three years but that is not the case for Florbetapir, in spite of the manufacturer's request to CMS.

Detailed discussion about extending pass-through status for A9586 starts at the bottom of page 478 in the final rule, and one topic that can be found relates to the Medicare National Coverage Determination (NCD) on

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September 27, 2013. The NCD allows conditional coverage of amyloid PET under three Medicare-approved coverage with evidence development (CED) trials. CMS noted that information about these clinical trials (and billing and coding instructions) can be found at *https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence- Development/Amyloid-PET.html.*

For 2017 and subsequent years, CMS finalized a policy for newly approved pass-through drugs and biologicals. They will expire on a quarterly basis, instead of the previous annual basis, with a pass-through payment period as close to three years as possible.

However, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including diagnostic radiopharmaceuticals, contrast agents, and stress agents) fall into a policy-exception category. These products, as well as drugs and biologicals that function as supplies when used in a surgical procedure and anesthesia drugs, are always packaged when they do not have pass-through payment status.

The OPPS drug-packaging threshold for 2018 is $120. If the estimated per-day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, CMS will package the payment into the payment for the associated procedure in the upcoming calendar year. If the estimated per-day cost of the drug or biological is greater than the OPPS drug packaging threshold, it provides separate payment at the applicable relative average sale price (ASP) based payment amount (ASP+6 percent for 2018).

The good news is that the radiopharmaceuticals listed in the table to the right will continue to receive pass-through status.

Level II Codes	Descriptors	Pass-Through Payment Effective Dates	Payment Rate (APC)
A9515	Choline C11, diagnostic, per study dose (C-11 choline)	04/01/2016	$5,700.00 (9461)
A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie (Netspot™)	01/01/2017	$66.74 (9056)
A9588	Fluciclovine F-18, diagnostic, 1 millicurie (Axumin™)	01/01/2017	$389.55 (9052)
Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 mg (Vizamyl™)	01/01/2016	$3,498.00 (9459)
Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1millicuries (Neuraceq™)	01/01/2016	2,968.00 (9458)

Information Sources:

- For the final rule governing the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, go to *https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-23932.pdf.*
- For the Medicare Physician Fee Schedule (MPFS) final rule, go to *https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-23953.pdf.*

NO MORE NOPR CASE REGISTRATIONS: Will CMS Reconsider Coverage?

On the website of the National Oncologic PET Registry (NOPR), you will see a notice saying that it is "closed to accrual on December 14, 2017." What this means is that the current national coverage determination (NCD) and Medicare coverage for bone PET with F-18 sodium fluoride (NaF-PET) (under the coverage with evidence development [CED] policy) expires at midnight on that date, which means that no new case registrations will be allowed.

The NOPR Working Group has submitted a request to the Centers for Medicare & Medicaid Services (CMS) asking that coverage for NaF-PET be reconsidered "in light of the additional analyses of NOPR data along with Medicare claims data." Its announcement also says:

> *A coverage decision in response to this reconsideration request is dependent on the publication in peer-reviewed journals of these additional analyses, and the timing of the coverage decision is currently unknown. However, it is highly unlikely that CMS will issue a coverage decision before the expiration of the coverage under the current NCD.*

The NOPR web site also indicates that, until CMS issues a new NCD, all planned NOPR-covered NaF-PET studies must have been performed (and the PET Completion Form entered into the database) no later than December 14, 2017 at midnight EST. For any study performed on or before that date, entry of the PET Report Submission Form, the PET Scan Assessment Form, and the Post-PET Case Report Form will be allowed (within the time limits specified in the protocol). It directs participating sites to not schedule NaF-PET studies to be performed for Medicare patients after that time.

Going Back Two Years

In an October 16, 2017 update, the NOPR summarized the two-year history pertaining to the coverage of NaF-PET to identify bone metastasis.

In December 2015, CMS determined that the use of a NaF-18 positron emission tomography (PET) scan to identify bone metastasis of cancer is not reasonable and necessary to diagnose or treat an illness or injury or to improve the functioning of a malformed body member and, therefore, is not covered.

CMS stated that it would continue the requirement for CED for NaF-18 PET to identify bone metastasis of cancer for 24 months from the final decision date. It said that the extension is to allow confirmatory analyses to be performed and resulting evidence to be published to definitely answer the questions of whether the addition of NaF-18 PET imaging leads to:

- A change in patient management to more appropriate palliative care?
- A change in patient management to more appropriate curative care?
- Improved quality of life?
- Improved survival?

It also noted that all other uses and clinical indications for NaF-18 PET are nationally non-covered and that it would reconsider the NCD when the evidence has been published in a peer-reviewed journal.

Wrapping Things Up

At the close-out of NOPR (NaF-PET), the balances in individual PET facility escrow accounts will be refunded. To insure that funds are refunded properly, each PET facility must submit a refund request to *OPTOUT_NOPR@acr.org.*

The request must include the NOPR's facility ID number, name and address. In addition, the request must include the name and phone number of the person submitting the request and the date of the request. NOPR states that requests will be acknowledged, and a refund check will be issued to the requesting facility.

Questions on the above may be forwarded to the NOPR at *pet_registry@phila.acr.org.*

APPROPRIATE USE CRITERIA: New Codes, Modifiers and System Changes

Section 218(b) of the Protecting Access to Medicare Act (PAMA) of 2014 directed the Centers for Medicare & Medicaid Services (CMS) to develop the Appropriate Use Criteria (AUC) and Clinical Decision Support (CDS) Program for all advanced diagnostic imaging services.

In the 2016 and 2017 MPFS final rules, CMS addressed the first two steps of the AUC program, and in the 2018 MPFS proposed rule it discussed the third step, which included a recommendation for delayed implementation from January 1, 2018 to January 1, 2019—a date that it did not finalize. As a result of public comments requesting an implementation delay, CMS has moved the date to January 1, 2020.

Several medical specialty societies reported to CMS that their members could not be ready by the 2019 date. Others recommended that CMS start conducting more listening sessions, town-hall meetings and open-door forums so that stakeholders could share information and ideas about how the administrative burden of the program could be minimized.

CMS agreed it would do this and also announced a one-year "educational and operations testing period" that will begin on January 1, 2020. During this time, it will continue to pay claims whether or not they correctly include the AUC consultation information. This educational period will allow professionals to actively participate in the program while avoiding claims' denials.

CMS says that this one-year period also will give it an opportunity to make any needed claims processing adjustments before payments are impacted. According to the agency, there are aspects of the AUC program that are novel and complex for the CMS claims processing system and for ordering and furnishing professionals.

For example, CMS acknowledges that there are "additional considerations for the complex communication of AUC consultation information from the ordering professional to the furnishing professional and facility that must include that information when billing for the service are warranted." Their billing systems will need to translate the AUC consultation information onto Medicare claims in the form of codes and modifiers.

Radiologists' Responsibilities

In addition to reporting the national provider identifier (NPI) of the ordering professional (if different from the furnishing professional) on Medicare claims, CMS proposed that furnishing professionals (e.g., radiologists) answer and report the following information on Medicare claims for "applicable imaging services, furnished in an applicable setting, paid for under an applicable payment system" ordered on and after January 1, 2019: Which qualified Clinical Decision Support Mechanism (CDSM) did the ordering professional consult? Did the service ordered adhere to specified applicable AUC?

The above information must be supplied on both the practitioner claim that includes the professional component of the imaging service and on the hospital outpatient claim for the technical component of the imaging service. Claims for services for which payments are not made under the MPFS, outpatient prospective payment system, or ambulatory surgical center payment system would not be required to include consultation-related information.

An AUC consultation must take place, states CMS, for every applicable order although it also acknowledged that AUC may not be available for every imaging service performed. However, the agency expects such situations to be limited in scope and number and to decrease over time. In these cases, the furnishing professional would indicate that AUC is "not applicable" to the service ordered.

On this point, CMS indicates that qualified CDSMs must make available, at a minimum, AUC that "reasonably address common and important clinical scenarios within all priority clinical areas." Table 40 in the 2017 MPFS final rule lists the proposed priority clinical areas, which represents about 40 percent of advanced diagnostic imaging services paid for by Medicare in 2014. (See Table 1 below.)

Key Points of Appropriate Use Criteria

AUC present information in a manner that links the following:

- A specific clinical condition or presentation
- One or more services
- An assessment of the appropriateness of the service(s).

Each individual criterion is an evidence-based guideline for a particular clinical scenario that starts with a patient's presenting symptoms or condition. Evidence-based AUC for imaging can assist clinicians in selecting the study that is most likely to improve health outcomes for patients based on their clinical presentations.

AUC is integrated into the clinical workflow via electronic portals called clinical decision support mechanisms (CDSMs). While CDSMs can be standalone applications that require direct entry of patient information, they may be more effective when they automatically incorporate information such as specific patient characteristics, laboratory results, and lists of co-morbid diseases from electronic health records (EHRs) and other sources.

Table 1: Priority Areas for Advanced Diagnostic Imaging Services

To compile the *proposed* initial list below, CMS analyzed Medicare claims data from the CMS Chronic Conditions Data Warehouse (CCW) Part B non-institutional claim-line file for 2014. Information analyzed included HCPCS codes, ICD-9 diagnosis code(s), service dates, and Medicare payment amounts.

Clinical Areas	% of Total Services
Chest pain (includes angina, suspected myocardial infarction, and suspected pulmonary embolism)	12
Abdominal pain (any locations and flank pain)	8
Headache, traumatic and non-traumatic	6
Low back pain	5
Suspected stroke	5
Altered mental status	5
Cancer of the lung (primary or metastatic, suspected or diagnosed)	3
Cervical or neck pain	3

Information Sources:

- The above information can be found in the 2017 MPFS final rules and in the 2018 MPFS proposed rules.

Q & A: Focus on Nuclear Medicine

Radiopharmaceutical Therapy

Q. What would be the correct CPT code to bill for an ^{131}I therapy for hyperthyroidism? All we do in this case is administer the dose to the patient with the prescribed amount required for treatment.

A. The therapy codes are 79005–79999. In this case, the following is the appropriate code:

79005 Radiopharmaceutical therapy, by oral administration

Remember that if you are also charging for the radiopharmaceutical, there are different HCPCS codes for therapeutic as well as diagnostic ^{131}I in both a solid and liquid form. In order to insure that correct, compliant charging for this radiopharmaceutical is performed, the radiologist must specifically define in their dictated report the type of material used, the amount of material given and whether the dose was provided in a solid (i.e., capsule) or liquid (i.e., solution).

HCPCS code options for therapeutic ^{131}I are as follows:

Solid (i.e., capsule) Form

Therapeutic:

A9517 Iodine ^{131}I sodium iodide capsule(s), therapeutic, per millicurie

Diagnostic:

A9528 Iodine ^{131}I sodium iodide capsule(s), diagnostic, per millicurie

A9531 Iodine ^{131}I sodium iodide, diagnostic, per microcurie (up to **100** microcuries)

Liquid (i.e., solution) Form

Therapeutic:

A9530 Iodine ^{131}I sodium iodide solution, therapeutic, per millicurie

Diagnostic:

A9529 Iodine ^{131}I sodium iodide solution, diagnostic, per millicurie

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