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Billing, Coding and Reimbursement News

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2019 MEDICARE FINAL RULES ISSUED:
Slight Payment Decrease for Nuclear Medicine

The federal government's plan for a "patient-driven healthcare system" continues with the November 2, 2018 release of the 2019 final rule for the Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System. In a press release, CMS states that the policies in the final rule, which will take effect on January 1, 2019, strengthen the Medicare program by "providing seniors more choices and lower cost options."

After considering all other policy changes under the final rule, including estimated spending for pass-through payments, CMS expects that providers paid under the OPPS in 2019 will receive an overall 1.35 percent payment increase—down slightly from the 1.4 percent increase they received in 2018. The 2019 CF will be $79.490—an increase from the 2018 CF of $76.483.

However, hospitals that do not comply with the Hospital Outpatient Quality Reporting (OQR) Program reporting requirements are subject to a reduction of 2 percent from the outpatient fee schedule. CMS finalized the CF for hospitals that do not meet the OQR requirements at $77.955 (better than the $74.953 for 2018).

In the final 2019 Medicare Physician Fee Schedule, CMS indicated a CF of $36.04, which is a slight increase from the 2018 CF of $35.99. According to the agency's estimates, nuclear medicine providers will see an aggregate decrease in payments of 1 percent. On the opposite side of estimates, interventional radiologists will see a 2 percent increase and everyone else is somewhere in between.

Pass-Through Payment

On December 31, 2018, pass-through status for the three radiopharmaceuticals listed in Table 1 will expire. The 2019 status indicator (SI) for these codes will be "N," which means that payment will be packaged into other services, and no separate ambulatory payment classification (APC) reimbursement will be received.

Table 1: Pass-Through Status Expiring

2019 HCPCS Level II Code	Code Descriptors
A9515	Choline C 11, diagnostic, per study dose
Q9982	Flutemetamol F-18, diagnostic, per study dose, up to 5 millicuries
Q9983	Florbetaben F-18, diagnostic, per study dose, up to 8.1 millicuries

The radiopharmaceuticals listed in Table 2 will, however, have pass-through payment status in 2019.

Table 2: Pass-Through Status in 2019

2019 HCPCS Level II Code	Code Descriptors	APCs	APC Payment Rates
A9586	Florbetapir F-18, diagnostic, per study dose, up to 10 millicuries	9084	$3,023.162
A9587	Gallium Ga-68, dotatate, diagnostic, 0.1 millicurie		$66.741
A9588	Fluciclovine F-18, diagnostic, 1 millicurie	9052	$389.550
A9513*	Lutetium Lu 177, dotatate, therapeutic, 1 millicurie	9067	$251.750
C9407	Iodine I-131 iobenguane, diagnostic, 1 millicurie	9184	$320.120
C9408	Iodine I-131 iobenguane, therapeutic, 1 millicurie	9185	$320.120

**In 2018, the code used to report this radiopharmaceutical was C9031.*

Other Payment Provisions

In addition to pass-through payments and packaged payments, there are the products paid the average sales price (ASP) plus 6 percent. For example, drugs and therapeutic radiopharmaceuticals will still be paid at the ASP

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+ 6 percent (as they have been since 2010). The ASP + 6 percent includes the payment for the radiopharmaceutical's acquisition cost and any associated nuclear medicine handling and compounding costs incurred by the hospital pharmacy.

For 2019, the drug-packaging threshold payment for therapeutic radiopharmaceuticals is $125 (up from the $120 set for 2018). Radiopharmaceuticals that cost less than or are equal to $125 will be packaged and paid within the APCs of the related nuclear medicine service. Separate payment will be made for those that meet or exceed the threshold amount.

Site-Neutral Payments

CMS finalized its proposal to adopt site-neutral payments for clinic visits, which are the most common service billed under the OPPS. Currently, the Medicare program and its beneficiaries often pay more for the same type of clinic visit in the hospital outpatient setting than in the physician office setting.

Adopting the same payment for both sites, which CMS has done, will result in lower copayments for beneficiaries and savings for the Medicare program. This new policy will be phased in over the next two years.

ASC Services Expanded

CMS also will give patients more options on where to obtain care by increasing the services that can be furnished in ASCs.

For 2019, CMS finalized ASC policies that will:

- Expand the number of surgical procedures payable to ASCs
- Ensure ASC payment for procedures involving certain high-cost devices that parallel the payment amount provided to hospital outpatient departments
- Guarantee that ASCs remain competitive by addressing the differential between ASC payment rates and hospital outpatient

Information Source: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1695-FC.html*

NaF-18 PET TO IDENTIFY BONE METASTASIS:
CMS Rejects Payment Coverage—Again

To the disappointment of the nuclear imaging community, the Centers for Medicare & Medicaid Services (CMS) have once again indicated no coverage for the use of sodium fluoride-18 imaging (NaF-18 positron emission tomography [PET]) to identify bone metastasis of cancer. CMS issued the original NCD on June 4, 2009 and collected clinical utility data via the National Oncologic PET Registry (NOPR) for the last 10 years. The latest denial of the reconsideration came in a letter from CMS to the NOPR co-chairs.

The goal of collecting the clinical utility data was to convince CMS that use of NaF-PET results in positive changes in patient management and more appropriate curative or palliative care.

However, apparently, the NOPR data did not convince CMS. In its standard denial statement, CMS reiterated that "the evidence is not sufficient to determine that the results of NaF-18 PET imaging to identify bone metastases improve health outcomes of beneficiaries with cancer. Its conclusion is that this use is not reasonable and necessary as required by law for the Medicare program."

Reaction from the Field

The World Molecular Imaging Society (WMIS), the American College of Radiology, the Society of Nuclear Medicine and Molecular Imaging (SNMMI), and the members of the NOPR Working Group disagree with the decision.

NOPR co-chair Dr. Barry Siegel stated, "We are disappointed that CMS did not open a reconsideration and allow public comment on the published evidence to support coverage for NaF PET."

In a statement posted on the WMIS website, NOPR principal investigator Dr. Bruce Hillner stated, "The NOPR data clearly show that use of NaF PET led to more appropriate care for many cancer patients. We urge CMS to reconsider coverage for these potentially lifesaving and life-improving exams."

Shortly after the release of decision memo, the partners pushing for coverage announced that they were uncertain what the "path forward" would be. Despite this latest setback, SNMMI, WMIS, and ACR plan to continue their work to convince CMS it should support Medicare coverage and beneficiary access to NaF-PET.

Information Source: The current NCD for the above can be found in Section 220.6 of the *National Coverage Determinations Manual* at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf.*

NON-FDG PET FOR ONCOLOGY INDICATIONS: Look to Local Policies for Payments

The national Medicare policy for positron emission tomography (PET) for oncologic indications is for fluorodeoxyglucose (FDG) PET only.

However, the Centers for Medicare & Medicaid Services (CMS) do allow individual Medicare Administrative Contractors (MACs) to cover and pay for oncologic PET with other non-FDG radiopharmaceuticals if the Food & Drug Administration (FDA) has approved them for that purpose.

CMS states the following in section 220.6 of the *Medicare National Coverage Determinations Manual:*

Effective for dates of service on or after March 7, 2013, MACs may determine coverage within their respective jurisdictions for positron emission tomography (PET) using radiopharmaceuticals for their Food and Drug Administration (FDA) approved labeled indications for oncologic imaging.

Also in the Medicare NCD Manual, CMS emphasized the following points:

- Changing the "restrictive" language of prior PET decisions will not by itself suffice to expand Medicare coverage to new PET radiopharmaceuticals.
- The scope of this change extends only to FDA-approved indications for oncologic uses of PET tracers.
- This change does not include screening uses of PET scanning.
- Local coverage cannot be in conflict with NCDs or other national policies.
- Future NCDs, if any, regarding diagnostic PET imaging would not be precluded by this NCD.

Information Source: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf*

APPROPRIATE USE CRITERIA: CMS Finalizes Reporting Requirements

In the 2018 Medicare Physician Fee Schedule (MPFS) final rule, the Centers for Medicare & Medicaid Services (CMS) established the start date of January 1, 2020 for the Medicare Appropriate Use Criteria (AUC) Program for advanced diagnostic imaging services (magnetic resonance imaging [MRI], computed tomography [CT], nuclear medicine exams, and positron emission tomography [PET]).

For services ordered on and after this date, ordering providers must consult specified AUC using a qualified clinical decision support mechanism (CDSM) and provide the AUC data to the furnishing professional. Note that although mandatory use of AUC and CDSM begins on January 1, 2020, there is no financial penalty for failure to report the data until January 1, 2021.

In the 2019 MPFS proposed rule, CMS suggested several changes to fine-tune the AUC program established over the last several years. In the 2019 MPFS final rule, it modified some of its proposals as explained below.

Key Role for Radiologists

It is the responsibility of the furnishing professional and the facility to accurately report the AUC information on Medicare claims. It must be included on the practitioner's claim for the professional component and on the facility's claim for the technical component of the imaging service.

The fact that the primary furnishing professionals will be radiologists brings up an opportunity for them to be proactive with their ordering providers. Instead of waiting for the effective date—and waiting to "see what happens," radiologists could consider educating them now about the AUC and requirements.

Also, as the American College of Radiology (ACR) says on its website, "...as we get clarity around the claims-formatting requirements, radiology practices should begin the dialogue with their practice management vendor or billing company. Systems must be ready to accept the AUC data generated by the qualified CDS mechanism, because, as of January 2021, all claims will need to be properly formatted to be payable."

Applicable Settings

Initially, the AUC consultation-and-reporting requirements applied only in the following applicable settings:

- Physician's office
- Hospital outpatient department (including an emergency department)
- Ambulatory surgical center
- Any other provider-led outpatient setting determined appropriate by the Secretary of the Department of Health & Human Services.

CMS finalized its proposal to revise the definition of applicable setting to add an independent diagnostic testing facility (IDTF). This, it says, will ensure that the AUC program is in place across all outpatient settings where advanced diagnostic imaging services are furnished.

Ordering Professionals

Under the current law, "ordering professionals" (physicians or practitioners who order an applicable imaging service) must comply with the AUC consultation requirement. CMS proposed that the AUC consultation also may be performed by auxiliary clinical staff but did not specifically define who that included—an oversight that generated many public comments.

Based on these comments, CMS decided to not move forward with its proposal to specify the scope of individuals who can perform the AUC consultation as auxiliary personnel. It modified its proposal to clarify the following:

- In the event of a significant hardship, the requirement to consult AUC does not apply.
- When the consultation is not performed by the ordering professional, it may be performed by clinical staff under the direction of the ordering professional. "Clinical staff" include individuals who perform care-management services including chronic care management, behavioral health integration and transitional care management (TCM) services.

In the final rule, CMS goes into more detail about the clinical staff requirements.

Radiologists need to educate ordering providers about AUC.

Claims-Processing Plan

In the 2018 MPFS proposed rule CMS discussed the idea of using a combination of G-codes and modifiers to report the AUC consultation information on the Medicare claim. It also discussed using a unique consultation identifier (UCI)—an option that it did not finalize for a number of practical reasons.

Instead, it decided to use coding structures that are already in place (such as G-codes and modifiers) to report the required AUC information on Medicare claims because doing so would allow it to establish reporting requirements prior to the start of the program (January 1, 2020).

However, it also said it would consider future opportunities to use a UCI and would discuss with stakeholders.

Hardship Exceptions

An ordering professional experiencing any of the following would not be required to consult AUC using a qualified CDSM:

- Insufficient internet access specific to the location where an advanced diagnostic imaging service is ordered
- Electronic health record (EHR) or CDSM vendor issues (such as temporary technical problems)
- Extreme and uncontrollable circumstances (such as natural or man-made disasters that have a significant negative impact on healthcare operations, area infrastructure or communication systems).

In response to public comments, CMS did not finalize the proposed changes to the significant hardship exceptions and instead decided further evaluation was needed before moving forward.

Information Source:

Details about the AUC program can be found in Section III.D. of the final rule at *https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-24170.pdf.*

Q & A: Focus on PET Scans

Cardiac Scan

Q. Our nuclear medicine radiologists are currently performing cardiac PET scans in the office setting to evaluate for sarcoidosis. They are doing two cardiac PET scans using our hybrid scanner as follows:

- A myocardial PET perfusion imaging following administration of N-13 ammonia
- A limited area (i.e., chest) F-18 FDG PET/CT for myocardial viability/ metabolism.

Is this correctly reported using CPT code 78491 with HCPCS level II code A9526 and CPT code 78814 with HCPCS level II code A9552?

A. You would assign codes 78491 (myocardial imaging, PET, perfusion; single study at rest or stress) and 78459 (myocardial imaging, PET, metabolic evaluation) plus the appropriate radiopharmaceutical codes.

Be aware that sarcoidosis is not a nationally covered diagnosis for Medicare, so the claim may be denied for patients with this insurance. Unless your MAC has indicated that it will cover PET for sarcoidosis, we believe you should report the following, which is the code for non-covered exams for Medicare:

G0235 PET imaging, any site, not otherwise specified

Interrupted Scan

Q. We had a patient that was scheduled for a PET scan and received the injection. When we moved the patient to the table to start imaging, she became claustrophobic and couldn't continue with the imaging. Since we had already injected the patient, can we submit the PET code with modifier 52, or how should this be handled?

A. You are correct that you can report the PET code with a modifier.

The Society of Nuclear Medicine and Medical Imaging (SNMMI) has stated that once the radiopharmaceutical has been injected, the exam has started. Correct coding would include the charge for the radiopharmaceutical as well as the exam itself. The modifier that is assigned depends on the reason why the procedure was terminated. For hospital billing, modifier -52 is the most common used for this situation. For professional fee billing, options are either modifier -52 or -53.

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