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THE 2021 PHYSICIAN FEE SCHEDULE AND OPPS FINAL RULES RELEASED:

Conversion Factor, E/M Policies, and APCs

The 2021 final Medicare Physician Fee Schedule (PFS) rule and 2021 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (OPPS) arrived, released by the Centers for Medicare & Medicaid Services (CMS) on December 2, 2020. The policy changes include conversion factor changes resulting from the E/M policy updates and correlating budget neutrality adjustments, broad structural E/M changes, and updated APCs. Among the most consequential updates are the coming reimbursement cuts to nuclear medicine and radiology finalized in the rule.

Conversion Factor Set

For 2021, the conversion factor will have deep and lasting impacts on nuclear medicine and radiology. Nuclear medicine will see an eight percent decrease in payment, while an eleven percent decrease is expected for radiology, along with an aggregate decrease of nine percent for interventional radiology. Additionally, radiation oncology and radiation therapy centers are set to receive a six percent decrease. CMS set a 2021 conversion factor of $32.41, which accounts for the budget neutrality adjustment, a significant decrease from the 2020 factor of $36.09.

E/M Policy Changes

CMS has finalized the proposals included within the previous 2020 PFS rule that implements a new coding structure for office/outpatient evaluation and management (E/M) codes upon the American Medical Association's (AMA) recommendations, in addition to the RUC-recommended values. Among the provisions, the final rule sets separate payments for each of the levels of office/outpatient E/M. Expect this to replace the blended payments for levels 2-4. Additionally, a new add-on code is included for prolonged visits and a new add-on code for complex care is also available.

CMS finalized its proposal to revalue a group of code sets that include or depend on office/outpatient E/M visit valuation, which correlates with the increases in values finalized for 2021 E/M visits. Altogether, E/M visits reported using the correlating CPT codes make up around 40 percent of the permitted charges included in the PFS services. Even more, office/outpatient E/M visits make up around twenty percent of the PFS reimbursement.

Understand that nearly all specialties provide these services, but physicians and providers who do not typically provide services such as surgeries, interventions, and primarily diagnostic testing tend to account for a larger portion of the total E/M office visits reported. Among these types of practitioners are specialties like internal medicine, family practice, neurologists, rheumatologists, and endocrinologists. With all the comprehensive changes, CMS maintains that the policies will bolster its continuing efforts to ease administrative burden, strengthen payment accuracy, and transform the office/outpatient E/M visit code set to more accurately account for present practices in medicine.

During the final rule decision making for PFS 2020, for codes 99201 through 99215, CMS agreed to incorporate new coding and prefatory language along with interpretive guidance framework for the office/outpatient E/M visit codes developed by the AMA's CPT Editorial Panel. As you may know, these changes are set to be in effect starting January 1, 2021.

The sweeping changes have several key highlights. With the new coding structure soon to be implemented, note that history and exam will not be used to make the appropriate selection for the level of coding used in the office/outpatient E/M visits. However, an office/outpatient E/M visit is expected to

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incorporate a medically relevant history and exam, when medically appropriate. According to the American College of Radiology, "The clinically outdated system for number of body systems/areas reviewed and examined under history and exam will no longer apply, and the history and exam components will only be performed when, and to the extent, reasonable and necessary, and clinically appropriate."

Code 99201 (Level 1 office/outpatient visit, new patient), will be no more, as it is deleted for 2021. The justification for the deletion lies in the fact that CPT codes 99201 and 99202 both require straightforward medical decision making (MDM) and at present contain sufficient historical and exam element differences.

Levels two through five office/outpatient E/M visit code selection, and knowing the correct level to report, will be founded upon either the level of MDM or the total personal time involved by the reporting practitioner during the day of the visit. This incorporates both face-to-face and non-face-to-face time.

In terms of prolonged visits, the AMA established a new prolonged visit add-on CPT code, CPT code 99417, while ceasing to use CPT codes 99358 and 99359 (prolonged E/M visit without direct patient contact) for prolonged time reporting regarding these visits. In the final rule, CMS announced they would not reimburse for code 99417. Instead, CMS has established HCPCS code G2212 to use in lieu of 99417 when reporting these services to Medicare. The source of the disagreement between the AMA and CMS is the time threshold that must be met to use the additional code, and the counting of non-face-to-face prolonged time spent on a different date than the date of the E/M visits.

Separate payment will now exist in 2021 for HCPCS code G2211, which covers payment for the complexity of visits integral in evaluation and management that corresponds with services that provide a central focus for any necessary healthcare. In addition, the code provides for any corresponding medical services that encompass continuing care of a patient's "single, serious, or complex chronic condition."

As part of the 2021 rule making, the agency tackled the AMA RUC recommendations, and set new values for CPT codes 99202–99215. They also assigned RVUs to the new office/outpatient E/M prolonged visit HCPCS code G2212 (while assigning 0.00 RVUs for CPT code 99417) along with HCPCS code G2211. Expect to see these valuations effective as of January 1, 2021. Look to Table 1 below for further insight:

Table 1

HCPCS Code	Present Total Time	Present Work RVU	2021 Total Time	2021 Work RVU
99202	22	0.93	22	0.93
99203	29	1.42	40	1.6
99204	45	2.43	60	2.6
99205	67	3.17	85	3.5
99211	7	0.18	7	0.18
99212	16	0.48	18	0.7
99213	23	0.97	30	1.3
99214	40	1.5	49	1.92
92215	55	2.11	70	2.8
99417	N/A	N/A	15	0.00
G2212	N/A	N/A	15	0.61
G2211	N/A	N/A	11	0.33

During the 2020 MPFS proposed rule, CMS asked for input on times that corresponded with the office/outpatient E/M visits per the recommendations of the AMA RUC. The AMA RUC conducted a survey process in regards to valuation purposes. During this survey, the RUC asked participants to contemplate total time spent on the day of the visit, in addition to any pre-and post-service time occurring during a timeframe of three days before a visit and seven days following. When providing recommendations for CMS, the AMA RUC decided to average the survey results separately into categories of pre-service, day of service, and post-service times along with the total time results. Consequently, for some codes, the sums of the perspective times corresponding to those specified services periods failed to align with the RUC recommended total time. This method used to create recommendations occasionally provided conflicting time sets, essentially the surveyed component times conflicting with the total times as surveyed.

The imprecision of commenter information on the proposed rule about the reasoning behind the sum of minutes in the components and the differentiation from total minute time, along with the agency's perspective of view and system requirement that total time should be equivalent to the mathematical total of component times were two factors fueling the final decision. Based on these, CMS plans at the start of 2021 to incorporate the actual total times, or the sum of the component times as opposed to the total times previously advocated for by the RUC for 99202–92215.

Pass-Through Payment for OPPS

On December 31, 2020, pass-through status for the radiopharmaceuticals listed in Table 1 will expire. The 2021 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 2: Pass-Through Status Recently Expired or Expiring

2019 HCPCS	Group Title	2019 Payment Rate
A9586	Florbetapirf18 diagnostic, per study dose, up to 10 millicuries	9/30/2020
Q9982	Flutemetamol F18, diagnostic per study dose, up to 5 millicuries	9/30/2020
Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	9/30/2020
A9513	Lutetiam lu 177, dotatate, therapeutic 1 millicurie	6/30/2021
A9590	Iodine i-131 iobenguane, therapeutic. 1 millicurie	12/31/2021

Other Payment Provisions

The payment rate for drugs and therapeutic radiopharmaceuticals will remain at ASP + 6%, which was established in 2010.

Payment for the radiopharmaceutical and its processing services are made through the single ASP-based payment. View the table below for APC payment rates.

Table 3: Nuclear Medicine APCs for 2021

APC	Group Title	2020 Payment Rate	2021 Payment Rate
5591	Level 1 Nuclear Medicine & Related Services	$368.13	$377.12
5592	Level 2 Nuclear Medicine & Related Services	$471.98	$489.40
5593	Level 3 Nuclear Medicine & Related Services	$1,272.19	$1,305.94
5594	Level 4 Nuclear Medicine & Related Services	$1,443.09	$1,480.34
5661	Therapeutic Nuclear Medicine	$237.40	$ 249.62

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Information Sources: *https://www.federalregister.gov/public-inspection/2020-26815/medicare-program-cy-2021-payment-policies-under-the-physician-fee-schedule-and-other-changes-to-part*

https://www.acr.org/-/media/ACR/Files/Advocacy/AIA/CY-2021-MPFS-Proposed-Rule-Detailed-Summary-Final.pdf

http://s3.amazonaws.com/rdcms-snmmi/files/production/public/SNMMI_HOPPS2020Fvs2021P_8-4-20.pdf

https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year-1

https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1736-fc

https://www.cms.gov/medicaremedicare-fee-service-paymentphysicianfeeschedpfs-federal-regulation-notices/cms-1734-f

2020 NCCI EDIT CONTROVERSY CREATED CONFUSION:
SNMMI Wins Change for PTPs

With the release of the 2020 NCCI edits earlier this year, the Society for Nuclear Medicine and Molecular Imaging (SNMMI) identified errors in the National Correct Coding Initiative's proposed Procedure to Procedure (PTP) edits for some new and revised codes in 2020. Then on July 6, 2020, the society along with the American College of Radiology (ACR) outlined a full list of PTP edits collected from member feedback and additional sources submitting a letter to the Centers for Medicare & Medicaid Services (CMS). CMS announced that these edits will be corrected accordingly.

Codes Adjusted

- **78472/A95120, 78802/A95470, 78804/A95210:** For these codes, a PTP modifier indicator of "0" had been proposed by CMS. The society advocated that CMS add a modifier indicator of "1," which provides an NCCI-approved modifier to bypass the edit under the proper clinical conditions. CMS agreed and approved the recommended change to modifier "1."
- 7**8802/A95700, 78804/A95690, 78804/A95700:** For these codes, CMS had proposed a PTP modifier indicator of "0" for the correlating code pairs. The society advocated for the removal of "any edits for these code pairs as these are common NM services and tracers." Per the request, CMS accepted these recommendations for the code pairs.

Expect these PTP coding changes to be retroactive to January 1, 2020, with future implementation occurring in an edit update.

In addition, in March 2020, CMS deleted the January 1, 2020, PTP edits for the codes listed below based on incorrect errors:

78306	A9521
78306	A9557
78306	A9584
78803	A9503
78803	A9512
78803	A9521
78803	A9561
78803	A9570
78803	A9584
78808	A9505
78808	A9516
78808	A9528
78808	A9540
78808	A9541

Information Sources: *hhttps://www.snmmi.org/NewsPublications/NewsDetail.aspx?ItemNumber=34648*

https://www.snmmi.org/NewsPublications/NewsDetail.aspx?ItemNumber=33353

THE RADIOPHARMACEUTICAL PAYMENT EQUITY ACT EXAMINED:
Advancing the Cause of Radiopharmaceuticals

Radiopharmaceuticals are under payment threat. During the end of January 2020, the Society of Nuclear Medicine and Molecular Imaging (SNMMI) and other renowned industry stakeholders co-hosted a congressional briefing entitled "A New Hope: Advancements in Diagnostic Imaging and Alzheimer's." Other important co-hosts included the Council on Radionuclides and Radiopharmaceuticals (CORAR), and the Medical Imaging Technology Alliance (MITA). The briefing's mission was to advocate for easier access to diagnostic radiopharmaceuticals, most notably those used for amyloid PET imaging for diagnosis while creating an educational opportunity for congressional representatives by physicians, patients, and industry agents. Of paramount importance, event speakers advocated the equal and fair payment of radiopharmaceuticals along with the passage of the Medicare Diagnostic Radiopharmaceutical Payment Equity Act of 2019 (H.R. 3772).

Understanding the MDRP Equity Act

The Medicare Diagnostic Radiopharmaceutical Payment Equity Act of 2019, was originally introduced on July 16, 2019 as a bipartisan bill sponsored by Representative Scott Peters (CA-52), George Holding (NC-2), and Bobby Rush (IL-1). The bill, which has yet to pass, originally gained popular support amongst key stakeholders including the American Society of Radiology Technologists (ASTR), SNMMI, the Medical Imaging and Technology Alliance, and the Council on Radionuclides and Radiopharmaceuticals. The bill is designed to guarantee fair Medicare payment for diagnostic radiopharmaceuticals administered in precision testing while maintaining patient access to emerging and innovative imaging procedures. Specifically, it examines the structural issues of the Medicare packing methodology. According to SNMMI, "Medicare's packaged rates for such studies are the same regardless of whether they

| The Radiopharmaceutical Payment Equity Act Examined... continued on page 4 |

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involve a high-volume, lower-cost diagnostic radiopharmaceutical or a low-volume, higher-value precision diagnostic tool that can facilitate more targeted treatment --even when the cost of the precision medicine drug can substantially exceed the entire packaged reimbursement."

Centric to the bill, H.R 3772 seeks to transform the way in which Medicare operates radiopharmaceutical reimbursement for providers by unbundling them from the overarching Medicare reimbursement applied to nuclear medicine procedures.

Even though Medicare provides separate payment for diagnostic radiopharmaceuticals as drugs in the clinician office settings, the Centers for Medicare and Medicaid Services (CMS) started acting as though diagnostic radiopharmaceuticals were supplies and bundling or "packaging" the drugs with the procedure cost for hospital outpatient settings in 2008. This method deterred many providers from using several of the radiopharmaceuticals in the Medicare hospital outpatient setting. In the analysis of advocates, this yields less patient access while discouraging and inhibiting research and innovation.

According to ASTR, *"Diagnostic radiopharmaceuticals are drugs, as defined by statute, but despite acknowledging concerns about growing patient access issues as the industry evolves, CMS has treated them as supplies and has packaged them into procedural bundles, known as Ambulatory Payment Classifications. This bundling of radiopharmaceuticals as part of the APC has proved to be problematic since diagnostic radiopharmaceutical costs may vary widely within a nuclear medicine APC and may at times exceed the complete APC payment. This translates into a strong disincentive for hospitals to utilize innovative, targeted radiopharmaceuticals, serves to discourage investment in and research for new diagnostic radiopharmaceuticals and may impede patient access to the most appropriate diagnostic tools at readily accessible health care locations."* Ultimately, the ASTR also believes that the end result could be improper diagnoses along with unsatisfactory treatment plans.

Terri Wilson, Senior Director of Patient Access and Healthcare Policy at Blue Earth Diagnostics and current Chair of the MITA PET Group expressed in a web press release that:

"Under the current Medicare Hospital Outpatient Prospective Payment System (OPPS), cutting edge, effective radiopharmaceutical drugs are inappropriately packaged, which limits patient access and discourages innovation. The Medicare Diagnostic Radiopharmaceutical Payment Equity Act of 2019 fixes this structural flaw, allowing patients much-needed access to diagnostic radiopharmaceuticals for life-threatening conditions."

The stakeholders expect that if passed, H.R. 3772 will help patients to "receive the best available nuclear medicine and molecular imaging tests leading to quick and complete diagnoses, accurate treatment plans and ultimately a successful cure for Alzheimer's disease, Parkinson's disease, cardiovascular disease, cancer, and other illnesses."

Information Sources: *http://www.snmmi.org/NewsPublications/NewsDetail.aspx?ItemNumber=33361*

https://www.medicalimaging.org/mita-news/view/mita-applauds-introduction-of-h-r-3772-the-medicare-diagnostic-radiopharmaceutical-payment-equity-act-of-2019

http://cqrcengage.com/asrt/HR3772

https://www.auntminnie.com/index.aspx?sec=sup&sub=mol&pag=dis&ItemID=128000

https://www.snmmi.org/IssuesAdvocacy/content.aspx?ItemNumber=34002

https://s3.amazonaws.com/rdcms-snmmi/files/production/public/BILLS-116hr3772ih.pdf

APPROPRIATE USE CRITERIA DELAYED:
PAMA's Penalties Hit a Halt

In light of the public health emergency (PHE), the Centers for Medicare & Medicaid Services (CMS) has suspended plans to implement the Appropriate Use Criteria (AUC) into full implementation mode. Last year on January 1, 2020, the AUC program started a one year educational and operations testing phase to give providers time to voluntarily participate and prepare. The AUC as mandated by the Protecting Access to Medicare Act (PAMA) 2014, was originally supposed to engage in full implementation on January 1, 2021. Claims which failed to meet the criteria would not be reimbursed. However, CMS announced a delay of one year, extending the testing and operations period through 2021. CMS states "there are no payment consequences associated with the AUC program during CY 2020 and CY 2021. We encourage stakeholders to use this period to learn, test and prepare for the AUC program."

AUC Regulatory Policy Review

The Protecting Access to Medicare Act (PAMA) of 2014, Section 218(b), designated a new program designed to increase the rate of appropriate ordering of advanced diagnostic imaging services for Medicare beneficiaries. The four key areas of advanced imaging services subject to this rule are:

- computed tomography (CT)
- positron emission tomography (PET)
- nuclear medicine
- magnetic resonance imaging (MRI)

CMS had stated the AUC policy applies to all the above advanced diagnostic imaging services performed in a "physician's office, hospital outpatient department (including the emergency department), an ambulatory surgical center or an independent diagnostic testing facility (IDTF) and whose claims are paid under the physician fee schedule, hospital outpatient prospective payment system or ambulatory surgical center payment system."

The program requires that when a practitioner orders an advanced diagnostic imaging service for a Medicare beneficiary, he/she, or clinical staff acting under his/her direction, are obligated to consult a qualified Clinical Decision Support Mechanism (CDSM). The assessment of AUC occurs through these CDSM electronic portals. Providers can access imaging AUC through a stand-alone CDS system or by using CDS software that is incorporated into their electronic health record system.

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The CDSM provides a determination of whether a specific order complies with AUC or if the AUC was not applicable. Not applicable means that no such AUC exists to address the patient's clinical condition.

CMS has detailed that the processing systems will accept claims containing a current Procedural Terminology (CPT) or HCPCS C-code, with a line item HCPCS modifier appended to explain either the level of compliance to AUC, or an exception to the program, along with a separate line item G-code to describe the qualified CDSM consulted.

During 2021, the program will continue as an education and operations testing period. Over the course of this period, claims will not be denied if they fail to include proper AUC consultation information per the suspension of implementation under the PHE. For 2022, the new timeline for full implementation, failure to comply will be consequential. Expect to receive zero payment on claims that fail to comply. This means that payment will be denied for the professional and technical components along with any charges billed globally.

Claims for advanced diagnostic imaging services should include:

- The ordering professional's national provider identifier (NPI)
- Which CDSM was consulted among the multiple qualified CDSMs available
- Identifying if the service ordered would or would not adhere to consulted AUC
- Or if the consulted AUC was designated as not applicable to the ordered service.

The list is subject to updates. AUC consultation is still required for all advanced diagnostic imaging services and not only those that fall under the priority clinical areas.

Information Sources: *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10481.pdf*

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AUCDiagnosticImaging-909377.pdf

https://www.acr.org/-/media/ACR/NOINDEX/AC/PAMA-CDS-Flyer.pdf

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https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program

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