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March 8, 2022

David Rice
The Centers for Medicare and Medicaid Services
Division of Outpatient Care
7500 Security Boulevard
Baltimore, MD 21244

Dear Mr. Rice,
The American College of Radiology, representing over 40,000 diagnostic, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, appreciates the opportunity to submit comments regarding the placement of new and existing CPT codes for calendar year (CY) 2023 Hospital Outpatient Prospective Payment System.

Recommendations for Newly Established CPT codes

The ACR would like to thank CMS for the opportunity to share ACR's recommendations for the placement of newly established CPT codes into appropriate APCs for CY 2023. Below, we have outlined our recommendations for Category I CPT codes 368X1 and 368X2 as well as Category III CPT codes 0X33T, +0X34T, 0X36T, 0X04T, +0X05T, 0X82T, and +0X83T.

Newly Established Category I CPT Codes

CPT Code	Long Descriptor	Predecessor Code	ACR Proposed APC Placement	ACR Proposed Payment Rate

HEADQUARTERS
1891 Preston White Drive
Reston, VA 20191
703-648-8900

GOVERNMENT RELATIONS
505 Ninth St. N.W.
Suite 910
Washington, DC 20004
202-223-1670

CENTER FOR RESEARCH AND INNOVATION
50 South 16th St., Suite 2800
Philadelphia, PA 19102
215-574-3150

AMERICAN INSTITUTE FOR RADIOLOGIC PATHOLOGY
1100 Wayne Ave., Suite 1020
Silver Spring, MD 20910
703-648-8900

368X1	Percutaneous arteriovenous fistula creation, upper extremity, single access of both the peripheral artery and peripheral vein, including fistula maturation procedures (e.g., transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation.	G2170 (Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed)	5194	$16,402.31
368X2	Percutaneous arteriovenous fistula creation, upper extremity, separate access sites of the peripheral artery and peripheral vein, including fistula maturation procedures (e.g. transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance, and radiologic supervision and interpretation.	G2171 (Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed), and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed)	5194	$16,402.31

For CY 2023, category III CPT codes G2170 and G2171 will be replaced with a category I CPT codes 368X1 and 368X2. Based on clinical similarity and resource use to the predecessor codes, the ACR is recommending that codes 368X1 and 368X2 are most appropriately placed in APC 5194 with a payment rate of $16,402.31 with a J1 status indicator.

Newly Established Category III CPT Codes

CPT Code	Long Descriptor	ACR Proposed APC Placement	ACR Proposed Payment Rate
0X33T	Quantitative ultrasound tissue characterization (non-elastographic), including interpretation and report, obtained without diagnostic ultrasound examination of the same anatomy (e.g. organ, gland, tissue, target structure)	5521	$82.61
+0X34T	Quantitative ultrasound tissue characterization (non-elastographic), including interpretation and report, obtained with diagnostic ultrasound examination of the same anatomy (e.g. organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	5521	$82.61
0X36T	Automated analysis of an existing computed tomography study for vertebral fracture(s), including assessment of bone density when performed, data preparation, interpretation, and report	5521	$82.61
0X04T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	5521	$82.61
+0X05T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (List separately in addition to code for primary procedure)	5521	$82.61
0X82T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g. organ, gland, tissue, target structure) during the same session	5521	$82.61

+0X83T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g. organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	5521	$82.61

The ACR recommends that codes 0X33T, +0X34T, 0X36T, 0X04T, +0X05T, 0X82T, and +0X83T be placed in APC 5521 (Level 1 Imaging without Contrast) with a reimbursement rate of $82.61 and a S status indicator. These codes are effective July 1, 2022, with the exception of 0X36T, which is effective January 1, 2022. We believe that APC 5521 is most appropriate because no additional imaging studies are necessary to complete the analysis and/or characterization for these codes. This reimbursement rate ensures that these services are widely available to providers and Medicare beneficiaries.

Recommendations for Existing Category III CPT Codes 0623T-0626T

The ACR strongly urges CMS to change the Medicare OPPS status indicators for category III CPT codes 0623T-0626T, as they do not reflect the current status of the technology and procedure described by the codes. We also urge CMS to assign CPT code 0625T to an appropriate New Technology APC. The lack of appropriate hospital outpatient payment for this service is impacting clinician and Medicare beneficiary access to this technology, which is useful in the diagnosis and management of coronary artery disease (CAD).

CPT codes 0623T-0626T describe *Atherosclerosis Imaging-Quantitative Computed Tomography* (AI-QCT), a Food and Drug Administration (FDA)-cleared software and service (Cleerly Labs; Cleerly, Inc.) that provides quantitation and characterization of coronary atherosclerotic plaques and stenoses by analyzing images and data from a previously acquired, and separately billable, cardiac computed tomography angiography (CCTA).[1,2] Currently, hospitals are unable to obtain reimbursement from Medicare for AI-QCT under the OPPS due to the assignment of status indicator "E1" (*Not covered by any Medicare outpatient benefit category. Statutorily excluded by Medicare. Not reasonable and necessary.*). This diagnostic information cannot be accessed without this additional analysis service over and above the conventional CCTA service and does not meet the definition of the "E1" status indicator. As with other technology-enabled services currently payable under the OPPS (e.g., FFR_{CT} codes 0501T-0504T; Quantitative MRI for tissue analysis code 0648T-0649T), these codes fall within the Part B Medicare outpatient benefit category, are not statutorily excluded by Medicare, and are reasonable and necessary for the clinically indicated patient.

While the code sets describe different services, the construct of the codes for FFR_{CT} and AI-QCT are similarly structured into four codes including a global code and three for various components of each service. Currently, the status indicators for these code sets differs. However, as the services are both

cleared or granted by the FDA and structured similarly, we request that CMS change the OPPS status indicators for 0623T-0626T to match those of 0501T-0504T:

CPT Code	Short Descriptor	Component	Current OPPS Status Indicator	Requested OPPS Status Indicator
0501T	Cor ffr derived cor cta data	FFR_{CT} Global service	M	No change
0502T	Cor ffr data prep & transmis	FFR_{CT} Data prep & transmission	N	No change
0503T	Cor ffr alys gnrj ffr mdl	FFR_{CT} Technical analysis	S	No change
0504T	Cor ffr data review i&r	FFR_{CT} Interpretation & report	M	No change
0623T	Auto quantification c plaque	AI-QCT Global service	E1	**M**
0624T	Auto quan c plaq data prep	AI-QCT Data prep & transmission	E1	**N**
0625T	Auto quan c plaq cptr alys	AI-QCT Technical analysis	E1	**S**
0626T	Auto quan c plaq i&r	AI-QCT Interpretation & report	E1	**M**

OPPS Status indicators: E1= Not covered by any Medicare outpatient benefit category. Statutorily excluded by Medicare. Not reasonable and necessary; M=Items and Services Not Billable to the MAC; N=Items and Services Packaged into APC Rates; S=Procedure or Service, Not Discounted When Multiple

The ACR also understands that Cleerly, Inc. has applied for a New Technology APC for CPT code 0625T. There is no hospital cost data available yet for this code, which went into effect in January 2021, so a New Technology APC would be appropriate at this time. We support this application and ask CMS to assign CPT code 0625T to an appropriate New Technology APC that will enable clinician and Medicare beneficiary access to the technology.

In summary, we believe the current "E1" OPPS status indicators for category III CPT codes 0623T-0626T are inappropriate and we urge the CMS to change them to match those of codes 0501T-0504T. We also urge CMS to assign HCPCS code 0625T to an appropriate New Technology APC.

The ACR looks forward to continuing to work with CMS on issues relating to APC assignment for new and existing CPT codes. For any questions, please contact Kimberly Greck (kgreck@acr.org) or Christina Berry (cberry@acr.org).

Sincerely

Norman Thomson III, MBA, M.D., FACR
Chair, ACR HOP/APC Committee

CC:
Marjorie Baldo, CMS
Christina Berry, ACR
Kimberly Greck, ACR

References

1. https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190868.pdf
2. https://www.accessdata.fda.gov/cdrh_docs/pdf20/K202280.pdf