CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 4513	**Date: February 4, 2020**
	Change Request 11605

Transmittal 4494, dated January 15, 2020, is being rescinded and replaced by Transmittal 4513, dated, February 4, 2020, 2020 to add new section 12.d.Radiopharmaceuticals with Pass-Through Status as a Result of Division N, Title I, Subtitle A, Section 107(a) of the Further Consolidated Appropriations Act of 2020 (Public Law 116-94) and new section 19.Extravascular Implantable Cardioverter Defibrillator (EV ICD). Existing sections 12.d through 12.e. were re-numbered. Old section 12.e. became section 12.f. and existing section 19.Coverage Determinations became section 20. New table 11. Radiopharmaceuticals Receiving Pass-Through Status in Accordance with Public Law 116-94 Effective January 1, 2020, and new table 14. Extravascular Implantable Cardioverter Defibrillator (EV ICD) Effective January 1, 2020, were added and existing tables 11 through 13 were re-numbered. This Transmittal is no longer sensitive. This instruction may now be posted to the Internet. All other information remains the same.

SUBJECT: January 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)

I. SUMMARY OF CHANGES: This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the January 2020 OPPS update. The January 2020 Integrated Outpatient Code Editor (I/OCE) will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this Change Request (CR). This Recurring Update Notification applies to Chapter 4, section 50.7.

The January 2020 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming January 2020 I/OCE CR.

EFFECTIVE DATE: January 1, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 6, 2020

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	4/Table of Contents
N	4/10.6.3.7/Payment Adjustment for Certain Cancer Hospitals Beginning CY 2019
N	4/10.6.3.8/Payment Adjustment for Certain Cancer Hospitals Beginning CY 2020
N	4/20.6.19/Use of HCPCS Modifier – CG
R	4/60.3/Devices Eligible for Transitional Pass-Through Payments
N	4/61.2.1/Bypass Edit Modifier “CG” for Claims on Which Specified Procedures are to be Reported With Device Codes
R	4/180.7/Inpatient-only Services

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 4513	Date: January 31, 2020	Change Request: 11605

Transmittal 4494, dated January 15, 2020, is being rescinded and replaced by Transmittal 4513, dated, February 4, 2020, 2020 to add new section 12.d.Radiopharmaceuticals with Pass-Through Status as a Result of Division N, Title I, Subtitle A, Section 107(a) of the Further Consolidated Appropriations Act of 2020 (Public Law 116-94) and new section 19.Extravascular Implantable Cardioverter Defibrillator (EV ICD). Existing sections 12.d through 12.e. were re-numbered. Old section 12.e. became section 12.f. and existing section 19.Coverage Determinations became section 20. New table 11. Radiopharmaceuticals Receiving Pass-Through Status in Accordance with Public Law 116-94 Effective January 1, 2020, and new table 14. Extravascular Implantable Cardioverter Defibrillator (EV ICD) Effective January 1, 2020, were added and existing tables 11 through 13 were re-numbered. This Transmittal is no longer sensitive. This instruction may now be posted to the Internet. All other information remains the same.

SUBJECT: January 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)

EFFECTIVE DATE: January 1, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 6, 2020

I. GENERAL INFORMATION

A. Background: This recurring update notification describes changes to and billing instructions for various payment policies implemented in the January 2020 OPPS update. The January 2020 Integrated Outpatient Code Editor (I/OCE) will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this Change Request (CR). This recurring update notification applies to chapter 4, section 50.7.

The January 2020 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming January 2020 I/OCE CR.

B. Policy:

1. a. New Device Pass-Through Categories

Section 1833(t)(6)(B) of the Social Security Act requires that, under the OPPS, categories of devices be eligible for transitional pass-through payments for at least two (2), but not more than three (3) years. Section 1833(t)(6)(B)(ii)(IV) of the Act requires that we create additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices.

We are establishing five new device pass-through categories as of January 1, 2020. Table 1, attachment A, provides a listing of new coding and payment information concerning the new device categories for transitional pass-through payment.

b. Device Offset from Payment:

Section 1833(t)(6)(D)(ii) of the Act requires that we deduct from pass-through payments for devices an amount that reflects the device portion of the APC payment amount. This deduction is known as the device offset, or the portion(s) of the APC amount that is associated with the cost of the pass-through device. The device offset from payment represents a deduction from pass-through payments for the applicable pass-through device.

i. We have determined the device offset amounts for APC 5115 (Level 5 Musculoskeletal Procedures) and APC 5116 (Level 6 Musculoskeletal Procedures) that are associated with the costs of the device category described by HCPCS code C1734 (Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)). The device in the category described by HCPCS code C1734 should always be billed with one of the following Current Procedural Terminology (CPT) codes:

- CPT code 27870 (Arthrodesis, ankle, open) which is assigned to APC 5115 for Calendar Year (CY) 2020;
- CPT code 28705 (Arthrodesis; pantalar) which is assigned to APC 5116 for Calendar Year (CY) 2020;
- CPT code 28715 (Arthrodesis; triple) which is assigned to APC 5115 for Calendar Year (CY) 2020 or;
- CPT code 28725 (Arthrodesis; subtalar) which is assigned to APC 5115 for Calendar Year (CY) 2020.

ii. We have determined the device offset amount for APC 5231 (Level 1 Implantable Cardioverter-Defibrillator (ICD) and Similar Procedures) that is associated with the cost of the device category described by HCPCS code C1824 (Generator, cardiac contractility modulation (implantable)). The device in the category described by HCPCS code C1824 should always be billed with CPT code 0408T (Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes) which is assigned to APC 5231 for Calendar Year (CY) 2020.

iii. We have determined the device offset amount for APC 5491 (Level 1Intraocular Procedures) that is associated with the cost of the device category described by HCPCS code C1839 (Iris prosthesis). The device in the category described by HCPCS code C1839 should always be billed with CPT code 66999 (Unlisted procedure, anterior segment of eye), which is assigned to APC 5491 for Calendar Year (CY) 2020.

iv. We have determined the device offset amount for APC 5193 (Level 3 Endovascular Procedures) that is associated with the cost of the device category described by HCPCS code C1982 (Catheter, pressure-generating, one-way valve, intermittently occlusive). The device in the category described by HCPCS code C1982 should always be billed with CPT Code 37243 (Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction), which is assigned to APC 5193 for Calendar Year (CY) 2020.

v. We have determined the device offset amount for APC 5376 (Level 6 Urology and Related Services) that is associated with the cost of the device category described by HCPCS code C2596 (Probe, image-guided, robotic, waterjet ablation). The device in the category described by HCPCS code C2596 should always be billed with CPT code 0421T (Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibrationand/or dilation, and internal urethrotomy are included when performed)), which is assigned to APC 5376 for Calendar Year (CY) 2020.

Also, refer to https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html for the most current device pass-through information.

c. Transitional Pass-Through Payments for Designated Devices

Certain designated new devices are assigned to APCs and identified by the I/OCE as eligible for payment based on the reasonable cost of the new device reduced by the amount included in the APC for the procedure that reflects the packaged payment for device(s) used in the procedure. The I/OCE will determine the proper payment amount for these APCs as well as the coinsurance and any applicable deductible. All

related payment calculations will be returned on the same APC line and identified as a designated new device. We refer readers to Addendum P of the CY 2020 final rule with comment period for the most current OPPS HCPCS Offset file. Addendum P is available via the Internet on the CMS website.

d. Alternative Pathway for Devices That Have a Food and Drug Administration (FDA) Breakthrough Designation

For devices that have received FDA marketing authorization and a Breakthrough Device designation from the FDA, CMS provided an alternative pathway to qualify for device pass-through payment status, under which devices would not be evaluated in terms of the current substantial clinical improvement criterion for the purposes of determining device pass-through payment status. The devices would still need to meet the other criteria for pass-through status. This applies to devices that receive pass-through payment status effective on or after January 1, 2020.

2. New Separately Payable Procedure Codes

a. Medical Procedures

Effective January 1, 2020, new HCPCS codes C9757 and C9758 have been created as described in Table 2, attachment A.

b. Blood Products

Effective January 1, 2020, new HCPCS code P9099 has been created as described in Table 3, attachment A.

3. Billing for Devices Under the OPPS

Effective for dates of service beginning on or after January 1, 2019, providers may bypass the claims processing edit that requires a device HCPCS for the procedure. For certain device-intensive procedures that describe situations in which a device may not be required, providers may bypass the claims processing edits that require a device by reporting modifier “CG”. In light of this policy change, we are modifying section 61.2 of chapter 4 of the Medical Claims Processing Manual, publicatioin100-04.

4. Comprehensive APCs (C-APCs)

a. Two New Comprehensive APCs (C-APCs) Effective January 1, 2020

Comprehensive APCs provide a single payment for a primary service, and payment for all adjunctive services reported on the same claim is packaged into payment for the primary service. With a few exceptions, all other services reported on a hospital outpatient claim in combination with the primary service are considered to be related to the delivery of the primary service and packaged into the single payment for the primary service.

Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As stated in the CY 2020 OPPS/ASC final rule with comment period, as a result of our annual review of the services and the APC assignments under the OPPS, we finalized the addition of two new C-APCs under the existing C-APC payment policy effective January 1, 2020. The new C-APCs that are effective January 1, 2020, include:

- C-APC 5182 (Level 2 Vascular Procedures) and
- C-APC 5461 (Level 1 Neurostimulator and Related Procedures).

A list of these new C-APCs is found in Table 4, attachment A. The addition of these new C-APCs increases the total number of C-APCs to 67 for CY 2020. We note that Addendum J to the CY 2020 OPPS/ASC final

rule with comment period contains all of the data related to the C–APC payment policy methodology, including the list of complexity adjustments and other information for CY 2019. In addition, we note that HCPCS codes assigned to comprehensive APCs are designated with status indicator "J1" in the latest OPPS Addendum B, which can be downloaded from this CMS website, specifically, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html.

b. Exclusion of Procedures Assigned to New Technology APCs from the C-APC Policy

For CY 2020, we finalized a policy to continue to exclude payment for any procedure that is assigned to a New Technology APC from being packaged when included on a claim with a "J1" service assigned to a C-APC. We also finalized a policy to exclude payment for any procedures that are assigned to a New Technology APC from being packaged into the payment for comprehensive observation services (C-APC 8011) assigned to status indicator "J2" when the New Technology procedures are included on a claim with "J2" procedures. We note that HCPCS codes assigned to comprehensive APCs are designated with status indicator "J1" or "J2" in the latest OPPS Addendum B, which can be downloaded from this CMS website, specifically, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html. Further information on C-APC 8011 (Comprehensive Observation Services) can be found in the CY 2020 OPPS/ASC final rule with comment period.

5. Changes to the Inpatient – Only list (IPO) for CY 2020

The Medicare Inpatient-Only (IPO) list includes procedures that are typically only provided in the inpatient setting and therefore are not paid under the OPPS. For CY 2020, CMS is removing 11 procedures from the IPO list. The changes to the IPO list for CY 2020 are included in Table 5, attachment A.

6. Changes to Medical Review for Certain Inpatient Hospital Admissions under Medicare Part A

For CY 2020 and subsequent years, we finalized a policy to exempt procedures that have been removed from the Inpatient-Only (IPO) list from certain medical review activities related to compliance with the 2-midnight rule, which states that generally services are considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation (78 FR 50913 through 50954).

Specifically, procedures that have been removed from the IPO list are not eligible for referral to Recovery Audit Contractors (RACs) for noncompliance with the 2-midnight rule within the 2-calendar years following their removal from the IPO list. These procedures will not be considered by the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) in determining whether a provider exhibits persistent noncompliance with the 2-midnight rule for purposes of referral to the RAC nor will these procedures be reviewed by RACs for "patient status" within the 2-calendar years following their removal from the IPO list. During this 2-year period, BFCC-QIOs will have the opportunity to review claims for procedures that have been recently removed from the IPO list in order to provide education for practitioners and providers regarding compliance with the 2-midnight rule, but claims identified as noncompliant with the 2-midnight rule will not be denied with respect to the site-of-service under Medicare Part A.

7. Supervision of Outpatient Therapeutic Services

The generally applicable minimum required level of supervision for hospital outpatient therapeutic services will change on January 1, 2020, from direct supervision to general supervision for services furnished by all hospitals and Critical Access Hospitals (CAHs). General supervision is defined in regulation at 42 Code of Federal (CFR) 410.32(b)(3)(i) to mean that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure. All of the policy safeguards that have been in place to ensure the safety, health, and quality standards of the

outpatient therapeutic services that beneficiaries receive will continue to be in place under our new policy. These safeguards include allowing providers and physicians the discretion to require a higher level of supervision to ensure a therapeutic outpatient procedure is performed without risking a beneficiary's safety or their quality of the care, as well as the presence of outpatient hospital and CAH Conditions of Participation (CoPs), and other state and federal laws and regulations.

Additionally, as we noted in the CY 2020 OPPS final rule, establishing general supervision as the default level of physician supervision for outpatient therapeutic services does not prevent a hospital or CAH from requiring a higher level of supervision for a particular service if they believe such a supervision level is necessary. Providers and physicians have flexibility to require a higher level of physician supervision for any service they furnish if they believe a higher level of supervision is required to ensure the quality and safety of the procedure and to protect a beneficiary from complications that might occur.

8. Method to Control for Unnecessary Increases in Utilization of Outpatient Services/G0463 with Modifier PO

For CY 2020, CMS had finalized a policy to use our authority under section 1833(t)(2)(F) of the Act to apply an amount equal to the site-specific Physician Fee Schedule (PFS) payment rate for nonexcepted items and services furnished by a nonexcepted off-campus Provider-Based Department (PBD) (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier "PO" on claim lines).

The PFS-equivalent amount paid to nonexcepted off-campus PBDs is 40 percent of OPPS payment (that is, 60 percent less than the OPPS rate) for CY 2020. We are completing the phase-in of the policy in CY 2020.

Specifically, the total 60-percent payment reduction will apply in CY 2020. In other words, these departments will be paid 40 percent of the OPPS rate (100 percent of the OPPS rate minus the 60-percent payment reduction that applies in CY 2020) for the clinic visit service in CY 2020.

9. Partial Hospitalization Program (PHP)

Final Updates to PHP Allowable HCPCS Codes

In the CY 2019 OPPS/ASC final rule with comment period, we proposed to delete 6 existing PHP allowable HCPCS codes (96101, 96102, 96103, 96118, 96119, 96120) and to replace them with 9 new PHP allowable codes (96130, 96131, 96132, 96133, 96136, 96137, 96138, 96139, 96146) for APCs 5853 and 5863, as of January 1, 2019, as detailed in Table 6, attachment A. In the CY 2020 OPPS/ASC final rule with comment period, we finalized those deletions and additions as proposed, effective January 1, 2019.

10. Payment Adjustment for Certain Cancer Hospitals Beginning CY 2020

For certain cancer hospitals that receive interim monthly payments associated with the cancer hospital adjustment at 42 CFR 419.43(i), Section 16002(b) of the 21st Century Cures Act requires that, for CY 2018 and subsequent calendar years, the target Payment-to-Cost Ratio (PCR) that should be used in the calculation of the interim monthly payments and at final cost report settlement is reduced by 0.01. For CY 2020, the target PCR, after including the reduction required by Section 16002(b), is 0.89.

11. Clarification on the Termination Date for CPT Code 3045F and the Effective Date of Its Replacement Codes 3051F and 3052F

In the October 2019 Update of the Hospital Outpatient Prospective Payment System (OPPS), specifically, Transmittal 4411, Change Request 11451, dated October 4, 2019, we stated that CPT code 3045F was deleted on September 30, 2019, and replaced with CPT codes 3051F and 3052F effective October 1, 2019. However, the American Medical Association (AMA) recently clarified in its Category II Codes document dated November 14, 2019, that the effective date of the deletion date for CPT code 3045F is January 1,

2020, and that the effective date of its replacement codes, specifically, CPT code 3051F and 3052F, is effective January 1, 2020. Table 7, attachment A, lists the long descriptors and status indicators for the codes. Refer to Addendum D1 of the CY 2020 OPPS/ASC final rule with comment period for the complete list of the OPPS payment status indicators and their definitions for CY 2020. Addendum D1 is available via the internet on the CMS website.

12. Drugs, Biologicals, and Radiopharmaceuticals

a. New CY 2020 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals

For CY 2020, several new HCPCS codes have been created for reporting drugs and biologicals in the hospital outpatient setting, where there have not previously been specific codes available. These new codes are listed in Table 8, attachment A.

b. Other Changes to CY 2019 HCPCS and CPT Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals

Many HCPCS and CPT codes for drugs, biologicals, and radiopharmaceuticals have undergone changes in their HCPCS and CPT code descriptors that will be effective in CY 2020. In addition, several temporary HCPCS C-codes have been deleted effective December 31, 2019 and replaced with permanent HCPCS codes effective in CY 2020. Hospitals should pay close attention to accurate billing for units of service consistent with the dosages contained in the long descriptors of the active CY 2020 HCPCS and CPT codes. Table 9, attachment A, notes those drugs, biologicals, and radiopharmaceuticals that have undergone changes in their HCPCS/CPT code, their long descriptor, or both. Each product's CY 2019 HCPCS/CPT code and long descriptor is noted in the two left hand columns and the CY 2020 HCPCS/CPT code and long descriptor is noted in the adjacent right hand columns.

c. Drugs and Biologicals that Will Change from Non-Payable Status (Status Indicator "E2") to Separately Payable Status (Status Indicator "K")

The status indicator for HCPCS code Q5115 (Injection, rituximab-abbs, biosimilar, (truxima), 10 mg) will be changed retroactively from status indicator"E2" to status indicator "K", effective November 11, 2019, in the January 2020 I/OCE. The status indicator for HCPCS code Q5114 (Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg) will be changed retroactively from status indicator "E2" to status indicator "K", effective November 29, 2019. These drugs are reported in Table 10, attachment A.

d. Radiopharmaceuticals with Pass-Through Status as a Result of Division N, Title I, Subtitle A, Section 107(a) of the Further Consolidated Appropriations Act of 2020 (Public Law 116-94)

Division N, Title I, Subtitle A, Section 107(a) of the Further Consolidated Appropriations Act of 2020 amended section 1833(t)(6) of the Social Security Act and added a new section 1833(t)(6)(J), which provides that, for a drug or biological furnished in the context of a clinical study on diagnostic imaging tests approved under a coverage with evidence development determination whose period of pass-through status under this paragraph concluded on December 31, 2018, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2019, such pass-through status shall be extended for a 9-month period beginning on January 1, 2020, through September 30, 2020.

There are two diagnostic radiopharmaceuticals covered by this provision: Q9982 (Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries) and Q9983 (Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries). These two diagnostic radiopharmaceuticals will have pass-through status reinstated effective January 1, 2020. These diagnostic radiopharmaceuticals are reported in Table 11, attachment A.

We note that because these diagnostic radiopharmaceuticals were previously packaged under the CY 2020 OPPS, their costs would have been included in the calculation of the geometric mean costs of the procedure codes and associated APCs with which they were performed. Based on the changes made by the Further Consolidated Appropriations Act of 2020, and corresponding status indicator changes to Q9982 and Q9983, we have updated the OPPS to reflect these changes. The only affected APC is APC 5594 (Level 4 Nuclear Medicine and Related Services) which previously had a national unadjusted payment rate of $1,443.16 and, after the removal of the packaged costs associated with HCPCS codes Q9982 and Q9983, now has a national unadjusted payment rate of $1,443.09. For more information, please see the updated Addendum A and B.

e. Drugs and Biologicals with Payments Based on Average Sales Price (ASP)

For CY 2020, payment for nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals that were not acquired through the 340B Program is made at a single rate of ASP + 6 percent (or ASP + 6 percent of the reference product for biosimilars). Payment for nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals that were acquired under the 340B program is made at the single rate of ASP – 22.5 percent (or ASP - 22.5 percent of the biosimilar’s ASP if a biosimilar is acquired under the 340B Program), which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological or therapeutic radiopharmaceutical. In CY 2020, a single payment of ASP + 6 percent for pass-through drugs, biologicals and radiopharmaceuticals is made to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items (or ASP + 6 percent of the reference product for biosimilars). Payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available. Effective January 1, 2020, payment rates for many drugs and biologicals have changed from the values published in the CY 2020 OPPS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from the third quarter of CY 2019. In cases where adjustments to payment rates are necessary, changes to the payment rates will be incorporated in the January 2020 FISS release. CMS is not publishing the updated payment rates in this Change Request implementing the January 2020 update of the OPPS. However, the updated payment rates effective January 1, 2020 can be found in the January 2020 update of the OPPS Addendum A and Addendum B on the CMS website at http://www.cms.gov/HospitalOutpatientPPS/.

f. Drugs and Biologicals Based on ASP Methodology with Restated Payment Rates

Some drugs and biologicals based on ASP methodology will have payment rates that are corrected retroactively. These retroactive corrections typically occur on a quarterly basis. The list of drugs and biologicals with corrected payments rates will be accessible on the CMS website on the first date of the quarter at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/OPPS-Restated-Payment-Rates.html.

Providers may resubmit claims that were impacted by adjustments to previous quarter’s payment files.

13. Skin Substitutes

a. Reassignment of Skin Substitute Products from the Low Cost Group to the High Cost Group

One skin substitute product, HCPCS code Q4208, has been reassigned from the low cost skin substitute group to the high cost skin substitute group based on updated pricing information. The product is listed in Table 12, attachment A.

b. Skin Substitute Procedure Edits

The payment for skin substitute products that do not qualify for pass-through status will be packaged into the payment for the associated skin substitute application procedure. The skin substitute products are divided into two groups: 1) high cost skin substitute products and 2) low cost skin substitute products for packaging purposes. Table 13, attachment A, lists the skin substitute products and their assignment as either a high cost

or a low cost skin substitute product, when applicable.

14. Changes to OPPS Pricer Logic

a. Rural Sole Community Hospitals (SCH) and Essential Access Community Hospitals (EACHs) will continue to receive a 7.1 percent payment increase for most services in CY 2020. The rural SCH and EACH payment adjustment excludes drugs, biologicals, items and services paid at charges reduced to cost, and items paid under the pass-through payment policy in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).

b. New OPPS payment rates and copayment amounts will be effective January 1, 2020. All copayment amounts will be limited to a maximum of 40 percent of the APC payment rate. Copayment amounts for each service cannot exceed the CY 2020 inpatient deductible of $1,408. For most OPPS services, copayments are set at 20 percent of the APC payment rate.

c. For hospital outlier payments under OPPS, there will be no change in the multiple threshold of 1.75 for 2019. This threshold of 1.75 is multiplied by the total line-item APC payment to determine eligibility for outlier payments. This factor also is used to determine the outlier payment, which is 50 percent of estimated cost less 1.75 times the APC payment amount. The payment formula is (cost-(APC payment x1.75))/2.

d. The fixed-dollar threshold for OPPS outlier payments increases in CY 2020 relative to CY 2019. The estimated cost of a service must be greater than the APC payment amount plus $5,075 in order to qualify for outlier payments.

e. For outliers for Community Mental Health Centers (bill type 76x), there will be no change in the multiple threshold of 3.4 for 2019. This threshold of 3.4 is multiplied by the total line-item APC payment for APC 5853 to determine eligibility for outlier payments. This multiple amount is also used to determine the outlier payment, which is 50 percent of estimated costs less 3.4 times the APC payment amount. The payment formula is (cost-(APC 5853 payment x3.4))/2.

f. Continuing our established policy for CY 2020, the OPPS Pricer will apply a reduced update ratio of 0.981 to the payment and copayment for hospitals that fail to meet their hospital outpatient quality data reporting requirements or that fail to meet CMS validation edits. The reduced payment amount will be used to calculate outlier payments.

g. Effective January 1, 2020, CMS is adopting the Fiscal Year (FY) 2020 Inpatient Prospective Payment System (IPPS) post-reclassification wage index values with application of the CY 2020 out-commuting adjustment authorized by Section 505 of the MMA to non- IPPS (non-Inpatient Prospective Payment System) hospitals as implemented through the Pricer logic.

h. Effective January 1, 2020, for claims with APCs, which require implantable devices and have significant device offsets (greater than 30%), a device offset cap will be applied based on the credit amount listed in the "FD" (Credit Received from the Manufacturer for a Replaced Medical Device) value code. The credit amount in value code "FD" which reduces the APC payment for the applicable procedure, will be capped by the device offset amount for that APC. The offset amounts for the above referenced APCs are available on the CMS website.

15. Update the Outpatient Provider Specific File (OPSF)

For January 1, 2020, contractors shall maintain the accuracy of the provider records in the Outpatient Provider Specific File (OPSF) as changes occur in data element values.

a) Updating the OPSF for Expiration of Transitional Outpatient Payments (TOPs)

Cancer and children's hospitals are held harmless under section 1833(t)(7)(D)(ii) of the Social Security Act and continue to receive hold harmless TOPs permanently. For CY 2020, cancer hospitals will continue to receive an additional payment adjustment.

b) Updating the OPSF for the Hospital Outpatient Quality Reporting (HOQR) Program Requirements

Effective for OPPS services furnished on or after January 1, 2009, subsection (d) hospitals that have failed to submit timely hospital outpatient quality data as required in Section 1833(t)(17)(A) of the Act will receive payment under the OPPS that reflects a 2 percentage point deduction from the annual OPPS update for failure to meet the HOQR program requirements. This reduction will not apply to hospitals not required to submit quality data or hospitals that are not paid under the OPPS.

For January 1, 2020, contractors shall maintain the accuracy of the provider records in the OPSF by updating the Hospital Quality Indicator field. CMS will release a Technical Direction Letter that lists Subsection (d) hospitals that are subject to and fail to meet the HOQR program requirements. Once this list is released, A/B Medicare Administrative Contractors (MACs) will update the OPSF by removing the '1', (that is, ensure that the Hospital Quality Indicator field is blank) for all hospitals identified on the list and will ensure that the OPSF Hospital Quality Indicator field contains '1' for all hospitals that are not on the list. CMS notes that if these hospitals are later determined to have met the HOQR program requirements, A/B MACs shall update the OPSF. For greater detail regarding updating the OPSF for the HOQR program requirements, see Transmittal 368, CR 6072, issued on August 15, 2008.

c) Updating the OPSF for Cost to Charge Ratios (CCR)

As stated in publication 100-04, Medicare Claims Processing Manual, chapter 4, section 50.1, contractors must maintain the accuracy of the data and update the OPSF as changes occur in data element values, including changes to provider cost–to-charge ratios and, when applicable, device department cost-to-charge ratios. The file of OPPS hospital upper limit CCRs and the file of Statewide CCRs are located on the CMS website at www.cms.gov/HospitalOutpatientPPS/ under "*Annual Policy Files*."

d) Updating the "County Code" Field

Prior to CY 2018, in order to include the outmigration in a hospital's wage index, we provided a separate table that assigned wage indexes for hospitals that received the outmigration adjustment. For the CY 2020 OPPS, the OPPS Pricer will continue to assign the out migration adjustment using the "County Code" field in the OPSF. Therefore, MACs shall ensure that every hospital has listed in the "County Code" field the Federal Information Processing Standards (FIPS) county code where the hospital is located to maintain the accuracy of the OPSF data fields.

e) Updating the "Wage Index Location Core-Based Statistical Areas (CBSA)" Field

We note that under historical and current OPPS wage index policy, hospitals that have wage index reclassifications for wage adjustment purposes under the IPPS would also have those wage index reclassifications applied under the OPPS on a calendar year basis. Therefore, MACs shall ensure that wage index reclassifications applied under the FY 2020 IPPS are also reflected in the OPSF on a CY 2020 OPPS basis.

f) Updating the "Payment Core-Based Statistical Areas (CBSA)" Field

In the prior layout of the OPSF, there were only two CBSA related fields: the "Actual Geographic Location CBSA" and the "Wage Index Location CBSA." These fields are used to wage adjust OPPS payment through the Pricer if there is not an assigned Special Wage Index (as has been used historically to assign the wage index for hospitals receiving the outmigration adjustment).

In Transmittal 3750, dated April 19, 2017, for Change Request 9926, we created an additional field for the "Payment CBSA," similar to the IPPS, to allow for consistency between the data in the two systems and identify when hospitals receive dual reclassifications. In the case of dual reclassifications, similar to the IPPS, the "Payment CBSA" field will be used to note the Urban to Rural Reclassification Under Section 1886(d)(8)(E) of the Act (§ 412.103). This "Payment CBSA" field is not used for wage adjustment purposes, but to identify when the 412.103 reclassification applies, because rural status is considered for rural sole community hospital adjustment eligibility. We further note that whereas the IPPS Pricer allows the Payment CBSA, even when applied as the sole CBSA field (without a Wage Index CBSA), to be used for wage adjusting payment, that field is not used for wage adjustment the OPPS.

16. Wage Index Policies in the CY 2020 OPPS

In the FY 2020 IPPS and CY 2020 IPPS we made the following changes to the wage index: we removed urban to rural reclassifications from the calculation of the rural floor, increased the wage index values for hospitals with a wage index value below the 25th percentile wage index value of 0.8457 across all hospitals, and applied a 5 percent cap for CY 2020 on any wage index values that decreased relative to CY 2019.

17. Imaging Cost-to-Charge Ratios

Since CY 2014, we have utilized a transitional policy to remove claims from providers that use a cost allocation method of ''square feet'' to calculate CCRs used to estimate costs associated with the APCs for Computerized Tomography (CT) and Magnetic Resonance Imaging (MRI). For CY 2020, we are implementing the first year of our two-year phased-in approach to end this transitional policy and include CT and MRI cost report data from all providers, regardless of cost allocation methodology. For CY 2020, we calculated the imaging payment rates under the transitional policy of excluding providers that use a "square feet" cost allocation method and under the standard methodology of including CT and MRI cost data from all providers, regardless of cost allocation method. For CY 2020, we are assigning the imaging APCs a payment rate that includes data representing 50 percent of the transition methodology payment rate and includes data representing 50 percent of the standard methodology payment rate. Beginning CY 2021, we will set the imaging APC payment rates at 100 percent of the payment rate using the standard payment methodology.

18. Correction to the Deductible and Coinsurance for HCPCS Code, G0404

While updating the list of preventive services for which coinsurance and/or the deductible is waived, we inadvertently included HCPCS code G0404 (Electrocardiogram, routine ECG with 12 leads; tracing only, without interpretation and report, performed as a screening for the initial preventive physical examination). In accordance with the requirements in section 4104 of the Affordable Care Act and the definitions/exclusions of preventive services described in 42 CFR 410.2, we are applying coinsurance and/or the deductible to HCPCS code G0404 in the CY 2020 OPPS.

19. Extravascular Implantable Cardioverter Defibrillator (EV ICD)

In the CY 2020 OPPS/ASC final rule that was published in the Federal Register on November 12, 2019, we stated that CPT codes 0571T through 0580T, which were effective January 1, 2020, would be assigned to OPPS status indicator "E1" to indicate that the codes are not payable by Medicare because the clinical trial associated with the codes has not met Medicare's standards for coverage. We further stated that if Medicare approved the EV ICD clinical trial for coverage, we would reassess the SI and APC assignments for the codes. Since the publication of the CY 2020 OPPS/ASC final rule, the EV ICD clinical study was approved by CMS for Medicare coverage on December 4, 2019 as a Category B IDE study. Therefore, we have revised the OPPS status indicator and APC assignments for the codes for the January 2020 update. Table 14 shows the status indicator and APC assignments for CPT codes 0571T through 0580T. The payment rates for CPT codes 0571T through 0580T can be found in Addendum B of the January 2020 OPPS Update that is posted on the CMS website.

20. Coverage Determinations

As a reminder, the fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, MACs determine that it is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
11605 - 04.1	Medicare contractors shall install the January 2020 OPPS Pricer.	X		X		X				
11605 - 04.2	Medicare contractors shall manually change the effective date of CPT codes 3051F and 3052F from October 1, 2019 to January 1, 2020 in their systems.	X		X						
11605 - 04.3	Medicare contractors shall adjust, as appropriate, claims brought to their attention with any retroactive changes that were received prior to implementation of January 2020 OPPS Pricer.	X		X						
11605 - 04.4	As specified in chapter 4, section 50.1, of the Claims Processing Manual, Medicare contractors shall maintain the accuracy of the data and update the OPSF file as changes occur in data element values. For CY 2020, this includes all changes to the OPSF identified in Section 15 of this Change Request.	X		X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
11605 - 04.5	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09	X		X		

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Marina Kushnirova, marina.kushnirova@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 1

Attachment A − Tables for the Policy Section

Table 1. – New Device Pass-Through Codes Effective January 1, 2020

HCPCS Code	Effective Date	SI	APC	Short Descriptor	Long Descriptor	Device Offset from Payment
C1734	1/01/2020	H	2026	Orth/devic/drug bn/bn,tis/bn	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	CPT 27870 - $5,805.17 CPT 28705 - $8,354.15 CPT 28715 – $6,096.73 CPT 28725 – $5,291.06
C1824	01/01/2020	H	2024	Generator, CCM, implant	Generator, cardiac contractility modulation (implantable)	$13,019.03
C1839	01/01/2020	H	2028	Iris prosthesis	Iris prosthesis	$149.82
C1982	01/01/2020	H	2025	Cath, pressure,valve-occlu	Catheter, pressure-generating, one-way valve, intermittently occlusive	$2124.38
C2596	01/01/2020	H	2027	Probe, robotic, water-jet	Probe, image-guided, robotic, waterjet ablation	$0.00

Table 2. – New Separately Payable Procedure Codes for Medical Procedures Effective January 1, 2020

HCPCS Code	Short Descriptor	Long Descriptor	APC	SI
C9757	Spine/lumbar disk surgery	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and	5115	J1

		repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar		
C9758	Interatrial shunt ide	Blinded procedure for nyha class iii/iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study	1589	T

Table 3. – New Procedure Codes for Blood Products Effective January 1, 2020

HCPCS Code	Short Descriptor	Long Descriptor	APC	SI
P9099	Blood component/product noc	Blood component or product not otherwise classified	N/A	E2

Table 4. — New Comprehensive APCs for CY 2020

CY 2020 APC	CY 2020 APC Descriptor
5182	Level 2 Vascular Procedures
5461	Level 1 Neurostimulator and Related Procedures

Table 5. — Changes to the IPO list for CY 2020

CY 2020 CPT Code	CY 2020 Long Descriptor	Final Action	CY 2020 OPPS APC Assignment	CY 2020 OPPS Status Indicator
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty) with or without autograft or allograft	Remove from the IPO	5115	J1
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/ or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar;	Remove from the IPO	5115	J1

CY 2020 CPT Code	CY 2020 Long Descriptor	Final Action	CY 2020 OPPS APC Assignment	CY 2020 OPPS Status Indicator
22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; each additional interspace and segment (list separately in addition to code for primary procedure)	Remove from the IPO	N/A	N
63265	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical	Remove from the IPO	5114	J1
63266	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; thoracic	Remove from the IPO	5114	J1
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar	Remove from the IPO	5114	J1
63268	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; sacral	Remove from the IPO	5114	J1
00802	Anesthesia for procedures on lower anterior abdominal wall; panniculectomy	Remove from the IPO	N/A	N
00865	Anesthesia for extraperitoneal procedures in lower abdomen, including urinary tract; radical prostatectomy (suprapubic, retropubic)	Remove from the IPO	N/A	N
00944	Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); vaginal hysterectomy	Remove from the IPO	N/A	N
01214	Anesthesia for open procedures involving hip joint; total hip arthroplasty	Remove from the IPO	N/A	N

Table 6. — Final Changes to the Allowable HCPCS Codes for PHP APCs 5853 & 5863

Existing Code	Final Action	Final Replacement(s) Codes	Final APC Action
96101	Delete	96130, 96131, and may also include 96136, 96137, 96138, 96139, 96146	Add
96102	Delete	96130, 96131, and may also include 96136, 96137, 96138, 96139, 96146	Add
96103	Delete	96130, 96131, and may also include 96136 96137, 96138, 96139, 96146	Add
96118	Delete	96132, 96133, and may also include 96136, 96137, 96138, 96139, 96146	Add
96119	Delete	96132, 96133, and may also include 96136, 96137, 96138, 96139, 96146	Add
96120	Delete	96132, 96133, and may also include 96136, 96137, 96138, 96139, 96146	Add

Table 7. — Status Indicators and Long Descriptors for 3045F, 3051F, and 3052F, Effective January 1, 2020

CPT Code	Long Descriptor	January 2020 OPPS

		SI
3045F	Most recent hemoglobin a1c (hba1c) level 7.0-9.0% (dm)	D
3051F	Most recent hemoglobin a1c (hba1c) level greater than or equal to 7.0% and less than 8.0% (dm)	E1
3052F	Most recent hemoglobin a1c (hba1c) level greater than or equal to 8.0% and less than or equal to 9.0% (dm)	E1

Table 8. ─ New CY 2020 HCPCS Codes Effective for Certain Drugs, Biologicals, and Radiopharmaceuticals

CY 2020 HCPCS Code	CY 2020 Long Descriptor	CY 2020 SI	CY 2020 APC
C9054	Injection, lefamulin (xenleta), 1 mg	G	9332
C9055	Injection, brexanolone, 1mg	G	9333
J0179	Injection, brolucizumab-dbll, 1 mg	K	9340
J0642	Injection, levoleucovorin (khapzory), 0.5 mg	G	9334
J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	K	9337
J7332	Hyaluronan or derivative, triluron, for intra-articular injection, 1 mg	K	9338
J9199	Injection, gemcitabine hydrochloride (infugem), 200 mg	N	N/A
J9309	Injection, polatuzumab vedotin-piiq, 1 mg	G	9331
Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg	K	9341
Q5115	Injection, rituximab-abbs, biosimilar, (truxima), 10 mg	K	9336

Table 9. ─ Other CY 2020 HCPCS and CPT Code Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals

CY 2019 HCPCS Code	CY 2019 Long Descriptor	CY 2020 HCPCS Code	CY 2020 Long Descriptor
C9407	Iodine i-131 iobenguane, diagnostic, 1 millicurie	A9590	Iodine i-131, iobenguane, 1 millicurie
C9408	Iodine i-131 iobenguane, therapeutic, 1 millicurie	A9590	Iodine i-131, iobenguane, 1 millicurie

Table 10. – Drugs and Biologicals with a Retroactive Change in Status Indictor

HCPCS Code	Long Descriptor	Old SI	New SI	APC	Effective Date
Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg	E2	K	9341	11/29/2019
Q5115	Injection, rituximab-abbs, biosimilar, (truxima), 10 mg	E2	K	9336	11/11/2019

Table 11. ─ Radiopharmaceuticals Receiving Pass-Through Status

in Accordance with Public Law 116-94 Effective January 1, 2020

CY 2020 HCPCS Code	CY 2020 Long Descriptor	CY 2020 SI	CY 2020 APC
Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459
Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	G	9458

Table 12. – Reassignment of Skin Substitute Product from the Low Cost Group to the High Cost Group Effective January 1, 2020

CY 2020 HCPCS Code	CY 2020 Short Descriptor	CY 2020 SI	Low/High Cost Skin Substitute
Q4208	Novafix per sq cm	N	High

Table 13. – Skin Substitute Assignments to High Cost and Low Cost Groups for CY 2020

CY 2020 HCPCS Code	CY 2020 Short Descriptor	CY 2019 High/Low Cost Assignment	CY 2020 High/Low Cost Assignment
C9363	Integra meshed bil wound mat	High	High
Q4100	Skin substitute, nos	Low	Low
Q4101	Apligraf	High	High
Q4102	Oasis wound matrix	Low	Low
Q4103	Oasis burn matrix	High	High
Q4104	Integra bmwd	High	High
Q4105	Integra drt or omnigraft	High	High
Q4106	Dermagraft	High	High
Q4107	Graftjacket	High	High
Q4108	Integra matrix	High	High*
Q4110	Primatrix	High	High*
Q4111	Gammagraft	Low	Low
Q4115	Alloskin	Low	Low
Q4116	Alloderm	High	High
Q4117	Hyalomatrix	Low	Low
Q4121	Theraskin	High	High*
Q4122	Dermacell, awm, porous sq cm	High	High
Q4123	Alloskin	High	High*
Q4124	Oasis tri-layer wound matrix	Low	Low

CY 2020 HCPCS Code	CY 2020 Short Descriptor	CY 2019 High/Low Cost Assignment	CY 2020 High/Low Cost Assignment
Q4126	Memoderm/derma/tranz/integup	High	High
Q4127	Talymed	High	High
Q4128	Flexhd/allopatchhd/matrixhd	High	High
Q4132	Grafix core, grafixpl core	High	High
Q4133	Grafix stravix prime pl sqcm	High	High
Q4134	Hmatrix	Low	Low
Q4135	Mediskin	Low	Low
Q4136	Ezderm	Low	Low
Q4137	Amnioexcel biodexcel 1sq cm	High	High
Q4138	Biodfence dryflex, 1cm	High	High
Q4140	Biodfence 1cm	High	High
Q4141	Alloskin ac, 1cm	High	High*
Q4143	Repriza, 1cm	High	High
Q4146	Tensix, 1cm	High	High
Q4147	Architect ecm px fx 1 sq cm	High	High
Q4148	Neox neox rt or clarix cord	High	High
Q4150	Allowrap ds or dry 1 sq cm	High	High
Q4151	Amnioband, guardian 1 sq cm	High	High
Q4152	Dermapure 1 square cm	High	High
Q4153	Dermavest, plurivest sq cm	High	High
Q4154	Biovance 1 square cm	High	High
Q4156	Neoxflo or clarixflo 1 mg	High	High
Q4157	Revitalon 1 square cm	High	High*
Q4158	Kerecis omega3, per sq cm	High	High*
Q4159	Affinity1 square cm	High	High
Q4160	Nushield 1 square cm	High	High
Q4161	Bio-connekt per square cm	High	High
Q4163	Woundex, bioskin, per sq cm	High	High
Q4164	Helicoll, per square cm	High	High*
Q4165	Keramatrix, kerasorb sq cm	Low	Low
Q4166	Cytal, per square centimeter	Low	Low
Q4167	Truskin, per sq centimeter	Low	Low
Q4169	Artacent wound, per sq cm	High	High

CY 2020 HCPCS Code	CY 2020 Short Descriptor	CY 2019 High/Low Cost Assignment	CY 2020 High/Low Cost Assignment
Q4170	Cygnus, per square cm	Low	Low
Q4173	Palingen or palingen xplus	High	High
Q4175	Miroderm	High	High
Q4176	Neopatch, per sq centimeter	High	High
Q4178	Floweramniopatch, per sq cm	High	High
Q4179	Flowerderm, per sq cm	High	High
Q4180	Revita, per sq cm	High	High
Q4181	Amnio wound, per square cm	High	High*
Q4182	Transcyte, per sq centimeter	Low	Low
Q4183	Surgigraft, 1 sq cm	High	High*
Q4184	Cellesta or duo per sq cm	High	High*
Q4186	Epifix 1 sq cm	High	High
Q4187	Epicord 1 sq cm	High	High
Q4188	Amnioarmor 1 sq cm	Low	Low
Q4190	Artacent ac 1 sq cm	Low	Low
Q4191	Restorigin 1 sq cm	Low	Low
Q4193	Coll-e-derm 1 sq cm	Low	Low
Q4194	Novachor 1 sq cm	High	High*
Q4195+	Puraply 1 sq cm	High	High
Q4196+	Puraply am 1 sq cm	High	High
Q4197	Puraply xt 1 sq cm	High	High
Q4198	Genesis amnio membrane 1 sqcm	Low	Low
Q4200	Skin te 1 sq cm	Low	Low
Q4201	Matrion 1 sq cm	Low	Low
Q4203	Derma-gide, 1 sq cm	High	High*
Q4204	Xwrap 1 sq cm	Low	Low
Q4205	Membrane graft or wrap sq cm	Low	Low
Q4208	Novafix per sq cm	Low	High
Q4209	Surgraft per sq cm	Low	Low
Q4210	Axolotl graf dualgraf sq cm	Low	Low
Q4211	Amnion bio or axobio sq cm	Low	Low
Q4214	Cellesta cord per sq cm	Low	Low
Q4216	Artacent cord per sq cm	Low	Low
Q4217	Woundfix biowound plus xplus	Low	Low
Q4218	Surgicord per sq cm	Low	Low
Q4219	Surgigraft dual per sq cm	Low	Low
Q4220	Bellacell hd, surederm sq cm	Low	Low
Q4221	Amniowrap2 per sq cm	Low	Low
Q4222	Progenamatrix, per sq cm	Low	Low
Q4226	Myown harv prep proc sq cm	Low	Low

* These products do not exceed either the proposed MUC or PDC threshold for CY 2020, but are assigned to the high cost group because they were assigned to the high cost group in CY 2019.
+ Pass-through payment status in CY 2020. Pass-through payment status expires September 30, 2020.

Table 14. -- Extravascular Implantable Cardioverter Defibrillator (EV ICD)
Effective January 1, 2020

CPT Code	Long Descriptor	CY 2020 OPPS SI	CY 2020 OPPS APC
0571T	Insertion or replacement of implantable cardioverter defibrillator system, with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed	J1	5232
0572T	Insertion of substernal implantable defibrillator electrode	J1	5222
0573T	Removal of substernal implantable defibrillator electrode	Q2	5221
0574T	Repositioning of previously implanted substernal implantable defibrillator-pacing electrode	Q2	5221
0575T	Programming device evaluation (in person) of implantable cardioverter defibrillator system with substernal electrode, with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional	Q1	5741
0576T	Interrogation device evaluation (in person) of implantable cardioverter defibrillator system with substernal electrode, with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter	Q1	5741
0577T	Electrophysiological evaluation of implantable cardioverter defibrillator system with substernal electrode (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)	J1	5211
0578T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional	M	N/A
0579T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results	Q1	5741
0580T	Removal of substernal implantable defibrillator pulse generator only	Q2	5221

Medicare Claims Processing Manual
Chapter 4 - Part B Hospital
(Including Inpatient Hospital Part B and OPPS)

Table of Contents

(Rev.4513, Issued: 02-04-2020)

Transmittals for Chapter 4

10.6.3.7 - Payment Adjustment for Certain Cancer Hospitals Beginning CY 2019

10.6.3.8 - Payment Adjustment for Certain Cancer Hospitals Beginning CY 2020

20.6.19 - Use of HCPCS Modifier – CG

61.2.1 – Bypass Edit Modifier "CG" for Claims on Which Specified Procedures are to be Reported With Device Codes

10.6.3.7 - Payment Adjustment for Certain Cancer Hospitals Beginning CY 2019
(Rev.4513, Issued: 02-04-2020, Effective: 01-01- 2020, Implementation: 01-06-2020)

Section 16002(b) of the 21st Century Cures Act requires that, for CY 2018 and subsequent calendar years, the target PCR that should be used in the calculation of the interim monthly payments associated with the cancer hospital adjustment, as described above in section 10.6.3, and at final cost report settlement is reduced by 0.01. After including this reduction, for hospital outpatient services furnished on or after January 1, 2019 through December 31, 2019, the target PCR is 0.88.

10.6.3.8 - Payment Adjustment for Certain Cancer Hospitals Beginning CY 2020
Rev.4513, Issued: 02-04-2020, Effective: 01-01- 2020, Implementation: 01-06-2020)

Section 16002(b) of the 21st Century Cures Act requires that, for CY 2018 and subsequent calendar years, the target PCR that should be used in the calculation of the interim monthly payments associated with the cancer hospital adjustment, as described above in section 10.6.3, and at final cost report settlement is reduced by 0.01. After including this reduction, for hospital outpatient services furnished on or after January 1, 2020 through December 31, 2020, the target PCR is 0.89.

20.6.19 - Use of HCPCS Modifier - CG
Rev.4513, Issued: 02-04-2020, Effective: 01-01- 2020, Implementation: 01-06-2020)
*Effective January 1, 2019, the modifier –CG, **"Policy criteria applied",** can be reported with certain device-intensive procedures to reflect situations in which a device was not used during the device-intensive procedure.*

This modifier would be reported on the UB–04 form (CMS Form 1450) for hospital outpatient device-intensive procedures. Reporting of this modifier is not required for Critical access hospitals (CAHs). While this modifier is required, it does not have an effect on payment.

60.3 - Devices Eligible for Transitional Pass-Through Payments
Rev.4513, Issued: 02-04-2020, Effective: 01-01- 2020, Implementation: 01-06-2020)

The definition of and criteria for devices eligible for establishment of new categories for transitional pass-through payments was discussed and defined in a final rule with comment period published in the "Federal Register" on November 1, 2002, (67 FR 66781). Two of the criteria were also modified by means of a final rule with comment period published in the "Federal Register" on November 10, 2005 (70 FR 68628). As of January 1, 2010, implantable biologicals that are surgically inserted or implanted (through a surgical incision or natural orifice) are being evaluated for device pass-through payment as modified by means of a final rule with comment period and published in the November 20, 2009 "Federal Register" (74 FR 60471). As of January 1, 2015, skin substitutes are being evaluated for device pass-through payment as modified by means of a final rule with comment period and published in the November 10, 2015 "Federal Register" (79 FR 66885). As of January 1, 2016, the application process for device pass-through payments will add a rulemaking component to the existing quarterly process and a requirement will ensure that medical devices seeking pass-through payments are "new," as modified by means of a final rule with comment period and published in the November 13, 2015 "Federal Register (80 FR 70417). As of January 1, 2017, the pass-through payment time period has been refined by having the pass-through start date begin with the date of first payment and by allowing pass-through status to expire quarterly as modified by means of a final rule with comment period and published in the November 14, 2016 "Federal Register (81 FR 79655). Also, in calculating the pass-through payment, the "Implantable Devices Charged to Patients Cost to Charge Ration (CCR)" will replace the hospital-specific CCR, when available and device offsets will be calculated from the HCPCS payment rate, instead of the APC payment rate (81 FR 79655 through 79656). *As of January 1, 2020, devices that have received FDA marketing authorization and a Breakthrough Device designation from the FDA have an alternative pathway to qualify for device pass-through payment status, under which devices would not be evaluated in terms of the current substantial clinical improvement criterion for the*

purposes of determining device pass-through payment status. The devices must still meet the other criteria for pass-through status.

The regulations regarding transitional pass-through payment for devices are compiled at 42 CFR 419.66. Additionally, the eligibility criteria for CMS to establish a new category for pass-through payment are discussed on the CMS Web site at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html

61.2.1 – Bypass Edit Modifier "CG" for Claims on Which Specified Procedures are to be Reported With Device Codes

(Rev.4513, Issued: 02-04-2020, Effective: 01-01- 2020, Implementation: 01-06-2020)

For certain device-intensive procedures, providers may bypass the device edit requiring at least one device HCPCS code for the procedure. For situations where no device was performed with certain device-intensive procedures, providers may bypass the edit by reporting modifier "CG".

180.7 - Inpatient-only Services

Rev.4513, Issued: 02-04-2020, Effective: 01-01- 2020, Implementation: 01-06-2020)

Section 1833(t)(1)(B)(i) of the Act allows CMS to define the services for which payment under the OPPS is appropriate and the Secretary has determined that the services designated to be "inpatient only" services are not appropriate to be furnished in a hospital outpatient department. "Inpatient only" services are generally, but not always, surgical services that require inpatient care because of the nature of the procedure, the typical underlying physical condition of patients who require the service, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. An example of an "inpatient only" service is CPT code 33513, "Coronary artery bypass, vein only; four coronary venous grafts." The designation of services to be "inpatient-only" is open to public comment each year as part of the annual rulemaking process. Procedures removed from the "inpatient only" list may be appropriately furnished in either the inpatient or outpatient settings and such procedures continue to be payable when furnished in the inpatient setting.

There is no payment under the OPPS for services that CMS designates to be "inpatient-only" services. These services have an OPPS status indicator of "C" in the OPPS Addendum B and are listed together in Addendum E of each year's OPPS/ASC final rule. For the most current Addendum B and for Addendum E published with the OPPS notices and regulations, see http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

Excluding the handful of exceptions discussed below, CMS does not pay for an "inpatient-only" service furnished to a person who is registered in the hospital as an outpatient and reports the service on the outpatient hospital bill type (TOB 13X). CMS also does not pay for all other services on the same day as the "inpatient only" procedure.

There are two exceptions to the policy of not paying for outpatient services furnished on the same day with an "inpatient-only" service that would be paid under the OPPS if the inpatient service had not been furnished:

Exception 1: If the "inpatient-only" service is defined in CPT to be a "separate procedure" and the other services billed with the "inpatient-only" service contain a procedure that can be paid under the OPPS and that has an OPPS SI=T on the same date as the "inpatient-only" procedure or OPPS SI = J1 on the same claim as the "inpatient-only" procedure, then the "inpatient-only" service is denied but CMS makes payment for the separate procedure and any remaining payable OPPS services. The list of "separate procedures" is available with the Integrated Outpatient Code Editor (I/OCE) documentation. See http://www.cms.gov/Medicare/Coding/OutpatientCodeEdit/.

Exception 2: If an "inpatient-only" service is furnished but the patient expires before inpatient admission or transfer to another hospital and the hospital reports the "inpatient only" service with modifier "CA", then

CMS makes a single payment for all services reported on the claim, including the "inpatient only" procedure, through one unit of APC 5881, (Ancillary outpatient services when the patient dies.) Hospitals should report modifier CA on only one procedure.

As of January 1, 2020, procedures that have been removed from the inpatient-only (IPO) list are exempt from certain medical review activities related to compliance with the 2-midnight rule, which states that generally services are considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation (78 FR 50913 through 50954).

Specifically, procedures that have been removed from the IPO list are not eligible for referral to Recovery Audit Contractors (RACs) for noncompliance with the 2-midnight rule within the 2-calendar years following their removal from the IPO list. These procedures will not be considered by the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) in determining whether a provider exhibits persistent noncompliance with the 2-midnight rule for purposes of referral to the RAC nor will these procedures be reviewed by RACs for "patient status" within the 2-calendar years following their removal from the IPO list.

During the 2-year exemption period, BFCC-QIOs will have the opportunity to review claims for procedures that have been recently removed from the IPO list in order to provide education for practitioners and providers regarding compliance with the 2-midnight rule, but claims identified as noncompliant with the 2-midnight rule will not be denied with respect to the site-of-service under Medicare Part A.