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January 2018 Update of the Hospital Outpatient Prospective Payment System (OPPS)

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Related Change Request (CR) Number: 10417
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Effective Date: January 1, 2018
Related CR Transmittal Number: R3941CP
Implementation Date: January 2, 2018

Note: This article was revised on January 9, 2019, to show that more information on the 2-midnight rule, as it applies to total knee arthroplasty, is available in MLN Article SE19002. All other information is unchanged

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for providers and suppliers submitting claims to Medicare Administrative Contractors (MACs), including Home Health and Hospice (HH&H) MACs, for services provided to Medicare beneficiaries and paid under the Outpatient Prospective Payment System (OPPS).

PROVIDER ACTION NEEDED

Change Request (CR) 10417 describes changes to the OPPS to be implemented in the January 2018 update. Make sure your billing staffs are aware of these changes.

BACKGROUND

CR10417 describes changes to and billing instructions for various payment policies implemented in the January 2018 OPPS update. The January 2018 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).

The January 2018 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming January 2018 I/OCE CR10385. Once the I/OCE CR is issued, a related MLN Matters article will be available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10385.pdf.

Key changes to and billing instructions for various payment policies implemented in the January 2018 OPPS update are as follows:

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New Device Pass-Through Categories

Section 1833(t)(6)(B) of the Social Security Act (the 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 the Centers for Medicare & Medicaid Services (CMS) create additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices.

Effective January 1, 2018, there are no device categories eligible for pass-through payment. However, an existing device described by HCPCS code C2623 (*Catheter, transluminal angioplasty, drug coated, non-laser*) was approved on August 25, 2017, by the Food and Drug Administration (FDA) for a new indication, specifically the treatment of patients with dysfunctional Arteriovenous (AV) fistulae.

Accordingly, in this January 2018 update, devices described by HCPCS code C2623 are eligible for pass through status retroactive to August 25, 2017, when the device is billed with Current Procedural Terminology (CPT) code 36902 (*Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty*) or CPT code 36903 *(Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transcatheter placement of intravascular stent(s), peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis segment)*. This device pass through status will be applied retroactively from August 25, 2017, through December 31, 2017.

Refer to https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html for the most current device pass-through information.

Transitional Pass-Through Payments for Designated Devices

Certain designated new devices are assigned to Ambulatory Payment Classifications (APCs) and identified by the 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. 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.

Refer to https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files-Items/2018-Annual-Policy-Files.html for the most current OPPS HCPCS Offset File.

Device Offset from Payment for Device Category

Section 1833(t)(6)(D)(ii) of the Act requires CMS to deduct from pass-through payments for devices an amount that reflects the portion of the APC payment amount. With respect to device code C2623, CMS has previously determined that the costs associated with C2623 are not reflected in the APC payment amount. Therefore, CMS is not applying a device offset to the retroactive pass-through payments for C2623. Retroactive pass-through payments for August 25, 2017, through December 31, 2017, will only apply when HCPCS code C2623 is billed with CPT code 36902 or CPT code 36903. The device/procedure offset pair requirements for HCPCS code C2623 listed in Change Request 9553, Transmittal 3483 are no longer applicable effective January 1, 2018.

New Separately Payable Procedure Code

Effective January 1, 2018, new HCPCS code C9748 has been created, as described in Table 1.

Table 1. — New Separately Payable Procedure Code Effective January 1, 2018

HCPCS Code	Short Descriptor	Long Descriptor	January 2018 OPPS STATUS INDICATOR (SI)	January 2018 OPPS APC
C9748	Prostatic rf water vapor tx	Transurethral destruction of prostate tissue; by radiofrequency water vapor (steam) thermal therapy	J1	5373

Argus Retinal Prosthesis Add-on Code (C1842)

Effective January 1, 2017, CMS created HCPCS code C1842 (Retinal prosthesis, includes all internal and external components; add-on to C1841) and assigned it the Status Indicator (SI) of "N." HCPCS code C1842 was created to resolve a claims processing issue for Ambulatory Surgical Centers (ASCs) and should not be reported on institutional claims by hospital outpatient department providers. HCPCS code C1842 is included in the Calendar Year (CY) 2018 Annual HCPCS file.

Changes to New Technology APCs 1901 – 1908

Effective January 1, 2018, two additional New Technology APCs (1907 and 1908) are created.

In addition, the payment ranges for APCs 1901 – 1906 have been changed. All changes are documented in Table 2.

Table 2. — CY 2018 Additional New Technology APC Groups

CY 2018 APC	CY 2018 APC Title	CY 2018 SI	Updated or New APC
1901	New Technology - Level 49 ($100,001-$115,000)	S	Updated
1902	New Technology - Level 49 ($100,001-$115,000)	T	Updated
1903	New Technology - Level 50 ($115,001-$130,000)	S	Updated
1904	New Technology - Level 50 ($115,001-$130,000)	T	Updated
1905	New Technology - Level 51 ($130,001-$145,000)	S	Updated
1906	New Technology - Level 51 ($130,001-$145,000)	T	Updated
1907	New Technology - Level 52 ($145,001-$160,000)	S	New
1908	New Technology - Level 52 ($145,001-$160,000)	T	New

Services Eligible for New Technology APC Assignment and Payments

Under OPPS, services eligible for payment through New Technology APCs are those codes that are assigned to the series of New Technology APCs published in Addendum A of the latest OPPS update. OPPS considers any HCPCS code assigned to the APCs below to be a "new technology procedure or service." As of January 1, 2018, the range of New Technology APCs include:

- APCs 1491 through 1500
- APCs 1502 through 1537
- APCs 1539 through 1585,
- APCs 1589 through 1599
- APCs 1901 through 1908

The application for consideration as a New Technology procedure or service is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html, At that website, under the

"Downloads" section, refer to the document, entitled "For a New Technology Ambulatory Payment Classification (APC) Designation Under the Hospital Outpatient Prospective Payment System (OPPS)" for information on the requirements for submitting an application. The list of HCPCS codes and payment rates assigned to New Technology APCs are in Addendum B of the latest OPPS update regulation each year at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html.

Payment Changes for X-rays Taken Using Film and Computed Radiography Technology

On December 18, 2015, the Consolidated Appropriations Act of 2016 was signed into law (Public Law 114-113). Section 502 of the Consolidated Appropriations Act requires that Medicare implement the following provisions under the hospital OPPS for the technical component of imaging services:

- Reduce payment by 20 percent for an X-ray taken using film, beginning January 1, 2017, and
- Reduce payment by 7 percent from January 1, 2018 through December 31, 2022, and
- Thereafter to 10 percent, beginning January 1, 2023,

For an imaging service that is an X-ray taken using computed radiography technology.

In response to these provisions, CMS established modifiers "FX," effective January 1, 2017, and "FY," effective January 1, 2018. Below is additional information related to these modifiers. CMS notes that Section 502(b) of Division O, Title V of the Consolidated Appropriations Act of 2016 amended Section 1833(t)(16) of the Act by adding new subparagraph (F).

Payment Modifier for X-ray Taken Using Film, Effective January 1, 2017

Consistent with the requirements set forth in Section 1833(t)(16)(F)(i) and in accordance with provisions allowed under Section 1833(t)(16)(F)(iv) of the Act, CMS established modifier "FX" (*X-ray taken using film*) to identify imaging services that are X-rays taken using film. As stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79729 through 79730) and in the January 2017 Update of the OPPS (Change Request 9930, Transmittal 3685, dated December 22, 2016), hospitals are required to use this modifier to report imaging services that are x-rays taken using film, effective January 1, 2017.

The use of the FX modifier is applicable to all imaging services that are X-rays taken using film and results in a payment reduction of 20 percent, beginning January 1, 2017. All imaging services are listed in the OPPS Addendum B.

Payment Modifier for X-ray Taken Using Computed Radiography Technology, Effective January 1, 2018

Consistent with the requirements set forth in Section 1833(t)(16)(F)(ii) and in accordance with provisions allowed under Section 1833(t)(16)(F)(iv) of the Act, CMS established modifier "FY" (*X-ray taken using computed radiography technology/cassette-based imaging*) to identify an

imaging service that is an X-ray taken using computed radiography technology. Effective January 1, 2018, hospitals are required to use this modifier to report imaging services that are X-rays taken using computed radiography technology.

The use of this modifier results in a payment reduction of 7 percent from January 1, 2018, through December 31, 2022, and thereafter to 10 percent beginning January 1, 2023, for imaging services that are X-rays taken using computed radiography technology/cassette-based imaging. All imaging services are listed in the OPPS Addendum B.

Deletion of Modifier "CP"

Modifier "CP" became effective in CY 2016 and was used to identify adjunctive services on a claim related to a procedure assigned to a Comprehensive Ambulatory Payment Classification (C-APC) procedure. The use of the modifier was required for CYs 2016 and 2017 and the data collection period for this modifier was set to conclude on December 31, 2017. Accordingly, for CY 2018, CMS is deleting modifier "CP" and discontinuing its required use.

Also, for CY 2018, for the C-APC for Stereotactic Radio Surgery (SRS), specifically, C-APC 5627 (Level 7 Radiation Therapy), CMS will continue to make separate payments for the 10 planning and preparation services adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC-based technology when furnished to a beneficiary within 30 days of the SRS treatment. The 10 planning and preparation codes listed in Table 3 will be paid according to their assigned SI when furnished within 30 days of SRS treatment delivery.

Table 3. – Excluded Planning and Preparation CPT Codes

CPT Code	CY 2018 Short Descriptor	CY 2018 SI
70551	MRI brain stem w/o dye	Q3
70552	MRI brain stem w/dye	Q3
70553	MRI brain stem w/o & w/dye	Q3
77011	Ct scan for localization	N
77014	Ct scan for therapy guide	N
77280	Set radiation therapy field	S
77285	Set radiation therapy field	S
77290	Set radiation therapy field	S
77295	3-d radiotherapy plan	S
77336	Radiation physics consult	S

Changes to the Inpatient-Only (IPO List)

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 2018, CMS is removing Total Knee Arthroplasty (TKA) from the IPO list as well as five other procedures. CMS is also adding one procedure to the IPO list. The changes to the IPO list for CY 2018 are included in

Table 4.

Table 4. — Changes to the Inpatient Only List for CY 2018

CY 2018 CPT Code	CY 2018 Long Descriptor	Status	CY 2018 OPPS APC Assignment	CY 2018 OPPS SI
27447	Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)	Removed	5115	J1
43282	Laparoscopy, surgical, repair of para-esophageal hernia, includes fundoplasty, when performed; with implantation of mesh	Removed	5362	J1
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only	Removed	5303	J1
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only	Removed	5361	J1
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components	Removed	5303	J1
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing; includes robotic assistance, when performed	Removed	5362	J1

CY 2018 CPT Code	CY 2018 Long Descriptor	Status	CY 2018 OPPS APC Assignment	CY 2018 OPPS SI
92941	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel	Added	N/A	C

Revisions to the Laboratory Date of Service (DOS) Policy

a. Laboratory Test/Service Performed by an Independent Laboratory

In the CY 2018 OPPS/ASC final rule (82 FR 52533-52540), CMS discussed an additional exception to current laboratory DOS regulations at 42 Code of Federal Regulations (CFR) 414.510. This new exception to the laboratory DOS policy permits independent laboratories to bill Medicare directly for molecular pathology tests and Advanced Diagnostic Laboratory Tests (ADLTs), which are excluded from the OPPS packaging policy, if the specimen was collected from a hospital outpatient during a hospital outpatient encounter and the test was performed following the patient's discharge from the hospital outpatient department.

Consequently, Hospital Outpatient Departments (HOPDs) should no longer bill Medicare for molecular pathology tests and ADLTs performed by independent laboratories following the patient's discharge from the HOPD, and independent laboratories will no longer have to seek payment from the HOPD for these tests, if all of the conditions are met.

Note there are no current codes designated as ADLTs; however, molecular pathology codes are currently assigned to OPPS SI "A" to indicate that they are not paid under the OPPS, but may be paid under a different Medicare payment system.

b. Laboratory Test/Service Performed by a Hospital Laboratory

For a molecular pathology test or ADLT test performed by a hospital laboratory, refer to the "Medicare Claims Processing Manual," Chapter 16, Laboratory Services, Section 50.3, Hospitals.

OPPS Status Indicator Updates for Clinical Laboratory Fee Schedule (CLFS) Molecular Pathology Tests and Advanced Diagnostic Laboratory Tests (ADLTs)

Under the OPPS, Medicare conditionally packages laboratory tests and only pays separately for certain types of laboratory tests. Molecular pathology tests and ADLTs are paid separately at

the CLFS rate rather than the OPPS. The current list of molecular pathology tests is available in the OPPS Addendum B (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html) and are identified with status indicator "A."

However, for the January 2018 OPPS update, there are no laboratory tests currently designated by CMS as ADLTs under the CLFS. As stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79594), CMS will assign SI "A" (*Not paid under OPPS. Paid by Medicare Administrative Contractors (MACs) under a fee schedule or payment system other than OPPS)* to ADLTs once a laboratory test has been granted ADLT status under the CLFS.

Prior to ADLT designation, applicants must submit an application to CMS requesting ADLT status for a laboratory test. Once a test is designated by CMS as an ADLT under paragraph (1) of the definition of advanced diagnostic laboratory test in 42 CFR 414.502, CMS will update the OPPS Addendum B on a quarterly basis to reflect the appropriate SI assignment.

Billing Instructions for 340B-Acquired Drugs

As finalized in the CY 2018 OPPS/ASC final rule with comment period, separately payable Part B drugs (assigned SI "K"), other than vaccines (assigned SI "L" or "M") and drugs on pass-through payment status (assigned SI "G") that are acquired through the 340B Program or through the 340B prime vendor program, will be paid at the Average Sales Price (ASP) minus 22.5 percent, when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment.

Hospital types that are excepted from the 340B payment policy in CY 2018 include rural Sole Community Hospitals (SCHs), children's hospitals, and Prospective Payment System (PPS)-exempt cancer hospitals. These excepted hospitals will continue to receive ASP + 6 percent payment for separately payable drugs.

Medicare will continue to pay separately payable drugs that were not acquired under the 340B Program at ASP + 6 percent.

In addition, effective January 1, 2018, hospitals paid under the OPPS that are not excepted from the 340B drug payment policy for CY 2018 are required to report modifier "JG" on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. Since rural SCHs, children's hospitals and PPS-exempt cancer hospitals are excepted from the 340B payment adjustment in CY 2018, these hospitals will report informational modifier "TB" for 340B-acquired drugs, and will continue to be paid at the ASP + 6 percent.

The 340B modifiers and their descriptors are listed in Table 5.

Table 5 – Modifiers for 340B-Acquired Drugs

2-Digit HCPCS Modifier	Short Descriptor	Long Descriptor	Effective Date
JG	340B acquired drug	Drug or biological acquired with 340B drug pricing program discount	01/01/2018
TB	Tracking 340B acquired drug	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes	01/01/2018

Drugs, Biologicals, and Radiopharmaceuticals

a. New CY 2018 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals

For CY 2018, 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 6.

Table 6 – New CY 2018 HCPCS Codes Effective for Certain Drugs, Biologicals, and Radiopharmaceuticals

CY 2018 HCPCS Code	CY 2018 Long Descriptor	CY 2018 SI	CY 2018 APC
C9014	Injection, cerliponase alfa, 1 mg	G	9014
C9015	Injection, c-1 esterase inhibitor (human), Haegarda, 10 units	G	9015
C9016	Injection, triptorelin extended release, 3.75 mg	G	9016
C9024	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	G	9302
C9028	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028
C9029	Injection, guselkumab, 1 mg	G	9029
J0604	Cinacalcet, oral, 1 mg, (for ESRD on dialysis)	B	N/A
J0606	Injection, etelcalcetide, 0.1 mg	K	9031
J1555	Injection, immune globulin (cuvitru), 100 mg	K	9034

CY 2018 HCPCS Code	CY 2018 Long Descriptor	CY 2018 SI	CY 2018 APC
J7211	Injection, factor viii, (antihemophilic factor, recombinant), (kovaltry), 1 i.u.	K	9075
J7345	Aminolevulinic acid hcl for topical administration, 10% gel, 10 mg	G	9301
J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495
Q2040	Tisagenlecleucel, up to 250 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion	K	9081
Q4176	Neopatch, per square centimeter	N	N/A
Q4177	Floweramnioflo, 0.1 cc	N	N/A
Q4178	Floweramniopatch, per square centimeter	N	N/A
Q4179	Flowerderm, per square centimeter	N	N/A
Q4180	Revita, per square centimeter	N	N/A
Q4181	Amnio wound, per square centimeter	N	N/A
Q4182	Transcyte, per square centimeter	N	N/A

b. Other Changes to CY 2018 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 2018. In addition, several temporary HCPCS C-codes have been deleted, effective December 31, 2017, and replaced with permanent HCPCS codes effective CY 2018. 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 2018 HCPCS and CPT codes.

Table 7 notes those drugs, biologicals, and radiopharmaceuticals that have undergone changes in their HCPCS/CPT code, their long descriptor, or both. Each product's CY 2017 HCPCS/CPT code and long descriptor are noted in the two left-hand columns and the CY 2018 HCPCS/CPT code and long descriptor are noted in the adjacent right-hand columns.

Table 7 – Other CY 2018 HCPCS and CPT Code Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals

CY 2017 HCPCS Code	CY 2017 Long Descriptor	CY 2018 HCPCS Code	CY 2018 Long Descriptor
C9490	Injection, bezlotoxumab, 10 mg	J0565	Injection, bezlotoxumab, 10 mg
C9484	Injection, eteplirsen, 10 mg	J1428	Injection, eteplirsen, 10 mg
C9486	Injection, granisetron extended release, 0.1 mg	J1627	Injection, granisetron, extended release, 0.1 mg
Q9986	Injection, hydroxyprogesterone caproate (Makena), 10 mg	J1726	Injection, hydroxyprogesterone caproate (Makena), 10 mg
Q9985	Injection, hydroxyprogesterone caproate, not otherwise specified, 10 mg	J1729	Injection, hydroxyprogesterone caproate, not otherwise specified, 10 mg
C9489	Injection, nusinersen, 0.1 mg	J2326	Injection, nusinersen, 0.1 mg
C9494	Injection, ocrelizumab, 1 mg	J2350	Injection, ocrelizumab, 1 mg
Q9989	Ustekinumab, for Intravenous Injection, 1 mg	J3358	Ustekinumab, for Intravenous Injection, 1 mg
C9140	Injection, Factor VIII (antihemophilic factor, recombinant) (Afstyla), 1 I.U.	J7210	Injection, factor viii, (antihemophilic factor, recombinant), (Afstyla), 1 i.u.
Q9984	Levonorgestrel-releasing intrauterine contraceptive system (Kyleena), 19.5 mg	J7296	Levonorgestrel-releasing intrauterine contraceptive system (Kyleena), 19.5 mg
C9483	Injection, atezolizumab, 10 mg	J9022	Injection, atezolizumab, 10 mg
C9491	Injection, avelumab, 10 mg	J9023	Injection, avelumab, 10 mg
C9485	Injection, olaratumab, 10 mg	J9285	Injection, olaratumab, 10 mg

c. Drugs and Biologicals with Payments Based on Average Sales Price (ASP), Effective January 1, 2018

For CY 2018, payment for non-pass-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 minus 22.5 percent if 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 2018, 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. 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, 2018, payment rates for many drugs and biologicals have changed from the values published in the CY 2018 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 2017. In cases where adjustments to payment rates are necessary, changes to the payment rates will be incorporated in the January 2018 Fiscal Intermediary Shared System (FISS) release.

CMS is not publishing the updated payment rates in CR10417 implementing the January 2018 update of the OPPS. However, the updated payment rates effective January 1, 2018, are in the January 2018 update of the OPPS Addendum A and Addendum B at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html.

d. 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 the previous quarter's payment files.

e. Biosimilar Payment Policy

Effective January 1, 2018, the payment rate for biosimilars in the OPPS will generally continue to be the same as the payment rate in the physician office setting, calculated as the ASP of the biosimilar described by the HCPCS code + 6 percent of the ASP of the reference product. Biosimilars will also be eligible for transitional pass-through payment for which payment will be made at the ASP of the biosimilar described by the HCPCS code + 6 percent of the ASP of the reference product. A biosimilar that does not have pass-through status, but instead has SI of "K," will be paid the ASP of the biosimilar minus 22.5 percent of the ASP of the reference

product, effective January 1, 2018.

In addition, effective January 1, 2018, newly approved biosimilar biological products with a common reference product will no longer be grouped into the same billing code with other biosimilars. CMS will issue guidance on coding, including instructions for new codes for biosimilars that are currently grouped into a common payment code and the use of modifiers separate from CR10417. However, until such guidance is released, providers should continue to use applicable existing HCPCS codes and report a biosimilar modifier that identifies the manufacturer of the specific product. The modifier does not affect payment determination, but is used to distinguish between biosimilar products that appear in the same HCPCS code, but are made by different manufacturers. A list of the biosimilar biological product HCPCS codes and modifiers is available on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Part-B-Biosimilar-Biological-Product-Payment.html.

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 8 lists the skin substitute products and their assignment as either a high-cost or a low-cost skin substitute product, when applicable.

Table 8 --- Skin Substitute Assignments to High-Cost and Low-Cost Groups for CY 2018

CY 2018 HCPCS Code	CY 2018 Short Descriptor	CY 2018 SI	CY 2018 High/Low Assignment
C9363	Integra Meshed Bil Wound Mat	N	High
Q4100	Skin Substitute, NOS	N	Low
Q4101	Apligraf	N	High
Q4102	Oasis Wound Matrix	N	Low
Q4103	Oasis Burn Matrix	N	High
Q4104	Integra bmwd	N	High

CY 2018 HCPCS Code	CY 2018 Short Descriptor	CY 2018 SI	CY 2018 High/Low Assignment
Q4105	Integra drt or omnigraft	N	High
Q4106	Dermagraft	N	High
Q4107	GraftJacket	N	High
Q4108	Integra Matrix	N	High
Q4110	Primatrix	N	High
Q4111	Gammagraft	N	Low
Q4115	Alloskin	N	Low
Q4116	Alloderm	N	High
Q4117	Hyalomatrix	N	Low
Q4121	Theraskin	N	High
Q4122	Dermacell	N	High
Q4123	Alloskin	N	High
Q4124	Oasis Tri-layer Wound Matrix	N	Low
Q4126	Memoderm/derma/tranz/integup	N	High
Q4127	Talymed	N	High
Q4128	Flexhd/Allopatchhd/Matrixhd	N	High
Q4131	Epifix or epicord	N	High
Q4132	Grafix core, grafixpl core	N	High
Q4133	Grafix prime grafix pl prime	N	High
Q4134	Hmatrix	N	Low
Q4135	Mediskin	N	Low
Q4136	Ezderm	N	Low
Q4137	Amnioexcel or Biodexcel, 1cm	N	High

CY 2018 HCPCS Code	CY 2018 Short Descriptor	CY 2018 SI	CY 2018 High/Low Assignment
Q4138	Biodfence dryflex, 1cm	N	High
Q4140	Biodfence 1cm	N	High
Q4141	Alloskin ac, 1cm	N	High
Q4143	Repriza, 1cm	N	High
Q4146	Tensix, 1 cm	N	High
Q4147	Architect ecm px fx 1 sq cm	N	High
Q4148	Neox neox rt, or clarix cord	N	High
Q4150	Allowrap ds or dry 1 sq cm	N	High
Q4151	Amnioband, guardian 1 sq cm	N	High
Q4152	Dermapure 1 square cm	N	High
Q4153	Dermavest, plurivest sq cm	N	High
Q4154	Biovance 1 square cm	N	High
Q4156	Neox 100 or clarix 100	N	High
Q4157	Revitalon 1 square cm	N	High
Q4158	Kerecis omega3, per sq cm	N	High
Q4159	Affinity 1 square cm	N	High
Q4160	NuShield 1 square cm	N	High
Q4161	Bio-Connekt per square cm	N	High
Q4163	Woundex, bioskin, per sq cm	N	High
Q4164	Helicoll, per square cm	N	High
Q4165	Keramatrix, per square cm	N	Low
Q4166	Cytal, per square cm	N	Low
Q4167	Truskin, per square cm	N	Low

CY 2018 HCPCS Code	CY 2018 Short Descriptor	CY 2018 SI	CY 2018 High/Low Assignment
Q4169	Artacent wound, per square cm	N	High
Q4170	Cygnus, per square cm	N	Low
Q4172*	Puraply or puraply am	N	High
Q4173	Palingen or palingen xplus	N	High
Q4175	Miroderm	N	High
Q4176*	Neopatch, per square centimeter	N	Low
Q4178*	Floweramniopatch, per sq cm	N	Low
Q4179*	Flowerderm, per square centimeter	N	Low
Q4180*	Revita, per sq cm	N	Low
Q4181*	Amnio wound, per square centimeter	N	Low
Q4182*	Transcyte, per square centimeter	N	Low

* HCPCS codes Q4176, Q4178, Q4179, Q4180, Q4181, and Q4182 were assigned to the low-cost group in CY 2018 OPPS/ASC final rule with comment period. Pass-through status for HCPCS code Q4172 ended on December 31, 2017.

New HCPCS Codes for Pathogen Reduced Platelets and Pathogen Testing for Platelets

For the January 2018 update, the HCPCS Workgroup deleted HCPCS codes Q9987 and Q9988 for Medicare reporting and replaced the codes with two new HCPCS codes effective January 1, 2018. Specifically, to report the service described by HCPCS code Q9988 based on the code descriptor in effect for July 1, 2017, through December 31, 2017, providers must instead report HCPCS code P9073 (Platelets, pathogen reduced, each unit) instead of HCPCS code Q9988 effective January 1, 2018. Providers reporting the service described by HCPCS code Q9987 based on the code descriptor in effect for July 1, 2017, through December 31, 2017 shall instead report HCPCS code P9100 (Pathogen(s) test for platelets) instead of HCPCS code Q9987 effective January 1, 2018. Note that HCPCS code P9100 should be reported to describe the test used for the detection of bacterial contamination in platelets as well as any other test that may be used to detect pathogen contamination. Table 9 describes blood platelet coding changes that are effective January 1, 2018. The coding changes associated with these codes were also published on the CMS HCPCS Quarterly Update website effective January 2018, at https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-

Update.html. The payment rates for HCPCS codes P9073 and P9100 can be found in the January 2018 OPPS Addendum B, which is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html.

Table 9. –Blood Platelet Coding Changes Effective January 1, 2018

HCPCS Code	Short Descriptor	Long Descriptor	January 2018 OPPS SI	January 2018 OPPS APCS
P9073	Platelets, pathogen reduced	Platelets, pathogen reduced, each unit	**R**	**9536**
P9100	Pathogen test for platelets	Pathogen(s) test for platelets	**S**	**1493**

Payment Adjustment for Certain Cancer Hospitals Beginning CY 2018

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 which 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 2018, the target PCR, after including the reduction required by Section 16002(b), is 0.88.

Section 4011 of the 21st Century Cures Act

Section 4011 of the 21st Century Cures Act created a new subsection (t) in Section 1834 of the Social Security Act that requires CMS to make available to the public a searchable Internet website that compares estimated payment and beneficiary liability for an appropriate number of items and services paid under the OPPS and the ASC Payment System. Consistent with this statute, CMS plans to first make this website available during CY 2018.

CMS believes that making available a comparison for all services that receive separate payment under both the OPPS and ASC payment system would be most useful to the public with regards to displaying the comparison for an “appropriate number of such items and services.” CMS believes that displaying the national unadjusted payments and copayment amounts will allow the user to make a meaningful comparison between the systems for items and services paid under both systems. CMS may consider providing payment and copayment comparisons at the locality or provider level for future years.

Along with the comparison information that CMS will make available to the public in accordance with the requirements of Section 4011, CMS also plans to include a disclaimer statement that notes some of the payment policy differences in each care setting and that notes the limitations

of the comparison tool, to provide users with some context for why there might be potential differences. In the case of the OPPS copayments, CMS plans to include an additional indicator where the service is likely to be capped at the Part A inpatient deductible, based on the unadjusted copayments, under the OPPS coinsurance rules.

Changes to OPPS Pricer Logic

a. Rural SCHs and Essential Access Community Hospitals (EACHs) will continue to receive a 7.1 percent payment increase for most services in CY 2018. 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, 2018. 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 2018 inpatient deductible of $1,340. 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 2018. 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 the estimated cost less 1.75 times the APC payment amount. The payment formula is (cost-(APC payment x 1.75))/2.

d. The fixed-dollar threshold for OPPS outlier payments increases in CY 2018 relative to CY 2017. The estimated cost of a service must be greater than the APC payment amount plus $4,150 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 2017. 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 x 3.4))/2.

f. Continuing Medicare's established policy for CY 2018, the OPPS Pricer will apply a reduced update ratio of 0.980 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, 2018, CMS is adopting the FY 2018 IPPS post-reclassification wage index values with application of the CY 2018 out-commuting adjustment authorized by

Section 505 of the MMA to non-IPPS hospitals as implemented through the Pricer logic.

h. Effective January 1, 2014, for claims with APCs, which require implantable devices and have significant device offsets (greater than 40%), 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 at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

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. 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.

ADDITIONAL INFORMATION

The official instruction, CR10417, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3941CP.pdf.

More information regarding the "Two-Midnight Rule" as it relates to total knee arthroplasty is available in MLN Matters article SE19002 at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE19002.pdf.

If you have questions, your MACs may have more information. You can review their website at http://go.cms.gov/MAC-website-list.

DOCUMENT HISTORY

Date of Change	Description
January 9, 2019	This article was revised to show that more information on the 2-midnight rule, as it applies to total knee arthroplasty, is available in MLN Article SE19002.
December 22, 2017	Initial article released.