



Medicare Hospital and Chargemaster Version LifePoint Custom

KEY CONCEPTS OUTLINE

Module 14: Strategies and Key Issues by Revenue Code: Ancillary Services

- I. Pharmacy (025x; 063x and 087x) and Radiopharmaceuticals (0343 & 0344)
 - A. Guidance on billing drugs and biologicals and on some radiopharmaceuticals is in *Medicare Claims Processing Manual*, Chapter 17, Drugs & Biologicals and Chapter 13, Radiology Services and Other Diagnostic Procedures, respectively.
 - B. Coverage of inpatient drugs
 1. All medically necessary drugs provided to inpatients during their stay generally are covered. Drugs for inpatient hospital and inpatient skilled nursing facility (SNF) beneficiaries are included in the respective prospective payment system (PPS) rates with a few exceptions, discussed below.
 2. Drugs for use outside the hospital needed to facilitate discharge are covered under Part A for inpatients. <*Medicare Benefit Policy Manual*, Chapter 1, § 30.5>
 - C. Coverage of outpatient drugs – Medicare covers drugs under three circumstances:
 1. Statutorily covered drugs
 - a. Blood clotting factors for hemophilia patients;
 - b. Drugs used in immunosuppressive therapy when the organ transplant from which the need arises for the immunosuppressive drugs was covered and paid by Part A Medicare; <MLN 10235 October 17, 2017>
 - c. Erythropoietin for dialysis patients; and
 - d. Certain oral anti-cancer drugs and anti-emetics used in certain situations <*Medicare Benefit Policy Manual*, Chapter 15 § 50.5>
 2. Drugs provided incident to a physician's service.

- a. Drugs provided incident to a physician's or nonphysician practitioner (NPP)'s service that are not usually self-administered by the patient. <See *Medicare Benefit Policy Manual*, Chapter 15 § 50>
- b. The MAC makes the determination whether a particular drug is usually self-administered or not, applying the following guidelines: <See *Medicare Benefit Policy Manual*, Chapter 15 § 50.2.A>
 - 1. The determination a drug is self-administered is not patient-specific. The decision is based on the usual method of administration for all Medicare beneficiaries who use the drug. <See *Medicare Benefit Policy Manual*, Chapter 15 § 50.2.C>
 - 2. Drugs administered by any method other than injection and infusion are considered to be usually self-administered, with limited exceptions. <See *Medicare Benefit Policy Manual*, Chapter 15 § 50.2.B>

Self-administered drugs include oral drugs, suppositories, topically applied drugs, and inhalation drugs.
 - 3. Drugs administered by subcutaneous injection are presumed to be usually self-administered. <See *Medicare Benefit Policy Manual*, Chapter 15 § 50.2.C.3>
 - 4. Drugs administered intravenously or by intramuscular injection are presumed to be not usually self-administered. <See *Medicare Benefit Policy Manual*, Chapter 15 § 50.2.C.1 and 2>
 - 5. Each MAC publishes a Self-Administered Drug (SAD) Exclusion List with the injectable drugs the MAC has determined to be usually self-administered and therefore not covered. The MAC SAD Exclusion Lists are posted on the Medicare Coverage Database. <CMS.gov, "Medicare Coverage Database" website>
- 3. Drugs integral to procedures
 - a. Medicare covers certain self-administered drugs if they are an integral component of a procedure or are directly related to it or facilitate the performance of or recovery from the procedure. <See *Medicare Benefit Policy Manual*, Chapter 15 § 50.2.M>
 - b. Examples of drugs integral to a procedure:
 - 1. Sedatives administered in preoperative area

2. Eye drops and certain other drugs related to eye procedures
3. Barium and low osmolar contrast media
4. Topical solutions used in photodynamic therapy
5. Antibiotic ointment such as bacitracin

C. Coding and edit issues.

i. HCPCS Codes

1. Drugs and biologicals are billed with a HCPCS code, if one exists, and units of service consistent with the HCPCS code description. < *Medicare Claims Processing Manual*, Chapter 17 § 10, 90.2>
 - a. If the provider furnishes a dose of a drug that does not equal a multiple of the units specified in the HCPCS code for the drug, the provider should round to the next highest unit when reporting the drug. < *Medicare Claims Processing Manual*, Chapter 17 § 10, 40>

Example: A patient is administered 7mgs of a drug. The HCPCS code long descriptor indicates "per 5 mgs". The hospital should report units of 2 for the drug.

- b. Biosimilar biologic products are reported with HCPCS codes specific to the product and manufacturer. <82 *Fed. Reg.* 53186-187, *Medicare Claims Processing Manual Transmittal 3966*>

Link: Biosimilar Biological Products under Medicare-Related Sites - General

- c. If a drug with status indicator G or K is reported without an accompanying administration or procedure code, edit 99 of the IOCE will cause the claim to be returned to the provider. < *Medicare Claims Processing Manual*, Chapter 4 § 230.2 and Chapter 17 § 10; *IOCE Specifications*, Section 5.12 and Section 6.2, Edit 99 (Supplement)>
 - i. Exception: Blood clotting factors and certain biological response modifiers may be billed without an accompanying administration or procedure code. < *IOCE Specifications*, Section 5.12 (Supplement)>

- ii. The codes excluded from IOCE edit 99 are available in the IOCE Quarterly Data Files, Report-Tables folder, "DATA_HCPCS", column CV "BYPASS_E99" available on the IOCE homepage. The current list is included in the materials behind the outline.

Link: OCE Specifications under Medicare-Related Sites - Hospital

ii. Modifiers

1. Modifier -JW or -JZ for Drugs in Single-Dose Containers or Single-Use Packages¹

- a. Separately payable drugs and biologicals (i.e., with status indicator "A", "G", or "K") packaged in single-dose containers must be reported with modifier -JW or modifier -JZ. <87 *Fed. Reg.* 69712 – 69718; see JW/JZ FAQs, Q2, Q12, Q17>
 - i. CMS has published "Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy, Frequently Asked Questions", referred to in this section as the JW/JZ FAQs, available on OPPS Homepage of the CMS website, and included in the materials behind the outline.
 - ii. Modifiers -JW and -JZ apply to drugs supplied in "single-dose" containers or "single-use" packages based on the FDA-approved labeling. <See JW/JZ FAQs, Q7>
 - iii. Modifier -JW has been required since January 1, 2017. Modifier -JZ is effective January 1, 2023, and will be required July 1, 2023. Claims for drugs packaged in single-dose containers submitted without either modifier -JW or -JZ will be returned as un-processable beginning October 1, 2023. <87 *Fed. Reg.* 69717; see JW/JZ FAQs, Q5, Q11>
 - iv. Modifiers -JW and -JZ are not reported on drugs that are packaged for payment purposes (i.e., with status indicator "N"), vaccines, or on drugs reported on inpatient claims. <See JW/JZ FAQs, Q6, Q7, Q21>
- b. Modifier -JW
 - i. Modifier- JW ("Drug amount discarded/not administered to any patient") is used to report the discarded amount from a single-dose container if a portion is administered to the patient and the remainder discarded. <*Medicare Claims Processing Manual*, Chapter 17 § 40>

¹ Referred to collectively as "single-dose containers" in the remainder of the outline.

- a) The discarded amount of a single-dose container is calculated by subtracting the amount administered from the amount on the label of the purchased container. <87 Fed. Ref. 69718; see JW/JZ FAQs, Q3>
 - 1) The provider is not limited to calculating the discarded amount based on the smallest vial size available for purchase, but rather should use the labeled amount of the product actually purchased. <87 Fed. Reg. 69718>
 - 2) Noridian, the Jurisdiction E and F MAC, continues to have a published policy requiring the billed amount to equal the smallest dose available for purchase from the manufacturer. <Noridian LCA A55932; Noridian LCA A53024>
- b) Providers must document the amount of the discarded drug or biological in the patient's medical record. <Medicare Claims Processing Manual, Chapter 17 § 40>
 - 1) The discarded amount can be automatically calculated and documented by software, as long as the wastage is documented accurately. <JW/JZ FAQs, Q16>
- c) Unused portions of multi-use vials may not be billed to Medicare. <Medicare Claims Processing Manual, Chapter 17 § 40>
 - ii. Report the administered portion and the discarded portion of a single-dose container on separate lines, with modifier JW on the line for the discarded portion. <Medicare Claims Processing Manual, Chapter 17 § 40>
- c. Modifier JZ
 - i. Modifier -JZ ("Zero drug amount discarded/not administered to any patient") is used to report a drug administered from a single-dose container with no wastage (i.e., the full amount of the vial or package is administered). <See JW/JZ FAQs, Q2, Q17>

- a) The policy for modifier -JZ is aligned with modifier -JW and -JZ is required for single dose containers for which the -JW modifier would be required if there were any discarded amount. <87 *Fed. Reg.* 69712; see JW/JZ FAQs, Q2>

A patient presents to the oncology center of a hospital and received 2.7 mg of bortezomib (HCPCS code J9041 is reported for 0.1 mg of bortezomib) and the hospital was unable to use the remainder for another patient and had to dispose of it. Bortezomib is supplied in a 3.5 mg vial and must be reconstituted for administration. Bortezomib is packaged in a single use vial that must be used within 8 hours once reconstituted. How should this drug be billed to Medicare?

The hospital would report J9041 with 27 units and J9041JW with 8 units.

2. Modifier -JG or -TB for 340B Acquired Drugs

- a. Drugs acquired through the 340B drug discount program² are reported with either modifier -JG or -TB by OPPS hospitals for informational purposes. <87 *Fed. Reg.* 71974-76>
- i. CMS has published “Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS), Frequently Asked Questions, April 2, 2018”, referred to in this section as the 340B FAQs, available on OPPS Homepage of the CMS website.

Caution: Parts of the 340B FAQs refer to discounting policy that has been invalidated by the Supreme Court. See Attachment A for a Review of CMS’ 340B Drug Discount Policy. For 2023, CMS adopted a policy to require the modifiers -JG and -TB for informational purposes only, reported in the same manner they were under the prior discount policy. Presumably, sections clarifying correct reporting of the modifiers are still applicable even though the discount policy is no longer in effect.

- ii. A 340B acquired drug is a drug purchased at or below the 340B ceiling price from the manufacturer or purchased through the 340B Prime Vendor Program. <340B FAQs, Q1>

² The 340B Program, administered by the Health Resources and Services Administration (HRSA), allows Federal grant recipients, CAHs, and specified Disproportionate Share Hospitals to purchase “covered outpatient drugs” at discounted prices from drug manufacturers.

- iii. Modifiers -JG and -TB do not apply to drugs not purchased through the 340B program or vaccines with status indicators "F", "L", or "M" and are voluntary for drugs with status indicator "N". <340B FAQs, Q8>
- b. Modifier -JG (Drug or Biological Acquired with 340B Drug Pricing Program Discount) must be reported on 340B acquired drugs with status indicator "K" furnished by OPPS hospitals. <87 Fed. Reg 71974-76>
 - i. Modifier -JG is not reported by children's hospitals, PPS-exempt cancer hospitals, and rural sole community hospitals. <87 Fed. Reg. 71974-76; 340B FAQs, Q1, Q8>
 - ii. Modifier -JG is not applied to status indicator "G" drugs. <87 Fed. Reg. 71974; 340B FAQs, Q8, Q10>
 - a) The IOCE will return an informational only line-item rejection if modifier -JG is reported on a status indicator G (pass-through) drug. <IOCE Specifications, Section 6.2, Edit 122 (Supplement)>
- c. Modifier -TB (Drug or biological Acquired with 340B Drug Pricing Discount Program, Reported for Informational Purposes) must be reported on the following 340B acquired drugs:
 - a) Drugs with status indicator "G" by all OPPS hospitals, *including* children's hospitals, PPS-exempt cancer hospitals, and rural sole community hospitals. <340B FAQs, Q8, Q12>
 - b) Drugs with status indicator "K" by children's hospitals, PPS-exempt cancer hospitals and rural sole community hospitals. <87 Fed. Reg. 71974-76; 340B FAQs, Q8>
- 3. If multiple modifiers apply (e.g., -JG, -PO or -JW for wasted drugs), sequence modifier -JG first, followed by -JW, followed by -PO or -PN. <340B FAQs, Q14>
- iii. Reporting HCPCS on packaged drugs
 - a. Hospitals may report the HCPCS codes and charges for drugs that are packaged into payments for the corresponding drug administration or other separately payable services. Historical hospital cost data may assist with future payment packaging decisions for such drugs.
 - a. Alternatively, and increasingly an important option to exercise due to MUE limits on packaged drugs, hospitals may report the charges under revenue code 0250 without HCPCS.

- b. Drugs are billed in multiples of the dosage specified in the HCPCS code long descriptor.
- c. If the drug dose used in the care of a patient is not a multiple of the HCPCS code dosage descriptor, the provider rounds to the next highest unit based on the HCPCS long descriptor for the code to report the dose provided.

D. Inpatient and outpatient payment considerations

1. Inpatient drugs are paid under DRG except for:

- a. Hemophilia agents < *Medicare Claims Processing Manual*, Chapter 3, § 20.7.3>
- b. Part B covered vaccines such as influenza and pneumococcal < *Medicare Claims Processing Manual*, Chapter 3, § 10.4A>
 - i. These drugs should be billed on separate 012x claims for separate payment.

2. Medicare pays for outpatient covered drugs and biologicals in three ways:

- a. Separate payment under the “pass-through” provisions for new drugs and biologicals < *Medicare Claims Processing Manual*, Chapter 17 § 90.2 B>; or
- b. Separate payment as a “non-pass-through” under certain provisions for payment of outpatient drugs and biologicals < *Medicare Claims Processing Manual*, Chapter 17 §90.2 C>; or
 - a. Separate payment is at ASP +6% based on the HCPCS and units reported for each status “K” and “G” drug
- c. Packaged into payment for other services on the claim.
 - a. Skin substitutes – low cost, high cost and implanted.
 - b. Skin substitutes are a heterogeneous group of biologic, synthetic, or biosynthetic materials that can provide temporary or permanent coverage of open skin wounds.
 - 1. Low-cost skin substitute product codes must be billed with the low-cost skin substitute application procedure codes or the claim will be returned to the provider. <78 *Fed. Reg.* 74934-39; IOCE Specifications, Table 4 (Edit 87) and Appendix P>

- a. Low-cost skin substitute procedure codes are HCPCS Level II codes C5271–C5278. <78 *Fed. Reg.* 74934-39; IOCE Specifications, Appendix O>
 - b. Low-cost skin substitute products are all packaged (designated with a status indicator N)
- 2. High-cost skin substitute product codes must be billed with the high-cost skin substitute application procedure codes or the claim will be returned to the provider. <78 *Fed. Reg.* 74934-39; IOCE Specifications, Table 4 (Edit 87) and Appendix P>
 - a. High-cost skin substitute procedure codes are CPT® codes 15271–15278.
 - b. The following skin substitute products are designated “high cost”:
 - i. Packaged skin substitute products (designated with a status indicator N)
 - ii. Pass-through skin substitute products (designated with status indicator G).
- 3. Skin substitute products designated as neither “high cost” nor “low cost” are billed with surgical procedure codes outside the skin application procedure code ranges (i.e., they are not reported with 15271–15278 or C5271–5278).

E. General ledger (GL) and finance considerations

- 1. Since drugs represent a specific type of service in the Medicare cost report and in NUBC, drug charges are required to be billed separately and not bundled into procedures except for anesthesia gases billed under anesthesia (037x).
- 2. Expenses to GL roll into drugs charged to patients regardless of the location.
Note: This instruction may not apply to infusion/oncology centers with their own on-site pharmacy and may change due to provider-based departments not grandfathered in under Section 603.
- 3. Be sure that drugs stored in cabinets in clinics are under policy and control of pharmacy to meet requirements to be billed under pharmacy revenue codes.
<42 *C.F.R.* 482.25(a)>
- 4. Drugs must represent a cost to the hospital and be part of recognized compendia. Patients cannot brown-bag drugs (i.e., bring their own drugs

obtained under Part D) to the hospital (or physician office), and drugs covered by Part A and Part B cannot be covered by Part D. <Medicare Benefit Policy Manual, Chapter 1, § 30>

1. For outpatient claims requiring drug HCPCS but which the hospital did not incur an acquisition cost, CMS has provided instructions at MM10521 Effective January 2, 2009, including in the materials behind the outline.
5. Acquisition cost, pharmacy overhead, and nuclear medicine handling costs should be reported in the line-item charge for the drug or biological. <Medicare Claims Processing Manual, Chapter 17, § 90.2>
6. Cost, average wholesale price (AWP), average sales price (ASP), average manufacturer's price (AMP):
 - a. If current price structure is not off cost, but a proxy such as ASP exists, consider cost due to increased emphasis on price transparency
7. Handling fee, dispensing fee:
 - a. Drug markups can vary by type of drug (oral/topical, injectable, infused, chemotherapy, compounded, etc.); markup may include handling or dispensing fee, or it may be added in separately after markup
8. Cap or ceiling—not recommended due to how CMS uses claims data for rate setting.
9. Over the counter (OTC) drug markup, including SADs:
 - a. Hospitals often have very low markups for OTC drugs that are recognizable to patients. This was particularly important when hospitals were encouraged to bill Medicare patients for non-covered SADs.

F. Revenue codes:

1. [Separately paid] drugs and biologicals with HCPCS codes should be reported with revenue code 0636 "Drugs Requiring Detailed Coding," except for radiopharmaceuticals and cell and gene therapy products. Diagnostic radiopharmaceuticals are reported with revenue code 343, and therapeutic radiopharmaceuticals are reported with revenue code 344. Cell and Gene Therapy Products are reported with revenue code 089x effective April 1, 2019. <National Uniform Billing Committee UB-04 Date Specifications Manual, Program Memorandum A-02-129>

2. [Packaged] drugs and biologicals that do not have a HCPCS code should be billed with the appropriate revenue code in the "General Pharmacy" revenue code series 025X, which does not require a HCPCS code for reporting.
<National Uniform Billing Committee UB-04 Data Specifications Manual>
3. SADs that are covered as packaged supplies should be reported "under the revenue code associated with the cost center under which the hospital accumulates the costs of the drugs," presumably revenue code 0250.
<Medicare Benefit Policy Manual, Chapter 15, § 50.2 M>
 - a. Revenue code 0637 "Self-administrable Drugs" should not be reported for covered, packaged SADs because the OCE identifies it as an excluded revenue code. <IOCE Specifications, Table 3 Edit Return Buffer>

Recent OIG guidance regarding writing off SADs:

The HHS Office of Inspector General has stated that hospitals will not be subject to administrative sanctions if they discount or waive amounts owed for non-covered SADs, subject to the following conditions:

The discounts or waivers are for drugs received for ingestion or administration in outpatient settings;

The policy is uniformly applied without regard to diagnosis or type of treatment;

The policy is not marketed or advertised; and

The hospital does not claim the discounted or waived amounts as bad debt or otherwise shift the burden of these costs to the Medicare or Medicaid program, other payers, or individuals. <OIG Policy Statement Regarding Hospitals That Discount or Waive Amounts Owed by Medicare Beneficiaries for Self-Administered Drugs Dispensed in Outpatient Settings, dated October 29, 2015>

G. Charge capture issues

1. Charge on dispense—One common method of charging drugs is either from dispensing cabinets or via pharmacy dispensing the drug after filling the order.
2. Charge on administration—An increasingly common and the most accurate means to charge for drugs is based on actual administration. This may be an option in the EMR that requires the entire facility to be able to comply, so if

every department is not set up on the same medication administration record (MAR), this option may not be possible.

II. IV Therapy (026x); Chemotherapy (0331, 0332, & 0335); Vaccine Administration (0771); Oncology (028x); Blood Administration (0391)

A. Guidance can be found in *Medicare Claims Processing Manual*, Chapter 4, Section 230

B. HCPCS coding and edits

1. Hospitals are expected to use the revenue code that relates to the expense, some MACs may have edits on drug administration charges requiring revenue code 0260 instead of 0450 and other more department-specific revenue codes.
2. Hospitals are instructed to use the full set of CPT® codes, including those codes referencing the concepts of initial, concurrent, and sequential, to bill for drug administration services furnished in the hospital outpatient department. Additionally, hospitals are instructed to continue billing the HCPCS codes that most accurately describe the service(s) provided.
3. Hospitals are reminded to bill a separate evaluation and management (E/M) code (with modifier -25) only if a significant, separately identifiable E/M service is performed in the same encounter with OPPS drug administration services. Ensure sufficient facility documentation exists to support this separately billed service.
4. Drug administration services are to be reported with a line-item date of service on the day they are provided. In addition, only one initial drug administration service is to be reported per vascular access site per encounter, including during an encounter where observation services span more than one calendar day.
5. MACs may have LCDs defining what drugs can be billed with chemotherapy drug administration codes.
6. Initial drug administration code charges should include routine supplies used for infusions such as catheters, lumens, tubing, etc. Drugs and solutions are always separately charged under pharmacy revenue codes.

B. Inpatient and outpatient payment concepts

1. CPT®/HCPCS codes are needed on drug administration charges for outpatients and payment for packaged drugs is included in the drug administration service when appropriate.

2. Note that when a drug administration service is integral to another procedure, such as postoperative pain management, the drug administration codes are not billed separately, but the drug charges are.

C. Key GL and finance concepts

1. If blood administration charges are billed from blood bank, reassign nursing expense from the departments where the service is rendered to the blood bank cost center for expense associated with blood administration to match the revenue when blood administration is billed out of the blood bank as is the case with exploding charges.
2. Drug administration charges are best reported under revenue codes that represent the departments that incur the labor expense (e.g., ED, each nursing unit, separate observation unit if one exists, and clinics).

D. Coverage

1. When the drug is medically necessary and must be administered under supervision by qualified staff, the drug administration charges are also covered.
2. Vaccine administration should be billed under revenue code 0771.
3. Appropriate drug administration HCPCS codes should be billed in addition to the HCPCS code for the drug administered. < *Medicare Claims Processing Manual*, Chapter 4, § 230.2; Chapter 17, § 10>

E. Charge capture

1. Use specially trained staff, HIM/coding staff, or clinical staff. The specific method may depend on the department, its manager/director, and available resources.
 - a. Consider working with information services to write a custom drug administration charge capture report from the discharge MAR that sorts infused and injected drugs based on the drug hierarchy, route of administration, and drug to facilitate efficient charge capture.
 - b. Note Epic has an Infusion Calculator application that with modification can propose valid drug administration charges following the hierarchy for most accounts based on MAR documentation.
2. For infusions started outside the hospital, applicable in the ED:

- a. Bill for all services provided using the HCPCS code(s) that most accurately describe the service(s) they provided.
 - b. Report an initial hour of infusion, even if the hospital did not initiate the infusion, and additional HCPCS codes for additional or sequential infusion services if needed. <Medicare Claims Processing Manual, Chapter 4>
- 3. See Handout 17 for an Example MAR Report for Drug Administration Charge Capture.
- 4. Clinic:
 - a. Revenue center 0280 is an appropriate alternative for medical oncology clinics for the visit and procedure services other than drug administration. Note that commercial payers may expect chemotherapy drug charges and/or cancer diagnoses with 0280 charges on the claim.
 - b. Observation/nursing units:
 - i. How will drug administration charges be captured, and who will capture them?
- 5. Long-term chemotherapy with implantable vs. external pumps
 - a. G0498 for long-term chemotherapy infusion via an external pump to be used instead of 96416, which is now to be used solely for refill and programming of an implantable long-term chemotherapy pump service.
 - b. G0498 should not be cross walked from 96416 because this code includes the external pump expense and the expense of the return visit to disconnect the pump on a subsequent day.
 - c. Modifier -52 should be applied if the pump is to be disconnected by a different provider.
 - d. The external pump should not be billed by a separate supplier. <See MM9749 effective January 1, 2016, and MM10005 effective April 1, 2017>
- 6. Exploding blood administration (CPT® code 36430) charge for each unit of blood product dispensed from blood bank module in lab:
 - a. Revenue will be included with the blood bank department. There should be allocation of expenses from performing departments to the

blood bank department on the cost report to match expense with revenue.

b. Blood administration (transfusion):

- (i) Blood administration is billed using revenue code 391, the appropriate HCPCS code that describes the type of transfusion service, and a unit of service equal to 1. < *Medicare Claims Processing Manual*, Chapter 4, §231.8>
- (ii) The transfusion/blood administration code is billed on a per date of service basis, not by the number of units of blood product transfused. Administration charges may be “tiered” to account for the costs of transfusing multiple units over a longer period if the per unit method is not summed per date of service.

III. Medical/Surgical Supplies, Prosthetics & Orthotic and Implantable Devices (027x and 062x) & DME (029x), and IDEs (0624)

A. Coverage:

- 1. Supplies needed for inpatient care and integral to outpatient services and procedures are medically necessary and covered.
- 2. Durable medical equipment (DME) prosthetics, orthotics, and supplies (POS):
 - a. DME, by definition, is for use in the home, so it is not covered or chargeable/billable by the hospital on its claim.
 - i. Equipment used in the hospital that would meet the definition of DME is usually both depreciable and reusable and does not result in a separate charge (e.g., wheelchairs, walkers, pumps).
 - ii. Any DME or oxygen furnished to inpatients under a Part A covered stay is included in the SNF or hospital PPS rate.
 - iii. When an inpatient in a hospital or SNF is not entitled to Part A inpatient benefits, payment may not be made under Part B for DME, or oxygen provided in the hospital or SNF because such facilities do not qualify as a patient's home.
 - iv. The definition of DME in §1861(n) of the SSA provides that DME is covered by Part B only when intended for use in the home, which explicitly does not include a SNF or hospital. (*Medicare Benefit Policy Manual*, Chapter 15.)

- v. This does not preclude separate billing by a DME supplier for DME furnished “after discharge.”
- i. Implantable POS are covered and payable under IPPS or OPPOS. NUBC defines implants and this definition is applicable to all providers and payers per HIPAA transaction sets.
- ii. Experimental devices that are implanted and have been granted an FDA Investigational Device Exemption (IDE) number should be reported with revenue code 0624; the IDE number is reported in the HCPCS field.
- iii. When defective equipment or a defective medical device is replaced under a warranty, hospital or other provider services rendered by parties other than the warrantor are covered despite the warrantor’s liability. <Medicare Benefit Policy Manual, Chapter 16, Section 40.4>
- b. Braces and other external POS have specific benefits.
 - i. These may be prescribed and billed by POS suppliers unless the POS is fitted during surgery as part of an inpatient Part A or Part B service, in which case it must be billed on the inpatient or hospital Part B claim.
 - ii. External POS that can be prescribed can be supplied by the hospital and billed as a packaged, covered charge on the hospital outpatient claim, but payment is unconditionally packaged and there is no separate payment.

Tip: Consider having prescriptions written for all external POS not integral to a procedure so that these supplies are paid separately to the supplier.

Caution: POS HCPCS codes can be used on hospital outpatient claims, and when this is the only service provided at an encounter, the MAC will pay the POS fee schedule amount.

B. Coding and billing

1. CMS creates HCPCS “C” codes for implantable devices that are [packaged into device-intensive procedures and] eligible for pass-through payment. <Medicare Claims Processing Manual, Chapter 4, § 60.1>
 - a. CMS defines “device-intensive procedures” as procedures where 30% or more of the payment rate is associated with the device.

- b. L8699 (*Prosthetic implant, not otherwise specified*) can be used for implantable devices that do not have a C code.
 - c. C1889 (*Implantable/insertable device, not otherwise classified*) can be used for implants that do not have a C code assigned to satisfy the generic C code edit when device-intensive procedures are billed.
 - d. C9899 (*Implanted prosthetic device, payable only for inpatients who do not have inpatient coverage*) is used on 012x claims for patients having no Part A benefits or exhausting their Part A benefits for all devices.
 - e. Hospitals should bill implantable prosthetic devices with HCPCS code C9899 ("Implantable prosthetic device, payable only for inpatients who do not have inpatient coverage"). <See *Medicare Claims Processing Manual*, Chapter 4 § 240.3>
 - i. The provider should report the HCPCS code for the device, if one exists, or a narrative description of the device in the remarks section. <*Medicare Claims Processing Manual*, Transmittal 1628, IV. Supporting Information>
 - ii. The MAC prices the device according to its pass-through amount, DME fee schedule amount, or the device offset amount for packaged devices, and the beneficiary co-insurance is set at 20% of the payment amount determined by the MAC. <See *Medicare Claims Processing Manual*, Chapter 4 § 240.3>
 - iii. This code should not be used on inpatient Part B claims for inpatient cases denied as not reasonable and necessary because the surgical service that includes payment for the device is payable. <See *Medicare Claims Processing Manual*, Chapter 4 § 240.3>
2. If a device-intensive procedure is reported without a device code, IOCE edit 92 will trigger the claim to be returned to the provider (RTP'd). <80 *Fed. Reg.* 70422; *IOCE Specifications*, Table 4 and Special Processing Condition 5>
- a. The lists of device-intensive procedures and devices are available in the IOCE Quarterly Data Files ("Q_CD_HcpcsMap", "DeviceProcedure" and "Device" columns) available on the IOCE homepage.

- b. Specified procedures involving only a revision and not replacement will not trigger edit 92 when reported with modifier -CG (Policy Criteria Applied). <IOCE Specifications, Section 5.7>

Link: OCE Specifications under Medicare-Related Sites – Hospital

See also the Link: "Device Category C-Codes" for a current list of codes and an explanation of pricing for pass-through devices

- c. The list of procedures that bypass edit 92 when reported with modifier -CG is available in the IOCE Quarterly Data Files, Data Table Reports folder, "DATA_HCPCS", column DC "BYPASS_E92_MODIFIER" available on the IOCE homepage.
3. If the device includes multiple components, each of which have a category C code, then all the applicable categories should be used to bill the item.
 - a. Items with multiple component devices that fall in more than one category (e.g., kits or systems other than those explicitly identified in the long descriptors), hospitals should code the appropriate category separately for each component.
 - b. For example, the Rotablator™ Rotational Angioplasty System (with catheter and advancer) consists of both a catheter and an advancer/sheath. Hospitals should report:
 - i. C1724 for the catheter; and
 - ii. C1894 for the advancer/sheath.
 4. When medical and surgical supplies (other than prosthetic and orthotic devices as described in the *Medicare Claims Processing Manual*, Chapter 20, §10.1) described by HCPCS codes with status indicators other than "H" or "N" are provided incident to a physician's service by a hospital outpatient department, the HCPCS codes for these items should not be reported because these items represent [packaged] supplies. <*Medicare Claims Processing Manual*, Chapter 4, Section 10>
 - a. Revenue code 0274 should be used for prosthetic and orthotic devices. However, HCPCS codes with status indicator "A" that are not prosthetic and orthotic devices should not have the HCPCS code print on the claim. This includes:

- i. Take-home surgical dressings that are billed under revenue code 0623.
 - ii. Surgical dressings used in the home between wound care appointments are separately payable when furnished by a POS supplier and billed separate from the hospital claim.
- b. For example, the emergency department initiates the intravenous administration of a drug through an infusion pump described by HCPCS code E0781 (Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient), complete the drug infusion, and discontinue use of the infusion pump before the patient leaves the hospital outpatient department, HCPCS code E0781 should not be reported because the infusion pump was used as a supply and would be paid through OPPS payment for the drug administration service. The hospital should include the charge associated with the infusion pump on the claim.
- c. In another example, the hospital outpatient staff performs a surgical procedure on a patient in which temporary bladder catheterization is necessary and use a catheter described by HCPCS code A4338 (Indwelling catheter; Foley type, two-way latex with coating (Teflon, silicone, silicone elastomer, or hydrophilic, etc.), each).
 - i. The hospital should not report A4338 because the catheter was used as a supply and would be paid through OPPS payment for the surgical procedure.
 - ii. The hospital should include the charge associated with the urinary catheter on the claim.
- d. When hospital outpatient staff provide a prosthetic or orthotic device, and the HCPCS code that describes that device includes the fitting, adjustment, or other services necessary for the patient's use of the item.
 - i. Do not bill a visit or procedure HCPCS code to report the charges associated with the fitting, adjustment, or other related services.
 - 1. The HCPCS code for the device already includes the fitting, adjustment, or other similar services.
 - ii. For example, if the hospital outpatient staff provides the orthotic device described by HCPCS code L1830 (KO, immobilizer, canvas longitudinal, prefabricated, includes fitting and adjustment), the

hospital should only bill HCPCS code L1830 and should not bill a visit or procedure HCPCS code to describe the fitting and adjustment.

C. Inpatient and outpatient payment considerations

1. Inpatient—the case rate is expected to pay for all covered supplies and devices used during the inpatient stay.
 - a. DME delivered two days prior to discharge: CMS presumes that the pre-discharge delivery of DMEPOS is appropriate when the conditions are met in the *Medicare Claims Processing Manual*, Chapter 20, Section 110.3.1.
 - b. Delivery of the item no more than two days from discharge: The item is delivered for fitting and is intended for use in the home; the supplier ensures the patient takes the item home.

Case Study

Facts: A Medicare inpatient receives a back brace immediately following surgery due to the sensitive nature of the procedure. The patient is discharged one day later.

Analysis: Since the item is fitted while the patient is in the hospital immediately following surgery, it appears the item is not solely for home use and the hospital must pay the supplier for the brace.

Modified Facts: The supplier brings the brace to the patient on the morning of discharge and fits the brace, instructing the patient on how to put it on, how to remove it, and when to wear it. The patient wears the brace home when discharged.

Analysis: The hospital requests the supplier bill Medicare for the brace under the “two-day” rule.

- c. New technology add-on [may be implantable or non-implantable devices, drugs, or biologics] for inpatients under the IPPS—hospitals can receive an additional “add-on” payment for designated “new medical services and technology” if the hospital’s costs exceed a specified threshold. <42 CFR § 412.87(a)>
- i. Each year, CMS announces additions and deletions to the list of qualifying new technology in the IPPS final rule.

1. The new technology add-on payment is intended to be temporary. Once CMS has gathered enough data on the new technology to “recalibrate” the applicable weight of the DRG involving the new technology, the add-on payment will no longer be available. <42 C.F.R. § 412.87(b)(2)>
 2. The regulations provide that a new technology should only be treated as “new” for two or three years from the time that product came on the market. <42 C.F.R. § 412.87(b)(2)>
 3. The current list of new technologies is included in the materials behind the outline.
3. Outpatient payment for devices is either packaged or as separate pass-through device payment.
- a. Pass-through device payment and new technology payments:
 - i. Separate outpatient pass-through payment is made for certain new devices that are “implantable.” Once assigned pass-through status, the device remains a pass-through for at least two years, but no more than three years. Upon expiration of the pass-through status for a device, CMS packages the costs of the device into the procedures it is associated with. <Medicare Claims Processing Manual, Chapter 17, § 90.2 C>
 - ii. CMS publishes an offset file annually with the amount of the CPT®/HCPCS payment for a procedure attributable to packaged devices. The offset file is available on the OPPS Annual Policy Files portion of the CMS website and is Addendum P in proposed and final rules.
 - a. Note that the offset is still calculated at the procedure level and not the device C code level. This means that the offset includes the cost of other devices that are required to be billed with C codes and not the specific predecessor device that the pass-through payment is designed to compensate. Therefore, it is possible the offset is based on several devices and is significantly more than the specific pass-through device.
 - b. The OCE ensures the offset is not less than zero.
 - iii. Warranty/recalls:
 - a. No-cost/full-credit and partial-credit devices—the payment for certain procedures is discounted if the hospital receives a device implanted

during the procedure at a discount of 50% or more of the cost of the device. <80 *Fed. Reg.* 70423–424, 72 *Fed. Reg.* 47250–251>

1. For outpatient surgeries, the policy applies to procedures defined as device-intensive, which are listed in Addendum P of the OPPS final rule.
 2. For inpatient surgeries, the policy applies to a list of designated MS-DRGs, which are assigned based on the implantation of a device. <72 *Fed. Reg.* 47250–51, see *Medicare One Time Notification Transmittal 1494* and each year's *IPPS Final Rule*>
- b. Billing procedures for no-cost/full-credit and partial-credit devices:
1. Value code FD—if a provider receives a credit of 50% or greater of the cost of a device implanted during a procedure subject to the policy, the provider must report the amount of the credit with value code FD. <80 *Fed. Reg.* 70423–424, *Medicare Claims Processing Manual*, Chapter 3, § 100.8; see *Medicare One-Time Notification Transmittal 1494*>
 2. Condition codes
 - a) Condition code 49 is used when a credit is received because a device was replaced due to a malfunction prior to the anticipated life cycle of the product. <*Medicare Claims Processing Manual*, Chapter 3, § 100.8; *Medicare Claims Processing Manual*, Chapter 4, § 61.3.5>
 - b) Condition code 50 is used when a credit is received due to a FDA or manufacturer's recall of the product. <*Medicare Claims Processing Manual*, Chapter 3, § 100.8; *Medicare Claims Processing Manual*, Chapter 4, § 61.3.5>
 - c) Condition code 53 is used when the device was received for initial placement as part of a clinical trial or as a free sample. <*Medicare Claims Processing Manual*, Chapter 4, § 61.3.5; *Medicare Claims Processing Manual*, Chapter 32, § 67.2.1>
 - d) Charges for free devices—devices received for free should be reported with a \$0 charge or, if the hospital's system requires a charge for each line item, with a token charge (e.g., \$1). <*Medicare Claims Processing Manual*, Chapter 4, § 61.3.5>
- c. Payment for procedures implanting devices received at reduced cost

- i. For outpatient procedures, the lesser of the amount of the credit reported with value code FD or the full unadjusted offset amount for the procedure is deducted from the payment for the procedure. *<Medicare Claims Processing Manual, Chapter 4, § 61.3.6>*
 - ii. For inpatient procedures, the amount of the credit reported with value code FD is subtracted from the otherwise applicable MS-DRG payment amount. *<Medicare Claims Processing Manual, Chapter 3, § 100.8>*
- d. For billing cases subject to the reduction, hospitals may either:
 - i. Submit a claim for the service without the applicable condition code and submit an adjustment claim with the correct condition code once a credit has been determined. This process is presumably used in cases where the credit is not determined by the manufacturer until the device is submitted to them for testing.
 - ii. Hold the claim until a determination is made on the amount of the credit. *<72 Fed. Reg. 47250>*

D. General ledger and finance considerations:

- 1. Markup policy should be followed for supplies and implants
- 2. Pass-through devices may need a separate markup to ensure coverage of cost
- 3. Cost bands for supply/implant markups
 - i. Cost bands refer to a methodology to create "shell" records for supplies and map multiple items that meet the definition of the shell record with the same HCPCS and revenue code definitions and where the cost/invoice amount is within the band. Then an average charge is created for the shell record.
 - ii. If the pass-through device is purchased as part of a kit with other non-pass-through supplies, the pass-through device should be billed on a separate line with the appropriate HCPCS code. *<Medicare Claims Processing Manual, Chapter 4, § 60.4>*

- 1) To ensure no pass-through payment is received for the non-pass-through supplies, they must not be included in the line for the pass-through device and should be billed on a separate line. <Medicare Claims Processing Manual, Chapter 4, § 60.4>

Cost Bands

CDM	Description	Rev Code	HCPCS
123456	Bone Screw \$26-\$75	0278	C1713
124567	Bone Screw \$76-\$125	0278	C1713
125789	Bone Screw \$126-\$175	0278	C1713
126789	Bone Screw \$176-\$225	0278	C1713
127891	Bone Screw \$226-\$275	0278	C1713

E. Charge capture:

1. Drive off completed orders (i.e., bedside supplies for which there is not a separate procedure charge)
2. Preference cards for surgery—ensure proper credit of amounts of unused supplies
3. Package into procedures for clinics, ED, and other departments (not for implantable devices or pass-through supplies)
4. Use procedure to device and device to procedure edits to monitor for correct C-category charges for implantable devices

Tip: In the case of the physician needing two devices, because the first one does not fit properly or achieve the desired result (not due to a defect in the device itself), it is appropriate to charge both devices.

<See Transmittal a02129 Section XXII.E>

IV. Laboratory (030x) and Pathology (031x), Blood (038x) and Blood Processing and Storage (0392) <Medicare Claims Processing Manual, Chapter 16>

A. Coverage of laboratory services

1. Inpatient laboratory tests medically necessary for the inpatient stay are covered and paid via the inpatient payment methodology.
2. The Medicare *National Coverage Determinations (NCD) Coding Policy Manual and Change Report, Clinical Diagnostic Laboratory Services (Lab NCD Manual)* applies to outpatient lab services.
 - a. The *Lab NCD Manual* contains national policy decisions “granting, limiting, or excluding Medicare coverage” for clinical diagnostic lab tests. <Program Memorandum AB-02-110>
 - b. Although the *Lab NCD Manual* is available on CMS’ website, it is not part of CMS’ “internet-only” manual system. However, portions of the *Lab NCD Manual* are incorporated into the *National Coverage Determinations Manual* (Pub. 100-03) included in CMS’ “internet-only” manual system.
 - c. The *Lab NCD Manual* contains national policies. The MACs may not issue or maintain local policies (i.e., LCDs) that are inconsistent with the *Lab NCD Manual*. <Program Memorandum AB-02-110>
 - d. There are three “lists” of diagnosis codes applicable to each NCD:
 - (i) Non-Covered ICD-10-CM Codes for All NCD Edits
 - i. This is a master list set forth at the beginning of the NCD manual.
 - ii. This list applies to all NCDs and represents diagnoses for which a laboratory test covered by an NCD will never be a covered Medicare benefit. <Program Memorandum AB-02-110>
 - iii. Tests performed for one of these diagnoses may be billed to the patient without an ABN. <*Medicare Claims Processing Manual, One-Time Notification Transmittal 11*>
 - iv. If a test performed for one of these diagnoses is billed to Medicare, the test should be billed with the -GY modifier as discussed in a previous module. <*Medicare Claims Processing Manual, One-Time Notification Transmittal 11*>
 - (ii) ICD-10-CM Codes Covered by Medicare
 - i. This list is set forth in the body of each NCD.
 - ii. These codes are presumed to support medical necessity. <Program Memorandum AB-02-110>

(iii) ICD-10-CM Codes That Do Not Support Medical Necessity

- i. This list is set forth in the body of each NCD. In many cases, this list includes all diagnosis codes not included in one of the two lists discussed above.
 - ii. These codes represent diagnoses that generally do not support medical necessity but for which there may be exceptions. <Program Memorandum AB-02-110>
 - iii. Tests performed for one of these diagnoses may be billed to the patient if the patient was given an effective ABN. <Program Memorandum AB-02-110>
3. Tests must be ordered by a treating physician/NPP with a diagnosis or sign/symptom.
 - a. Regarding diagnostic laboratory and certain other services, the Budget Act of 1997, Section 4317, "Physicians Reporting Diagnosis Codes When a Diagnostic Test Is Ordered," states that "if the Secretary requires the entity furnishing the services to provide diagnostic or other medical information to the entity, the physician or practitioner ordering the service shall provide that information to the entity at the time the service is ordered by the physician or practitioner."
 - i. A laboratory or other provider must report on a claim for Medicare payment the diagnostic code(s) furnished by the ordering physician. In the absence of such coding information, the laboratory or other provider may determine the appropriate diagnostic code based on the ordering physician's narrative diagnostic statement or seek diagnostic information from the ordering physician/practitioner. However, a laboratory or other provider may not report on a claim for Medicare payment a diagnosis code in the absence of physician-supplied diagnostic information supporting such code.
4. Surgical pathology services include the gross and microscopic examination of organ tissue performed by a physician, except for autopsies, which are not covered by Medicare. Surgical pathology services paid under the Physician Fee Schedule are reported under the following CPT® codes specified in *Transmittal 382*, November 26, 2004 CR 3467.
5. Screening tests are covered only if there is a statutory benefit (HIV, HPV, and PSA are a few with Medicare benefits).
 - a. Tests that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are not covered except when there is

a statutory provision that explicitly covers tests for screening as described. If a person is tested to rule out or to confirm a suspected diagnosis because the patient has signs and/or symptoms, this is considered a diagnostic test, not a screening test.

6. Tests must be performed in a CLIA-licensed laboratory at the level of licensure. < *Medicare Claims Processing Manual*, Chapter 16 Section 70.5 - CLIA Categories and Subcategories >
7. A laboratory may be licensed or exempted from licensure in several major procedure categories.
 - a. CLIA Waived Tests 70.8—Certificate of Waiver: Effective September 1, 1992, all laboratory testing sites (except as provided in 42 *C.F.R.* § 493.3(b)) must have a CLIA certificate of waiver, a certificate for provider-performed microscopy procedures, a certificate of registration, a certificate of compliance, or a certificate of accreditation to legally perform clinical laboratory testing on specimens from individuals in the United States.

The FDA approves CLIA waived tests on a flow basis. The CMS identifies CLIA waived tests by providing an updated list of waived tests to the A/B MACs on a quarterly basis via a Recurring Update Notification. To be recognized as a waived test, some CLIA-waived tests have unique HCPCS procedure codes, and some must include a -QW modifier with the HCPCS code.

- b. Complexity—there are different levels of licensure for different types of clinical lab tests.
- c. Physician-performed microscopy (PPM): < *Medicare Claims Processing Manual*, Chapter 16 70.6—Certificate for Provider-Performed Microscopy Procedures >
 - (i) Effective January 19, 1993, a laboratory that holds a certificate for provider-performed microscopy procedures may perform only those tests specified as provider-performed microscopy procedures and waived tests and no others.

The Fern test often performed in the obstetrics department is an example of a PPM test (Q0114).

See the link – Categorization of Tests.

B. Coding and billing issues relating to outpatient clinical diagnostic laboratory services

1. Date of service

- a. The date of service should be the specimen collection date, not the date the test was actually performed. <42 C.F.R. § 414.510(a); *Medicare Claims Processing Manual*, Chapter 16 § 40.8>

- b. Exceptions

- (i) Specimens stored for more than 30 days

- (a) A specimen that is stored for more than 30 calendar days prior to testing is considered to have been archived, and the date of service is the date the specimen was obtained from storage. <42 C.F.R. § 414.510(b)(2)(ii); *Medicare Claims Processing Manual*, Chapter 16 § 40.8>

- (ii) Specimens stored for 30 days or less and chemotherapy sensitivity tests performed on live tissue

- (a) The date of service should be the date the test was performed if all the following criteria are met:
 1. The specimen was collected during a hospital surgical procedure and it would have been medically inappropriate to have collected the specimen in another way;
 2. The test was ordered or the decision regarding the chemotherapeutic agent was made at least 14 days following discharge from the hospital;
 3. The results of the test did not guide treatment during the hospital stay; and
 4. The test was reasonable and medically necessary for treatment of an illness. <42 C.F.R. § 414.510 (b)(2)(i), and (b)(3); *Medicare Claims Processing Manual*, Chapter 16 § 40.8>

- (iii) Molecular pathology and advanced diagnostic laboratory tests (ADLT) and effective January 1, 2021, cancer multi-analyte algorithmic analyses (MAAA) tests

- (a) The date of service should be the date the test was performed if all of the following are met:

1. The test was performed following discharge from a hospital outpatient department encounter;
 2. The specimen was collected from a hospital outpatient during the encounter;
 3. It was medically appropriate to collect the sample from the outpatient during the encounter;
 4. The results of the test do not guide treatment provided during the hospital outpatient encounter; and
 5. The test was reasonable and medically necessary for the treatment of an illness. <42 C.F.R. § 414.510(5)>
 6. The test is not performed by a blood bank or center.
- (b) This has the effect of separating the outpatient lab test from the outpatient encounter, enabling the performing lab to bill Medicare directly for the test to seek payment. *If a test meets all requirements for the new exception to the DOS policy in § 414.510(b)(5), the DOS of the test must be the date the test was performed, which means the laboratory performing the test must bill Medicare for the test. <82 Fed. Reg. 59398>*
- (c) All performing labs of outpatient ADLT and molecular pathology services should be billing CMS directly except for those furnished by blood and blood centers that continue to bill the hospital that sent the specimen.
- c. The date of service for a specimen collection that spans two calendar days is the date the collection ended. <42 C.F.R. § 414.510(b)(1); *Medicare Claims Processing Manual*, Chapter 16 § 40.8>

See the link: Laboratory Date of Service

CMS maintains an up-to-date list of HCPCS codes subject to this outpatient date of service exception policy.

2. Repeat tests on the same day
 - a. Limitations on payment for repeat tests

- i. Laboratory tests repeated on the same day are covered and billable “when it is necessary to obtain multiple results for clinical reasons,” but payment is generally packaged into other services on the claim. *<Medicare Claims Processing Manual, Chapter 16 § 100.5.1; 80 Fed. Reg. 70350>*

Caution: *Separate payment for repeat tests may be affected by a Medically Unlikely Edit (MUE) if the number of tests exceeds the allowed units for the MUE.*

3. Modifier usage

- a. Repeat tests should be reported with the -59 modifier (distinct procedural services) if the specimens were obtained from distinct anatomical areas or wounds; otherwise repeat tests should be reported with modifier -91 (repeat clinical diagnostic laboratory services). *<Program Memorandum AB-02-030>*
- b. Modifier -91 is limited to repeat tests performed “when it is necessary to obtain multiple results in the course of treatment.” *<Medicare Claims Processing Manual, Chapter 16 § 100.5.1; Medicare Contractor Beneficiary and Provider Communications Manual, Chapter 5 § 20.4>*

4. Organ/disease panels

- a. What is an organ/disease panel?
 - i. “Panels” are groups of lab test performed together, typically using automated testing equipment. *<Medicare Claims Processing Manual, Chapter 16 § 90>*
 - ii. Medicare uses the CPT manual definitions to define the tests included in each panel. *<Medicare Claims Processing Manual, Chapter 16 § 90.2>*
 - iii. A panel code should not be billed unless all of the tests included in the panel were performed. *<Medicare Claims Processing Manual, Chapter 16 § 90.2>*
 - iv. Separate payment is available for additional tests performed beyond those included on the panel. *<Medicare Claims Processing Manual, Chapter 16 § 90.2>*
- b. Billing for panels

- i. CMS does not require the use of the panel codes; each test in a panel may be billed separately; however, payment is not to exceed the lesser of billed charges, the fee amount for the panel, or the sum of the fee amount for all component tests. <Medicare Claims Processing Manual, Chapter 16 § 90.2>

Caution: Use of the defined panel codes will ensure proper payment and avoid calculation errors and potential overpayments related to billing the panel tests individually.

- c. The following panel is assigned status indicator E1 (not covered by any Medicare outpatient benefit category/statutorily excluded/not reasonable and necessary):

- i. Code 80050—General health panel

Caution: Medicare may cover one or more of the individual tests included in these panels if the individual tests are medically necessary. In order to ensure patients aren't charged personally for covered services, tests in these panels should be billed individually to ensure proper application of medical necessity policies. Modifier -GY may be used for tests that are purely screening/preventative and don't fit a covered screening/preventative benefit.

5. Blood, blood products, and blood processing and storage

a. Blood processing and storage

- i. Blood processing and storage includes blood product collection; safety testing; retyping; pooling; irradiating; leukocyte-reducing; freezing and thawing; and blood delivery, monitoring, and storage. <Medicare Claims Processing Manual, Chapter 4 § 231.1>

b. Billing for blood processing and storage

- i. Blood processing and storage is billed using revenue code 0390 (Blood Storage and Processing) or 0399 (Blood Storage and Processing/Other Processing and Storage). <Medicare Claims Processing Manual, Chapter 4 § 231.1>

- a) Revenue codes 0390 and 0399 are excluded from inpatient Part B claims, but 0392 would be accepted. *< Medicare Claims Processing Manual, Chapter 3 § 240.1>*
- c. Blood processing and storage is reported with the appropriate HCPCS code for the blood product transfused and the number of units transfused. *< Medicare Claims Processing Manual, Chapter 4 § 231.1>*
- d. The line item date of service for blood processing and storage is the date of the transfusion, not the date of the blood processing. *< Medicare Claims Processing Manual, Chapter 4 § 231.1>*

6. Blood and blood products

- a. Blood products must be reported on a separate line on the same claim as the blood processing and storage. *< Medicare Claims Processing Manual, Chapter 4 § 231.2>*
- b. The hospital may not charge for blood product if the blood is replaced by the beneficiary, another donor, or a blood bank (i.e., the blood product was donated). *< Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3 § 20.5.4.1>*

Presumably, plasma is the only blood product providers may charge for separately because of limitations on payment to donors for other donated blood products. Although donated blood products can't be charged to the patient, if the hospital incurs a cost from a blood bank for processing and storage of a donated unit of blood, it should be reported with the other blood processing and storage costs for that unit on the blood processing and storage revenue code line.

7. Billing for blood products

- a. Blood products are billed using revenue code series 038X (Blood). *< Medicare Claims Processing Manual, Chapter 4 § 231.2>*
- b. Blood products are reported with the appropriate HCPCS code for the blood product with modifier -BL and the number of units transfused. *< Medicare Claims Processing Manual, Chapter 4 § 231.2>*
- c. Modifier -BL should also be appended to the HCPCS code for the storage and processing. *< Medicare Claims Processing Manual, Chapter 4 § 231.2>*

- i. The same HCPCS code with modifier -BL, number of units, and line-item date of service must be present on both the line for the blood product and the blood processing and storage or the claim will trigger OCE edit 73 and be returned to the provider. <IOCE Specifications, Appendix J "Billing for Blood/Blood Products">
 - ii. The line-item date of service for blood products is the date of the transfusion. <Medicare Claims Processing Manual, Chapter 4 § 231.2>
- 9. Processing and storage for unused blood and blood products
 - a. Blood and blood products, and processing and storage may not be charged if not transfused to the patient, except as specified below. The costs for the blood or blood products and the blood processing and storage for these unused units should be reported on the hospital's cost report under the blood cost center. <Medicare Claims Processing Manual, Chapter 4 § 231.7>
 - b. Exception for autologous blood collection
 - (i) When autologous blood is collected but not transfused, a charge for autologous blood collection may be billed.
 - a. The line-item date of service should reflect the date the hospital is certain the blood will not be transfused (i.e., date of procedure or discharge) rather than the date of the autologous collection. <Medicare Claims Processing Manual, Chapter 4 § 231.3>
 - b. The HCPCS code should reflect one of the autologous blood collection codes rather than the "P" code of the blood product transfused. <Medicare Claims Processing Manual, Chapter 4 § 231.3>
 - (ii) Exception for frozen, thawed, split, or irradiated blood
 - a. When blood has been frozen, thawed, split, or irradiated in preparation for transfusion but not transfused, a charge for the freezing, thawing, splitting, or irradiating service provided may be billed.
 - b. The line-item date of service should reflect the date the hospital is certain the blood will not be transfused (i.e., date of procedure or discharge) rather than the date of the freezing, thawing, splitting, or irradiating service. <Medicare Claims Processing Manual, Chapter 4 §§ 231.6 and 231.7>

- c. The HCPCS code should reflect one of the blood freezing, thawing, splitting, or irradiating codes rather than the “P” code of the blood product transfused. < *Medicare Claims Processing Manual*, Chapter 4 §§ 231.6 and 231.7 >

C. Inpatient and outpatient payment concepts

1. Inpatient lab tests are paid under the DRG case rate for IPPS hospitals.
 2. Payment for outpatient hospital clinical diagnostic laboratory services are packaged or paid separately.
 - a. CMS makes separate payment under Clinical Lab Fee Schedule for certain outpatient hospital clinical diagnostic laboratory services
 - i. Medicare makes separate payment for clinical diagnostic laboratory services if they are:
 1. Select screening/preventive lab tests with an explicit benefit, like HIV or HPV screening
 2. Molecular pathology, advanced diagnostic lab tests (ADLTs), and pathology tests with status indicators other than Q4 (discussed below)
 - a. “Advanced diagnostic laboratory test” means a clinical diagnostic laboratory test that is developed, offered, and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and meets one of the following criteria:
 - i. The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result
 - ii. The test is cleared or approved by the Food and Drug Administration
 - iii. The test meets other similar criteria established by the Secretary
3. Provided on a day when no other outpatient services are provided and billed on a separate claim.

- a. Laboratory services with status indicator Q4 are not packaged, but rather paid separately on the CLFS when no other services are billed on the same claim as the laboratory service. *<80 Fed. Reg. 70350; Medicare Claims Processing Manual, Transmittal 3425>*
 - i. No modifier is necessary to receive separate payment for laboratory services with status indicator Q4 that are separately payable under this policy. *<80 Fed. Reg. 70349; Medicare Claims Processing Manual, Transmittal 3425>*
 - b. Reference laboratory services:
 - i. Laboratory services provided to non-patients (commonly called reference lab services) are paid separately on the CLFS if no other OPPS services are provided to the patient on the same day. *<Medicare Claims Processing Manual, Transmittal 2845>*
 - ii. Specimen is sent to the hospital for testing, but is not an inpatient or outpatient and is not physically present at the hospital. *<Medicare Benefit Policy Manual, Chapter 6, § 70.5; Medicare Claims Processing Manual, Transmittal 2845>*
 - iii. Test is billed as an outpatient test (i.e., the claim changes from 0141 to 0131) if the patient receives other outpatient services on the same day as the specimen is received by the hospital. *<Medicare Benefit Policy Manual, Chapter 6, § 70.5>*
 - a. Non-patient reference laboratory services should be billed on TOB 14X. *<Medicare Claims Processing Manual, Transmittals 734 and 2845; NUBC Official UB-04 Data Specifications Manual>*
4. Typically, no deductible or coinsurance applies to outpatient lab tests.
6. ESRD & SNF consolidated billing:
- i. Dialysis facility—effective for items and services furnished on or after January 1, 2011, Section 153b of the Medicare Improvements for Patients and Providers Act (MIPPA) requires that all ESRD-related laboratory tests be reported by the ESRD facility, whether provided directly or under arrangements with an independent laboratory.
 - ii. When laboratory services are billed by a laboratory other than the ESRD facility and the laboratory service furnished is designated as a laboratory test that is included in the ESRD PPS (i.e., ESRD-related), the claim will be rejected or denied. See the link “ESRD Consolidated Billing” for the list of items and services subject to consolidated billing, including the list of

ESRD-related laboratory tests that are routinely performed for the treatment of ESRD. If an ESRD-related laboratory service was furnished to an ESRD beneficiary for reasons other than for the treatment of ESRD, the supplier may submit a claim for separate payment using modifier -AY. See Pub.100-04, Chapter 8 for more information regarding outpatient ESRD hospital, independent facility, and physician/supplier claims.

- iii. Three pricing modifiers identify the different payment situations for ESRD AMCC services. The physician that orders the tests is responsible for identifying the appropriate modifier when ordering the test, as follows:
 - 1. Modifier -CD: AMCC test has been ordered by an ESRD facility or MCP physician that is part of the composite rate and is not separately billable
 - 2. Modifier -CE: AMCC test has been ordered by an ESRD facility or MCP physician that is a composite-rate test but is beyond the normal frequency covered under the rate and is separately reimbursable based on medical necessity
 - 3. Modifier -CF: AMCC test has been ordered by an ESRD facility or MCP physician that is not part of the composite rate and is separately billable
 - iv. ESRD clinical laboratory tests identified with modifiers -CD, -CE, or -CF may not be billed as organ or disease panels. All ESRD clinical laboratory tests must be billed individually.
- 7. Laboratory services provided to a SNF inpatient under Part A are billed by the SNF, not the laboratory, due to consolidated billing for SNFs.
 - i. Only one laboratory may bill for a referred laboratory service. The referring laboratory is responsible for ensuring the reference laboratory does not bill Medicare for the referred service when the referring laboratory does so (or intends to do so). In the event the reference laboratory bills or intends to bill Medicare, the referring laboratory may not do so. <Medicare Claims Processing Manual, Chapter 7, SNF Part B Billing>
 - ii. When no Part A program payment is possible, some or all services may be medically necessary and can be covered as ancillary services under Part B. The following services may be billed by the SNF or the rendering provider or supplier under an arrangement with the SNF: diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests.

8. Preoperative tests performed within three days of the **inpatient** admission for surgery will be packaged into the DRG and not paid separately.
 - a. Note there is no requirement to package or bundle outpatient pre-operative tests onto the same claim as the outpatient surgery and doing so results in less payment than what is allowable and appropriate. Outpatient preoperative tests should be billed on separate, per encounter claims.
9. All claims submitted for laboratory tests subject to CLIA are edited at the CLIA certificate level. However, the HCPCS codes that are considered a laboratory test under CLIA change each year. CMS identifies the new HCPCS (non-waived, non-provider-performed procedure) codes, including any modifiers that are subject to CLIA edits, by providing an updated listing of these tests to the A/B MACs (A) and (B) on an annual basis via a Recurring Update Notification. A facility that submits a claim for any test mentioned in the list of HCPCS codes that are subject to CLIA must have either a valid, current CLIA certificate of registration (certificate type 9), a CLIA certificate of compliance (certificate type 1), or a CLIA certificate of accreditation (certificate type 3). <Medicare Claims Processing Manual, Chapter 16, Section 70.9, HCPCS Subject to and Excluded From CLIA Edits>

D. Coding and edits

1. Specimen collection by venipuncture or catheter is coded with a separate code, distinct from the laboratory test. The codes represent method of collection and in some case specimen type. <Medicare Claims Processing Manual, Chapter 16 § 60.1.2>
2. A specimen collection fee for home health and skilled nursing patients is applicable if:
 - a. The specimen is used to perform a test paid under the CLFS;
 - b. The specimen is collected by a trained technician from a Medicare patient who is homebound or a non-hospital inpatient when no qualified personnel are available at the facility to collect the specimen; and
 - c. The specimen is collected through venipuncture or urine sample by catheterization.
3. The allowed amount for specimen collection is included in the laboratory fee schedule distributed annually by CMS. <Medicare Claims Processing Manual, Chapter 16, Section 60.1.2>

4. Travel Allowance

- a. Medicare pays a travel allowance, in addition to the specimen collection fee, for patients who are homebound or inpatients in a facility other than a hospital.
 - (i) For travel of 20 eligible miles or less, a flat-rate travel allowances applied, billed with P9604, or
 - (ii) For travel more than 20 eligible miles or to more than one location, a per mile travel allowance is applied, billed with P9603. <Medicare Claims Processing Manual, Chapter 16 § 60.2>

E. Charge capture

1. Laboratory information systems (LIS) typically have modules for different types of laboratory tests such as chemistry and hematology and also blood bank. Only completed tests should be billed. Caution for devices that produce automated test results on specimens when the tests were not ordered.
 - a. Caution: Blood gas machines and automated electrolyte tests. Do not interface charges for electrolyte tests from blood gas machines. Determine whether the same tests are to be performed by the lab for the same patient. Only one set of lab tests are medically necessary and billable. In addition, the parameters for the electrolyte tests may not be the same as the clinical lab tests. Also, the results may not be tracked in the same manner.
2. An LIS (sometimes known as a laboratory management or information management system) is a software-based system with features that support a modern laboratory's operations. Key features include workflow and data tracking support, flexible architecture, and data exchange interfaces.
3. The LIS is typically interfaced to the AR system and automates specimen collection and testing via bar codes, automatically printed tube labels with accession numbers tied to the patient account, time of specimen collection, patient identification, etc. A sub-module often exists to track collections per day, to sum to one unit per day for outpatient accounts, and to track individual panel tests.
4. Reflex tests—a reflex test is a laboratory test performed (and charged for) after an initially ordered and resulted test. Reflex testing occurs when an initial test result meets pre-determined criteria (e.g., positive or outside normal parameters), and the primary test result is inconclusive without the reflex or follow-up test. It is performed automatically without the intervention of the ordering physician. Reflex testing may prevent the need for additional specimen procurement from the patient. To be covered, the reflex test needs

to add valuable diagnostic information and be consistent with best medical practices. Certain confirmatory reflex tests are required by law, but generally each laboratory establishes its own criteria for medically appropriate reflex tests. A laboratory must disclose to the ordering physician its protocol for performing reflex testing and provide the physician with the opportunity to decline the follow-up tests. This medical staff/physician disclosure methodology should be documented.

- V. Diagnostic Radiology (032x), Other Imaging (040x), Nuclear Medicine (034x), CT Scan (035x); Magnetic Technology (061x), PET and MEG (086x), Radiation Therapeutic (non-chemotherapy) (0333, 0339, but, due to very different definitions, 0330 should not be used)
 - A. Guidance is in *Medicare Claims Processing Manual*, Chapter 13, Radiology Services and Other Diagnostic Procedures
 - B. Coverage
 - 1. *CoPs* for radiology and nuclear medicine services are at 42 *C.F.R.* § 482.26 and 42 *C.F.R.* § 482.53, respectively.
 - a. Under hospital *CoPs*, radiology and nuclear medicine services must be provided only on the order of a practitioner with clinical privileges or authorized by the medical staff and governing body to order such services consistent with applicable state law. <42 *C.F.R.* § 482.26(b)(4), 42 *C.F.R.* § 482.53(d)(4)>
 - (i) Mammogram exceptions—beneficiaries may self-refer themselves for a screening mammogram without an order from a treating physician. <*Benefit Policy Manual*, Chapter 15, § 280.3>
 - (ii) Bone mass measurement must be ordered by a practitioner treating the patient after an evaluation of the beneficiary's need for the measurement and the medically appropriate procedure to be used. <42 *C.F.R.* § 410.31(b)(1)(i)>
 - 2. The service must be furnished under the appropriate level of physician supervision as identified in the MPFS. <*Benefit Policy Manual*, Chapter 6, §20.4.4>
 - a. Supervision for diagnostic services must be provided by a physician or a non-physician practitioner (NPP) to the extent they are authorized to do so under their scope of practice and applicable State law. <See 42 *C.F.R.* 410.28(e)>

- (i) NPPs able to provide supervision for diagnostic services are physician assistants, nurse practitioners, clinical nurse specialists, certified nurse-midwives, or certified registered nurse anesthetists. <See 42 *C.F.R.* 410.28(e)>
 - b. Exception: Diagnostic mammography, regulated by the FDA, and laboratory and pathology services in the 80000 series of the *CPT Manual* are excluded from supervision requirements in 410.32. <42 *C.F.R.* § 410.32(b)(2)(i), (vi)>
 - c. Radiology Assistants authorized by the state and privileged by the hospital can perform personal supervision of imaging tests if the state scope of practice so allows. <Transmittal 251, CR11043, November 30, 2018>
3. Medicare defines three levels of supervision for hospital outpatient diagnostic services:
- a. General supervision, indicated by a "01" on the MPFS, requires the service to be furnished under the overall direction and control of the physician, but the physician need not be present during the performance of the procedure. <42 *C.F.R.* § 410.32 (b)(3)(i)>
 - (i) The training of the nonphysician personnel who perform the diagnostic procedure is the continuing responsibility of the hospital. <42 *C.F.R.* § 410.28 (e); see *Medicare Benefit Policy Manual*, Chapter 6, § 20.4.4>
 - b. Direct supervision, indicated by a "02" on the MPFS, parallels the requirements for direct supervision of therapeutic services. <42 *C.F.R.* § 410.28(e); see *Medicare Benefit Policy Manual*, Chapter 6, § 20.4.4>
 - (i) The physician must be immediately available, meaning physically present and interruptible, and able to furnish assistance and direction throughout the performance of the procedure. <*Medicare Benefit Policy Manual*, Chapter 6, § 20.4.4>
 - (ii) The physician must have within his or her scope of practice and hospital-granted privileges the ability to personally perform all services being supervised. <*Medicare Benefit Policy Manual*, Chapter 6, § 20.4.4>
 - (a) The physician must be able to step in and take over provision of the service and not merely respond in an emergency. <*Medicare Benefit Policy Manual*, Chapter 6, § 20.4.4>

- (b) The physician need not be able to operate specialized equipment, but he or she must be knowledgeable about the test and clinically appropriate to furnish the test. The physician must be able to take over the procedure and change the procedure and the course of care for the patient. <Medicare Benefit Policy Manual, Chapter 6, § 20.4.4>
- 1. For services furnished under arrangement by the hospital in non-hospital locations, the supervising physician must meet requirements for services furnished by non-hospital entities, which in general requires them to be in the same office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. <42 C.F.R. § 410.28 (e)(2); see 42 C.F.R. § 410.32 (b)(3)(ii)>
- c. Personal supervision, indicated by a "03" on the MPFS, requires the physician be in the room during the performance of the procedure. <Benefit Policy Manual, Chapter 15, § 80; 42 C.F.R. § 410.32 (b)(3)(iii)>
 - (i) (For services rendered on or after 01/01/2019 diagnostic imaging procedures performed by a Registered Radiologist Assistant (RRA) who is certified and registered by the American Registry of Radiologic Technologists (ARRT) or a Radiology Practitioner Assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants (CBRPA), and is authorized to furnish the procedure under state law, may be performed under direct supervision). <Transmittal 251, CR11043, November 30, 2018>
- 5. Positron Emission Tomography (PET) is a noninvasive imaging procedure that assesses perfusion and the level of metabolic activity in various organ systems of the human body. A positron camera (tomograph) is used to produce cross-sectional tomographic images, which are obtained by detecting radioactivity from a radioactive tracer substance (radiopharmaceutical) that emits a radioactive tracer substance (radiopharmaceutical FDG) such as 2 – [F-18] fluoro-D-glucose FDG that is administered intravenously to the patient. The *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1, §220.6, contains additional coverage instructions to indicate the conditions under which a PET scan is performed. <Medicare Claims Processing Manual, Chapter 13, Section 60, Positron Emission Tomography (PET) Scans – General Information>
- 6. CMS has implemented the appropriate use criteria (AUC) and clinical decision support (CDS) mechanism requirements for advanced imaging per the Protecting Access to Medicare Act (PAMA). Initial requirements can be found at 42 C.F.R. § 414.94. The 2016 MPFS rules established the Provider Led

Entities (PLEs) that will develop the AUC. The 2017 MPFS rules established the CDS requirements, and the 2018 and 2019 MPFS rules established some billing and date guidelines.

a. AUC refers to criteria only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for an individual's specific clinical condition. To the extent feasible, such criteria must be evidence-based. An AUC set is a collection of individual appropriate use criteria. An individual criterion is information presented in a manner that links a specific clinical condition or presentation; one or more services; and an assessment of the appropriateness of the services. <CMS.gov, "Appropriate Use Criteria Program" website>

b. Appropriate Use Criteria (AUC) for Advanced Imaging Services

(i) Overview

(a) An ordering physician must consult a Clinical Decision Support Mechanism (CDSM) before ordering advanced imaging services for a Medicare patient, and information about the CDSM, or an exception, must be reported on the claim for the advanced imaging service in order for the claim to be paid.

(b) A CDSM is an interactive, electronic tool for use by clinicians that communicates appropriate use criteria (AUC) information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition. <Medicare One Time Notification Transmittal 2404>

(ii) Implementation

(a) CMS has designated CY2020 – CY2022 the Educational and Operational Testing Period for AUC reporting requirements and claims will not be denied for failure to report or misreporting AUC/CDSM information. <Medicare One Time Notification Transmittal 2404; CMS.gov "Appropriate Use Criteria Program" website; 86 Fed. Reg. 65240>

CMS announced on the AUC Program page of their website that the Educational and Operations Testing Period will continue until further notice, and they are unable to forecast when the penalty phase will begin.

(b) Even though claims will not be denied, the ordering practitioner is required to consult the CDSM and the rendering providers are required to report AUC/CDSM information on claims effective January 1, 2023. <Medicare One Time Notification Transmittal 2404; see 42 C.F.R. § 414.94(j) and (k)>

(c) CMS expects the AUC requirements to be fully implemented January 1, 2023, when information regarding the CDSM consulted or an applicable exception must be reported on the claim for advanced imaging services in order for the claim to be paid. <See Medicare One Time Notification Transmittal 2404>

(iii) Ordering Practitioner Requirements

(a) The ordering physician must consult a CDSM, unless an exception applies, when ordering applicable advanced imaging services that will be furnished in an applicable setting and paid under an applicable payment system. <See Medicare One Time Notification Transmittal 2404; see 42 C.F.R. § 414.94(j) and (k)>

(b) Exceptions to consulting CDSM for AUC:

1. Emergency services provided to patients with emergency medical conditions, as defined under EMTALA (modifier -MA);
2. Tests ordered for inpatients or paid under Part A;
3. Significant hardship for the ordering practitioner due to insufficient internet access (modifier -MB), EHR or CDSM vendor issues (modifier -MC), or extreme and uncontrollable circumstances (modifier -MD). <See 42 C.F.R. § 414.94(j) and (k); 83 Fed. Reg. 59697-700>
 - a. If a significant hardship applies, the ordering practitioner self-attests at the time of ordering the advanced imaging service and communicates this to the furnishing provider who will include the appropriate modifier on the CPT code for the applicable advanced imaging service. <83 Fed. Reg. 59697-700; see Medicare One Time Notification Transmittal 2404>
 - b. For more details on circumstances representing a significant hardship, see the CY 2019 Medicare Physician Fee Schedule Final Rule, 83 Fed. Reg. 59699-700.

4. The requirement to consult a CDSM may be met by delegating to clinical staff acting under the direction of the ordering practitioner. <See 42 C.F.R. § 414.94(j)(2)>

(iv) Applicable Advanced Imaging Services

- (a) CMS has provided a list of CPT codes that represent applicable advanced imaging services, including CT, PET, MRI, and other nuclear medicine tests. <See *Medicare One Time Notification Transmittal 2404*>

(v) Applicable Settings

- (a) Applicable furnishing settings that must report AUC information include physician offices, independent diagnostic testing facilities, ambulatory surgery centers (ASC), and hospital outpatient departments, including emergency departments. <See *Medicare One Time Notification Transmittal 2404*; see 42 C.F.R. § 414.94(a)>

(vi) Applicable Payment Systems

- (a) Applicable payment systems include the Medicare Physician Fee Schedule, the OPPS, and the ASC payment system. <See *Medicare One Time Notification Transmittal 2404*; see 42 C.F.R. § 414.94(a)>

(vii) Reporting Requirements

- (a) An applicable advanced imaging service must be reported with an appropriate informational modifier -MA through -MH indicating if a CDSM was consulted, if the order adheres to the AUC of the CDSM or if a special circumstance applies (e.g. a hardship exception). <See *Medicare One Time Notification Transmittal 2404*; see *MLN Matters SE20002*>
- (b) If modifiers -ME (the order adheres to AUC), -MF (the order does not adhere to AUC), or -MG (the service does not have AUC) are reported, a G code representing the CDSM consulted must also be reported. <See *Medicare One Time Notification Transmittal 2404*; see *MLN Matters SE20002*>
- (c) CMS has provided a list of G-codes (G1000-G1010) corresponding to various approved CDSMs, including G1011 for CDSM not otherwise specified for newly approved CDSM products. <See

Medicare One Time Notification Transmittal 2404; see MLN Matters SE20002>

- (d) The CDSM G codes are reported with the same date of service as the advanced imaging service, a revenue code corresponding to the advanced imaging service (i.e., the same revenue code as the advanced imaging service or the corresponding XXX9 revenue code), and a nominal charge of \$.01. For claims examples see *MLN Matters SE20002*. <See *MLN Matters SE20002*>
- (e) If the ordering practitioner does not provide the furnishing provider AUC related information, modifier -MH is reported. <See *Medicare One Time Notification Transmittal 2404; see MLN Matters SE20002*>
- (f) The ordering providers NPI must be reported on the claim for advanced imaging services in the K3 segment, using the AUC indicator and LX to indicate the service line. <See *MLN Matters SE20002*>

C. Inpatient and outpatient payment concepts

- 1. Inpatient radiology and radiation therapy are covered under the respective inpatient payment methodology.
 - a. Caution: To ensure the inpatient cost is as little as possible, only services medically necessary to the inpatient stay should be performed and billed on an inpatient claim. For example, PET is rarely required for an inpatient stay.
- 2. Outpatient radiology and radiation therapy is paid via the OPPS for Medicare

E. General ledger and finance considerations

- 1. Separating expense departments by modality—ensure correct expense accounting and assignment of major movable equipment (MME).
 - a. CMS determined that hospitals used square footage to assign MME in cost reports for MRI. 2017 was the last year in a four-year transition period for hospitals to make adjustments. CMS has encouraged providers, through OPPS rulemaking, to change the MME capital allocation statistic from square footage to dollar value depreciation to more accurately align equipment costs to the appropriate cost center for rate setting purposes. CMS extended the time frame for hospitals to update their statistical basis through 2018. Only 15% of providers needing to update their basis did so in the four years CMS provided. In the 2018 OPPS final rule, CMS

extended this for another year. CMS no longer excludes providers using square footage and will phase-in the associated reductions to MRI and CT payment rates: 50% for 2020 and another 50% for 2021.

- b. Hospitals should consult their cost report staff and initiate a change from square footage if this is the statistical basis used for apportioning MME.
- 3. Pricing of imaging procedures is market-sensitive. Consider hospital prices that can compete with freestanding imaging centers.

F. Coding and edit issues

- 1. For diagnostic radiology tests capable of being performed on right and left sides, consider hard coding -RT and -LT modifiers on two charge codes for each test and build in RIS to match order by laterality
 - a. Radiology services can be billed as -RT and -LT, or for payers demanding modifier -50, a billing bridge routine can be written to sum the two lines—put modifier -50 and a unit of one. This enables the ordering system as well as the CDM to regain the LT and RT for orders.
- 2. Radiation therapy
- 3. Intensity modulated radiation therapy (IMRT)
 - a. Certain specified treatment planning codes are included in and should not be reported in addition to IMRT planning code 77301 (“Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications”) when provided prior to or as part of the IMRT plan. <Medicare Claims Processing Manual, Chapter 4 § 200.3.1>
 - (i) The list of specified treatment planning codes that should not be reported with IMRT planning (CPT code 77301) is provided in *Medicare Claims Processing Manual*, Chapter 4 § 200.3.1.
 - (ii) This reporting limitation applies whether the services described by the specified treatment planning codes are provided on the same or a different date of service as the IMRT planning (CPT code 77301). <Medicare Claims Processing Manual, Chapter 4 § 200.3.1>

TIP: Consider establishing a separate and unique IMRT planning outpatient account type opened upon the Radiation Oncologist decision to perform IMRT planning for a patient and discharged upon completion of the IMRT planning code 77301.

All orders for CT and other imaging and tests and services necessary to complete the IMRT plan performed over several days and different patient encounters should be ordered and charged to this account.

Upon claim development, all the other charges for the discrete IMRT planning services should be added to the IMRT planning code 77301 to correctly report all the resources utilized in performing the IMRT planning service. Note that this is a CPT requirement and should be followed for all payers.

4. Stereotactic radiosurgery (SRS)

a. Reporting of SRS

(i) Delivery of SRS is differentiated between the type of equipment use for single session cranial SRS and delivery of fractionated (multiple session) SRS for either cranial or other lesions. <Medicare Claims Processing Manual, Chapter 4 § 200.3.2>

(a) A single session of cranial SRS delivered with multi-source cobalt-60 based equipment should be reported with CPT code 77371 ("Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multisource cobalt 60 based"). <Medicare Claims Processing Manual, Chapter 4 § 200.3.2>

(b) A single session of cranial SRS delivered with linear accelerator ("Linac") based equipment should be reported with CPT code 77372 ("Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based"). <Medicare Claims Processing Manual, Chapter 4 § 200.3.2>

(c) For any fractionated (multiple session) SRS delivered, including multiple session cranial SRS, each fraction or session, including the first, is reported with CPT® code 77373 (“Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions”) <Medicare Claims Processing Manual, Chapter 4 § 200.3.2>

(ii) In addition to treatment delivery, SRS planning services should also be reported as appropriate. <Medicare Claims Processing Manual, Chapter 4 § 200.3.2>

b. Payment for SRS

(i) Payment for single session cobalt-60 (CPT® code 77371) or Linac (CPT® code 77372) cranial SRS is made through C-APC 5627 (“Level 7 Radiation Therapy”).

(a) Payment for 10 specific planning and preparation codes is not included in the C-APC for SRS, and they are paid separately whether they are reported on the same or different claim and/or day as the treatment delivery service. <82 Fed. Reg. 59243, Medicare Claims Processing Manual, Chapter 4 § 200.3.2>

CMS deviated from the standard methodology for payment of C-APCs because claims data showed that planning services for Linac were often provided on a different date of service. This resulted in planning services being included for rate setting with cobalt-60 SRS but not Linac, affecting proper rate setting for the C-APC for SRS.

5. Special radiology payment modifiers

a. Modifier -CT

(i) Specified computed tomography (CT) scans furnished on equipment that does not meet the NEMA standard³ must be reported with modifier -CT. <Medicare Claims Processing Manual, Chapter 4 § 20.6.13>

³ National Electrical Manufacturers Association (NEMA) Standard XR-29-2013 (“Standard Attributes on CT Equipment Related to Dose Optimization and Management”)

- (a) Modifier -CT applies to CT scan codes specified in the IOCE Quarterly Data Files available on the IOCE homepage; see "Q_CD_HcpcsMap," "NonStandardCTScan" column.
 - (ii) If a CT scan reported with modifier -CT is paid separately, the payment is reduced by 15%. <Medicare Claims Processing Manual, Transmittal 3685>
 - (iii) If a CT scan is paid as part of an Imaging Family Composite APC (APCs 8005 and 8006), the APC Composite payment is reduced by 15%. <Medicare Claims Processing Manual Transmittal 3685; IOCE Specifications, Appendix K>
 - (a) No reduction is applied to CT scans reported with modifier -CT, which are packaged into payment for other services (i.e., composite, or comprehensive APCs). <IOCE Specifications, Special Processing Conditions>
- b. Modifier -FX
 - (i) An x-ray taken using film must be reported with modifier -FX. <Medicare Claims Processing Manual, Chapter 4 § 20.6.14>
 - (ii) If an x-ray reported with modifier -FX is paid separately, the payment is reduced by 7%. <Medicare Claims Processing Manual, Chapter 4 § 20.6.14>
- c. Modifier -FY
 - (i) An x-ray taken using computed radiography technology/cassette-based imaging must be reported with modifier -FY. <Medicare Claims Processing Manual, Chapter 4 § 20.6.15>
 - (ii) If an x-ray reported with modifier -FY is paid separately, the payment is reduced by 7%. <Medicare Claims Processing Manual, Chapter 4 § 20.6.15>

G. Charge capture

1. Visit codes for radiation oncology consultation visits are often missed in charge capture and CDMs for radiation oncology. A G0463 for outpatient hospital visit should be billed for each radiation oncology consultation and/or follow-up visit where treatments are not also performed or where the visit is not significant and separately identifiable qualifying for modifier -25.

2. Ensure technologists have access to change the ordered exam to the performed exam so that exams charged are correct per what is performed. Often the order specifies contrast and/or number of films or laterality incorrectly and must be corrected for accurate CPT® coding from the RIS.
 - a. Note that changed orders, while correct for billing, result in different CPT codes and may conflict with prior authorizations by CPT® code where retroactive changes to authorizations are not allowed. Caution is advised for advanced imaging exams.

VI. Operating Room Services (036x), GI Services (075x), Anesthesia (037x) and Recovery Services (071x), Extra-corporeal Shock Wave Treatment (ESWT) (079x), & Ambulatory Surgery (049x)

A. Coverage

1. *CoPs* for surgical and anesthesia services are found at 42 *C.F.R.* § 482.51 and 42 *C.F.R.* § 482.52, respectively. These describe requirements for management and timeliness of preoperative H&P, for example.
2. Most surgical procedures are covered when medically necessary. Documentation of tried and failed other more conservative treatments prior to surgery is becoming a more significant part of proving medical necessity.
3. CMS has implemented a prior authorization program for specified outpatient hospital procedures. <See 42 *C.F.R.* 419.82; 84 *Fed. Reg.* 61447, 85 *Fed. Reg.* 86236-248>
 - a. CMS has published a "Prior Authorization (PA) Program for Certain Hospital Outpatient Department (OPD) Services Operational Guide", referred to in this section as the Operational Guide, available on the CMS website.

Link: Prior Authorization for Certain Hospital Outpatient Department Services – HCPCS Codes under Medicare -Related Sites - General

- b. The prior authorization process only applies to services paid through Medicare Fee-for-Service and provided in OPDS hospital outpatient departments. <84 *Fed. Reg.* 61453>
- c. Categories of Services Requiring Prior Authorization by Medicare
 - (i) CMS finalized five categories of services requiring prior authorization, effective July 1, 2020: Blepharoplasty, Rhinoplasty, Panniculectomy, Botulin Toxin Injections, Vein Ablation.

(ii) CMS finalized two additional categories of services requiring prior authorization, effective July 1, 2021: Cervical Fusion with Disc Removal, and Implanted Spinal Neurostimulators.

(iii) CMS finalized one additional category of services requiring prior authorization, effective July 1, 2023: Facet Joint Interventions.

d. Exemption from Prior Authorization

(i) CMS may exempt a provider from the prior authorization process when a provider demonstrates compliance by achieving a 90% provisional affirmation rate with at least 10 submitted claims. <42 C.F.R. 419.83(c); 84 Fed. Reg. 61448; Medicare Program Integrity Manual, Chapter 3 § 3.10.2, Operational Guide, Section 5>

4. Part of determining the medical necessity is the correct patient status (i.e., inpatient vs outpatient) and may also include the correct site of service (i.e., office or clinic, ASC versus hospital).
 - a. Medicare limits coverage of certain procedures solely to inpatient.
5. Medicare has special *CoPs* for hospitals performing transplants. <42 C.F.R. § 482.68-104>
6. CMS limits coverage for certain surgical procedures, such as bariatric surgery, to both covered indications as well as to covered facilities that have demonstrated competency for the procedures, typically with a minimum volume as well as other requirements.
 - a. Search the National Coverage Database for the most current NCDs.
7. MACs may also limit coverage of surgical procedures with LCDs.
8. Typically, surgical procedures that do not require overnight recovery are approved for the outpatient setting, including ASCs.
9. Best practice is for the medical record of the performing facility to include all required documentation to substantiate coverage, including prior and failed conservative treatments, and the site of service/status of the patient.
10. Commercial insurances often require authorization of elective surgery, including status/site of service as well as length of stay.
11. Some procedures require a custom implant to be built. Consider having patients sign a waiver/ABN stating that they will pay the invoice cost of the

custom implant if they elect not to proceed with surgery after the implant has been ordered.

B. Coding and edit issues.

1. Inpatient-only procedures

- a. CMS has determined certain procedures are not appropriate to be provided in a hospital outpatient department and designates them “inpatient only” procedures. <Medicare Claims Processing Manual, Chapter 4 § 180.7>

- (i) See Handout 18 for a Sample Workflow for Inpatient Only Procedures.

- (ii) CMS makes changes to the list of inpatient-only procedures on an annual basis in the OPPS final rule. <82 Fed. Reg. 59381-82>

- (iii) Inpatient-only procedures have an OPPS status indicator of C on Addendum B. The complete list of inpatient-only procedures is also published in Addendum E to the OPPS final rule every year. <Medicare Claims Processing Manual, Chapter 4 § 180.7>

Link: *OPPS – Regulations and Notices under Medicare-Related Sites – Hospital*

- b. Inpatient-only procedures performed on an outpatient basis.

- (i) Subject to certain exceptions discussed below, if an inpatient-only procedure is performed on an outpatient basis, no payment will be made for the inpatient-only procedure or any other services furnished on the same date as the inpatient-only procedure. <IOCE Specifications, Edits 18 and 49>

2. Exceptions to the inpatient-only rule

- a. Emergency inpatient-only procedure and patient dies or is transferred

- (i) If an inpatient-only procedure is furnished on an emergency basis while the patient is still an outpatient and the patient dies or is transferred to another hospital prior to being admitted, payment is made for the inpatient-only procedure and all other services provided

CMS modified the emergency exception to the inpatient-only list in 2017 to allow payment for patients transferred to another hospital, retroactive to January 2016. For more information, refer to the IOCE.

that day under a single APC. <IOCE Specifications, Special Processing Conditions, #3>

(ii) Billing

- (a) The HCPCS code for the inpatient-only procedure should be reported with the -CA modifier. <IOCE Specifications, Special Processing Conditions, #3>
- (b) The patient discharge status code (UB-04, FL 17) must reflect the patient expired or was transferred. <IOCE Specifications, Special Processing Conditions, #3>
- (c) The claim will be returned to the provider under IOCE edit 70 if modifier -CA is reported without a patient discharge status code of 20, expired, or a designated transfer code.⁴ <IOCE Specifications, Special Processing Conditions, #3 and Table 4>

b. Payment

- (i) Payment for an emergency inpatient-only procedure reported with modifier -CA is made under comprehensive APC 5881 "Ancillary Outpatient Services When Patient Dies" (\$7,077.28). <68 *Fed. Reg.* 63467; 80 *Fed. Reg.* 70339; Addendum A>
- (ii) Limitations <IOCE Specifications, Special Processing Conditions, #3>
 - (a) Payment will only be made for one -CA procedure.
 - (b) All other line items billed on the same day as a -CA procedure paid under APC 5881 are packaged, including line items that trigger other Comprehensive APCs (i.e., assigned to status indicator J1). <IOCE Specifications, Appendix L>

3. Patient is admitted as an inpatient within three days of the procedure.

- a. If an inpatient-only procedure is furnished on an outpatient basis, and the patient is admitted as an inpatient within three days, the inpatient-only procedure is included on the inpatient claim according to the

⁴ **2/82:** Discharged/transferred to a Short Term General Hospital for Inpatient Care/with a Planned Acute Care Hospital Inpatient Readmission; **5/85:** to a Designated Cancer Center or Children's Hospital/with a Planned Acute Care Hospital Inpatient Readmission; **62/90:** to an Inpatient Rehabilitation Facility (IRF), including Rehabilitation Distinct Part Units of a Hospital/with a Planned Acute Care Hospital Inpatient Readmission; **63/91:** to a Medicare Certified Long Term Care Hospital (LTCH)/with a Planned Acute Care Hospital Inpatient Readmission; **65/93:** to a Psychiatric Hospital or Psychiatric Distinct Part of a Hospital/with a Planned Acute Care Hospital Inpatient Readmission; or **66/94:** to a Critical Access Hospital (CAH)/with a Planned Acute Care Hospital Inpatient Readmission.

usual requirements under the three-day payment window. <Medicare Claims Processing Manual, Chapter 4 § 180.7; Medicare Claims Processing Manual, Transmittal 3238>

- b. Emergency inpatient-only procedure and the patient survives.
 - (i) When an inpatient-only procedure is furnished on an emergency basis while the patient is still an outpatient and the patient survives the procedure, the patient should be admitted and an inpatient claim submitted including the inpatient-only procedure. <67 Fed. Reg. 66798; Program Memorandum A-02-129; Medicare Claims Processing Manual, Transmittal 3238>

4. Separate procedure exception

- a. Inpatient-only procedures on the separate procedure list are bypassed when performed incidental to a surgical procedure with status indicator T or J1. <IOCE Specifications, Special Processing Conditions, #3>
 - (i) If an inpatient-only procedure on the separate-procedure list is billed with a status indicator T or J1 procedure, the inpatient-only code is rejected and the claim is processed according to the usual OPPS rules. <IOCE Specifications, Special Processing Conditions>
 - (ii) The "separate-procedure list" is available in the IOCE Quarterly Data Files available on the OCE homepage.

Link: OCE Specifications under Medicare-Related Sites – Hospital
See "Q_CD_HcpcsMap," column AJ.

5. Multiple procedure reduction for surgical services

- a. Multiple procedure reduction mechanics
 - a) If more than one surgical procedure with a status indicator of T is performed during a single surgical encounter:
 - a) Full payment is made for the procedure with the highest payment rate; and
 - b) All other "T" procedures are discounted 50%. <42 C.F.R. § 419.44(a); Medicare Claims Processing Manual, Chapter 4 § 10.5>
- b. Multiple "T" procedures performed during separate encounters on the same day

- a) The multiple procedure reduction is not applicable if the status indicator T procedures are performed in separate surgical encounters on the same day. <42 C.F.R. § 419.44(a); IOCE Specifications, Appendix D>
- b) Reporting:
 - a) If multiple status indicator T procedures are performed during separate encounters on the same day, one of the following modifiers must be reported so the multiple procedure reduction is not applied by the IOCE:
 - 1) -76: procedure repeated the same day by the same physician
 - 2) -77: procedure repeated the same day by a different physician
 - 3) -78: return to the operating room for a related procedure during the postoperative period (presumably the same day)
 - 4) -79: unrelated procedure or service by the same physician during the postoperative period (presumably the same day) <IOCE Specifications, Appendix D>
 - b) Multiple unrelated procedures or services by different physicians
 - 1) Modifier -79 contains the phrase “same physician” and does not address multiple unrelated procedures by different physicians in the postoperative period, presumably because this situation does not require a modifier for reporting by physicians. Arguably, the phrase “same physician” would be read as “same facility” in the hospital outpatient reporting context.
 - 2) Reporting modifier -79 for unrelated procedures by different physicians in the postoperative period (i.e., in separate encounters) results in no multiple procedure reduction applying to the procedures, as is appropriate under the policy. <42 C.F.R. § 419.44(a); IOCE Specifications, Appendix D>

Caution: Although modifier -59 may be used to override NCCI edits when services occur in different patient encounters, it does not turn off the multiple procedure reduction when appropriate.

6. Terminated/discontinued procedures.

- a. Termination of procedures when anesthesia is planned or provided
- b. The term “anesthesia” includes local anesthesia, regional blocks, conscious sedation, deep sedation, and general anesthesia for purposes of reporting terminated procedures. <Medicare Claims Processing Manual, Chapter 4 § 20.6.4(A)>
 - i. “Procedural pre-medication” is not considered anesthesia for purposes of reporting terminated procedures. <Medicare Claims Processing Manual, Chapter 4 § 20.6.4(A)>
- c. Three possible scenarios
 - a. Termination prior to the patient being prepped and taken to the procedure room.
 - a) The procedure is not reported at all. <Medicare Claims Processing Manual, Chapter 4 § 20.6.4(C)>
 - b) However, consider reporting an outpatient visit for the assessment that resulted in the terminated/cancelled procedure when due to a clinical reason and documented.
 - b. Termination after the patient has been prepped and taken to the procedure room but before anesthesia was provided.
 - a) Under these circumstances, the terminated procedure is reported with modifier -73. <Medicare Claims Processing Manual, Chapter 4 § 20.6.4(B)>
 - b) Payment for procedures not assigned to a device-intensive APC, reported with modifier -73, is reduced by 50%. <Medicare Claims Processing Manual, Chapter 4 § 20.6.4(B), 42 CFR 419.44(b)(2)>
 - c) Payment for device-intensive procedures, reported with modifier -73, is reduced by the device offset amount for the HCPCS code, and then the result is further reduced by 50%. <See IOCE Specifications, Special Processing Conditions, #5; Medicare Claims Processing Manual, Chapter 4 § 20.6.4(B)>
 - a) The list of device-intensive procedures and corresponding device offset amounts are available in the IOCE Quarterly Data Files (“Q_CD_OffsetHcpcs”) available on the IOCE homepage.

Link: OCE Specifications under Medicare-Related Sites – Hospital

- c. Termination after anesthesia induction or after the procedure has begun (e.g., incision made, intubation started, scope inserted).
 - a) Under these circumstances, the terminated procedure is reported with modifier -74. <Medicare Claims Processing Manual, Chapter 4 § 20.6.4(A)>
 - b) Paid at 100%. <Medicare Claims Processing Manual, Chapter 4 § 20.6.4(B), 42 CFR 419.44(b)(1)>
- d. Limitations on the use of modifiers -73 and -74
 - a. Modifiers -73 and -74 are used when a procedure requiring anesthesia was terminated due to extenuating circumstances or circumstances that threaten the well-being of the patient. <Medicare Claims Processing Manual, Chapter 4 § 20.6.4(A)>
 - a) Modifier -74 may also be used if a procedure is discontinued, reduced, or cancelled at the physician's discretion after induction of anesthesia. <Medicare Claims Processing Manual, Chapter 4 § 20.6.4(A)>
 - b. Modifiers -73 and -74 are only to be used with discontinued surgical and diagnostic procedures when anesthesia was planned or provided. <Medicare Claims Processing Manual, Chapter 4 § 20.6.4(A)>
 - a) Modifiers -73 and -74 should not be used to indicate discontinued radiology procedures or the discontinuation of other procedures when anesthesia administration was not planned. <Medicare Claims Processing Manual, Chapter 4 § 20.6.4(A)>
- e. Termination of procedures when anesthesia is not planned
 - a) Modifier -52 should be reported if the patient is prepared and taken to the room where the procedure was to be performed and the procedure was discontinued. <Medicare Claims Processing Manual, Chapter 4 § 20.6.4 (B)>
 - b) Modifier -52 is also used to report procedures, especially radiology procedures, when the service described by a code is not performed in its entirety and no code exists for the services that were provided. <Medicare Claims Processing Manual, Chapter 4 § 20.6.6>
 - c) Codes reported with modifier -52 are paid at 50% of the applicable APC. <Medicare Claims Processing Manual, Chapter 4 § 20.6.4 (B); 42 CFR § 419.44(b)(3)>

7. Bilateral procedures

a. Bilateral procedures may be reported with:

- i. Inherently bilateral HCPCS codes (i.e., a single code representing the procedure performed bilaterally)—if a procedure, with a code that is inherently bilateral, is performed more than once in a day, the procedure may be reported on separate lines with a modifier -76 on the second set of procedures. <Medicare Claims Processing Manual, Transmittal 1702>
- ii. “Conditional bilateral” HCPCS codes (i.e., a code that is inherently unilateral, but can be reported with a modifier to indicate it was performed bilaterally).
- a. For OPPS purposes, conditional bilateral codes have a “1” in the “bilateral surgery” field in the Medicare Physician Fee Schedule. <IOCE Specifications, Appendix D>

Link: Physician Fee Schedule – Online Lookup under Medicare-Related Sites – Physician/Practitioner

- b. Procedures, with a code that is conditionally bilateral, performed bilaterally, should be reported as a single line item with modifier -50 and a unit of “1.” <Medicare Claims Processing Manual, Chapter 4 §§ 20.6, 20.6.2>
 - (i) The -RT and -LT modifiers should not be used when the -50 modifier applies. <Medicare Claims Processing Manual, Chapter 4 §§ 20.6, 20.6.2>
 - (ii) If a bilateral procedure is billed with a modifier -50 and units greater than 1, IOCE Edit 74 will trigger, causing the claim to be returned to the provider. <IOCE Specifications, Table 4>
- c. Payment for procedures reported with modifier -50
 - (i) Bilateral procedures with a status indicator other than T, reported with modifier -50, are not subject to the multiple procedure discount. The payment rate for the line item representing both procedures is 2.0 times the payment rate for the procedure. <IOCE Specifications, Appendix D>
 - (ii) Bilateral procedures with a status indicator T, reported with modifier -50, are subject to the multiple procedure discount.

(a) If the payment rate for the procedure done bilaterally is the highest payment rate of all status indicator T procedures on the claim, the payment for the line item representing both procedures will be 1.5 times the payment rate for the procedure. <IOCE Specifications, Appendix D>

(b) If the payment rate for the procedure done bilaterally is lower than another status indicator T procedure on the claim, the payment for the line item representing both procedures will be 1.0 times the payment rate for the procedure. <IOCE Specifications, Appendix D>

C. Inpatient and outpatient payment concepts

1. Inpatient surgery is paid via the surgical DRG or other inpatient case method.
2. Outpatient surgery is paid via the OPPS system or other ambulatory surgery case rates and is depends on correct CPT®/HCPCS coding for surgery.
3. Payment of medically necessary anesthesia is included in the payment for surgery but can be reported separately via revenue code 0370; it does not require HCPCS reporting.
 - a. Many providers have charges for monitored anesthesia care, conscious sedation, general, and regional anesthesia. Charges are often time-based, matching OR times when the procedure is in the OR. A single charge per service can be used for non-OR procedures, such as those in the ED.
 - b. Hospitals are not required to report anesthesia CPT® codes, but rather can report all charges under revenue code 0370 without HCPCS as packaged services. This includes CPT® codes for monitored sedation.
4. Multiple outpatient procedures in the same operative session are subject to multiple procedure reductions, typically where the highest payment rate is paid 100% and other rates are paid 50%.
 - a. Note that Medicare does not have a limit, but often commercial insurances have a limit of three procedures that will be separately paid with the multiple procedure reduction.

D. General ledger finance considerations

1. Most hospitals include anesthesia gases in the anesthesia charge and do not separately bill gases under pharmacy. However, injectable anesthesia agents are typically billed as pharmacy items. The drug administration codes are not separately billed as these are integral to the surgery/anesthesia.

2. Often the general ledger separates the following perioperative departments into separate expense and revenue departments:
 - a. Short stay
 - b. Surgery suites
 - c. Anesthesia
 - d. Post acute recovery area
 - e. Endoscopy suites
 - f. Lithotripsy
3. Surgery is often charged by time and by levels.
 - a. Levels relate to increasing complexity and acuity of cases whereby more equipment and staff are needed to support the surgery. Usually, the initial time unit is front loaded for room cleaning and sterilization, and setup of routine supplies, equipment, and devices.
4. Payers reduce terminated procedures and apply multiple procedure discounts. Correctly priced, time-based surgery charging should account for multiple procedures.
 - a. Caution is advised when surgical CPT® codes are hardcoded in the CDM.
5. Surgery suites that are separate from the main hospital surgery theater should be identified with separate general ledger account numbers. Distinct part ASCs should have their own revenue and expense centers; also, consider separating them on the cost report.
6. Note that revenue code 0361 is often used with numerous departments for surgical procedure charges that are “hard coded” in the CDM.
 - a. CMS maps this revenue code to surgery, whereas 0761 is mapped to “other” along with clinic. Note that the staff and other expense associated with procedures billed with revenue code 0361 or 0761 reside in the non-surgery departments. Ensure that the correct reclassification occurs on the cost report or consider alternative revenue codes for these services. Determine whether the revenue code edits are in the FISS system or on the claims clearinghouse system.

E. Charge capture

1. Surgery information systems start with surgery scheduling that defines the procedure and date and sets up a "shell template" for the perioperative and surgical record. Often preference cards of the main supplies defined for each procedure and surgeon are set up and pre-populate the patient account in a "pre-post" status until surgery is complete and the final item count is made.
2. Devices must have a device registry. Bar coding may facilitate the device/implant registry.
3. Surgery staff review and edit the "pre-post" charges and ensure time, device, and anesthesia charges are complete.

outs. For example, for specialty 01, the contractor would enter a number of all providers that have a status of opt out as of the close of the quarter.

The CMS will no longer accept faxed, e-mailed or mailed copies of the opt out report.

The report is due in CROWD 30 days after the end of each quarter (e.g., a report for the quarter April 1, 2010, through June 30, 2010, is due July 30, 2010.)

50 - Drugs and Biologicals

(Rev. 1, 10-01-03)

B3-2049, A3-3112.4.B, HO-230.4.B

The Medicare program provides limited benefits for outpatient drugs. The program covers drugs that are furnished “incident to” a physician’s service provided that the drugs are not usually self-administered by the patients who take them.

Generally, drugs and biologicals are covered only if all of the following requirements are met:

- They meet the definition of drugs or biologicals (see §50.1);
- They are of the type that are not usually self-administered. (see §50.2);
- They meet all the general requirements for coverage of items as incident to a physician’s services (see §§50.1 and 50.3);
- They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice (see §50.4);
- They are not excluded as noncovered immunizations (see §50.4.4.2); and
- They have not been determined by the FDA to be less than effective. (See §§50.4.4).

Medicare Part B does generally not cover drugs that can be self-administered, such as those in pill form, or are used for self-injection. However, the statute provides for the coverage of some self-administered drugs. Examples of self-administered drugs that are covered include blood-clotting factors, drugs used in immunosuppressive therapy, erythropoietin for dialysis patients, osteoporosis drugs for certain homebound patients, and certain oral cancer drugs. (See §110.3 for coverage of drugs, which are necessary to the effective use of Durable Medical Equipment (DME) or prosthetic devices.)

50.1 - Definition of Drug or Biological

(Rev. 1, 10-01-03)

B3-2049.1

Drugs and biologicals must be determined to meet the statutory definition. Under the statute §1861(t)(1), payment may be made for a drug or biological only where it is included, or approved for inclusion, in the latest official edition of the United States Pharmacopoeia National Formulary (USP-NF), the United States Pharmacopoeia-Drug Information (USD-DI), or the American Dental Association (AOA) Guide to Dental Therapeutics, except for those drugs and biologicals unfavorably evaluated in the ADA Guide to Dental Therapeutics. The inclusion of an item in the USP DI does not necessarily mean that the item is a drug or biological. The USP DI is a database of drug information developed by the U.S. Pharmacopoeia but maintained by Micromedex, which contains medically accepted uses for generic and brand name drug products. Inclusion in such reference (or approval by a hospital committee) is a necessary condition for a product to be considered a drug or biological under the Medicare program, however, it is not enough. Rather, the product must also meet all other program requirements to be determined to be a drug or biological. Combination drugs are also included in the definition of drugs if the combination itself or all of the therapeutic ingredients of the combination are included, or approved for inclusion, in any of the above drug compendia.

Drugs and biologicals are considered approved for inclusion in a compendium if approved under the established procedure by the professional organization responsible for revision of the compendium.




50.2 - Determining Self-Administration of Drug or Biological (Rev. 157, Issued: 06-08-12, Effective: 07-01-12, Implementation: 07-02-12)

The Medicare program provides limited benefits for outpatient prescription drugs. The program covers drugs that are furnished “incident to” a physician’s service provided that the drugs are not usually self-administered by the patients who take them. Section 112 of the Benefits, Improvements & Protection Act of 2000 (BIPA) amended sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act to redefine this exclusion. The prior statutory language referred to those drugs “which cannot be self-administered.” Implementation of the BIPA provision requires interpretation of the phrase “not usually self-administered by the patient”.

A. Policy



Fiscal intermediaries, carriers and Medicare Administrative Contractors (MACs) are instructed to follow the instructions below when applying the exclusion for drugs that are usually self-administered by the patient. Each individual contractor must make its own individual determination on each drug. Contractors must continue to apply the policy that not only the drug is medically reasonable and necessary for any individual claim, but also that the route of administration is medically reasonable and necessary. That is, if a drug is available in both oral and injectable forms, the injectable form of the drug must be medically reasonable and necessary as compared to using the oral form.

 For certain injectable drugs, it will be apparent due to the nature of the condition(s) for which they are administered or the usual course of treatment for those conditions, they are, or are not, usually self-administered. For example, an injectable drug used to treat migraine headaches is usually self-administered. On the other hand, an injectable drug, administered at the same time as chemotherapy, used to treat anemia secondary to chemotherapy is not usually self-administered.

B. Administered



The term “administered” refers only to the physical process by which the drug enters the patient’s body. It does not refer to whether the process is supervised by a medical professional (for example, to observe proper technique or side-effects of the drug). Injectable drugs, including intravenously administered drugs, are typically eligible for inclusion under the “incident to” benefit. With limited exceptions, other routes of administration including, but not limited to, oral drugs, suppositories, topical medications are considered to be usually self-administered by the patient.

C. Usually

For the purposes of applying this exclusion, the term “usually” means more than 50 percent of the time for all Medicare beneficiaries who use the drug. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from coverage and the contractor may not make any Medicare payment for it. In arriving at a single determination as to whether a drug is usually self-administered, contractors should make a separate determination for each indication for a drug as to whether that drug is usually self-administered.

After determining whether a drug is usually self-administered for each indication, contractors should determine the relative contribution of each indication to total use of the drug (i.e., weighted average) in order to make an overall determination as to whether the drug is usually self-administered. For example, if a drug has three indications, is not self-administered for the first indication, but is self-administered for the second and third indications, and the first indication makes up 40 percent of total usage, the second indication makes up 30 percent of total usage, and the third indication makes up 30 percent of total usage, then the drug would be considered usually self-administered.

Reliable statistical information on the extent of self-administration by the patient may not always be available. Consequently, CMS offers the following guidance for each contractor’s consideration in making this determination in the absence of such data:

-  1. Absent evidence to the contrary, presume that drugs delivered intravenously are not usually self-administered by the patient.
-  2. Absent evidence to the contrary, presume that drugs delivered by intramuscular injection are not usually self-administered by the patient. (Avonex, for example, is delivered by intramuscular injection, not usually self-administered by the patient.) The

contractor may consider the depth and nature of the particular intramuscular injection in applying this presumption. In applying this presumption, contractors should examine the use of the particular drug and consider the following factors:



3. Absent evidence to the contrary, presume that drugs delivered by subcutaneous injection are self-administered by the patient. However, contractors should examine the use of the particular drug and consider the following factors:

A. Acute Condition - Is the condition for which the drug is used an acute condition? If so, it is less likely that a patient would self-administer the drug. If the condition were longer term, it would be more likely that the patient would self-administer the drug.

B. Frequency of Administration - How often is the injection given? For example, if the drug is administered once per month, it is less likely to be self-administered by the patient. However, if it is administered once or more per week, it is likely that the drug is self-administered by the patient.

In some instances, carriers may have provided payment for one or perhaps several doses of a drug that would otherwise not be paid for because the drug is usually self-administered. Carriers may have exercised this discretion for limited coverage, for example, during a brief time when the patient is being trained under the supervision of a physician in the proper technique for self-administration. Medicare will no longer pay for such doses. In addition, contractors may no longer pay for any drug when it is administered on an outpatient emergency basis, if the drug is excluded because it is usually self-administered by the patient.

D. Definition of Acute Condition

For the purposes of determining whether a drug is usually self-administered, an acute condition means a condition that begins over a short time period, is likely to be of short duration and/or the expected course of treatment is for a short, finite interval. A course of treatment consisting of scheduled injections lasting less than 2 weeks, regardless of frequency or route of administration, is considered acute. Evidence to support this may include Food and Drug Administration (FDA) approval language, package inserts, drug compendia, and other information.



E. By the Patient

The term “by the patient” means Medicare beneficiaries as a collective whole. The carrier includes only the patients themselves and not other individuals (that is, spouses, friends, or other care-givers are not considered the patient). The determination is based on whether the drug is self-administered by the patient a majority of the time that the drug is used on an outpatient basis by Medicare beneficiaries for medically necessary indications. The carrier ignores all instances when the drug is administered on an inpatient basis.

The carrier makes this determination on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis. In evaluating whether beneficiaries as a collective whole self-administer, individual beneficiaries who do not have the capacity to self-administer any drug due to a condition other than the condition for which they are taking the drug in question are not considered. For example, an individual afflicted with paraplegia or advanced dementia would not have the capacity to self-administer any injectable drug, so such individuals would not be included in the population upon which the determination for self-administration by the patient was based. Note that some individuals afflicted with a less severe stage of an otherwise debilitating condition would be included in the population upon which the determination for “self-administered by the patient” was based; for example, an early onset of dementia.

F. Evidentiary Criteria

Contractors are only required to consider the following types of evidence: peer reviewed medical literature, standards of medical practice, evidence-based practice guidelines, FDA approved label, and package inserts. Contractors may also consider other evidence submitted by interested individuals or groups subject to their judgment.

Contractors should also use these evidentiary criteria when reviewing requests for making a determination as to whether a drug is usually self-administered, and requests for reconsideration of a pending or published determination.

Note that prior to August 1, 2002, one of the principal factors used to determine whether a drug was subject to the self-administered exclusion was whether the FDA label contained instructions for self-administration. However, CMS notes that under the new standard, the fact that the FDA label includes instructions for self-administration is not, by itself, a determining factor that a drug is subject to this exclusion.



G. Provider Notice of Noncovered Drugs

Contractors must describe on their Web site the process they will use to determine whether a drug is usually self-administered and thus does not meet the “incident to” benefit category. Contractors must publish a list of the injectable drugs that are subject to the self-administered exclusion on their Web site, including the data and rationale that led to the determination. Contractors will report the workload associated with developing new coverage statements in CAFM 21208.

Contractors must provide notice 45 days prior to the date that these drugs will not be covered. During the 45-day time period, contractors will maintain existing medical review and payment procedures. After the 45-day notice, contractors may deny payment for the drugs subject to the notice.

Contractors must not develop local coverage determinations (LCDs) for this purpose because further elaboration to describe drugs that do not meet the ‘incident to’ and the

‘not usually self-administered’ provisions of the statute are unnecessary. Current LCDs based solely on these provisions must be withdrawn. LCDs that address the self-administered exclusion and other information may be reissued absent the self-administered drug exclusion material. Contractors will report this workload in CAFM 21206. However, contractors may continue to use and write LCDs to describe reasonable and necessary uses of drugs that are not usually self-administered.

H. Conferences Between Contractors

Contractors’ Medical Directors may meet and discuss whether a drug is usually self-administered without reaching a formal consensus. Each contractor uses its discretion as to whether or not it will participate in such discussions. Each contractor must make its own individual determinations, except that fiscal intermediaries may, at their discretion, follow the determinations of the local carrier with respect to the self-administered exclusion.

I. Beneficiary Appeals

If a beneficiary’s claim for a particular drug is denied because the drug is subject to the “self-administered drug” exclusion, the beneficiary may appeal the denial. Because it is a “benefit category” denial and not a denial based on medical necessity, an Advance Beneficiary Notice (ABN) is not required. A “benefit category” denial (i.e., a denial based on the fact that there is no benefit category under which the drug may be covered) does not trigger the financial liability protection provisions of Limitation On Liability (under §1879 of the Act). Therefore, physicians or providers may charge the beneficiary for an excluded drug.

J. Provider and Physician Appeals

A physician accepting assignment may appeal a denial under the provisions found in Pub. 100-04, Medicare Claims Processing Manual, chapter 29.

K. Reasonable and Necessary

Contractors will make the determination of reasonable and necessary with respect to the medical appropriateness of a drug to treat the patient’s condition. Contractors will continue to make the determination of whether the intravenous or injection form of a drug is appropriate as opposed to the oral form. Contractors will also continue to make the determination as to whether a physician’s office visit was reasonable and necessary. However, contractors should not make a determination of whether it was reasonable and necessary for the patient to choose to have his or her drug administered in the physician’s office or outpatient hospital setting. That is, while a physician’s office visit may not be reasonable and necessary in a specific situation, in such a case an injection service would be payable.

L. Reporting Requirements

Each carrier, intermediary and Medicare Administrative Contractor (MAC) must report to CMS its complete list of injectable drugs that the contractor has determined are excluded when furnished incident to a physician's service on the basis that the drug is usually self-administered. The CMS expects that contractors will review injectable drugs on a rolling basis and update their list of excluded drugs as it is developed and no less frequently than annually. For example, contractors should not wait to publish this list until every drug has been reviewed. Contractors must enter their self-administered drug exclusion list to the Medicare Coverage Database (MCD). This database can be accessed at www.cms.hhs.gov/mcd. See Pub.100-08, Medicare Program Integrity Manual, Chapter 3, Section 3.3, "Policies and Guidelines Applied During Review", for instructions on submitting these lists to the MCD.



M. Drugs Treated as Hospital Outpatient Supplies

In certain circumstances, Medicare pays for drugs that may be considered usually self-administered by the patient when such drugs function as supplies. This is the case when the drugs provided are an integral component of a procedure or are directly related to it, i.e., when they facilitate the performance of or recovery from a particular procedure. Except for the applicable copayment, hospitals may not bill beneficiaries for these types of drugs because their costs, as supplies, are packaged into the payment for the procedure with which they are used. Listed below are examples of when drugs are treated as supplies and hospitals should bill Medicare for the drug as a supply and should not separately bill the beneficiary.

- Sedatives administered to a patient while he or she is in the preoperative area being prepared for a procedure.
- Mydriatic drops instilled into the eye to dilate the pupils, anti-inflammatory drops, antibiotic drops/ointments, and ocular hypotensives that are administered to a patient immediately before, during, or immediately following an ophthalmic procedure. This does not refer to the patient's eye drops that the patient uses pre- and postoperatively.
- Barium or low osmolar contrast media provided integral to a diagnostic imaging procedure.
- Topical solution used with photodynamic therapy furnished at the hospital to treat nonhyperkeratotic actinic keratosis lesions of the face or scalp.
- Antibiotic ointments such as bacitracin, placed on a wound or surgical incision at the completion of a procedure.



The following are examples of when a drug is not directly related or integral to a procedure, and does not facilitate the performance of or recovery from a procedure. Therefore the drug is not considered a packaged supply. In many of these cases the drug

itself is the treatment instead of being integral or directly related to the procedure, or facilitating the performance of or recovery from a particular procedure.

- Drugs given to a patient for his or her continued use at home after leaving the hospital.
- Oral pain medication given to an outpatient who develops a headache while receiving chemotherapy administration treatment.
- Daily routine insulin or hypertension medication given preoperatively to a patient.
- A fentanyl patch or oral pain medication such as hydrocodone, given to an outpatient presenting with pain.
- A laxative suppository for constipation while the patient waits to receive an unrelated X-ray.

These two lists of examples may serve to guide hospitals in deciding which drugs are supplies packaged as a part of a procedure, and thus may be billed under Part B.

Hospitals should follow CMS' guidance for billing drugs that are packaged and paid as supplies, reporting coded and uncoded drugs with their charges under the revenue code associated with the cost center under which the hospital accumulates the costs for the drugs.



50.3 - Incident To Requirements

(Rev. 1, 10-01-03)

B3-2049.3

In order to meet all the general requirements for coverage under the incident-to provision, an FDA approved drug or biological must:

- Be of a form that is not usually self-administered;
- Must be furnished by a physician; and
- Must be administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision.

The charge, if any, for the drug or biological must be included in the physician's bill, and the cost of the drug or biological must represent an expense to the physician. Drugs and biologicals furnished by other health professionals may also meet these requirements. (See §§170, 180, 190 and 200 for specific instructions.)

Whole blood is a biological, which cannot be self-administered and is covered when furnished incident to a physician's services. Payment may also be made for blood fractions if all coverage requirements are satisfied and the blood deductible has been met.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



**OIG Policy Statement Regarding Hospitals That Discount or Waive
Amounts Owed by Medicare Beneficiaries for Self-Administered Drugs Dispensed
in Outpatient Settings**

The purpose of this Policy Statement is to assure hospitals that they will not be subject to Office of Inspector General (OIG) administrative sanctions for discounting or waiving amounts Medicare beneficiaries may owe for self-administered drugs (SADs) they receive in outpatient settings when those drugs are not covered by Medicare Part B, subject to the conditions specified herein. This Policy Statement is designed to address the question whether various guidance documents issued by the Centers for Medicare & Medicaid Services (CMS), including a Program Memorandum outlining changes in the Outpatient Prospective Payment System (OPPS) for calendar year 2003, require hospitals to bill and collect (or make good faith efforts to collect) their usual and customary charges for SADs that are not covered by Medicare Part B (Noncovered SADs) to comply with OIG's fraud and abuse authorities. That Program Memorandum stated that:

[n]either the OPPS nor other Medicare payment rules regulate the provision or billing by hospitals of non-covered drugs to Medicare beneficiaries. However, a hospital's decision not to bill the beneficiary for non-covered drugs potentially implicates other statutory and regulatory provisions, including the prohibition on inducements to beneficiaries, section 1128A(a)(5) of the [Social Security] Act, or the anti-kickback statute, section 1128B(b) of the Act.¹

Medicare Part B generally covers care that Medicare beneficiaries receive in hospital outpatient settings such as emergency departments and observation units; however, Medicare Part B covers only certain drugs in these settings. Specifically, Medicare Part B covers drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them.²

Although some or all of the SADs a Medicare beneficiary receives in an outpatient setting may be covered by Medicare Part D, most hospital pharmacies do not participate in Medicare Part D.³ CMS has stated that only hospitals with pharmacies that dispense prescriptions to outpatients and have contracts with Medicare Part D plans should bill the contracted plans directly as in-network pharmacies; otherwise, the hospitals should bill the Medicare beneficiaries for any Noncovered

¹ CMS, "2003 Update of the Hospital Outpatient Prospective Payment System (OPPS)," Program Memorandum Intermediaries, Transmittal A-02-129 (Change Request 2503, January 3, 2003).

² Section 1861(s)(2)(B) of the Social Security Act (the Act); *Medicare Benefit Policy Manual*, CMS, Pub. 100-02, Chapter 15, "Covered Medical and Other Health Services," Sections 50, 50.2.

³ See, e.g., "How Medicare Covers Self-Administered Drugs Given in Hospital Outpatient Settings," CMS Product No. 11333, revised Feb. 2011, available at <https://www.medicare.gov/Pubs/pdf/11333.pdf>.

SADs that the hospitals dispense.⁴ Consequently, Medicare beneficiaries may be billed for Noncovered SADs they received as outpatients—often at amounts much higher than they would have paid at retail pharmacies—even if those drugs are covered under their Medicare Part D plans.⁵

Ordinarily, routine discounts or waivers of costs owed by Medicare beneficiaries, including cost-sharing amounts, potentially implicate the Federal anti-kickback statute,⁶ the civil monetary penalty and exclusion laws related to kickbacks,⁷ and the Federal civil monetary penalty law prohibiting inducements to beneficiaries.⁸ Nonetheless, in the limited circumstances described in this Policy Statement, hospitals will not be subject to OIG administrative sanctions if they discount or waive amounts that Medicare beneficiaries owe for Noncovered SADs (including Noncovered SADs that may be covered under Medicare Part D) the beneficiaries receive in outpatient settings, subject to the following conditions:

- This Policy Statement applies only to discounts on, or waivers of, amounts Medicare beneficiaries owe for Noncovered SADs that the beneficiaries receive for ingestion or administration in outpatient settings;⁹
- Hospitals must uniformly apply their policies regarding discounts or waivers on Noncovered SADs (e.g., without regard to a beneficiary’s diagnosis or type of treatment);
- Hospitals must not market or advertise the discounts or waivers; and
- Hospitals must not claim the discounted or waived amounts as bad debt or otherwise shift the burden of these costs to the Medicare or Medicaid programs, other payers, or individuals.

Nothing in this Policy Statement requires hospitals to discount or waive amounts owed by Medicare beneficiaries for Noncovered SADs that the beneficiaries receive in outpatient settings.

Moreover, nothing in this Policy Statement affects the ability of a hospital to discount or waive any amounts owed by Medicare beneficiaries on the basis of a good-faith, individualized

⁴ See, e.g., “Information Partners Can Use On: Billing for Self-Administered Drugs Given in Outpatient Settings,” CMS Product No. 11331-P, revised Feb. 2011, available at <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/downloads/11331-P.pdf>.

⁵ If a self-administered drug is covered by a Medicare beneficiary’s Part D plan, the beneficiary may submit a paper claim to the Medicare Part D plan for reimbursement; however, the beneficiary typically would remain liable for the difference between what the hospital charged and what the Medicare Part D plan paid. See generally MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System* (June 2015), available at <http://www.medpac.gov/documents/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0>.

⁶ Section 1128B(b) of the Act, 42 U.S.C. § 1320a-7b(b).

⁷ Sections 1128(b)(7) and 1128A(a)(7) of the Act, 42 U.S.C. §§ 1320a-7(b)(7) and 1320a-7a(a)(7).

⁸ Section 1128A(a)(5) of the Act, 42 U.S.C. § 1320a-7a(a)(5).

⁹ A beneficiary is not considered an outpatient if the only service received from the hospital is the dispensing of a drug for subsequent self-administration.

determination of a beneficiary's financial need. Further, nothing in this Policy Statement affects the operation of CMS's programmatic rules and regulations.

Finally, nothing in this Policy Statement affects a hospital's responsibility to bill only for services performed and to comply with Federal and State billing laws and guidance in effect at the time.

General guidance about the Federal anti-kickback statute and other fraud and abuse authorities is available on OIG's website at <http://oig.hhs.gov/>. This guidance includes the "Special Fraud Alert: Routine Waivers of Copayments or Deductibles Under Medicare Part B;" the "Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries;" safe harbor regulations (and the "preamble" discussions that include explanatory information); compliance program guidance documents for various industry sectors; and OIG advisory opinions.

OIG reserves the right to reconsider the issues raised in this Policy Statement and, where the public interest requires, to rescind, modify, or terminate this Policy Statement.

Questions regarding this Policy Statement may be directed to Jennifer Williams, Senior Counsel, Office of Counsel to the Inspector General, at (202) 401-4133.

/Daniel R. Levinson/

October 29, 2015

Daniel R. Levinson
Inspector General

Date

HCPCS	LO_ VERS	HI_ VERS	DESCRIPTION	BYPASS_ E99
J2506	86	90	Inj pegfilgrast ex bio 0.5mg	1
J7170	84	90	Inj., emicizumab-kxwh 0.5 mg	1
J7175	66	90	Inj, factor x, (human), 1iu	1
J7178	74	90	Inj human fibrinogen con nos	1
J7179	78	90	Vonvendi inj 1 iu vwf:rco	1
J7180	90	90	Factor xiii anti-hem factor	1
J7181	90	90	Factor xiii recomb a-subunit	1
J7182	66	90	Factor viii recomb novoeight	1
J7183	63	90	Wilate injection	1
J7185	63	90	Xyntha inj	1
J7186	63	90	Antihemophilic viii/vwf comp	1
J7187	63	90	Humate-p, inj	1
J7188	63	90	Factor viii recomb obizur	1
J7189	82	90	Factor viia recomb novoseven	1
J7190	63	90	Factor viii	1
J7192	63	90	Factor viii recombinant nos	1
J7193	63	90	Factor ix non-recombinant	1
J7194	63	90	Factor ix complex	1
J7195	63	90	Factor ix recombinant nos	1
J7198	63	90	Anti-inhibitor	1
J7200	66	90	Factor ix recombinan rixubis	1
J7201	66	90	Factor ix alprolix recomb	1
J7202	74	90	Factor ix idelvion inj	1
J7203	83	90	Factor ix recomb gly rebiny	1
J7204	80	90	Inj recombin esperoct per iu	1
J7205	66	90	Factor viii fc fusion recomb	1
J7207	74	90	Factor viii pegylated recomb	1
J7208	90	90	Inj. jivi 1 iu	1
J7209	74	90	Factor viii nuwiq recomb 1iu	1
J7210	78	90	Inj, afstyla, 1 i.u.	1
J7211	82	90	Inj, kovaltry, 1 i.u.	1
J7212	83	90	Factor viia recomb sevenfact	1

Medicare Program
Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy
Frequently Asked Questions

Policy: Effective January 1, 2017, providers and suppliers are required to report the JW modifier on all claims that bill for drugs and biologicals (hereafter, drug) separately payable under Medicare Part B with unused and discarded amounts (hereafter, discarded amounts) from single-dose containers or single-use packages (hereafter, single-dose containers). Also, providers and suppliers must document the amount of discarded drugs in Medicare beneficiaries' medical records. Through subsequent rulemaking, we codified the requirement to use the JW modifier for single-dose container drug that are separately payable under Part B. We will use the JW and JZ modifiers to calculate discarded drug refunds effective January 1, 2023.

Effective July 1, 2023, providers and suppliers are required to report the JZ modifier on all claims that bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts.

Resources:

2023 Physician Fee Schedule Final Rule ([87 FR 69710 - 69734, November 18, 2022](#))

2023 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule ([87 FR 71988, 72082 - 72083, November 23, 2022](#))

MLN Matters [placeholder]; and

Chapter 17 of the CMS Medicare Claims Processing Manual (Section 40) -

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf>

MODIFIER	SHORT DESCRIPTOR (28-character limit)	LONG DESCRIPTOR
JW	Discarded drug not administered	Drug amount discarded/not administered to any patient
JZ	Zero drug wasted	Zero drug amount discarded/not administered to any patient

General

Q1. What is the JW modifier?

A1. The JW modifier is a Healthcare Common Procedure Coding System (HCPCS) Level II modifier required to be reported on a claim to report the amount of drug that is discarded and eligible for payment under the discarded drug policy (explained in the answer to question #3). The modifier should only be used for claims that bill single-dose container drugs.

Q2. What is the JZ modifier?

A2. The JZ modifier is a HCPCS Level II modifier reported on a claim to attest that no amount of drug was discarded and eligible for payment. The modifier should only be used for claims that bill for single-dose container drugs.



To align with the JW modifier policy, the JZ modifier is required when there are no discarded amounts of a single-dose container drug for which the JW modifier would be required if there were discarded amounts.

Q3. What is the payment policy for drugs payable under Medicare Part B for which there are discarded amounts?

A3. When a provider must discard an amount of drug from a single-dose container after administering a dose to a Medicare beneficiary, the program provides payment for the discarded amount, as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling. The discarded amount is any amount that is not part of the prescribed dose and not intended to have a therapeutic effect in the patient. Even if certain amounts are extracted from the vial or are required to be in the vial to administer the prescribed dose, we do not consider them to be used if they are not intended for therapeutic effect as part of the prescribed dose. Generally, the discarded amount is the labeled amount on the single-dose container (or containers if more than one is required) minus the dose (the dose being the prescribed amount of drug administered to the patient). Also see question #8, which addresses overfill amounts.

Q4. Why did CMS establish a policy for the JW and JZ modifiers (discarded drug policy)?

A4. Prior to January 1, 2017, the discarded drug policy allowed Medicare Administrative Contractors (MACs) to choose whether to require the JW modifier. MACs also were able to issue jurisdiction-specific instructions for the use of the modifier. Effective January 1, 2017, CMS established a consistent policy among all MAC jurisdictions that required the use of the JW modifier for drugs separately payable under Medicare Part B with discarded amounts from single-dose containers.

Subsequently, section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-9, November 15, 2021) (hereafter, the Infrastructure Act) amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drugs. This provision specifies that discarded amounts of refundable single-dose container or single-use package drugs are to be determined using a mechanism such as the JW modifier or any successor modifier that includes discarded amount data.

To implement section 90004 of the Infrastructure Act, we finalized the use the JW modifier or any successor modifier that includes the same data to determine the total number of billing units of a billing and payment code (such as a HCPCS code) of a refundable single-dose container or single-use package drug, if any, that were discarded for dates of service during a quarter, and we finalized that the JW modifier identify discarded billing units of a billing and payment code for the purpose of calculating the refund amount as described in section 1847A(h)(3) of the Act.

Because of observed low compliance with JW modifier use (leading to incomplete JW modifier data)¹ and because the discarded drug refund amounts rely on this data, we established that a separate modifier, the JZ modifier, will be required on claims for single-dose container drugs to attest when there are no discarded amounts no later than July 1, 2023.



Q5. Are the JW and JZ modifiers required on claims that bill for single-dose container drugs?

A5. Effective January 1, 2017, the JW modifier must be used to report discarded amounts of a single-dose container drug in order to obtain payment for a discarded amount of drug from single dose or single use packaging.

¹ National Academies of Sciences, Engineering, and Medicine. 2021. Medications in single-dose vials: Implications of discarded drugs. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25911>.

No later than July 1, 2023, the JZ modifier is required to attest that there were no discarded amounts and no JW modifier amount is reported. (Overfill is discussed in question #8). Starting October 1, 2023, claims for drugs from single-dose containers that do not use the modifiers as appropriate may be returned as un-processable until claims are properly resubmitted.

Q6. In which settings is a billing provider required to use either the JW or JZ modifier?


A6. The JW and JZ modifier policy applies to all providers and suppliers who buy and bill separately payable drugs under Medicare Part B. The JW and JZ modifiers are mostly reported on claims from the physician's office and hospital outpatient settings for beneficiaries who receive drugs incident to physicians' services. The JW and JZ modifier requirements also apply to Critical Access Hospitals (CAHs), since drugs are separately payable in the CAH setting.

The modifiers also may apply to some drugs furnished by suppliers such as pharmacies. However, we believe that those suppliers would likely not have discarded amounts to report on claims. Suppliers who dispense drugs and do not actually administer the drug, or who sell partial vials of sterile products, are not expected to report discarded amounts on claims, as the claim is typically submitted prior to the administration of the drug, and the billing provider is not at the site of administration to measure discarded amounts.

The JW and JZ modifiers do not apply to drugs administered in a Rural Health Clinic (RHC) or a Federally Qualified Health Center (FQHC). Drugs administered in RHCs and FQHCs are generally not separately payable under Part B. Instead, their payment is included in the RHC's all-inclusive rate or the FQHC's prospective payment system rate for the patient's visit.


The JW and JZ modifiers are not intended for use on claims for hospital inpatient admissions that are billed under the Inpatient Prospective Payment System. (See question #22 for additional information).

Q7. To which drugs does the policy apply? How can a provider or supplier identify a drug that must be billed using the JW or JZ modifier?

 **A7.** In general, the JW and JZ modifier policy applies to all drugs separately payable under Medicare Part B that are described as being supplied in a "single-dose" container or "single-use" package based on FDA-approved labeling. The use of these modifiers is not appropriate for drugs that are from multiple-dose containers.

Even if a drug is excluded from the definition of "refundable single-dose container or single-use package drug" (and not subject to the discarded drug refund), for example, multiple source drugs, claims for such drugs furnished from a single-dose container are still required to use the JW and JZ modifiers.

The JW and JZ modifier policy does not apply for drugs that are not separately payable, such as packaged OPPS or ASC drugs, or drugs administered in the FQHC or RHC setting.

 The JW and JZ modifiers are not required for vaccines described under section 1861(s)(10) of the Act that are furnished from single-dose containers. Since the influenza, pneumococcal, and COVID-19 vaccines, specified in section 1861(s)(10) of the Act, are often roster billed by mass immunizers, and roster billing cannot accommodate modifiers, it would be impractical to require the JW and JZ modifiers for such vaccines. Such a requirement would likely result in substantial operational issues for mass immunizers and impair patient access to these vaccines.

Q8. Does the JW modifier apply to drug overfill?

A8. The JW modifier must not be used to report discarded amounts of overfill. Since January 1, 2011, CMS regulations have expressly prohibiting billing for overfill, which is any amount of drug greater than the amount identified on the package or label. Additional information on the overfill policy is available in the Physician Fee Schedule Final Rule published in the November 29, 2010 Federal Register (75 FR 73466-70), which is available at <https://www.federalregister.gov/documents/2010/11/29/2010-27969/medicare-program-payment-policies-under-the-physician-fee-schedule-and-other-revisions-to-part-b-for>.

Q9. Is the JW modifier applicable when the dose administered is less than the billing unit?

A9. CMS does not use fractional billing units. Therefore, the JW modifier should not be used when the dose of the drug administered is less than the billing unit. In this situation, the billing provider or supplier would report administering the full billing unit along with the JZ modifier.

Q10. Does a provider or supplier have the option to bill using the JZ modifier now or should they wait until July 1, 2023?

A10. Providers and suppliers may report the JZ modifier prior to July 1, 2023. It is available for use beginning January 1, 2023.

Q11. What happens if a provider or supplier does not use the JW or JZ modifier on claims for drugs provided in single-dose containers?

A11. Claims that bill for drugs with discarded amounts furnished on or after January 1, 2017 through June 30, 2023 that do not use the JW modifier correctly may be subject to review. Claims that bill for drugs furnished on or after July 1, 2023 that do not report the JW or JZ modifier may be subject to provider audits. Claims that do not report the modifiers as appropriate on or after October 1, 2023 may be returned as unprocessable until claims are properly resubmitted.



Q12. Do the JW and JZ modifier requirements apply to single-dose container drugs that are billed using a Not Otherwise Classified (NOC) code?

A12. Although NOC codes do not specifically identify a drug, for consistency with the policy, the JW and JZ modifiers are required to be reported for drugs from single-use containers billed with a NOC code (for example, J3490, J3590, C9399).

Billing, Claims, and Documentation

Q13. What is the appropriate way for providers and suppliers to bill for single-dose container drug with discarded amounts using the JW modifier on claims?

A13. When a provider or supplier administers a separately payable drug under Medicare Part B from a single-dose container and there are discarded amounts, the provider or supplier must file a claim with two lines for the drug.

For the administered amount, one claim line must include the billing and payment code (such as a HCPCS code) describing the given drug, no modifier, and the number of units administered in the unit field. For the discarded amount, a second claim line must include the same billing and payment code as used for the administered amount, the JW modifier, and the number of units discarded in the units field.

For example, if a provider or supplier uses a single-dose container that is labeled to contain 100 units of a drug to administer 95 units to the patient and 5 units are discarded. The 95-unit dose is billed on one line, while the discarded 5 units must be billed on another line with the JW modifier. Both line items would be processed for payment.

Q14: What is the appropriate way for providers and suppliers to bill for single-dose container drugs with no discarded amounts using the JZ modifier on claims?

A14: When a billing provider or supplier administers a separately payable drug under Medicare Part B from a single-dose container and there are no discarded amounts, the provider or supplier must file a claim with one line for the drug.

For the administered amount, the claim line should include the billing and payment code (such as HCPCS code) describing the given drug, the JZ modifier (attesting that there were no discarded amounts), and the number of units administered in the units field.



Q15. Does CMS have specific requirements regarding documentation for discarded amounts of drugs, such as who is required to document the amount that is discarded, the format for whether calculated values are acceptable, or where the documentation should be stored? Is there a specific area in the medical record where the administered/discarded amounts should be documented?

A15. Other than the expectation that providers and suppliers will maintain accurate (medical and/or dispensing) records for all beneficiaries as well as accurate purchasing and inventory records for all drugs that were purchased and billed to Medicare², CMS has no specific requirements regarding the method, format, the medical staff responsible for making the record, or location of discarded amount data in a patient's medical record. Providers and suppliers should also check with the MAC that processes their Part B drug claims in case additional information on billing and documentation is available at the local level.

Q16 Will CMS accept an “automatic” calculation of discarded amounts, for example, a calculation done by software, as documentation of discarded amounts within the medical record?

A16. As long as the discarded amount is accurately documented, CMS does not dictate how it is calculated.

Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System



Q17. When billing for services furnished in the hospital outpatient setting, do the JW and JZ modifiers apply to all Part B claims, including Part B inpatient (Type of Bill 12X)? Are eligible and participating 340B providers exempt from the JW and JZ modifier reporting?

A17. The JW and JZ modifier requirement applies to all separately payable drugs assigned status indicators “G” (Pass-Through Drugs and Biologicals) or “K” (Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals) under the OPPS for which there is a discarded amount.

The JW and JZ modifier requirement applies to all separately payable drugs assigned payment indicator “K2” (Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate) in the ASC for which there is a discarded amount.

340B covered entities are not exempt from reporting the JW and JZ modifiers.

Q18. Are hospitals required to report the JW and JZ modifiers only when the applicable drug is billed with revenue code 636?

² General guidance on documentation is available in MLN Matters SE 1316 (<https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/SE1316.pdf>).

A18. The requirements for using the JW and JZ modifiers are independent of revenue codes reporting. Providers should always use the most appropriate revenue code that applies to the service they are reporting.

Q19. Do the JW and JZ modifiers apply to drugs administered in the hospital outpatient department?

A19. The JW and JZ modifier requirements apply to all separately payable drugs with status indicators “G” (Pass-Through Drugs and Biologicals) or “K” (Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals) under the OPSS for which there is a discarded amount.

Q20. Do the JW and JZ modifiers apply to drugs administered in the ASC setting?

A20. The JW and JZ modifier requirement applies to all separately payable drugs assigned payment indicator “K2” (Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPSS rate) under the ASC payment system for which there is a discarded amount.

Q21. Do the JW and JZ modifiers apply to OPSS drugs with status indicator “N” and ASC payment system drugs with payment indicator “N1”?

A21. No. The JW and JZ modifiers do not apply to drugs assigned status indicator N (Items and Services Packaged into APC Rates) under the OPSS. Similarly, the JW and JZ modifiers do not apply to drugs assigned payment indicator “N1” (Packaged service/item; no separate payment made) under the ASC payment system. See question #7 for additional information.

Q22. Are hospitals required to transfer the charges related to discarded amounts that the patient incurred when he/she was seen the day before being admitted (3-day or 1-day payment rule) to the inpatient claim?

A22. In circumstances where the 3-day/1-day payment window applies, all hospital outpatient services (and associated charges), including drugs, furnished to a beneficiary during the 3 days/1 day prior to the beneficiary’s inpatient admission are treated as inpatient services and must be included on the claim for the inpatient admission. Since drugs are not separately payable under Part B under the Inpatient Prospective Payment System (IPPS), the JW and JZ modifiers are not required in that situation.

January 2023 IOCE Quarterly Data Files
 Pass-through Radiopharmaceuticals, Skin Substitutes, Contrasts, and Stress Agents
 (DATA_HCPCS, Column CO, CP, CQ, and CR)

14 - 81

HCPCS	LO_	HI_	DESCRIPTION	PASS	PASS	PASS	PASS
				THROUGH	THROUGH	THROUGH	THROUGH
	VERS	VERS		RADIO	SKIN	CONTRAST	STRESS
				PHARM	PRODUCT		AGENT
A9591	82	90	Fluoroestradiol f 18	1	0	0	0
A9592	83	90	Copper cu 64 dotatate diag	1	0	0	0
A9593	84	90	Gallium ga-68 psma-11 ucsf	1	0	0	0
A9594	84	90	Gallium ga-68 psma-11, ucla	1	0	0	0
A9595	86	90	Piflu f-18, dia 1 millicurie	1	0	0	0
A9596	88	90	Gallium illuccix 1 millicure	1	0	0	0
A9602	89	90	Fluorodopa f-18 diag per mci	1	0	0	0
A9800	89	90	Gallium locametz 1 millicuri	1	0	0	0
C9067	81	90	Gallium ga-68 dotatoc	1	0	0	0

There are no pass-through skin substitute products, contrasts, or stress agents for January 2023.

Offset Amounts for Pass-through Radiopharmaceuticals, Skin Substitutes, Contrasts, and Stress Agents
(OFFSET_APC)

LIST_I					OFFSET
D	APC		LO_VERSION	HI_VERSION	AMOUNT
1	05591	Radiopharm	90	90	\$58.88
1	05592	Radiopharm	90	90	\$108.84
1	05593	Radiopharm	90	90	\$363.88
1	05594	Radiopharm	90	90	\$282.42
2	05054	Skin Substitute	90	90	\$789.43
2	05055	Skin Substitute	90	90	\$371.66
3	05571	Contrast	90	90	\$41.91
3	05572	Contrast	90	90	\$68.58
3	05573	Contrast	90	90	\$128.96
4	05593	Stress Agent	90	90	\$363.88
4	05722	Stress Agent	90	90	\$5.01

January 2023 IOCE Quarterly Data Files
High and Low Cost Skin Substitutes and Skin Substitute Procedures
(DATA_HCPCS, Columns BU, BV, BW, BX)

14 - 83

HCPCS	LO_ VERS	HI_ VERS	DESCRIPTION	SKIN SUB PROC	SKIN SUBST	SKIN SUB PROC	SKIN SUBST
				LOW	LOW	HIGH	HIGH
C5271	63	90	Low cost skin substitute app	1	0	0	0
C5272	63	90	Low cost skin substitute app	1	0	0	0
C5273	66	90	Low cost skin substitute app	1	0	0	0
C5274	63	90	Low cost skin substitute app	1	0	0	0
C5275	63	90	Low cost skin substitute app	1	0	0	0
C5276	63	90	Low cost skin substitute app	1	0	0	0
C5277	66	90	Low cost skin substitute app	1	0	0	0
C5278	63	90	Low cost skin substitute app	1	0	0	0
A4100	87	90	Skin sub fda clrd as dev nos	0	1	0	0
Q4100	63	90	Skin substitute, nos	0	1	0	0
Q4102	63	90	Oasis wound matrix	0	1	0	0
Q4111	63	90	Gammagraft	0	1	0	0
Q4115	63	90	Alloskin	0	1	0	0
Q4117	63	90	Hyalomatrix	0	1	0	0
Q4124	63	90	Oasis tri-layer wound matrix	0	1	0	0
Q4135	63	90	Mediskin	0	1	0	0
Q4136	63	90	Ezderm	0	1	0	0
Q4165	77	90	Keramatrix, kerasorb sq cm	0	1	0	0
Q4166	66	90	Cytal, per square centimeter	0	1	0	0
Q4204	74	90	Xwrap 1 sq cm	0	1	0	0
Q4214	77	90	Cellesta cord per sq cm	0	1	0	0
Q4216	77	90	Artacent cord per sq cm	0	1	0	0
Q4218	77	90	Surgicord per sq cm	0	1	0	0
Q4220	77	90	Bellacell hd, surederm sq cm	0	1	0	0
Q4221	77	90	Amniowrap2 per sq cm	0	1	0	0
Q4224	87	90	Hhf10-p per sq cm	0	1	0	0
Q4225	87	90	Amniobind, per sq cm	0	1	0	0
Q4236	90	90	Carepatch per sq cm	0	1	0	0
Q4247	80	90	Amniotext patch, per sq cm	0	1	0	0
Q4250	82	90	Amnioamp-mp per sq cm	0	1	0	0
Q4251	85	90	Vim, per square centimeter	0	1	0	0
Q4252	85	90	Vendaje, per square centimet	0	1	0	0
Q4253	85	90	Zenith amniotic membrane psc	0	1	0	0
Q4255	81	90	Reguard, topical use per sq	0	1	0	0
Q4256	87	90	Mlg complet, per sq cm	0	1	0	0
Q4257	87	90	Relese, per sq cm	0	1	0	0
Q4259	88	90	Celera per sq cm	0	1	0	0
Q4260	88	90	Signature apatch, per sq cm	0	1	0	0
Q4261	88	90	Tag, per square centimeter	0	1	0	0
Q4262	90	90	Dual layer impax, per sq cm	0	1	0	0
Q4263	90	90	Surgraft tl, per sq cm	0	1	0	0
Q4264	90	90	Cocoon membrane, per sq cm	0	1	0	0

January 2023 IOCE Quarterly Data Files
High and Low Cost Skin Substitutes and Skin Substitute Procedures
(DATA_HCPCS, Columns BU, BV, BW, BX)

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HCPCS	LO_ VERS	HI_ VERS	DESCRIPTION	SKIN	SKIN	SKIN	SKIN
				SUB PROC LOW	SUBST LOW	SUB PROC HIGH	SUBST HIGH
15271	63	90	Skin sub graft trnk/arm/leg	0	0	1	0
15272	63	90	Skin sub graft t/a/l add-on	0	0	1	0
15273	63	90	Skin sub grft t/arm/lg child	0	0	1	0
15274	63	90	Skn sub grft t/a/l child add	0	0	1	0
15275	63	90	Skin sub graft face/nk/hf/g	0	0	1	0
15276	63	90	Skin sub graft f/n/hf/g addl	0	0	1	0
15277	66	90	Skn sub grft f/n/hf/g child	0	0	1	0
15278	63	90	Skn sub grft f/n/hf/g ch add	0	0	1	0
A2001	87	90	Innovamatrix ac, per sq cm	0	0	0	1
A2002	88	90	Mirragen adv wnd mat per sq	0	0	0	1
A2005	90	90	Microlyte matrix, per sq cm	0	0	0	1
A2006	90	90	Novosorb synpath per sq cm	0	0	0	1
A2007	87	90	Restrata, per sq cm	0	0	0	1
A2008	90	90	Theragenesis, per sq cm	0	0	0	1
A2009	90	90	Symphony, per sq cm	0	0	0	1
A2010	90	90	Apis, per square centimeter	0	0	0	1
A2011	90	90	Supra sdrm, per sq cm	0	0	0	1
A2012	90	90	Suprathel, per sq cm	0	0	0	1
A2013	90	90	Innovamatrix fs, per sq cm	0	0	0	1
A2015	90	90	Phoenix wnd mtrx, per sq cm	0	0	0	1
A2016	90	90	Permeaderm b, per sq cm	0	0	0	1
A2017	90	90	Permeaderm glove, each	0	0	0	1
A2018	90	90	Permeaderm c, per sq cm	0	0	0	1
C9363	63	90	Integra meshed bil wound mat	0	0	0	1
Q4101	63	90	Apligraf	0	0	0	1
Q4103	63	90	Oasis burn matrix	0	0	0	1
Q4104	63	90	Integra bmwd	0	0	0	1
Q4105	66	90	Integra drt or omnigraft	0	0	0	1
Q4106	63	90	Dermagraft	0	0	0	1
Q4107	63	90	Graftjacket	0	0	0	1
Q4108	63	90	Integra matrix	0	0	0	1
Q4110	63	90	Primatrix	0	0	0	1
Q4116	63	90	Alloderm	0	0	0	1
Q4121	66	90	Theraskin	0	0	0	1
Q4122	77	90	Dermacell, awm, porous sq cm	0	0	0	1
Q4123	63	90	Alloskin	0	0	0	1
Q4126	63	90	Memoderm/derma/tranz/integup	0	0	0	1
Q4127	63	90	Talymed	0	0	0	1
Q4128	89	90	Flexhd/allopatchhd/sq cm	0	0	0	1
Q4132	70	90	Grafix core, grafixpl core	0	0	0	1
Q4133	74	90	Grafix stravix prime pl sqcm	0	0	0	1
Q4134	90	90	Hmatrix	0	0	0	1

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(DATA_HCPCS, Columns BU, BV, BW, BX)

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HCPCS	LO_ VERS	HI_ VERS	DESCRIPTION	SKIN	SKIN	SKIN	SKIN
				SUB PROC LOW	SUBST LOW	SUB PROC HIGH	SUBST HIGH
Q4137	74	90	Amnioexcel biodexcel 1sq cm	0	0	0	1
Q4138	63	90	Biodfence dryflex, 1cm	0	0	0	1
Q4140	63	90	Biodfence 1cm	0	0	0	1
Q4141	63	90	Alloskin ac, 1 cm	0	0	0	1
Q4143	66	90	Repriza, 1cm	0	0	0	1
Q4146	66	90	Tensix, 1cm	0	0	0	1
Q4147	63	90	Architect ecm px fx 1 sq cm	0	0	0	1
Q4148	70	90	Neox neox rt or clarix cord	0	0	0	1
Q4150	63	90	Allowrap ds or dry 1 sq cm	0	0	0	1
Q4151	63	90	Amnioband, guardian 1 sq cm	0	0	0	1
Q4152	63	90	Dermapure 1 square cm	0	0	0	1
Q4153	63	90	Dermavest, plurivest sq cm	0	0	0	1
Q4154	63	90	Biovance 1 square cm	0	0	0	1
Q4156	70	90	Neox 100 or clarix 100	0	0	0	1
Q4157	66	90	Revitalon 1 square cm	0	0	0	1
Q4158	70	90	Kerecis omega3, per sq cm	0	0	0	1
Q4159	63	90	Affinity1 square cm	0	0	0	1
Q4160	63	90	Nushield 1 square cm	0	0	0	1
Q4161	67	90	Bio-connekt per square cm	0	0	0	1
Q4163	70	90	Woundex, bioskin, per sq cm	0	0	0	1
Q4164	64	90	Helicoll, per square cm	0	0	0	1
Q4167	82	90	Truskin, per sq centimeter	0	0	0	1
Q4169	67	90	Artacent wound, per sq cm	0	0	0	1
Q4170	90	90	Cygnus, per sq cm	0	0	0	1
Q4173	67	90	Palingen or palingen xplus	0	0	0	1
Q4175	67	90	Miroderm	0	0	0	1
Q4176	80	90	Neopatch or therion, 1 sq cm	0	0	0	1
Q4178	72	90	Floweramniopatch, per sq cm	0	0	0	1
Q4179	78	90	Flowerderm, per sq cm	0	0	0	1
Q4180	71	90	Revita, per sq cm	0	0	0	1
Q4181	73	90	Amnio wound, per square cm	0	0	0	1
Q4182	82	90	Transcyte, per sq centimeter	0	0	0	1
Q4183	75	90	Surgigraft, 1 sq cm	0	0	0	1
Q4184	77	90	Cellesta or duo per sq cm	0	0	0	1
Q4186	74	90	Epifix 1 sq cm	0	0	0	1
Q4187	74	90	Epicord 1 sq cm	0	0	0	1
Q4188	82	90	Amnioarmor 1 sq cm	0	0	0	1
Q4190	82	90	Artacent ac 1 sq cm	0	0	0	1
Q4191	90	90	Restorigin 1 sq cm	0	0	0	1
Q4193	82	90	Coll-e-derm 1 sq cm	0	0	0	1
Q4194	75	90	Novachor 1 sq cm	0	0	0	1
Q4195	81	90	Puraply 1 sq cm	0	0	0	1

January 2023 IOCE Quarterly Data Files
High and Low Cost Skin Substitutes and Skin Substitute Procedures
(DATA_HCPCS, Columns BU, BV, BW, BX)

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HCPCS	LO_ VERS	HI_ VERS	DESCRIPTION	SKIN	SKIN	SKIN	SKIN
				SUB PROC LOW	SUBST LOW	SUB PROC HIGH	SUBST HIGH
Q4196	81	90	Puraply am 1 sq cm	0	0	0	1
Q4197	74	90	Puraply xt 1 sq cm	0	0	0	1
Q4198	82	90	Genesis amnio membrane 1sqcm	0	0	0	1
Q4199	87	90	Cygnus matrix, per sq cm	0	0	0	1
Q4200	82	90	Skin te 1 sq cm	0	0	0	1
Q4201	84	90	Matrion 1 sq cm	0	0	0	1
Q4203	75	90	Derma-gide, 1 sq cm	0	0	0	1
Q4205	81	90	Membrane graft or wrap sq cm	0	0	0	1
Q4208	78	90	Novafix per sq cm	0	0	0	1
Q4209	82	90	Surgraft per sq cm	0	0	0	1
Q4210	90	90	Axolotl graf dualgraf sq cm	0	0	0	1
Q4211	82	90	Amnion bio or axobio sq cm	0	0	0	1
Q4217	90	90	Woundfix biowound plus xplus	0	0	0	1
Q4219	82	90	Surgigraft dual per sq cm	0	0	0	1
Q4222	82	90	Progenamatrix, per sq cm	0	0	0	1
Q4226	81	90	Myown harv prep proc sq cm	0	0	0	1
Q4227	82	90	Amniocore per sq cm	0	0	0	1
Q4229	88	90	Cogenex amnio memb per sq cm	0	0	0	1
Q4232	82	90	Corplex, per sq cm	0	0	0	1
Q4234	81	90	Xcellerate, per sq cm	0	0	0	1
Q4235	90	90	Amniorepair or altiply sq cm	0	0	0	1
Q4237	82	90	Cryo-cord, per sq cm	0	0	0	1
Q4238	82	90	Derm-maxx, per sq cm	0	0	0	1
Q4239	82	90	Amnio-maxx or lite per sq cm	0	0	0	1
Q4248	90	90	Dermacyte amn mem allo sq cm	0	0	0	1
Q4249	82	90	Amniplay, per sq cm	0	0	0	1
Q4254	90	90	Novafix dl per sq cm	0	0	0	1
Q4258	88	90	Enverse, per sq cm	0	0	0	1

Attachment A
Review of CMS' 340B Drug Discount Policy

A. Policy from 2018-2022:

- a. From 2018 – 2022, drugs reported with modifier -JG, i.e., 340B acquired drugs, were paid at ASP minus 22.5% rather than ASP +6% like all other separately payable drugs.
- b. In CY2018, the savings from this provision was redistributed to all other payments under budget neutrality provisions, increasing payments for non-drug OPPS rates by 3.2%

B. Policy invalidated by the Supreme Court

- a. In June 2022, the Supreme Court unanimously found the policy to be unlawful because CMS had not done a required survey of acquisition costs to justify paying 340B drugs at a different rate than other drugs.
- b. Three timeframes to consider in the repayment of the discounts invalidated by the Supreme Court:
 - i. **2018 – 2021:** CMS indicated in the CY2023 OPPS Final Rule that they will issue a separate proposed rule before the CY2024 OPPS proposed rule in July of 2023 addressing repayment of these discounts, taking into consideration the funds that were already distributed across other payments through the budget neutrality adjustment that was applied.
 - ii. **2022:** A September 28, 2022 court case required CMS to pay ASP +6% for the remainder of the year.
 1. September 28 – December 31, 2022: MACs are paying or automatically reprocessing claims at the full ASP +6% rate.
 2. January 1 – September 27, 2022: MACs have posted guidance on their websites on submitting TOB 137 or 13Q depending on timely filing, CC D9, remarks “340B adjustment”.
 - iii. **2023:** Drugs acquired under 340B are paid at ASP +6%.
 1. CMS made a budget neutrality adjustment of -3.09% to all non-drug OPPS payments to reverse the budget neutrality adjustment applied in CY2018.

Institutional Billing for No Cost Items

MLN Matters Number: MM10521

Related Change Request (CR) Number: 10521

Related CR Release Date: March 30, 2018

Effective Date: January 1, 2009

Related CR Transmittal Number: R4013CP

Implementation Date: June 29, 2018

PROVIDER TYPES AFFECTED

This MLN Matters® article is intended for Institutions (Part A) billing Medicare Administrative Contractors (MACs) for no cost items provided to Medicare beneficiaries.

WHAT YOU NEED TO KNOW

Change Request (CR) 10521 provides clarification of the billing instructions specific to drugs provided at no cost when claims processing edits prevent drug administration charges from being billed when the claim does not contain a covered/billable drug charge. This is not a new policy but a reminder of the policy in place. Please make sure your billing staffs are aware of this clarification.

Background

The Medicare Claims Processing Manual Chapter 32 - Billing Requirements for Special Services section 67.2 outlines institutional billing for no cost items as follows.

Institutional providers should not have to report the usage of a no cost item. However, for some claims (for example, Outpatient Prospective Payment System (OPPS) claims), providers may be required to bill a no cost item due to claims processing edits that require an item (even if received at no cost) to be billed along with an associated service (for example, a specified device must be reported along with a specified implantation procedure).

For OPPS claims, when a drug is provided at no cost, claims processing edits prevent drug administration charges from being billed when the claim does not contain a covered/billable drug charge. Therefore, for drugs provided at no cost in the hospital outpatient department, providers must report the applicable drug HCPCS code and appropriate units with a token charge of less than \$1.01 for the item in the covered charge field and mirror this less than \$1.01 amount reported in the non-covered charge field. Providers must also bill the corresponding drug administration charge with the appropriate drug administration CPT or HCPCS code.

ADDITIONAL INFORMATION

The official instruction, MM10521, issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4013CP.pdf>.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/>.

DOCUMENT HISTORY

Date of Change	Description
March 30, 2018	Initial article released.

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Medicare Hospital Version

FY2023 IPPS New Technology Summary

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
RYBREVANT™ (amivantamab, for the treatment of metastatic non-small cell lung cancer (NSCLC). Continued for FY2023	XW033B7, or XW043B7	\$6,405.89	86 <i>Fed. Reg.</i> 44988-996; 87 <i>Fed. Reg.</i> 48913
COSELA™ (trilaciclib, used to decrease the incidence of chemotherapy-induced myelosuppression in adult patients administered prior to a certain treatment for extensive-stage small cell lung cancer (ES-SCLC) Continued for FY2023	XW03377, or XW04377	\$5,526.30 (FY2022) \$5,612.10 (FY2023)	86 <i>Fed. Reg.</i> 45008-17; 87 <i>Fed. Reg.</i> 48912-913
ABECMA® (idecabtagene vicleucel, a B-cell maturation antigen (BCMA)-directed genetically modified autologous chimeric antigen receptor (CAR) T-cell immunotherapy for relapsed or refractory multiple myeloma and is a 5 th line plus treatment) Continued for FY2023	XW033K7, or XW043K7	\$272,675.00*(FY2022) \$289,532.75 (FY2023)	86 <i>Fed. Reg.</i> 45028-35; * as corrected in 86 <i>Fed. Reg.</i> 58032; 87 <i>Fed. Reg.</i> 48912-913
StrataGraft™ Skin Tissue, a viable bioengineered, regenerative skin construct (BRSC) for treatment of severe thermal burns. Continued for FY2023	XHRPXF7	\$44,200.00	86 <i>Fed. Reg.</i> 45079-90; 87 <i>Fed. Reg.</i> 48913
TECARTUS® (brexucabtagene autoleucel, a CD19 directed genetically modifier autologous T-cell immunotherapy for relapsed and refractory mantle cell lymphoma, a form of CAR-T. Continued for FY2023	XW033M7, or XW043M7	\$259,350*	86 <i>Fed. Reg.</i> 45090-104; * as corrected in 86 <i>Fed. Reg.</i> 58033; 87 <i>Fed. Reg.</i> 48913
VEKLURY® (remdesivir, a nucleotide analog that inhibits viral RNA-dependent RNA polymerases, demonstrating activity countering viral pathogens such as SARS-CoV-2 (COVID-19)) Continued for FY2023	XW033E5, or XW043E5	\$2,028.00	86 <i>Fed. Reg.</i> 45104-116; 87 <i>Fed. Reg.</i> 48913

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
ZEPZELCA (lurbinectedin, a marine derived, synthetic antineoplastic compound for treatment of metastatic small cell lung cancer (SCLC) with disease progression on chemotherapy) Continued for FY2023	XW03387, or XW04387	\$8,622.90 (FY2022) \$9,145.50 (FY2023)	86 <i>Fed. Reg.</i> 45116-126; 87 <i>Fed. Reg.</i> 48912-913
Aprevo™ (an interbody fusion implant that stabilizes the lumbar spinal column and facilitates fusion during lumbar fusion procedures for spinal deformity, custom made from patient CT scans) Continued for FY2023	XRG(A,B,C,D)0R7 XRG(A,B,C,D)3R7 XRG(A,B,C,D)4R7	\$40,950.00 *	86 <i>Fed. Reg.</i> 45127-133; * as corrected in 86 <i>Fed. Reg.</i> 67875; 87 <i>Fed. Reg.</i> 48913
aScope Duodeno (a sterile, single-use endoscope for endoscopy and endoscopic treatment of the upper gastrointestinal tract) Continued for FY2023	XFJB8A7, or XFJD8A7	\$1,715.59 ¹ (FY2022) \$1,296.75 (FY2023)	86 <i>Fed. Reg.</i> 45133-135; 87 <i>Fed. Reg.</i> 48913, 48915
Caption Guidance™ (an artificial intelligence (AI) guided medical imaging acquisition software system for cardiac ultrasound images, providing real-time guidance during transthoracic echocardiography) Continued for FY2023	X2JAX47	\$1,868.10	86 <i>Fed. Reg.</i> 45135-138; 87 <i>Fed. Reg.</i> 48913
Harmony™ Transcatheter Pulmonary Valve System (a bioprosthetic heart valve from porcine pericardial tissue for treatment of congenital heart disease) Continued for FY2023	02RH38M	\$26,975.00	86 <i>Fed. Reg.</i> 45146-149; 87 <i>Fed. Reg.</i> 48913
INTERCEPT Fibrinogen Complex (PRCFC) (a blood product for treatment of fibrinogen deficiency-related bleeding, including massive hemorrhage) Continued for FY2023			
Shockwave C2 Intravascular Lithotripsy System (for lithotripsy-enabled, low-pressure dilation of calcified, stenotic de novo coronary arteries prior to stenting) Continued for FY2023	02F03ZZ, 02F13ZZ, 02F23ZZ, or 02F33ZZ	\$3,666.00	86 <i>Fed. Reg.</i> 45151-153; 87 <i>Fed. Reg.</i> 48913

¹ The preamble text established a payment limit of \$1,715.59, however, the table on 86 *Fed. Reg.* 45585 shows a payment limit of \$1,715.58. The limit in the table appears to be an error based on other corrections in the correction notice of October 20, 2021 which corrected the amount in the table to match the amount discussed in the preamble text for other services, however, the amounts for aScope Duodeno and EXALT™ Model D Single-Use Duodenoscope were not corrected.

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
FETROJA® (cefiderocol) (an injectable siderophore cephalosporin for hospital-acquired bacterial pneumonia/ ventilator- associated bacterial pneumonia Continued for FY2023	XW033A6, or XW043A6 * reported with ICD-10-CM codes Y95 and J14, J15.0, J15.1, J15.5, J15.6, or J15.8; OR J95.851 and B96.1, B96.20, B96.21, B96.22, B96.23, B96.29, B96.3, B96.5, or B96.89	\$8,579.84** (75% add-on limit)	86 Fed. Reg. 45156-157; * as corrected in 86 Fed. Reg. 67875; ** as corrected in 86 Fed. Reg. 58032; 87 Fed. Reg. 48913-914
RECARBRIO™ (imipenem, cilastatin, and relebactam) (a novel b-lactamase inhibitor for treatment of hospital acquired bacterial pneumonia/ ventilator associated bacterial pneumonia caused by susceptible Gram-negative bacteria) Continued for FY2023	XW033U5, or XW043U5 *reported with ICD-10-CM codes Y95 and J14, J15.0, J15.1, J15.5, J15.6, or J15.8 for HABP ; OR XW033A6 or XW043A6 reported with ICD-10-CM codes J95.851 and B96.1, B96.20, B96.21, B96.22, B96.23, B96.29, B96.3, B96.5, or B96.89 for VABP	\$9,576.51** (75% add-on limit)	86 Fed. Reg. 45157-159; * as corrected in 86 Fed. Reg. 58023; further corrected in 86 Fed. Reg. 67875; ** as corrected in 86 Fed. Reg. 58032; 87 Fed. Reg. 48913-914
CARVYKTI™ (ciltacabtagene autoleucel)(an autologous chimeric-antigen receptor (CAR)T-cell therapy directed against B cell maturation antigen (BCMA) for treatment of patients with multiple myeloma New for FY2023	XW033A7, or XW043A7	\$289,532.75	87 Fed. Reg. 48920-925
DARZALEX Faspro® (a combination of daratumumab (a monoclonal CD38-directed cytolytic antibody) and hyaluronidase (an endoglycosidase) for the treatment of light chain amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone (CyBorD) in newly diagnosed patients) New for FY2023	XW01318	\$5,159.41	87 Fed. Reg. 48925-937

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
Hemolung Respiratory Assist System (Hemolung RAS) (for treatment of acute hypercapnic respiratory failure using extracorporeal circuit to remove CO ₂ directly from the blood) New for FY2023	5A0920Z	\$6,500	87 Fed. Reg. 48937-948
LIVTENCITY™ (maribavir) (a cytomegalovirus (CMV) pUL97 kinase inhibitor for treatment of post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) to ganciclovir, valganciclovir, cidofovir, or foscarnet) New for FY2023	XW0DX38, XW0G738, or XW0H738	\$32,500	87 Fed. Reg. 48937-954
CERAMENT® G (an injectable bone-void filler made of calcium sulfate, hydroxyapatite, and gentamicin sulfate for surgical treatment of osteomyelitis) New for FY2023	XW0V0P7	\$4,918.55	87 Fed. Reg. 48961-966
Gore® TAG® Thoracic Branch Endoprosthesis (TBE) (a modular device consisting of three components, an Aortic Component, a Side Branch Component, and an optional Aortic Extender Component, each pre-mounted on a catheter delivery system for treatment of thoracic aortic aneurysms, traumatic aortic transection, and aortic dissection) New for FY2023	02VW3DZ, or 02VX3EZ	\$27,807.00	87 Fed. Reg. 48966-969
iFuse Bedrock Granite Implant System (a sterile, single-use permanent implant intended to provide sacropelvic fusion of the sacroiliac joint and fixation to the pelvis when used in conjunction with commercially available pedicle screw fixation systems as a foundational element) New for CY2023	XNH6058, XNH6358, XNH7058, XNH7358, XRG058, XRG358, XRGF058, or XRGF358	\$9,828.00	87 Fed. Reg. 48969-974

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
Thoraflex™ Hybrid Device (a sterile single-use, gelatin sealed Frozen Elephant Trunk (FET) surgical medical device, deployed through an opened aortic arch and positioned into the descending thoracic aorta for repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta, with or without involvement of the ascending aorta, in cases of aneurysm and/or dissection) New for CY2023	X2RX0N7, in combination with X2VW0N7	\$22,750	87 Fed. Reg. 48974-975
ViviStim® Paired VNS System (a paired vagus nerve stimulation therapy intended to stimulate the vagus nerve during rehabilitation therapy to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment) New for CY2023	X0HQ3R8	\$23,400.00	87 Fed. Reg. 48975-977
DefenCath™ (solution of taurolidine (13.5 mg/mL) and heparin (1000 USP Units/ML)(a proprietary formulation of taurolidine, a thiadiazinane antimicrobial, and heparin, an anti-coagulant for use as catheter lock solution, to reduce the risk of catheter-related bloodstream infections (CRBI) from in-dwelling catheters in patients undergoing hemodialysis (HD) through a central venous catheter (CVC) Conditional approval, subject to receiving FDA marketing authorization by July 1, 2023	XY0YX28	\$14,259.38* (75% add-on limit)	87 Fed. Reg. 48978-82; * 87 Fed. Reg. 66561

Medicare Benefit Policy Manual, Chapter 6, Excerpt

As specified at 42 CFR 410.28(f), for services furnished on or after February 21, 2002, the provisions of paragraphs (a) and (d)(2) through (d)(4), inclusive, of 42 CFR 410.32 apply to all diagnostic laboratory tests furnished by hospitals and CAHs to outpatients.

Physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives who operate within the scope of practice under State law may order and perform diagnostic tests, as discussed in 42 CFR 410.32(a)(2) and corresponding guidance in chapter 15, section 80 of this manual. However, this manual guidance and the long established regulation at 42 CFR 410.32(b)(1) also state that diagnostic x-ray and other diagnostic tests must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act. Some of these non-physician practitioners may perform diagnostic tests without supervision, see the regulation at 410.32(b)(2) and 42 CFR 410.32(b)(3). Thus, while physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives only require physician supervision included in any collaboration or supervision requirements particular to that type of practitioner when they personally perform a diagnostic test, these practitioners are not permitted to function as supervisory “physicians” for the purposes of other hospital staff performing diagnostic tests.



20.4.4 - Coverage of Outpatient Diagnostic Services Furnished on or After January 1, 2010

(Rev. 152, Issued: 12-29-11, Effective: 01-01-12, Implementation: 01-03-12)

Covered diagnostic services to outpatients include the services of nurses, psychologists, technicians, drugs and biologicals necessary for diagnostic study, and the use of supplies and equipment. When a hospital sends hospital personnel and hospital equipment to a patient’s home to furnish a diagnostic service, Medicare covers the service as if the patient had received the service in the hospital outpatient department.

As specified at 42 CFR 410.28(a), for services furnished on or after January 1, 2010, Medicare Part B makes payment for hospital or CAH diagnostic services furnished to outpatients, including drugs and biologicals required in the performance of the services (even if those drugs or biologicals are self-administered), if those services meet the following conditions:

1. They are furnished by the hospital or under arrangements made by the hospital or CAH with another entity (see section 20.1 of this chapter);
2. They are ordinarily furnished by, or under arrangements made by the hospital or CAH to its outpatients for the purpose of diagnostic study; and
3. They would be covered as inpatient hospital services if furnished to an inpatient.

As specified at 42 CFR 410.28(e), payment is allowed under the hospital outpatient prospective payment system for diagnostic services only when those services are furnished under the appropriate level of supervision specified in accordance with the

definitions in this manual and at 42 CFR 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii) of general, direct and personal supervision.

Physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives who operate within their scope of practice under State law may order and perform diagnostic tests, as discussed in 42 CFR 410.32(a)(2) and corresponding guidance in chapter 15, section 80 of this manual. However, this guidance and the long established regulation at 42 CFR 410.32(b)(1) also state that diagnostic x-ray and other diagnostic tests must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act and may not be supervised by nonphysician practitioners. Sections 410.32(b)(2) and (3) provide certain exceptions that allow some diagnostic tests furnished by certain non-physician practitioners to be furnished without physician supervision. While these nonphysician practitioners including physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives cannot provide the required physician supervision when other hospital staff are performing diagnostic tests, when these nonphysician practitioners personally perform a diagnostic service they must meet only the physician supervision requirements that are prescribed under the Medicare coverage rules at 42 CFR Part 410 for that type of practitioner when they directly provide a service. For example, under section 410.75 nurse practitioners must work in collaboration with a physician, and under section 410.74 physician assistants must practice under the general supervision of a physician.

With respect to individual diagnostic tests, the supervision levels listed in the quarterly updated Medicare Physician Fee Schedule (PFS) Relative Value File apply. For diagnostic services not listed in the PFS, Medicare contractors, in consultation with their medical directors, define appropriate supervision levels in order to determine whether claims for these services are reasonable and necessary. Updates to the PFS Relative Value Files will be issued in future Recurring Update Notifications. For guidance regarding the numeric levels assigned to each CPT or HCPCS code in the PFS Relative Value File, see Chapter 15 of this manual, Section 80, “Requirements for Diagnostic X-ray, Diagnostic Laboratory, and Other Diagnostic Tests.”

For diagnostic services furnished during calendar year (CY) 2010 whether directly or under arrangement in the hospital or in an on-campus outpatient department of the hospital, as defined at 42 CFR 413.65, “direct supervision” means that the physician must be present on the same campus where the services are being furnished. For services furnished in an off-campus provider based department as defined at 42 CFR 413.65, he or she must be present within the off-campus provider based department. The physician must be immediately available to furnish assistance and direction throughout the performance of the procedure. The physician does not have to be present in the room when the procedure is performed. “In the hospital” means the definition specified in 42CFR 410.27(g), which is areas in the main building(s) of the hospital or CAH that are under the ownership, financial, and administrative control of the hospital or CAH; that are operated as part of the hospital or CAH; and for which the hospital or CAH bills the services furnished under the hospital’s or CAH’s CMS Certification Number.

For diagnostic services furnished during CY 2011 and following, whether directly or under arrangement in the hospital or in an on-campus or off-campus outpatient department of the hospital as defined at 42 CFR 413.65, “direct supervision” means that the physician must be immediately available to furnish assistance and direction throughout the performance of the procedure. As discussed below, the physician is not required to be present in the room where the procedure is being performed or within any other physical boundary as long as he or she is immediately available.

For services furnished during CY 2010 and following under arrangement in nonhospital locations, “direct supervision” means the definition specified in the PFS at 42 CFR 410.32(b)(3)(ii). The supervisory physician must remain present within the office suite where the service is being furnished and must be immediately available to furnish assistance and direction throughout the performance of the procedure. The supervisory physician is not required to be present in the room where the procedure is being performed.

Immediate availability requires the immediate physical presence of the supervisory physician. CMS has not specifically defined the word “immediate” in terms of time or distance; however, an example of a lack of immediate availability would be situations where the supervisory physician is performing another procedure or service that he or she could not interrupt. Also, for services furnished on-campus, the supervisory physician may not be so physically distant on-campus from the location where hospital outpatient services are being furnished that he or she could not intervene right away. The hospital or supervisory physician must judge the supervisory physician’s relative location to ensure that he or she is immediately available.

For services furnished in CY 2011 and following, which require direct supervision, the supervisory practitioner may be present in locations such as physician offices that are close to the hospital or provider based department of a hospital where the services are being furnished but are not located in actual hospital space, as long as the supervisory physician remains immediately available. Similarly, as of CY 2011 for services requiring direct supervision, the supervisory practitioner may be present in a location in or near an off-campus hospital building that houses multiple hospital provider based departments where the services are being furnished as long as the supervisory physician is immediately available.

The supervisory physician must have, within his or her State scope of practice and hospital-granted privileges, the knowledge, skills, ability, and privileges to perform the service or procedure. Specially trained ancillary staff and technicians are the primary operators of some specialized diagnostic testing equipment, and while in such cases CMS does not expect the supervisory physician to operate this equipment instead of a technician, the physician that supervises the provision of the diagnostic service must be knowledgeable about the test and clinically able to furnish the test.

The supervisory responsibility is more than the capacity to respond to an emergency, and includes the ability to take over performance of a procedure or provide additional orders.

CMS would not expect that the supervisory physician would make all decisions unilaterally without informing or consulting the patient's treating physician or nonphysician practitioner. In summary, the supervisory physician must be clinically appropriate to supervise the service or procedure.

As specified at 42 CFR 410.28(f), for services furnished on or after February 21, 2002, the provisions of paragraphs (a) and (d)(2) through (d)(4), inclusive, of 42 CFR 410.32 apply to all diagnostic laboratory tests furnished by hospitals and CAHs to outpatients.



20.4.5 - Outpatient Diagnostic Services Under Arrangements (Rev. 143, Issued: 04-29-11, Effective: 05-31-11, Implementation: 05-31-11)

When the hospital makes arrangements with others for diagnostic services, such services are covered under Part B as diagnostic tests whether furnished in the hospital or in other facilities. Diagnostic services furnished under arrangement in on-campus hospital locations, off-campus hospital locations, and in nonhospital locations must be furnished under the appropriate level of physician supervision according to the requirements of 42 CFR 410.28(e) and 410.32(b)(3), as discussed in the applicable sections above.

Independent laboratory services furnished to an outpatient under arrangements with the hospital are covered only under the "diagnostic laboratory tests" provisions of Part B (see Section 10, above), but are to be billed along with other services to outpatients. See Pub. 100-02, Medicare Benefit Policy Manual, Chapter 1, "Inpatient Hospital Services," Section 50.3, for: (1) the definition of an independent clinical laboratory; (2) the requirements which such a laboratory must meet; and (3) instructions to the intermediary when it is not approved. The "cost" to the hospital for diagnostic laboratory services for outpatients obtained under arrangements is the reasonable charge by the laboratory.

Laboratory services may also be furnished to a hospital outpatient under arrangements by:

1. The laboratory of another participating hospital; or
2. The laboratory of an emergency hospital or participating skilled nursing facility that meets the hospital conditions of participation relating to laboratory services.

20.5 - Outpatient Therapeutic Services (Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08) Sources: 42 CFR 410.27; 65 FR 18536, April 7, 2000

20.5.1 - Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After August 1, 2000, and Before January 1, 2010 (Rev. 128, Issued: 05-28-10, Effective: 07-01-10, Implementation: 07-06-10)

This content is from the eCFR and is authoritative but unofficial.

Title 42 - Public Health

Chapter IV - Centers for Medicare & Medicaid Services, Department of Health and Human Services

Subchapter B - Medicare Program

Part 410 - Supplementary Medical Insurance (SMI) Benefits

Subpart B - Medical and Other Health Services

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

Source: 51 FR 41339, Nov. 14, 1986, unless otherwise noted.

Editorial Note: Nomenclature changes to part 410 appear at 62 FR 46037, Aug. 29, 1997.

§ 410.28 Hospital or CAH diagnostic services furnished to outpatients: Conditions.

- (a) Medicare Part B pays for hospital or CAH diagnostic services furnished to outpatients, including drugs and biologicals required in the performance of the services (even if those drugs or biologicals are self-administered), if those services meet the following conditions:
 - (1) They are furnished by or under arrangements made by a participating hospital or participating CAH, except in the case of an SNF resident as provided in § 411.15(p) of this chapter.
 - (2) They are ordinarily furnished by, or under arrangements made by, the hospital or CAH to its outpatients for the purpose of diagnostic study.
 - (3) They would be covered as inpatient hospital services if furnished to an inpatient.
- (b) Drugs and biologicals are also subject to the limitations specified in § 410.29(b) and (c).
- (c) Diagnostic services furnished by an entity other than the hospital or CAH are subject to the limitations specified in § 410.42(a).
- (d) Rules on emergency services furnished to outpatients by nonparticipating hospitals are set forth in subpart G of part 424 of this chapter.
- (e) Medicare Part B makes payment under section 1833(t) of the Act for diagnostic services furnished by or under arrangements made by the participating hospital only when the diagnostic services are furnished under one of the three levels of supervision (as defined in paragraphs (e)(1) through (3) of this section) specified by CMS for the particular service by a physician or, to the extent that they are authorized to do so under their scope of practice and applicable State law, by a nonphysician practitioner (physician assistant, nurse practitioner, clinical nurse specialist, certified nurse-midwife or certified registered nurse anesthetist).
 - (1) **General supervision.** General supervision means the procedure is furnished under the physician's or nonphysician practitioner's overall direction and control, but the physician's or nonphysician practitioner's presence is not required during the performance of the procedure. Under general supervision at a facility accorded provider-based status, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the facility.
 - (2) **Direct supervision.**

- (i) For services furnished directly or under arrangement in the hospital or in an on-campus or off-campus outpatient department of the hospital, as defined in § 413.65 of this chapter, “direct supervision” means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room where the procedure is performed.
 - (ii) For services furnished under arrangement in nonhospital locations, “direct supervision” means the physician or nonphysician practitioner must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed.
 - (iii) Until the later of the end of the calendar year in which the PHE as defined in § 400.200 of this chapter ends or December 31, 2021, the presence of the physician or nonphysician practitioner under paragraphs (e)(2)(i) and (ii) of this section includes virtual presence through audio/video real-time communications technology (excluding audio-only).
- (3) Personal supervision. Personal supervision means the physician or nonphysician practitioner must be in attendance in the room during the performance of the procedure.
- (f) The rules for clinical diagnostic laboratory tests set forth in §§ 410.32(a) and (d)(2) through (d)(4) of this subpart are applicable to those tests when furnished in hospitals and CAHs.

[51 FR 41339, Nov. 14, 1986, as amended at 58 FR 30668, May 26, 1993; 63 FR 26307, May 12, 1998; 65 FR 18536, Apr. 7, 2000; 66 FR 58809, Nov. 23, 2001; 74 FR 60680, Nov. 20, 2009; 75 FR 72259, Nov. 24, 2010; 85 FR 19286, Apr. 6, 2020; 87 FR 72285, Nov. 23, 2022]

Attachment 1**Medicare Appropriate Use Criteria Program for Advanced Diagnostic Imaging – Code List****HCPCS Advanced Imaging Procedure Codes****Magnetic Resonance Imaging/Magnetic Resonance Angiography**

70336, 70540, 70542, 70543, 70544, 70545, 70546, 70547, 70548, 70549, 70551, 70552, 70553, 70554, 70555, 71550, 71551, 71552, 71555, 72141, 72142, 72146, 72147, 72148, 72149, 72156, 72157, 72158, 72159, 72195, 72196, 72197, 72198, 73218, 73219, 73220, 73221, 73222, 73223, 73225, 73718, 73719, 73720, 73721, 73722, 73723, 73725, 74181, 74182, 74183, 74185, 75557, 75559, 75561, 75563, 75565, 76498, 77046, 77047, 77048, 77049

Computerized Tomography

70450, 70460, 70470, 70480, 70481, 70482, 70486, 70487, 70488, 70490, 70491, 70492, 70496, 70498, 71250, 71260, 71270, 71275, 72125, 72126, 72127, 72128, 72129, 72130, 72131, 72132, 72133, 72191, 72192, 72193, 72194, 73200, 73201, 73202, 73206, 73700, 73701, 73702, 73706, 74150, 74160, 74170, 74174, 74175, 74176, 74177, 74178, 74261, 74262, 74712, 74713, 75571, 75572, 75573, 75574, 75635, 76380, 76497

Single-Photon Emission Computed Tomography

76390

Nuclear Medicine

78012, 78013, 78014, 78015, 78016, 78018, 78020, 78070, 78071, 78072, 78075, 78099, 78102, 78103, 78104, 78110, 78111, 78120, 78121, 78122, 78130, 78135, 78140, 78185, 78191, 78195, 78199, 78201, 78202, , 78215, 78216, 78226, 78227, 78230, 78231, 78232, 78258, 78261, 78262, 78264, 78265, 78266, 78267, 78268, 78278, 78282, 78290, 78291, 78299, 78300, 78305, 78306, 78315, 78350, 78351, 78399, 78414, 78428, 78429, 78430, 78431, 78432, 78433, 78434, 78445, 78451, 78452, 78453, 78454, 78456, 78457, 78458, 78459, 78466, 78468, 78469, 78472, 78473, 78481, 78483, 78491, 78492, 78494, 78496, 78499, 78579, 78580, 78582, 78597, 78598, 78599, 78600, 78601, 78605, 78606, 78608, 78609, 78610, 78630, 78635, 78645, 78650, 78660, 78699, 78700, 78701, 78707, 78708, 78709, 78725, 78730, 78740, 78761, 78799, 78800, 78801, 78802, 78803, 78804, 78811, 78812, 78813, 78814, 78815, 78816, 78830, 78831, 78832, 78835, 78999

C codes

C8900, C8901, C8902, C8903, C8905, C8908, C8909, C8910, C8911, C8912, C8913, C8914, C8918, C8919, C8920, C8931, C8932, C8933, C8934, C8935, C8936

HCPCS Modifiers

- MA Ordering professional is not required to consult a clinical decision support mechanism due to service being rendered to a patient with a suspected or confirmed emergency medical condition
- MB Ordering professional is not required to consult a clinical decision support mechanism due to the significant hardship exception of insufficient internet access
- MC Ordering professional is not required to consult a clinical decision support mechanism due to the significant hardship exception of electronic health record or clinical decision support mechanism vendor issues
- MD Ordering professional is not required to consult a clinical decision support mechanism due to the significant hardship exception of extreme and uncontrollable circumstances
- ME The order for this service adheres to the appropriate use criteria in the clinical decision support mechanism consulted by the ordering professional
- MF The order for this service does not adhere to the appropriate use criteria in the qualified clinical decision support mechanism consulted by the ordering professional
- MG The order for this service does not have appropriate use criteria in the clinical decision support mechanism consulted by the ordering professional
- MH Unknown if ordering professional consulted a clinical decision support mechanism for this service, related information was not provided to the furnishing professional or provider

QQ Ordering professional consulted a qualified clinical decision support mechanism for this service and the related data was provided to the furnishing professional (effective date: 7/1/18)

G codes

- G1000 Clinical Decision Support Mechanism Applied Pathways, as defined by the Medicare Appropriate Use Criteria Program
- G1001 Clinical Decision Support Mechanism eviCore, as defined by the Medicare Appropriate Use Criteria Program
- G1002 Clinical Decision Support Mechanism MedCurrent, as defined by the Medicare Appropriate Use Criteria Program
- G1003 Clinical Decision Support Mechanism Medicalis, as defined by the Medicare Appropriate Use Criteria Program
- G1004 Clinical Decision Support Mechanism National Decision Support Company, as defined by the Medicare Appropriate Use Criteria Program
- G1005 Clinical Decision Support Mechanism National Imaging Associates, as defined by the Medicare Appropriate Use Criteria Program
- G1006 Clinical Decision Support Mechanism Test Appropriate, as defined by the Medicare Appropriate Use Criteria Program
- G1007 Clinical Decision Support Mechanism AIM Specialty Health, as defined by the Medicare Appropriate Use Criteria Program
- G1008 Clinical Decision Support Mechanism Cranberry Peak, as defined by the Medicare Appropriate Use Criteria Program
- G1009 Clinical Decision Support Mechanism Sage Health Management Solutions, as defined by the Medicare Appropriate Use Criteria Program
- G1010 Clinical Decision Support Mechanism Stanson, as defined by the Medicare Appropriate Use Criteria Program
- G1011 Clinical Decision Support Mechanism, qualified tool not otherwise specified, as defined by the Medicare Appropriate Use Criteria Program



KNOWLEDGE • RESOURCES • TRAINING

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging- Approval of Using the K3 Segment for Institutional Claims

MLN Matters Number: SE20002

Related Change Request (CR) Number: N/A

Related CR Release Date: January 9, 2020

Effective Date: N/A

Related CR Transmittal Number: N/A

Implementation Date: January 1, 2020

PROVIDER TYPES AFFECTED

This Special Edition Article is for institutional providers billing Medicare Administrative Contractors (MACs) for services they provide to Medicare beneficiaries.

PROVIDER ACTION NEEDED

This article (SE20002) provides guidance for processing claims for certain institutional claims that are subject to the Appropriate Use Criteria (AUC) program for advanced diagnostic imaging services. The Centers for Medicare & Medicaid Services (CMS) will begin to accept claims with this information as of January 1, 2020. This is the beginning of the education and operations testing period for the AUC program. While there will not be payment penalties during this period, stakeholders and CMS can use this time to practice reporting and accepting AUC information on claims. The K3 segment will be used to report line level ordering professional information on institutional claims.

For other claims processing information for the AUC program including HCPCS modifiers and codes, please see MLN Matters article MM11268, Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging – Educational and Operations Testing Period - Claims Processing Requirements at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM11268.pdf>. For general information regarding the AUC program please visit <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index>.

Key Points

During CY 2020, CMS expects ordering professionals to begin consulting qualified clinical decision support mechanisms (CDSMs) and providing information to the furnishing practitioners and providers for reporting on their claims. Situations in which furnishing practitioners and providers do not receive AUC-related information from the ordering professional can be reported by modifier MH. During this phase of the program claims will not be denied for failing to include

AUC-related information or for misreporting AUC information on non-imaging claims, but inclusion is encouraged.

Required Reporting of Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging CDSM G-codes and Modifiers

A modifier (MA-MH) is reported on the same claim line as any Advance Diagnostic Imaging HCPCS code. When a qualified CDSM was consulted, the CDSM HCPCS modifier ME, MF or MG is reported on the Advance Diagnostic Imaging service HCPCS code. Additionally, a separate line with a CDSM G-code is reported.

Each reported CDSM G-code must contain the following line of service information:

- Date of the related Advanced Diagnostic Imaging service
- Nominal charge, e.g., a penny, for institutional claims submitted to the A/B MACs (A).

Reporting the ordering professional's National Provider Identifier (NPI) on institutional claims

In this Special Edition article, CMS clarifies the method of reporting the ordering professional's National Provider Identifier (NPI) on institutional claims for advanced diagnostic imaging services subject to the AUC program. This information for institutional claims, will be reported using the K3 segment. When reporting the NPI of the Ordering Professional on institutional claims, the K301 will use the following values for each service line that needs an Ordering Professional reported:

- **AUC** represents the program
- **LX** represents the service line followed by the service line number reported in LX01
- **DK** represents the Ordering Professional identifier followed by the Ordering Professional's NPI

If an Ordering Professional NPI is the same for multiple service lines, each service must be reported as a separate service line in the K301. The K301 supports 80 characters, which may allow up to four Ordering Professional NPI iterations in a single K301. Providers may send additional K3 segments as needed but each one must begin with the value of AUC as shown below and demonstrated in the attachments to this article.

K3 Examples:

Reporting 1 Ordering Professional NPI

K3*AUC LX1DK111111111~

Reporting 5 Ordering Professional NPIs

K3*AUC LX1DK111111111 LX11DK999999999 LX22DK111111111 LX433DK222222222~

K3*AUC LX444DK444444444~

Qualified CDSM specific HCPCS not yet available

Providers report the CDSM approved HCPCS G-codes for qualified CDSMs, when available. HCPCS G1011 is designated as “Clinical Decision Support Mechanism, qualified tool not otherwise specified”. When a CDSM has been qualified by CMS, but has not received an assigned HCPCS G-codes, providers report HCPCS G1011. It is important to remember that the key claim segments should be completed as follows:

2400 — SERVICE LINE

LX01:	Assigned Number	(Depends on claim service line #)
SV201:	Service Line Revenue Code	0359
SV202-1:	Product/Service ID Qualifier	HC
SV202-2:	Product/Service ID	G1011
SV202-7:	Description	CDSM (<i>insert Name of CDSM</i>)
SV203:	Line Item Charge Amount	.01
SV204:	Unit or Basis for Measurement Code	UN
SV205:	Service Unit Count	1
DTP01:	Date/Time Qualifier	472
DTP02:	Date Time Period Format Qualifier	D8
DTP03:	Date Time Period	20200115

LX*#~SV2*0359*HC:G1011::::CDSM (*insert Name of CDSM*)*.01*UN*1~DTP*472*D8*20200115~

Example if a claim is billed when AgileMD's CDSM is consulted prior to receiving HCPCS assignment:

2400 — SERVICE LINE

LX01:	Assigned Number	(Depends on claim service line #)
SV201:	Service Line Revenue Code	0359
SV202-1:	Product/Service ID Qualifier	HC
SV202-2:	Product/Service ID	G1011
SV202-7:	Description	CDSM AGILEMDS
SV203:	Line Item Charge Amount	.01
SV204:	Unit or Basis for Measurement Code	UN
SV205:	Service Unit Count	1

DTP01:	Date/Time Qualifier	472
DTP02:	Date Time Period Format Qualifier	D8
DTP03:	Date Time Period	20200115

LX*#~SV2*0359*HC:G1011:.....CDSM AG/LEMDS*.01*UN*1~DTP*472*D8*20200115~

Multiple consultations of the same CDSM

You can report the qualified CDSM G-codes with the same Revenue code as the Advanced Diagnostic Imaging service or in the Revenue Center that ends in "9" for the Advanced Diagnostic Imaging service.

For example, a CDSM G-code for a CT scan order for the head could be reported with either Revenue Code 0351 (CT SCAN/HEAD), which is the same as the imaging service, or Revenue Code 0359 (CT SCAN/OTHER).

A CDSM G-code on a MRI order for the head could be reported with either Revenue Code 0611 (MRI/BRAIN), which is the same as the imaging service, or 0619 (MRT/OTHER).

- A) If the multiple consultations of the same CDSM G-code were for the same revenue code series on the claim, the provider has options:

Option One

1 line would be reported rolling up all the CDSM queries into 1 Revenue code ending in "9" just 1 time with multiple units.

0351 test 1 unit

0352 test 2 unit

0359 CDSM 2 units

-or use the alternate approach -

Option Two

Every specific revenue code that had a CDSM queried, would be reported with the exact same Revenue Code (again, you could see roll-ups if there were 2 separate CPT codes used for the same service where one had with contrast and one had without contrast for the same specific Revenue Code).

0351 test 1 unit

0351 CDSM 1 unit

0352 test 1 unit

0352 CDSM 1 unit

- B) If the multiple consultations were for different revenue code series lines on the claim, there would be at least 1 line for each revenue code series depending on if you use the xxx9 approach for reporting or the specific revenue code approach.

Option One

1 line would be reported rolling up all the CDSM queries into 1 Revenue code ending in “9” just 1 unit for each CDSM query.

0351 test 1 unit

0359 CDSM 1 units

0611 test 1 unit

0619 CDSM 1 unit

-or use the alternate approach -

Option Two

Every specific revenue code that had a CDSM queried, would be reported with the exact same Revenue Code (again, you could see roll-ups if there were 2 separate CPT codes used for the same service where one had with contrast and one had without contrast for the same specific Revenue Code).

0351 test 1 unit

0351 CDSM 1 units

0611 test 1 unit

0611 CDSM 1 unit

Example of 2 separate CPT codes used for the same service where one had with contrast and one had without contrast for the same specific Revenue Code.

0351 test 1 unit with contrast

0351 test 1 unit without contrast

0351 CDSM 2 units

0611 test 1 unit with contrast

0611 test 1 unit without contrast

0611 CDSM 2 units

Claim Examples

The attached advanced diagnostic imaging UB-04 claim examples are provided to help you better understand the claims-based reporting concept of the AUC program. This concept is applicable to any of the claims that require AUC program billing to report information about the ordering professional's consultation with AUC.

ADDITIONAL INFORMATION

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging fact sheet is available at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AUCDiagnosticImaging-909377.pdf>.

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging – Educational and Operations Testing Period - Claims Processing Requirements is available at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM11268.pdf>.

If you have questions, your MACs may have more information. Find their website at <http://go.cms.gov/MAC-website-list>.

Various examples of reporting the K3 segment follow the Document History section of this article.

DOCUMENT HISTORY

Date of Change	Description
January 9, 2020	Initial article released.

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TABLE 3: OPPI IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2023 APC 8004 (Ultrasound Composite)	CY 2023 Approximate APC Geometric Mean Cost = \$302.65
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76981	Us parenchyma
76982	Us 1 st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2023 APC 8005 (CT and CTA without Contrast Composite)*	CY 2023 Approximate APC Geometric Mean Cost = \$227.67
0633T	Ct breast w/3d uni c-
0636T	Ct breast w/3d bi c-
70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
74176	Ct angio abd & pelvis
74261	Ct colonography, w/o dye
CY 2023 APC 8006 (CT and CTA with Contrast Composite)	CY 2023 Approximate APC Geometric Mean Cost = \$434.16
0634T	Ct breast w/3d uni c+
0635T	Ct breast w/3d uni c-/c+
0637T	Ct breast w/3d bi c+
0638T	Ct breast w/3d bi c-/c+
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye

70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye
70487	Ct maxillofacial w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o & w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o & w/dye
73206	Ct angio upr extrm w/o & w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o & w/dye
73706	Ct angio lwr extr w/o & w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
* If a “without contrast” CT or CTA procedure is performed during the same session as a “with contrast” CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.	
Family 3 - MRI and MRA with and without Contrast	
CY 2023 APC 8007 (MRI and MRA without Contrast Composite)*	CY 2023 Approximate APC Geometric Mean Cost = \$527.17
0609T	Mrs disc pain acquisj data
70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye

70544	Mr angiography head w/o dye
70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye
70554	Fmri brain by tech
71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
76391	Mr elastography
77046	Mri breast c- unilateral
77047	Mri breast c- bilateral
C8901	MRA w/o cont, abd
C8910	MRA w/o cont, chest
C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis
C8932	MRA, w/o dye, spinal canal
C8935	MRA, w/o dye, upper extr
C9762	Cardiac MRI seg dys strain
C9763	Cardiac MRI seg dys stress
CY 2023 APC 8008 (MRI and MRA with Contrast Composite)	
CY 2023 Approximate APC Geometric Mean Cost = \$845.72	
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o & w/dye
70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye
70549	Mr angiograph neck w/o & w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye

72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o & w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o & w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o & w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o & w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o&w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr
* If a “without contrast” MRI or MRA procedure is performed during the same session as a “with contrast” MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.	

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3. Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept

of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular beneficiary. The OPPS packages

HCPCS code 90935 (Hemodialysis procedure with single physician evaluation) may be reported and paid only if one of the following two conditions is met:

- 1) The patient is a hospital inpatient with or without ESRD and has no coverage under Part A, but has Part B coverage. The charge for hemodialysis is a charge for the use of a prosthetic device. See Benefits Policy Manual 100-02 Chapter 15 section 120. A. The service must be reported on a type of bill 12X or type of bill 85X. See the Benefits Policy Manual 100-02 Chapter 6 section 10 (Medical and Other Health Services Furnished to Inpatients of Participating Hospitals) for the criteria that must be met for services to be paid when a hospital inpatient has Part B coverage but does not have coverage under Part A; or
- 2) A hospital outpatient does not have ESRD and is receiving hemodialysis in the hospital outpatient department. The service is reported on a type of bill 13X or type of bill 85X.

CPT code 90945 (Dialysis procedure other than hemodialysis (e.g. peritoneal dialysis, hemofiltration, or other continuous replacement therapies)), with single physician evaluation, may be reported by a hospital paid under the OPPI or CAH method I or method II on type of bill 12X, 13X or 85X.

200.3 - Billing Codes for Intensity Modulated Radiation Therapy (IMRT) and Stereotactic Radiosurgery (SRS)

(Rev. 1445, Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

200.3.1 - Billing Instructions for IMRT Planning and Delivery

(Rev. 3685, Issued: 12-22-16, Effective: 01-01-17, Implementation: 01-03-17)

Payment for the services identified by CPT codes 77014, 77280, 77285, 77290, 77295, 77306 through 77321, 77331, and 77370 are included in the APC payment for CPT code 77301 (IMRT planning). These codes should not be reported in addition to CPT code 77301 when provided prior to or as part of the development of the IMRT plan. In addition, CPT codes 77280-77290 (simulation-aided field settings) should not be reported for verification of the treatment field during a course of IMRT.

200.3.2 - Billing for Multi-Source Photon (Cobalt 60-Based) Stereotactic Radiosurgery (SRS) Planning and Delivery

(Rev. 3941; Issued: 12-22-17; Effective: 01-01-18; Implementation: 01-02-18)

Effective for services furnished on or after January 1, 2014, hospitals must report SRS planning and delivery services using only the CPT codes that accurately describe the

service furnished. For the delivery services, hospitals must report CPT code 77371, 77372, or 77373.

CPT Code	Long Descriptor
77371	Radiation treatment delivery, stereotactic radiosurgery (srs), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source cobalt 60 based
77372	Radiation treatment delivery, stereotactic radiosurgery (srs), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based
77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions

As instructed in the CY 2014 OPPI/ASC final rule, CPT code 77371 is to be used only for single session cranial SRS cases performed with a Cobalt-60 device, and CPT code 77372 is to be used only for single session cranial SRS cases performed with a linac-based device. The term “cranial” means that the pathological lesion(s) that are the target of the radiation is located in the patient’s cranium or head. The term “single session” means that the entire intracranial lesion(s) that comprise the patient’s diagnosis are treated in their entirety during a single treatment session on a single day. CPT code 77372 is never to be used for the first fraction or any other fraction of a fractionated SRS treatment. CPT code 77372 is to be used only for single session cranial linac-based SRS treatment. Fractionated SRS treatment is any SRS delivery service requiring more than a single session of SRS treatment for a cranial lesion, up to a total of no more than five fractions, and one to five sessions (but no more than five) for non-cranial lesions. CPT code 77373 is to be used for any fraction (including the first fraction) in any series of fractionated treatments, regardless of the anatomical location of the lesion or lesions being radiated. Fractionated cranial SRS is any cranial SRS that exceeds one treatment session and fractionated non-cranial SRS is any non-cranial SRS, regardless of the number of fractions but never more than five. Therefore, CPT code 77373 is the exclusive code (and the use of no other SRS treatment delivery code is permitted) for any and all fractionated SRS treatment services delivered anywhere in the body, including, but not limited to, the cranium or head. 77372 is not to be used for the first fraction of a fractionated cranial SRS treatment series and must only be used in cranial SRS when there is a single treatment session to treat the patient’s entire condition.

In addition, for the planning services, hospitals must report the specific CPT code that accurately describes the service provided. The planning services may include but are not limited to CPT code 77290, 77295, 77300, 77334, or 77370.

CPT Code	Long Descriptor
77290	Therapeutic radiology simulation-aided field setting; complex
77295	Therapeutic radiology simulation-aided field setting; 3-dimensional
77300	Basic radiation dosimetry calculation, central axis depth dose calculation, tdf, nsd, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician
77334	Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts)
77370	Special medical radiation physics consultation

Effective for cranial single session stereotactic radiosurgery procedures (CPT code 77371 or 77372) furnished on or after January 1, 2016, costs for certain adjunctive services (e.g., planning and preparation) are not factored into the APC payment rate for APC 5627 (Level 7 Radiation Therapy). Rather, the ten planning and preparation codes, will be paid according to their assigned status indicator when furnished 30 days prior or 30 days post SRS treatment delivery. *A list of the excluded planning and preparation CPT codes is provided in the CY 2018 OP/AS final rule with comment period.*

200.4 - Billing for Amniotic Membrane

(Rev. 1445, Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

Hospitals should report HCPCS code V2790 (Amniotic membrane for surgical reconstruction, per procedure) to report amniotic membrane tissue when the tissue is used. A specific procedure code associated with use of amniotic membrane tissue is CPT code 65780 (Ocular surface reconstruction; amniotic membrane transplantation). Payment for the amniotic membrane tissue is packaged into payment for CPT code 65780 or other procedures with which the amniotic membrane is used.

200.5 - Reserved

(Rev. 1882, Issued: 12-21-09; Effective Date: 01-01-10; Implementation Date: 01-04-10)

200.6 - Billing and Payment for Alcohol and/or Substance Abuse Assessment and Intervention Services

(Rev. 1445, Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

HCPCS code 77372 (Linear accelerator-based)) are assigned to the same C-APC (C-APC 5627 Level 7 Radiation Therapy).

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70336), we stated that we had identified differences in the billing patterns for SRS procedures delivered using Cobalt-60-based and LINAC-based technologies. In particular, our claims data analysis revealed that services involving SRS delivered by Cobalt-60-based technologies (as described by HCPCS code 77371) typically included SRS treatment planning services (for example, imaging studies, radiation treatment aids, and treatment planning) and the actual deliveries of SRS treatment on the same date of service and reported on the same claim. In contrast, claims data analysis results revealed that services involving SRS delivered by LINAC-based technologies (as described by HCPCS code 77372) frequently included services related to SRS treatment (for example, imaging studies, radiation treatment aids, and treatment planning) that were provided on different dates of service and reported on claims separate from the actual delivery of SRS treatment.

We stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70336) that the intent of the C-APC policy is to package payment for all services adjunctive to the primary “J1” procedure and that we believed that all essential planning and preparation services related to the SRS treatment are adjunctive to the SRS treatment delivery procedure. Therefore, payment for these adjunctive services should be packaged into the C-APC payment for the SRS treatment instead of reported on a different claim and paid separately. To identify services that are adjunctive to the primary SRS treatment described by HCPCS codes 77371 and 77372, but reported on a different claim, we established modifier “CP” which became effective in CY 2016 and required the use of the modifier for CY 2016 and CY 2017.

To ensure appropriate ratesetting for the SRS C-APC, we believed it was necessary to unbundle payment for the adjunctive services for CY 2016 and CY 2017. Therefore, we finalized a policy to change the payment for SRS treatment for the 10 SRS planning and preparation services identified in our claims data (HCPCS codes 70551, 70552, 70553, 77011, 77014, 77280, 77285, 77290, 77295, and 77336) that were reported differentially using HCPCS codes 77371 and 77372 both on the same claim as the SRS services and on claims 1 month prior to the delivery of SRS services.

These codes were removed from the geometric mean cost calculations for C-APC 5627. In addition, for CY 2016 and CY 2017, we provided separate payment 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, even when the planning service was included on the same claim as the primary “J1” SRS treatment service. The use of the modifier “CP” was not required to identify these 10 planning and preparation codes.

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33564 and 33465), the data collection period for SRS claims with modifier “CP” began on January 1, 2016 and concludes on December 31, 2017. Based on our analysis of preliminary data collected with modifier “CP”, we have identified some additional services that are adjunctive to the primary SRS treatment and reported on a different claim outside of the 10 SRS planning and preparation codes that were removed from the SRS C-APC costs calculations and paid separately.

However, the “CP” modifier has been used by a small number of providers since its establishment. In addition, our analysis showed that several of the HCPCS codes that were billed with modifier “CP” belonged to the group of 10 SRS planning and preparation codes that we pay separately and do not require the use of modifier “CP”. Also, some providers erroneously included the modifier when reporting the HCPCS code for the delivery of the LINAC-based SRS treatment. As stated above, the data collection period for SRS claims with modifier “CP” was set to conclude on December 31, 2017. Accordingly, for CY 2018, we are deleting this modifier and discontinuing its required use.

For CY 2018, we also proposed to 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 1 month of the SRS treatment. The continued separate payment of these services will allow us to complete our analysis of the claims data including modifier “CP” from both CY 2016 and CY 2017 claims. As stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583), we will consider in the future whether repackaging all adjunctive services (planning, preparation, and imaging, among others) back into cranial single session SRS is appropriate.

We invited public comments on these proposals.

Comment: Commenters generally supported the proposal to continue to make separate payments for the planning and preparation services adjunctive to the delivery of the SRS treatment and requested that CMS continue to pay separately for these services in the future. Commenters also supported the deletion of modifier “CP”.

Response: We appreciate the commenters’ support.

After consideration of the public comments we received, we are finalizing our proposal 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 1 month of the SRS treatment.

(5) Complexity Adjustment for Blue Light Cystoscopy Procedures

As discussed in prior OPPS/ASC final rules with comment period, and most recently in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79668), we continue to believe that Cysview® (hexaminolevulinate HCl) (described by HCPCS code C9275) is a drug that functions as a supply in a diagnostic test or procedure and is therefore packaged with payment for the primary procedure. In addition, as discussed in section II.A.2.b.(1) of the CY 2018 OPPS/ASC proposed rule and this final rule with comment period, drugs that are not eligible for pass-through payment are always packaged when billed with a comprehensive service. To maintain the integrity of the OPPS, we believe it is generally not appropriate to allow exceptions to our drug packaging policy or comprehensive APC policy that would result in separate payment for the drug based on the product’s ASP+6 percent payment rate. While we did not propose in the CY 2018 proposed rule to pay separately for Cysview®, we have heard concerns from stakeholders that the payment for blue light cystoscopy procedures involving Cysview® may be creating a barrier to beneficiaries receiving access to reasonable and necessary care for which there may not be a clinically comparable alternative. Therefore, as we stated in the proposed rule, we revisited our payment policy for blue light cystoscopy procedures. As described in more detail below, we believe certain code combinations for blue light cystoscopy procedures should be eligible to qualify for a complexity



primary outpatient service when the specimen is collected at an outpatient encounter, while requiring the performing laboratory to bill Medicare for the non-PLA cancer-related protein based MAAAs.

Response: We appreciate the commenters' suggestion that we consider adding the OVERA test from Aspiria Labs (CPT 0003U), TissueCypher assay from Cernostics (CPT 0108U), EPI assay by Bio-Techne (CPT 0005U), and KidneyIntelX (CPT 0105U), to the laboratory DOS exception at § 414.510(b)(5). These PLA tests are relatively new, with none to minimal Medicare utilization, and at this time we do not have a sufficient understanding regarding how these tests may be used to guide treatment outside of the outpatient encounter and whether they should be unpackaged under OPPS. The tests would need to demonstrate a pattern of clinical use that make them relatively unconnected to the primary hospital outpatient service during which the specimen was collected and the results of these tests are typically used to determine post-hospital care. At this time, we cannot establish that these tests would generally be utilized for guiding treatment outside of the hospital encounter. Nevertheless, we intend to continue to study the laboratory DOS policy and determine whether any additional changes are warranted and may consider proposing changes to the laboratory DOS policy through notice-and-comment rulemaking in the future.

Comment: Commenters also recommended the inclusion of a particular protein-based MAAA test, CPT code 81490, in the laboratory DOS exception at § 414.510(b)(5). Commenters asserted that the use of this rheumatoid arthritis (RA) test is unconnected to the hospital outpatient encounter during which the specimen is collected and is instead used to determine potential future interventions outside of the hospital outpatient encounter; it is used by the rheumatologist to make longer-term changes in RA treatment. The commenters stated that this RA test appears to be generally less tied to a primary service in the hospital outpatient setting and does not appear to be a common or routine laboratory test that would otherwise be packaged into OPPS payment.

Response: In the CY 2021 OPPS/ASC proposed rule (85 FR 48799), we stated that we believed the results for the test described by CPT code 81490 are used to determine disease activity in rheumatoid arthritis patients, guide current therapy to reduce further joint

damage, and may be tied to the primary hospital outpatient service, that is, the hospital outpatient encounter during which the specimen was collected. Therefore, we stated that we believed that payment for CPT code 81490 remains appropriately packaged under the OPPS.

However, given commenter feedback, we are convinced that the pattern of clinical use for CPT code 81490 is generally unconnected to the hospital outpatient encounter during which the specimen is collected, as it is typically used to determine potential interventions outside of the hospital outpatient encounter and is generally used by the rheumatologist to make longer-term changes in RA treatment. Commenters informed us that physicians and patients utilize the objective information provided by the results of the test to make longer-term modifications in treatment, to monitor disease activity, and to prevent joint damage progression, and the results would generally not be utilized for the purposes of the hospital outpatient encounter. The commenters further stated that the output of the test is used to assess disease activity, including evaluating response to therapy, directing choice of second-line treatment in patients with inadequate response to the current first line therapy, and identifying patients in stable remission for therapy reduction. The test results appear to guide longer-term therapies and treatments; therefore, we believe that this test, identified by CPT code 81490, is generally less tied to the primary service the patient receives in the hospital outpatient setting and does not appear to be a common or routine laboratory test that would otherwise be packaged into OPPS payment. Given the similarity in clinical pattern of use, we believe that we have sufficient information to add CPT code 81490 to the list of tests included in the laboratory DOS exception at § 414.510(b)(5) at this time. In conclusion, for the reasons discussed previously in this section, we believe that cancer-related protein-based MAAAs, such as CPT codes 81500, 81503, 81535, 81536 and 81539, appear to have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged. Given the similarity in clinical pattern of use, we believe that CPT code 81490 should also be added to the list of tests in the laboratory DOS exception at § 414.510(b)(5). We believe these tests

should therefore be excluded from OPPS packaging policy and subject to the laboratory DOS exception at § 414.510(b)(5) as described in section II.A. of this final rule. We intend to continue to study the list of laboratory tests included the laboratory DOS exception policy and to determine whether any additional changes are warranted and may consider proposing future changes to this policy through notice-and-comment rulemaking.

For these reasons and in light of the commenters' suggestions, we are revising the current laboratory DOS exception at 42 CFR 414.510(b)(5) to include cancer-related protein-based MAAAs, such as CPT codes 81500, 81503, 81535, 81536, 81539, as well as the test described by CPT code 81490. We are also finalizing that we will exclude cancer-related protein-based MAAAs that do not currently exist, but that are developed in the future, from the laboratory DOS policy.

XIX. Physician-Owned Hospitals

A. Background

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless all requirements of an applicable exception are satisfied; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for any improperly referred designated health services. A financial relationship may be an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services (the Secretary) the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Section 1903(s) of the Act extends aspects of the physician self-referral prohibitions to Medicaid.

Section 1877(d) of the Act sets forth exceptions related to ownership or investment interests held by a physician (or an immediate family member of a physician) in an entity that furnishes designated health services. Section 1877(d)(2) of the Act provides an exception for ownership or investment interests in rural providers (the "rural provider exception"). In order to qualify for the rural provider exception, the designated health services must be

Inpatient-Only Separate Procedure Exception List (Data_HCPCS, Column AU "SEPARATE PROCEDURE")

HCPCS	LO_VERSION	HI_VERSION	DESCRIPTION	STATUS_INDICATOR
21750	86	90	Repair of sternum separation	C
21825	86	90	Treat sternum fracture	C
22010	86	90	I&d p-spine c/t/cerv-thor	C
22015	86	90	I&d abscess p-spine l/s/l	C
22110	86	90	Remove part of neck vertebra	C
22112	86	90	Remove part thorax vertebra	C
22114	86	90	Remove part lumbar vertebra	C
22116	86	90	Remove extra spine segment	C
22206	86	90	Incis spine 3 column thorac	C
22207	86	90	Incis spine 3 column lumbar	C
22208	86	90	Incis spine 3 column adl seg	C
22210	86	90	Incis 1 vertebral seg cerv	C
27005	86	90	Incision of hip tendon	C
27090	86	90	Removal of hip prosthesis	C
27140	86	90	Transplant femur ridge	C
27161	86	90	Incision of neck of femur	C
31725	63	90	Clearance of airways	C
32220	63	90	Release of lung	C
32225	63	90	Partial release of lung	C
32310	63	90	Removal of chest lining	C
33140	63	90	Heart revascularize (tmr)	C
33496	63	90	Repair prosth valve clot	C
33800	89	90	Aortic suspension	C
38100	63	90	Removal of spleen total	C
38101	63	90	Removal of spleen partial	C
38562	86	90	Removal pelvic lymph nodes	C
38564	63	90	Removal abdomen lymph nodes	C
38765	63	90	Remove groin lymph nodes	C
38770	63	90	Remove pelvis lymph nodes	C
38780	63	90	Remove abdomen lymph nodes	C
43848	63	90	Revision gastroplasty	C
44005	63	90	Freeing of bowel adhesion	C
44130	63	90	Bowel to bowel fusion	C
44300	86	90	Open bowel to skin	C
44314	86	90	Revision of ileostomy	C
44316	63	90	Devise bowel pouch	C
44322	63	90	Colostomy with biopsies	C
44345	86	90	Revision of colostomy	C
44346	86	90	Revision of colostomy	C
44680	63	90	Surgical revision intestine	C
44820	63	90	Excision of mesentery lesion	C
44850	63	90	Repair of mesentery	C
47460	63	90	Incise bile duct sphincter	C
47480	63	90	Incision of gallbladder	C
47900	63	90	Suture bile duct injury	C
49000	63	90	Exploration of abdomen	C

Inpatient-Only Separate Procedure Exception List (Data_HCPCS, Column AU "SEPARATE PROCEDURE")

49010	86	90	Exploration behind abdomen	C
49255	86	90	Removal of omentum	C
50100	90	90	Trnsxj/repos abrrnt rnl vsls	C
50340	63	90	Removal of kidney	C
50600	63	90	Exploration of ureter	C
50650	63	90	Removal of ureter	C
50900	63	90	Repair of ureter	C
51525	63	90	Removal of bladder lesion	C
51570	63	90	Removal of bladder	C
57270	63	90	Repair of bowel pouch	C
58400	63	90	Suspension of uterus	C
58605	63	90	Division of fallopian tube	C
58700	63	90	Removal of fallopian tube	C
58720	63	90	Removal of ovary/tube(s)	C
60521	63	90	Removal of thymus gland	C
60522	63	90	Removal of thymus gland	C
60540	63	90	Explore adrenal gland	C
60545	63	90	Explore adrenal gland	C
61210	63	90	Pierce skull implant device	C
61535	63	90	Remove brain electrodes	C

HCPCS	LO_VERSION	HI_VERSION	OFFSET
			AMOUNT
0200T	90	90	\$2,191.43
0221T	90	90	\$5,259.29
0234T	90	90	\$3,705.80
0236T	90	90	\$3,825.76
0237T	90	90	\$4,754.60
0238T	90	90	\$8,339.72
0253T	90	90	\$1,965.43
0268T	90	90	\$26,663.37
0275T	90	90	\$3,753.80
0308T	90	90	\$7,046.05
0335T	90	90	\$3,126.07
0404T	90	90	\$2,146.92
0408T	90	90	\$26,610.52
0409T	90	90	\$20,616.35
0410T	90	90	\$2,530.46
0414T	90	90	\$14,592.32
0421T	90	90	\$3,019.10
0424T	90	90	\$46,629.42
0425T	90	90	\$7,505.03
0426T	90	90	\$5,831.67
0427T	90	90	\$21,452.24
0431T	90	90	\$21,666.56
0442T	90	90	\$3,667.03
0449T	90	90	\$2,143.63
0505T	90	90	\$5,229.10
0511T	90	90	\$3,241.83
0515T	90	90	\$10,384.62
0516T	90	90	\$2,530.46
0517T	90	90	\$6,065.75
0519T	90	90	\$1,382.93
0520T	90	90	\$7,073.68
0524T	90	90	\$1,160.31
0525T	90	90	\$8,246.49
0526T	90	90	\$2,530.46
0527T	90	90	\$6,270.64
0571T	90	90	\$24,503.11
0572T	90	90	\$4,090.36
0583T	90	90	\$430.32
0587T	90	90	\$4,495.24
0594T	90	90	\$2,050.54
0600T	90	90	\$6,085.76
0601T	90	90	\$2,817.06
0614T	90	90	\$17,809.70
0616T	90	90	\$12,947.00
0617T	90	90	\$14,072.20
0618T	90	90	\$11,910.44
0619T	90	90	\$1,457.68
0620T	90	90	\$12,123.95
0627T	90	90	\$6,281.35
0629T	90	90	\$6,281.35
0644T	90	90	\$2,836.66
0647T	90	90	\$539.89
0651T	90	90	\$255.91
0652T	90	90	\$255.91
0653T	90	90	\$255.91
0671T	90	90	\$1,177.97
0707T	90	90	\$922.76
0744T	90	90	\$1,593.33
0775T	90	90	\$7,648.84

HCPCS	LO_VERSION	HI_VERSION	OFFSET AMOUNT
10035	90	90	\$217.02
11970	90	90	\$1,991.00
19281	90	90	\$807.96
19283	90	90	\$319.55
19285	90	90	\$356.93
19287	90	90	\$202.61
19296	90	90	\$3,640.29
20690	90	90	\$2,485.12
20692	90	90	\$5,764.64
20696	90	90	\$11,647.35
20900	90	90	\$2,500.99
20983	90	90	\$2,389.87
21122	90	90	\$1,913.74
21150	90	90	\$1,802.14
21195	90	90	\$2,697.60
21243	90	90	\$11,397.72
21244	90	90	\$2,118.78
21245	90	90	\$2,426.88
21256	90	90	\$2,479.74
21267	90	90	\$4,210.86
21346	90	90	\$2,385.23
21347	90	90	\$1,743.94
21365	90	90	\$1,820.83
21422	90	90	\$1,609.91
21450	90	90	\$202.01
21452	90	90	\$1,736.46
21453	90	90	\$1,628.07
21461	90	90	\$1,991.16
21462	90	90	\$1,916.41
21470	90	90	\$2,011.45
21742	90	90	\$1,993.77
21812	90	90	\$5,834.10
21813	90	90	\$757.43
22551	90	90	\$5,932.96
22554	90	90	\$5,598.93
22612	90	90	\$11,745.89
22630	90	90	\$13,070.70
22633	90	90	\$13,245.88
22856	90	90	\$11,461.22
22867	90	90	\$13,499.89
22869	90	90	\$9,821.29
22899	90	90	\$72.31
23395	90	90	\$2,292.63
23470	90	90	\$6,766.73
23472	90	90	\$7,877.13
23473	90	90	\$6,496.64
23485	90	90	\$5,514.12
23491	90	90	\$4,505.50
23515	90	90	\$2,539.36
23552	90	90	\$2,487.10
23585	90	90	\$2,499.01
23615	90	90	\$5,655.04
23616	90	90	\$11,476.55
23630	90	90	\$2,173.57
23680	90	90	\$4,870.85
24126	90	90	\$3,305.99
24340	90	90	\$2,282.05
24344	90	90	\$2,230.45
24360	90	90	\$3,473.34

HCPCS	LO_VERSION	HI_VERSION	OFFSET
			AMOUNT
24361	90	90	\$11,450.27
24362	90	90	\$8,155.05
24363	90	90	\$13,101.35
24365	90	90	\$7,158.18
24366	90	90	\$7,224.72
24370	90	90	\$5,531.08
24371	90	90	\$11,572.90
24400	90	90	\$2,035.32
24420	90	90	\$2,733.17
24430	90	90	\$5,289.69
24435	90	90	\$5,687.66
24498	90	90	\$4,471.58
24515	90	90	\$4,891.73
24516	90	90	\$5,167.04
24545	90	90	\$5,863.81
24546	90	90	\$5,909.48
24575	90	90	\$5,452.79
24579	90	90	\$4,552.48
24586	90	90	\$5,373.20
24587	90	90	\$6,257.86
24615	90	90	\$2,202.67
24635	90	90	\$2,682.89
24666	90	90	\$7,305.62
24685	90	90	\$2,164.31
25126	90	90	\$1,121.31
25332	90	90	\$964.74
25350	90	90	\$2,859.50
25390	90	90	\$2,397.80
25391	90	90	\$6,319.19
25400	90	90	\$2,715.31
25405	90	90	\$2,659.08
25415	90	90	\$2,262.20
25420	90	90	\$2,397.14
25426	90	90	\$1,101.66
25441	90	90	\$8,051.97
25442	90	90	\$13,394.78
25443	90	90	\$3,475.99
25444	90	90	\$8,289.45
25445	90	90	\$3,530.23
25446	90	90	\$14,629.81
25515	90	90	\$2,402.43
25526	90	90	\$2,275.43
25545	90	90	\$2,136.53
25574	90	90	\$2,573.75
25575	90	90	\$2,458.00
25607	90	90	\$2,824.45
25608	90	90	\$2,842.97
25609	90	90	\$2,866.12
25652	90	90	\$2,245.01
25800	90	90	\$2,899.85
25805	90	90	\$2,538.69
25810	90	90	\$5,340.58
25820	90	90	\$2,842.97
25825	90	90	\$2,289.98
26530	90	90	\$2,448.07
26531	90	90	\$3,071.83
26536	90	90	\$2,575.08
26541	90	90	\$895.68
26568	90	90	\$3,409.84

HCPCS	LO_VERSION	HI_VERSION	OFFSET
			AMOUNT
26820	90	90	\$2,406.40
26843	90	90	\$2,126.60
26844	90	90	\$2,457.34
27110	90	90	\$2,350.84
27130	90	90	\$6,591.89
27279	90	90	\$15,302.06
27357	90	90	\$2,751.02
27381	90	90	\$2,395.16
27396	90	90	\$1,989.68
27403	90	90	\$3,200.82
27412	90	90	\$4,777.09
27415	90	90	\$7,301.71
27427	90	90	\$2,524.14
27428	90	90	\$5,186.61
27429	90	90	\$5,198.36
27430	90	90	\$2,465.27
27438	90	90	\$4,600.75
27440	90	90	\$5,837.71
27442	90	90	\$5,750.29
27443	90	90	\$6,672.79
27446	90	90	\$5,925.13
27447	90	90	\$6,139.12
27477	90	90	\$3,043.39
27509	90	90	\$3,177.67
27637	90	90	\$2,757.64
27647	90	90	\$1,152.56
27652	90	90	\$2,429.55
27654	90	90	\$2,286.02
27656	90	90	\$1,148.10
27695	90	90	\$2,131.90
27696	90	90	\$2,358.12
27698	90	90	\$2,369.36
27700	90	90	\$3,488.56
27702	90	90	\$14,581.63
27705	90	90	\$2,233.10
27709	90	90	\$5,968.19
27720	90	90	\$2,655.77
27722	90	90	\$2,073.03
27726	90	90	\$2,594.92
27745	90	90	\$2,553.91
27756	90	90	\$2,612.78
27758	90	90	\$5,690.27
27759	90	90	\$4,848.67
27792	90	90	\$2,401.11
27814	90	90	\$2,386.56
27822	90	90	\$2,375.98
27823	90	90	\$2,367.38
27826	90	90	\$2,042.60
27827	90	90	\$5,016.99
27828	90	90	\$5,433.22
27829	90	90	\$2,489.09
27832	90	90	\$4,157.29
27870	90	90	\$6,680.62
27871	90	90	\$5,537.61
28102	90	90	\$3,159.81
28103	90	90	\$2,545.31
28202	90	90	\$1,989.02
28210	90	90	\$2,344.22
28261	90	90	\$893.71

HCPCS	LO_VERSION	HI_VERSION	OFFSET AMOUNT
28262	90	90	\$2,211.93
28291	90	90	\$2,951.45
28297	90	90	\$3,423.07
28298	90	90	\$2,190.77
28299	90	90	\$2,221.85
28300	90	90	\$2,381.93
28302	90	90	\$2,685.54
28305	90	90	\$2,031.35
28309	90	90	\$2,062.44
28310	90	90	\$1,989.02
28320	90	90	\$5,529.78
28322	90	90	\$2,546.63
28415	90	90	\$2,502.98
28420	90	90	\$5,734.63
28436	90	90	\$2,112.71
28445	90	90	\$2,387.22
28446	90	90	\$2,827.75
28485	90	90	\$2,338.27
28555	90	90	\$2,061.12
28585	90	90	\$2,602.86
28615	90	90	\$2,525.47
28705	90	90	\$11,036.41
28715	90	90	\$7,124.25
28725	90	90	\$6,200.45
28730	90	90	\$7,055.10
28735	90	90	\$7,155.57
28737	90	90	\$6,748.47
28740	90	90	\$3,273.58
28750	90	90	\$3,059.27
29855	90	90	\$3,293.42
29856	90	90	\$6,204.36
29867	90	90	\$5,473.67
29885	90	90	\$3,571.24
29888	90	90	\$2,420.95
29889	90	90	\$5,116.15
29899	90	90	\$2,624.69
29907	90	90	\$5,862.50
30468	90	90	\$2,013.06
30469	90	90	\$1,655.30
31636	90	90	\$2,696.33
31647	90	90	\$3,579.23
31660	90	90	\$3,066.94
31661	90	90	\$2,948.76
32994	90	90	\$2,077.04
33206	90	90	\$5,850.22
33207	90	90	\$5,916.32
33208	90	90	\$6,331.54
33212	90	90	\$4,901.74
33213	90	90	\$6,291.25
33214	90	90	\$6,125.99
33216	90	90	\$3,006.35
33217	90	90	\$3,889.56
33220	90	90	\$1,156.74
33221	90	90	\$11,231.21
33224	90	90	\$5,595.09
33226	90	90	\$920.20
33227	90	90	\$4,706.65
33228	90	90	\$6,113.60
33229	90	90	\$11,815.65

HCPCS	LO_VERSION	HI_VERSION	OFFSET
			AMOUNT
33230	90	90	\$16,739.52
33231	90	90	\$23,810.26
33233	90	90	\$3,455.30
33234	90	90	\$1,308.54
33235	90	90	\$1,131.94
33240	90	90	\$17,319.10
33249	90	90	\$23,287.42
33262	90	90	\$16,235.23
33263	90	90	\$16,187.32
33264	90	90	\$23,736.48
33270	90	90	\$23,665.92
33271	90	90	\$5,341.72
33274	90	90	\$11,419.67
33275	90	90	\$2,077.83
33285	90	90	\$5,916.38
33289	90	90	\$21,502.82
33900	90	90	\$3,290.75
33901	90	90	\$3,290.75
33902	90	90	\$5,325.06
33903	90	90	\$3,290.75
33999	90	90	\$334.55
34421	90	90	\$1,184.74
35881	90	90	\$2,125.80
36253	90	90	\$1,716.17
36254	90	90	\$916.93
36583	90	90	\$1,629.82
36835	90	90	\$1,472.50
36836	90	90	\$6,924.29
36837	90	90	\$8,832.72
36903	90	90	\$5,548.62
36904	90	90	\$1,611.56
36906	90	90	\$8,523.53
37183	90	90	\$1,887.97
37184	90	90	\$4,741.86
37187	90	90	\$5,385.15
37191	90	90	\$2,051.28
37192	90	90	\$957.74
37211	90	90	\$1,647.29
37221	90	90	\$4,216.40
37224	90	90	\$1,983.94
37225	90	90	\$5,845.85
37226	90	90	\$5,206.81
37227	90	90	\$9,387.56
37228	90	90	\$3,394.78
37229	90	90	\$8,112.98
37230	90	90	\$7,650.90
37231	90	90	\$7,750.53
37236	90	90	\$4,011.53
37238	90	90	\$4,374.57
37241	90	90	\$3,841.68
37242	90	90	\$4,288.59
41512	90	90	\$1,727.38
42900	90	90	\$1,103.57
43210	90	90	\$2,897.94
43212	90	90	\$2,915.41
43229	90	90	\$1,818.49
43240	90	90	\$3,267.06
43266	90	90	\$2,976.20
43284	90	90	\$4,415.52

HCPCS	LO_VERSION	HI_VERSION	OFFSET
			AMOUNT
43497	90	90	\$1,010.81
43647	90	90	\$7,807.43
43770	90	90	\$4,183.79
44370	90	90	\$3,343.06
44390	90	90	\$360.26
44402	90	90	\$1,817.48
44405	90	90	\$461.10
45327	90	90	\$3,456.25
45347	90	90	\$3,467.26
45389	90	90	\$3,380.26
46707	90	90	\$1,011.86
47383	90	90	\$2,546.66
47538	90	90	\$2,281.36
47539	90	90	\$1,762.75
47540	90	90	\$2,208.39
47553	90	90	\$1,129.52
47556	90	90	\$2,224.02
50570	90	90	\$1,049.68
50593	90	90	\$4,153.80
51715	90	90	\$1,209.29
51992	90	90	\$1,933.71
52327	90	90	\$2,225.54
53440	90	90	\$7,660.68
53444	90	90	\$10,766.91
53445	90	90	\$13,969.60
53447	90	90	\$13,331.37
53451	90	90	\$9,018.65
53452	90	90	\$6,368.51
54400	90	90	\$8,212.77
54401	90	90	\$13,817.27
54405	90	90	\$13,636.03
54410	90	90	\$12,889.82
54411	90	90	\$11,794.62
54416	90	90	\$12,689.29
54417	90	90	\$7,101.37
54660	90	90	\$1,854.54
55873	90	90	\$4,136.71
55874	90	90	\$2,364.73
55876	90	90	\$427.94
57288	90	90	\$1,460.99
58565	90	90	\$2,651.75
59072	90	90	\$118.65
61626	90	90	\$3,930.85
61885	90	90	\$18,677.48
61886	90	90	\$24,825.53
61888	90	90	\$6,267.94
62350	90	90	\$2,184.77
62360	90	90	\$12,151.65
62361	90	90	\$12,327.81
62362	90	90	\$12,495.50
63075	90	90	\$2,454.03
63610	90	90	\$877.37
63650	90	90	\$3,114.38
63655	90	90	\$14,383.02
63663	90	90	\$3,451.83
63664	90	90	\$5,774.30
63685	90	90	\$24,024.04
63741	90	90	\$2,750.12
63744	90	90	\$1,981.49

HCPCS	LO_VERSION	HI_VERSION	OFFSET AMOUNT
64448	90	90	\$359.62
64553	90	90	\$6,627.71
64555	90	90	\$4,676.19
64561	90	90	\$3,181.73
64568	90	90	\$24,094.50
64569	90	90	\$8,492.32
64575	90	90	\$8,503.07
64580	90	90	\$14,529.32
64581	90	90	\$4,223.82
64582	90	90	\$25,163.15
64583	90	90	\$3,705.30
64590	90	90	\$17,618.93
64628	90	90	\$7,443.93
64716	90	90	\$971.56
64802	90	90	\$542.13
64858	90	90	\$1,432.98
64865	90	90	\$2,715.52
64886	90	90	\$2,091.47
64891	90	90	\$3,968.55
64892	90	90	\$2,874.31
64893	90	90	\$2,747.03
64897	90	90	\$2,394.23
64910	90	90	\$2,873.07
64912	90	90	\$3,255.53
65770	90	90	\$3,615.27
65779	90	90	\$1,113.32
65781	90	90	\$1,971.82
66175	90	90	\$1,549.49
66179	90	90	\$1,283.78
66180	90	90	\$1,384.07
66183	90	90	\$2,079.70
66989	86	90	\$2,318.65
66991	86	90	\$2,318.65
69705	90	90	\$2,268.29
69706	90	90	\$2,246.93
69714	90	90	\$7,978.90
69716	90	90	\$4,044.90
69717	90	90	\$3,834.50
69719	90	90	\$4,044.90
69729	90	90	\$4,044.90
69730	90	90	\$4,044.90
69930	90	90	\$26,636.29
75741	90	90	\$1,053.36
75831	90	90	\$912.76
75870	90	90	\$940.16
75898	90	90	\$1,860.37
92920	90	90	\$1,609.99
92924	90	90	\$5,485.99
92928	90	90	\$3,703.68
92933	90	90	\$8,831.00
92937	90	90	\$3,509.42
92943	90	90	\$4,536.98
92986	90	90	\$1,709.61
92987	90	90	\$3,658.04
93580	90	90	\$11,675.61
93581	90	90	\$9,777.49
93582	90	90	\$11,100.17
93590	90	90	\$7,252.38
93591	90	90	\$6,317.92

HCPCS	LO_VERSION	HI_VERSION	OFFSET
			AMOUNT
93600	90	90	\$2,758.41
93602	90	90	\$2,122.84
93603	90	90	\$474.64
93619	90	90	\$2,176.02
93650	90	90	\$3,247.88
93653	90	90	\$9,218.75
93654	90	90	\$10,780.26
93656	90	90	\$11,144.22
95938	90	90	\$166.40
95961	90	90	\$339.55
C9600	90	90	\$3,969.06
C9602	90	90	\$9,562.77
C9604	90	90	\$4,097.51
C9607	90	90	\$8,853.34
C9728	90	90	\$512.81
C9739	90	90	\$2,968.02
C9740	90	90	\$6,273.53
C9764	90	90	\$5,611.25
C9765	90	90	\$9,026.83
C9766	90	90	\$9,938.96
C9767	90	90	\$10,048.90
C9769	90	90	\$6,164.84
C9771	90	90	\$1,992.76
C9772	90	90	\$4,581.57
C9773	90	90	\$8,193.72
C9774	90	90	\$9,293.08
C9775	90	90	\$9,143.64
C9777	90	90	\$1,010.81
C9778	90	90	\$1,436.88
C9780	85	90	\$2,557.66
C9781	90	90	\$4,044.90
C9782	90	90	\$5,425.16
C9783	90	90	\$3,290.75

Procedures that Bypass Edit 92 when Reported with Modifier -CG
(DATA_HCPCS, Column DC "BYPASS_E92_MODIFIER")

HCPCS	LO_ VERSION	HI_ VERSION	DESCRIPTION	BYPASS_E92_ MODIFIER
0200T	78	90	Perq sacral augmt unilat inj	1
0627T	90	90	Perq njx algc fluor lmbr 1st	1
0629T	90	90	Perq njx algc ct lmbr 1st	1
19281	90	90	Perq device breast 1st imag	1
19283	82	90	Perq dev breast 1st strtctc	1
19285	82	90	Perq dev breast 1st us imag	1
20900	86	90	Removal of bone for graft	1
21122	90	90	Reconstruction of chin	1
21150	90	90	Lefort ii anterior intrusion	1
21195	86	90	Reconst lwr jaw w/o fixation	1
21256	86	90	Reconstruction of orbit	1
21267	86	90	Revise eye sockets	1
21346	90	90	Opn tx nasomax fx w/fixj	1
21347	90	90	Opn tx nasomax fx multiple	1
21422	90	90	Treat mouth roof fracture	1
21450	86	90	Treat lower jaw fracture	1
21452	86	90	Treat lower jaw fracture	1
21453	90	90	Treat lower jaw fracture	1
21461	74	90	Treat lower jaw fracture	1
21742	90	90	Repair stern/nuss w/o scope	1
22551	86	90	Arthrd ant ntrbdy cervical	1
22612	90	90	Arthrd pst tq 1ntrspc lumbar	1
22630	86	90	Arthrd pst tq 1ntrspc lum	1
22633	90	90	Arthrd cmbn 1ntrspc lumbar	1
22899	90	90	Unlisted procedure spine	1
23395	90	90	Muscle transfer shoulder/arm	1
23473	74	90	Revis reconst shoulder joint	1
23485	86	90	Revision of collar bone	1
23515	90	90	Optx clavicular fx w/int fix	1
23552	90	90	Optx acrcly dslc aq/chrn grf	1
23585	90	90	Optx scapular fx w/int fixj	1
23615	90	90	Optx prox humrl fx w/int fix	1
23616	90	90	Optx prx hmrl fx fix rpr rpl	1
23630	90	90	Optx gr hmrl tbrs fx int fix	1
23680	90	90	Optx sho dislc neck fx fixj	1
24126	90	90	Exc/crtg b1 cst/tum rds algr	1
24340	90	90	Tenodesis biceps tdn at elbw	1
24344	86	90	Reconstruct elbow lat ligmnt	1
24370	74	90	Revise reconst elbow joint	1
24371	74	90	Revise reconst elbow joint	1
24400	90	90	Revision of humerus	1
24420	86	90	Revision of humerus	1
24430	86	90	Repair of humerus	1
24435	86	90	Repair humerus with graft	1
24545	74	90	Treat humerus fracture	1
24546	90	90	Treat humerus fracture	1
24575	78	90	Treat humerus fracture	1
24579	74	90	Treat humerus fracture	1
24586	86	90	Treat elbow fracture	1
24615	86	90	Treat elbow dislocation	1
24635	74	90	Treat elbow fracture	1
24666	74	90	Treat radius fracture	1

Procedures that Bypass Edit 92 when Reported with Modifier -CG
(DATA_HCPCS, Column DC "BYPASS_E92_MODIFIER")

HCPCS	LO_ VERSION	HI_ VERSION	DESCRIPTION	BYPASS_E92_ MODIFIER
24685	74	90	Treat ulnar fracture	1
25126	90	90	Remove/graft forearm lesion	1
25350	86	90	Revision of radius	1
25390	86	90	Shorten radius or ulna	1
25391	86	90	Lengthen radius or ulna	1
25400	86	90	Repair radius or ulna	1
25405	86	90	Repair/graft radius or ulna	1
25415	86	90	Repair radius & ulna	1
25420	86	90	Repair/graft radius & ulna	1
25426	86	90	Repair/graft radius & ulna	1
25515	74	90	Treat fracture of radius	1
25526	74	90	Treat fracture of radius	1
25545	78	90	Treat fracture of ulna	1
25574	74	90	Treat fracture radius & ulna	1
25575	74	90	Treat fracture radius/ulna	1
25652	86	90	Treat fracture ulnar styloid	1
25800	86	90	Fusion of wrist joint	1
25805	86	90	Fusion/graft of wrist joint	1
25810	86	90	Fusion/graft of wrist joint	1
25820	86	90	Fusion of hand bones	1
25825	86	90	Fuse hand bones with graft	1
26541	90	90	Repair hand joint with graft	1
26568	86	90	Lengthen metacarpal/finger	1
26820	86	90	Thumb fusion with graft	1
26843	86	90	Fusion of hand joint	1
26844	86	90	Fusion/graft of hand joint	1
27396	90	90	Transplant of thigh tendon	1
27430	90	90	Revision of thigh muscles	1
27637	86	90	Remove/graft leg bone lesion	1
27647	90	90	Resect talus/calcaneus tum	1
27654	82	90	Repair of achilles tendon	1
27656	86	90	Repair leg fascia defect	1
27695	90	90	Repair of ankle ligament	1
27696	82	90	Repair of ankle ligaments	1
27698	90	90	Repair of ankle ligament	1
27700	82	90	Revision of ankle joint	1
27705	78	90	Incision of tibia	1
27792	74	90	Treatment of ankle fracture	1
27814	74	90	Treatment of ankle fracture	1
27822	74	90	Treatment of ankle fracture	1
27823	74	90	Treatment of ankle fracture	1
27826	78	90	Treat lower leg fracture	1
27827	74	90	Treat lower leg fracture	1
27828	74	90	Treat lower leg fracture	1
27829	86	90	Treat lower leg joint	1
27832	86	90	Treat lower leg dislocation	1
28202	90	90	Repair/graft of foot tendon	1
28210	86	90	Repair/graft of foot tendon	1
28261	90	90	Revision of foot tendon	1
28299	86	90	Correction hallux valgus	1
28300	74	90	Incision of heel bone	1
28302	78	90	Incision of ankle bone	1

Procedures that Bypass Edit 92 when Reported with Modifier -CG
(DATA_HCPCS, Column DC "BYPASS_E92_MODIFIER")

HCPCS	LO_ VERSION	HI_ VERSION	DESCRIPTION	BYPASS_E92_ MODIFIER
28310	90	90	Revision of big toe	1
28415	74	90	Treat heel fracture	1
28420	74	90	Treat/graft heel fracture	1
28445	74	90	Treat ankle fracture	1
28485	74	90	Treat metatarsal fracture	1
28555	74	90	Repair foot dislocation	1
28585	74	90	Repair foot dislocation	1
28615	74	90	Repair foot dislocation	1
29855	74	90	Tibial arthroscopy/surgery	1
29856	74	90	Tibial arthroscopy/surgery	1
29885	86	90	Knee arthroscopy/surgery	1
30469	90	90	Rpr nsl vlv collapse w/rmdlg	1
33220	78	90	Repair lead pace-defib dual	1
33226	90	90	Reposition l ventric lead	1
33233	78	90	Removal of pm generator	1
33235	78	90	Removal pacemaker electrode	1
35881	90	90	Revise graft w/vein	1
36904	90	90	Thrmcb/nfs dialysis circuit	1
37192	74	90	Redo endovas vena cava filtr	1
37241	86	90	Vasc embolize/occlude venous	1
43210	90	90	Egd esophagogastrc fndoplsty	1
43497	86	90	Transorl lwr esophgl myotomy	1
44390	90	90	Colonoscopy for foreign body	1
45327	78	90	Proctosigmoidoscopy w/stent	1
57288	74	90	Repair bladder defect	1
59072	78	90	Umbilical cord occlud w/us	1
61888	82	90	Revise/remove neuroreceiver	1
62350	74	90	Implant spinal canal cath	1
63663	74	90	Revise spine eltrd perq aray	1
63664	74	90	Revise spine eltrd plate	1
64448	90	90	Njx aa&/strd fem nrv nfs img	1
64569	82	90	Revise/repl vagus n eltrd	1
64583	90	90	Rev/rplct hpglsl nstm ary pg	1
64865	90	90	Repair of facial nerve	1
64886	82	90	Nerve graft head/neck >4 cm	1
64891	74	90	Nerve graft hand/foot >4 cm	1
64892	90	90	Nerve graft arm/leg <4 cm	1
64893	90	90	Nerve graft arm/leg >4 cm	1
64897	90	90	Nerve graft arm/leg </4 cm	1
64910	78	90	Nerve repair w/allograft	1
64912	78	90	Nrv rpr w/nrv algrft 1st	1
65779	78	90	Cover eye w/membrane suture	1
66175	90	90	Trluml dil aq o/f can w/st	1
69719	90	90	Rplcm oi implt sk tc esp<100	1
93602	90	90	Intra-atrial recording	1
93619	90	90	Electrophysiology evaluation	1
95938	90	90	Somatosensory testing	1
C9782	87	90	Blind myocar trpl bon marrow	1
C9783	87	90	Blind cor sinus reducer impl	1

We utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide separate payment for C1823 for four quarters in CY 2022 for C1823, as its pass-through payment status expired on December 31, 2021 (86

FR 63570). Separate payment for HCPCS code C1823 under our equitable adjustment authority will end on December 31, 2022. Table 52 includes this date for the device described by HCPCS code C1823 and includes the

specific expiration dates for devices with pass-through status expiring at the end of the fourth quarter of 2022, in 2023, or in 2024.

BILLING CODE 4120-01-P

TABLE 52: DEVICES WITH PASS-THROUGH STATUS (OR ADJUSTED SEPARATE PAYMENT) EXPIRING AT THE END OF THE FOURTH QUARTER OF 2022, IN 2023, OR IN 2024

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	1/1/2019	12/31/2022*
C1824	Generator, cardiac contractility modulation (implantable)	1/1/2020	12/31/2022
C1982	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2022
C1839	Iris prosthesis	1/1/2020	12/31/2022
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2022
C2596	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2022
C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	7/1/2020	6/30/2023
C1052	Hemostatic agent, gastrointestinal, topical	1/1/2021	12/31/2023
C1062	Intravertebral body fracture augmentation with implant (e.g., metal, polymer)	1/1/2021	12/31/2023
C1825	Generator, neurostimulator (implantable), nonrechargeable with carotid sinus baroreceptor stimulation lead(s)	1/1/2021	12/31/2023
C1761	Catheter, transluminal intravascular lithotripsy, coronary	7/1/2021	6/30/2024

Pass-through Devices, Associated Procedure Codes, and Offset Amounts (set to expire 12/31/22)

(OFFSET_CODEPAIR)

CODE1		CODE2		LO_ VERS	HI_ VERS	OFFSET AMOUNT
C1734	Orth/devic/drug bn/bn,tis/bn	27870	Fusion of ankle joint open	78	89	\$0.00
C1734	Orth/devic/drug bn/bn,tis/bn	28705	Fusion of foot bones	78	89	\$0.00
C1734	Orth/devic/drug bn/bn,tis/bn	28715	Fusion of foot bones	78	89	\$0.00
C1734	Orth/devic/drug bn/bn,tis/bn	28725	Fusion of foot bones	78	89	\$0.00
C1823	Gen, neuro, trans sen/stim	0424T	Insj/rplc nstim apnea compl	86	89	\$8,147.20
C1824	Generator, ccm, implant	0408T	Insj/rplc cardiac modulj sys	86	89	\$12,314.74
C1839	Iris prosthesis	0616T	Insertion of iris prosthesis	81	89	\$657.47
C1839	Iris prosthesis	0617T	Insj iris prosth w/rmvl&insj	81	89	\$1,239.87
C1839	Iris prosthesis	0618T	Insj iris prosth sec io lens	81	89	\$1,239.87
C1982	Intro/sheath, fixed, peel-away	37242	Vasc embolize/occlude artery	86	89	\$4,089.03
C1982	Intro/sheath, fixed, peel-away	37243	Vasc embolize/occlude organ	86	89	\$2,234.30
C2596	Probe, robotic, water-jet	0421T	Waterjet prostate abltj compl	78	89	\$0.00

January 2023 IOCE Quarterly Data Files
Pass-through Devices, Associated Procedure Codes, and Offset Amounts
(OFFSET_CODEPAIR)

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CODE1		CODE2		LO_	HI_	OFFSET
				VERS	VERS	AMOUNT
C1052	Hemostatic agent, gi, topic	43227	Esophagoscopy control bleed	82	90	\$0.00
C1052	Hemostatic agent, gi, topic	43255	EGD control bleeding any	82	90	\$45.28
C1052	Hemostatic agent, gi, topic	44366	Small bowel endoscopy	82	90	\$32.39
C1052	Hemostatic agent, gi, topic	44378	Small bowel endoscopy	82	90	\$63.22
C1052	Hemostatic agent, gi, topic	44391	Colonoscopy for bleeding	82	90	\$0.00
C1052	Hemostatic agent, gi, topic	45334	Sigmoidoscopy for bleeding	82	90	\$26.10
C1052	Hemostatic agent, gi, topic	45382	Colonoscopy w/ control bleed	82	90	\$32.16
C1062	Intravertebral fx aug impl	22513	Perq vertebral augmentation	82	90	\$1,320.28
C1062	Intravertebral fx aug impl	22514	Perq vertebral augmentation	82	90	\$1,320.28
C1062	Intravertebral fx aug impl	22515	Perq vertebral augmentation	82	90	\$0.00
C1734*	Orth/devic/drug bn/bn,tis/bn	27870	Fusion of ankle joint open	78	90	\$0.00
C1734*	Orth/devic/drug bn/bn,tis/bn	28705	Fusion of foot bones	78	90	\$0.00
C1734*	Orth/devic/drug bn/bn,tis/bn	28715	Fusion of foot bones	78	90	\$0.00
C1734*	Orth/devic/drug bn/bn,tis/bn	28725	Fusion of foot bones	78	90	\$0.00
C1747	Endo, single, urinary tract	50575	Kidney endoscopy	90	90	\$570.84
C1747	Endo, single, urinary tract	50951	Endoscopy of ureter	90	90	\$169.87
C1747	Endo, single, urinary tract	50953	Endoscopy of ureter	90	90	\$442.95
C1747	Endo, single, urinary tract	50955	Ureter endoscopy & biopsy	90	90	\$423.20
C1747	Endo, single, urinary tract	50957	Ureter endoscopy & treatment	90	90	\$416.14
C1747	Endo, single, urinary tract	50961	Ureter endoscopy & treatment	90	90	\$461.75
C1747	Endo, single, urinary tract	50970	Ureter endoscopy	90	90	\$312.82
C1747	Endo, single, urinary tract	50972	Ureter endoscopy & catheter	90	90	\$760.57
C1747	Endo, single, urinary tract	50974	Ureter endoscopy & biopsy	90	90	\$1,069.75
C1747	Endo, single, urinary tract	50976	Ureter endoscopy & treatment	90	90	\$2,043.10
C1747	Endo, single, urinary tract	50980	Ureter endoscopy & treatment	90	90	\$405.33
C1747	Endo, single, urinary tract	52344	Cysto/uretero stricture tx	90	90	\$507.69
C1747	Endo, single, urinary tract	52345	Cysto/uretero w/up stricture	90	90	\$511.54
C1747	Endo, single, urinary tract	52346	Cystouretero w/ renal strict	90	90	\$602.82
C1747	Endo, single, urinary tract	52351	Cystouretero & or pyeloscope	90	90	\$169.55
C1747	Endo, single, urinary tract	52352	Cystouretero w/stone remove	90	90	\$320.51
C1747	Endo, single, urinary tract	52353	Cystouretero w/lithotripsy	90	90	\$252.04
C1747	Endo, single, urinary tract	52354	Cystouretero w/biopsy	90	90	\$428.37
C1747	Endo, single, urinary tract	52355	Cystouretero w/excise tumor	90	90	\$371.94
C1747	Endo, single, urinary tract	52356	Cysto/uretero w/lithotripsy	90	90	\$474.45
C1747	Endo, single, urinary tract	C9761	Cysto, litho, vacuum kidney	90	90	\$789.86
C1748	Endoscope, single, ugi	0652T	Egd flx tansnasal dx br/wa	87	90	\$0.00
C1748	Endoscope, single, ugi	0653T	Egd flx transnasal bx 1/ml	87	90	\$0.00
C1748	Endoscope, single, ugi	0654T	Egd flx transnasal tube/cath	87	90	\$0.00
C1748	Endoscope, single, ugi	43197	Esophagoscopy flex dx brush	87	90	\$0.00
C1748	Endoscope, single, ugi	43198	Esophagosc flex trnsn biopsy	87	90	\$0.00
C1748	Endoscope, single, ugi	43260	Ercp a/ specimen collection	80	90	\$0.00
C1748	Endoscope, single, ugi	43261	Endo cholangiopancreatograph	80	90	\$0.00
C1748	Endoscope, single, ugi	43262	Endo cholangiopancreatograph	80	90	\$0.00

January 2023 IOCE Quarterly Data Files
Pass-through Devices, Associated Procedure Codes, and Offset Amounts
(OFFSET_CODEPAIR)

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CODE1		CODE2		LO_ VERS	HI_ VERS	OFFSET AMOUNT
C1748	Endoscope, single, ugi	43263	Ercp sphincter pressure meas	80	90	\$0.00
C1748	Endoscope, single, ugi	43264	Ercp remove duct calculi	80	90	\$0.00
C1748	Endoscope, single, ugi	43265	Ercp lithotripsy calculi	80	90	\$0.00
C1748	Endoscope, single, ugi	43274	Ercp duct stent placement	80	90	\$0.00
C1748	Endoscope, single, ugi	43275	Ercp remove forgn body duct	80	90	\$0.00
C1748	Endoscope, single, ugi	43276	Ercp stent exchange w/dilate	80	90	\$0.00
C1748	Endoscope, single, ugi	43277	Ercp ea duct/ampulla dialte	80	90	\$0.00
C1748	Endoscope, single, ugi	43278	Ercp lesion ablate w/dilate	80	90	\$0.00
C1761	Cath, trans intra litho/coro	92928	Prq card stent w/ angio 1 vsi	84	90	\$0.00
C1761	Cath, trans intra litho/coro	92933	Prq card stent/ath/angio	84	90	\$8,831.00
C1761	Cath, trans intra litho/coro	92943	Prq card revasc chronic 1vsl	84	90	\$4,536.98
C1761	Cath, trans intra litho/coro	C9600	Perc drug-el cor stent sing	84	90	\$0.00
C1761	Cath, trans intra litho/coro	C9602	Perc d-e cor stent ather s	84	90	\$9,562.77
C1761	Cath, trans intra litho/coro	C9607	Perc d-e cor revasc chro sin	84	90	\$8,853.34
C1824*	Generator, ccm, implant	0408T	Insj/rplc cardiac modulj sys	86	90	\$12,314.74
C1825	Gen,neuro, carot sinus baro	0266T	Implt/rpl crtcd sns dev total	82	90	\$5,487.10
C1826	Gen,neuro, clo loop, rechg	63685	Insrt/redo spine n generator	90	90	\$24,024.04
C1827	Gen, neuro, imp led, ex cntr	64568	Inc for vagus n elect impl	90	90	\$24,094.50
C1831	Personalized interbody cage	22630	Arthrd pst tq 1ntrspc lum	85	90	\$0.00
C1831	Personalized interbody cage	22633	Arthrd cmbn 1ntrspc lumbar	85	90	\$0.00
C1832	Auto cell process sys	15100	Skin splt grft trnk/arm/leg	86	90	\$9.66
C1832	Auto cell process sys	15110	Epidrm autogrft trnk/arm/leg	86	90	\$0.00
C1832	Auto cell process sys	15115	Epidrm a-grft face/nck/hf/g	86	90	\$0.00
C1832	Auto cell process sys	15120	Skn splt a-grft fac/nck/hf/g	86	90	\$62.13
C1833	Cardiac monitor sys	0525T	Insj/replcmt compl iims	86	90	\$8,246.49
C1833	Cardiac monitor sys	0526T	Insj/rplcmnt iims eltrd only	86	90	\$2,530.46
C1833	Cardiac monitor sys	0527T	Insj/rplcmt iims implt mntr	86	90	\$6,270.64
C1833	Cardiac monitor sys	0528T	Pgrmg dev eval iims ip	86	90	\$0.00
C1834	Pressure sensor system, IM	20950	Fluid pressure muscle	89	90	\$0.00
C1839*	Iris prosthesis	0616T	Insertion of iris prosthesis	81	90	\$657.47
C1839*	Iris prosthesis	0617T	Insj iris prosth w/rmvl&insj	81	90	\$1,239.87
C1839*	Iris prosthesis	0618T	Insj iris prosth sec io lens	81	90	\$1,239.87
C1982*	Cath, pressure, valve-occlu	37242	Vasc embolize/occlude artery	86	90	\$4,089.03
C1982*	Cath, pressure, valve-occlu	37243	Vasc embolize/occlude organ	86	90	\$2,234.30
C2596*	Probe, robotic, water-jet	0421T	Waterjet prostate abltj compl	78	90	\$0.00

*Expired 12/31/22 per 2023 OPPS Final Rule Table 52, but extended an additional year by the Consolidated Appropriations Act of 2023 (note C1823 was also extended but not included on the January 2023 IOCE Quarterly Data File).

FY 2023**List of MS-DRGs Subject to the IPPS Policy for Replaced Devices Offered Without Cost or****With a Credit**

MDC	MS-DRG	MS-DRG Title
Pre-MDC	001	Heart Transplant or Implant of Heart Assist System with MCC
Pre-MDC	002	Heart Transplant or Implant of Heart Assist System without MCC
01	023	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator
01	024	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC
01	025	Craniotomy and Endovascular Intracranial Procedures with MCC
01	026	Craniotomy and Endovascular Intracranial Procedures with CC
01	027	Craniotomy and Endovascular Intracranial Procedures without CC/MCC
01	040	Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC
01	041	Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator
01	042	Peripheral, Cranial Nerve and Other Nervous System Procedures without CC/MCC
03	140	Major Head and Neck Procedures with MCC
03	141	Major Head and Neck Procedures with CC
03	142	Major Head and Neck Procedures without CC/MCC
05	215	Other Heart Assist System Implant
05	216	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC
05	217	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC
05	218	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC
05	219	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC
05	220	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC
05	221	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC
05	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock with MCC
05	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock without MCC
05	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock with MCC

MDC	MS-DRG	MS-DRG Title
05	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock without MCC
05	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC
05	227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC
05	242	Permanent Cardiac Pacemaker Implant with MCC
05	243	Permanent Cardiac Pacemaker Implant with CC
05	244	Permanent Cardiac Pacemaker Implant without CC/MCC
05	245	AICD Generator Procedures
05	258	Cardiac Pacemaker Device Replacement with MCC
05	259	Cardiac Pacemaker Device Replacement without MCC
05	260	Cardiac Pacemaker Revision Except Device Replacement with MCC
05	261	Cardiac Pacemaker Revision Except Device Replacement with CC
05	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC
05	265	AICD Lead Procedures
05	266	Endovascular Cardiac Valve Replacement And Supplement Procedures with MCC
05	267	Endovascular Cardiac Valve Replacement And Supplement Procedures without MCC
05	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC
05	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC
05	270	Other Major Cardiovascular Procedures with MCC
05	271	Other Major Cardiovascular Procedures with CC
05	272	Other Major Cardiovascular Procedures without CC/MCC
05	319	Other Endovascular Cardiac Valve Procedures with MCC
05	320	Other Endovascular Cardiac Valve Procedures without MCC
08	461	Bilateral or Multiple Major Joint Procedures Of Lower Extremity with MCC
08	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC
08	466	Revision of Hip or Knee Replacement with MCC
08	467	Revision of Hip or Knee Replacement with CC
08	468	Revision of Hip or Knee Replacement without CC/MCC
08	469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement
08	470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC
08	521	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC

MDC	MS-DRG	MS-DRG Title
08	522	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC