



Medicare Critical Access Hospital Version

KEY CONCEPTS OUTLINE

Module 9: Special Billing and Payment Topics for Outpatient Diagnostic Services and Drugs

- I. Coverage of Hospital Outpatient Diagnostic Services
 - A. Overview: Hospital outpatient diagnostic services must meet three requirements to be covered by Medicare:
 1. The service must be furnished in the hospital, a provider-based department of the hospital, or a non-hospital setting;
 2. In general, there must be an order for the service, as discussed below; and,
 3. The service must be rendered under the required level of physician supervision.

Course note: *References to hospital coverage in this module also apply CAHs, unless otherwise specified.*

- B. Location
 1. The service must be furnished directly or under arrangement by the hospital and must be furnished in the hospital, a provider-based department, or a non-hospital setting. <See 42 C.F.R. 410.28(a)(1); Medicare Benefit Policy Manual, Chapter 6 § 20.4.4>
- C. Order
 1. The service must be furnished on the order of a physician or NPP as discussed below:
 - a. Clinical Diagnostic Laboratory Tests
 - i. Clinical diagnostic laboratory tests must be provided only on the order of a physician or NPP who is treating the patient and uses the results in the management of the beneficiary's specific medical problem. <See 42 C.F.R. 410.28(f); see 42 C.F.R. 410.32(a)>

b. Mammogram exception

- i. A beneficiary may self-refer themselves for a screening mammogram without an order from a treating physician. <Medicare Benefit Policy Manual, Chapter 15 § 280.3>

c. Other diagnostic services

- i. Regulations at 42 *C.F.R.* 410.32 and *Medicare Benefit Policy Manual*, Chapter 15 § 80.6 contain other limitations on coverage of diagnostic services and require an order from the patient's treating physician. These requirements do not apply to hospital diagnostic services. <42 *C.F.R.* 410.32; 62 *Fed. Reg.* 59057; *Medicare Benefit Policy Manual*, Chapter 15 § 80.6>

a) For example:

- 1) Under hospital *Conditions of Participation*, radiology and nuclear medicine services must be provided only on the order of a physician or NPP 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)>
- 2) Bone mass measurement must be ordered by a physician or NPP 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)>

Caution: Although the requirements in 410.32 and the limitations in section 80.6 do not apply to orders for hospital outpatient diagnostic services, except laboratory services, presumably all diagnostic services require a physician order and specific regulations may require the order be from the treating physician or NPP. Providers should confirm the order requirements for specific diagnostic services.

D. Physician Supervision

1. Medicare defines three levels of supervision for hospital outpatient diagnostic services:
 - a. General supervision, indicated by a "01" on the MPFS, requires the service be furnished under the overall direction and control of the physician, but

they need not be present during the performance of the procedure. <See 42 *C.F.R.* 410.32(b)(3)(i)>

- i. Training of the non-physician personnel who perform the diagnostic procedure is the continuing responsibility of the hospital. <See 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, requires the physician be immediately available to provide assistance and direction throughout the performance of the procedure. <See 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. <See *Medicare Benefit Policy Manual*, Chapter 6 § 20.4.4>
 - a) During the COVID-19 PHE the presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce the exposure risk for the beneficiary or provider. <See 42 *C.F.R.* 410.28 (e)(1)>
 - ii. The physician must have within their scope of practice and hospital granted privileges the ability to personally perform all services being supervised. <See *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, not merely respond in an emergency. <See *Medicare Benefit Policy Manual*, Chapter 6 § 20.4.4>
 - b) The physician need not be able to operate specialized equipment, but they must be knowledgeable about the test and clinically appropriate to furnish the test. They must be able to take over the procedure and change the procedure and the course of care for the patient. <See *Medicare Benefit Policy Manual*, Chapter 6 § 20.4.4>
 - iii. 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. <See 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. <Medicare Benefit Policy Manual, Chapter 15 § 80; see 42 C.F.R. 410.32(b)(3)(iii)>
2. The service must be furnished under the appropriate level of supervision as identified in the Medicare Physician Fee Schedule (MPFS). <See Medicare Benefit Policy Manual, Chapter 6 § 20.4.4; 42 C.F.R. 410.28 (e)>

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

- a. Supervision of Diagnostic Services by Non-Physician Practitioners
 - i. Non-physician practitioners (NPPs) may be permitted to supervise the performance of diagnostic tests, subject to the discussion below. <See Medicare Benefit Policy Manual, Chapter 6 § 20.4.4; see 42 C.F.R. 410.28; see 42 C.F.R. 410.32; 85 Fed. Reg. 84590-592>
 - ii. Temporarily during the PHE and permanently effective January 1, 2021, CMS amended the regulations at 42 C.F.R. 410.32 to allow NPPs (nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs), certified registered nurse anesthetists (CRNAs), certified nurse midwives (CNMs)) to provide supervision of diagnostic services. <85 Fed. Reg. 27555-56 (COVID-19 IFC published May 8, 2020); 85 Fed. Reg. 84590-592; see 42 C.F.R. 410.32 (b)(1)>.
 - iii. Hospital diagnostic service coverage is governed by 42 C.F.R. 410.28, which incorporates 3 specific sections from 42 C.F.R. 410.32 regarding the definitions of general, direct, and personal supervision. It does not specifically reference the section amended by CMS to allow NPPs to provide supervision of diagnostic services and was not itself amended to include these provisions. <See 42 C.F.R. 410.28>
 - iv. The Benefit Policy Manual section regarding supervision of hospital diagnostic services references sections and policies regarding NPPs from 42 C.F.R. 410.32, including the section amended in CY2021 to allow NPPs to provide supervision of diagnostic services. The section has not been updated and continues to state that NPPs may not provide supervision of diagnostic services. Note, Chapter 15 generally applicable to diagnostic services has also not been updated with the regulatory change at the time of publishing, indicating CMS may simply be delayed in making the updates. <Medicare Benefit Policy Manual, Chapter 6 § 20.4.4>

Caution: Although CMS refers to 42 C.F.R. 410.32 for definitions of supervision and regarding provision of diagnostic services by NPPs in hospital departments, it is not clear the amendment to allow NPPs to supervise diagnostic services applies to hospital outpatient diagnostic services. The amended language in 410.32 is in a section specifically referring to services paid under the MPFS, and CMS did not mention application to hospital services in the discussion finalizing this amendment in the COVID-19 IFC or MPFS Final Rule. CMS also did not amend the applicable hospital diagnostic coverage regulation (410.28) or Benefit Policy Manual section to incorporate this change. Before relying on an NPP for supervision of hospital outpatient diagnostic services, a hospital should consult their MAC or CMS to ensure coverage.

- b. Exception for Provision of Diagnostic Services by NPPs
 - i. Non-physician practitioners may personally perform diagnostic tests with the level of supervision required for general coverage of that NPP's services. <See *Medicare Benefit Policy Manual*, Chapter 6 § 20.4.4; 85 *Fed. Reg.* 84590-592>
 - a) Diagnostic tests personally furnished by a qualified audiologist. <See *Medicare Benefit Policy Manual*, Chapter 6 § 20.4.4; See 42 *C.F.R.* 410.32(b)(2)(ii)>
 - b) Diagnostic psychological and neuropsychological testing personally furnished by a clinical psychologist or independent practicing psychologist or furnished under the general supervision of a physician, clinical psychologist, NP, CNS, PA, CRNA, or CNM to the extent they are authorized to perform the test under their scope of practice. <See *Medicare Benefit Policy Manual*, Chapter 6 § 20.4.4; See 42 *C.F.R.* 410.32(b)(2)(iii)>
 - c) Diagnostic tests personally performed by a specially qualified physical therapist, as permitted under state law. <See *Medicare Benefit Policy Manual*, Chapter 6 § 20.4.4; See 42 *C.F.R.* 410.32(b)(2)(iv)>
 - d) Diagnostic tests performed by an NP, CNS, CNM, or PA authorized to perform the test under applicable state law. <See *Medicare Benefit Policy Manual*, Chapter 6 § 20.4.4; See 42 *C.F.R.* 410.32(b)(2)(v), (vii), (ix)>

c. Other Exceptions to Supervision Requirements

- i. Diagnostic mammography, regulated by the FDA. <See 42 *C.F.R.* 410.32(b)(2)(i)>
- ii. Laboratory and pathology services in the 80000 series of the CPT. <See 42 *C.F.R.* 410.32(b)(2)(vi)>

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

A. General Overview

1. 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. <See *Medicare One Time Notification Transmittal 2404*>
 - a. 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.

B. Applicable Settings and Payment Systems

1. A consultation must take place for any applicable imaging service ordered by an ordering professional that would be furnished in an applicable setting ***and*** paid under an applicable payment system. <*Medicare One Time Notification Transmittal 2404*>

The applicable setting is where the imaging service is furnished, not the setting where the imaging service is ordered.

- a. Applicable 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*; 42 *C.F.R.* § 414.94(a)>
- b. Applicable payment systems that must report AUC information include the Medicare Physician Fee Schedule, the OPDS, and the ASC payment system. <See *Medicare One Time Notification Transmittal 2404*; 42 *C.F.R.* § 414.94(a)>

- i. A CAH is paid under the cost-based methodology for its outpatient services, including emergency departments.
- ii. A CAH is not required to report the informational HCPCS G-codes or the modifiers -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). <MLN Matters SE20002>
- iii. However, if the ordering professional is employed by or contracted with the CAH and orders an advanced imaging services for a Medicare patient that would be furnished in an applicable setting **and** paid under an applicable payment system, other than the CAH, the CDSM must be completed and provided to the performing facility.

C. Ordering Practitioner Requirements

1. When ordering applicable advanced imaging services that will be furnished in an applicable setting **and** paid under an applicable payment system, the ordering physician must consult a CDSM, unless an exception applies. <See *Medicare One Time Notification Transmittal 2404*; 42 *C.F.R.* § 414.94(j) and (k)>
2. Exceptions to consulting CDSM for AUC:
 - a. Emergency services provided to patients with emergency medical conditions, as defined under EMTALA (modifier -MA);
 - b. Tests ordered for inpatients or paid under Part A;
 - c. 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). <42 *C.F.R.* § 414.94(j) and (k); 83 *Fed. Reg.* 59697-700>
 - i. 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*>
 - ii. For more details on circumstances representing a significant hardship, see the CY 2019 Medicare Physician Fee Schedule Final Rule, 83 *Fed. Reg.* 59699-700.

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

D. Applicable Advanced Imaging Services

1. CMS has provided a list of CPT codes that represent applicable advanced imaging services, including CT, PET, MRI and other nuclear medicine tests, included in the materials behind the outline. <See *Medicare One Time Notification Transmittal 2404*>

E. Implementation

1. CMS designated CY 2020 through CY2022 as the Educational and Operational Testing Period for AUC reporting requirements and claims for imaging services provided in the applicable settings. Claims will not be denied for failure to report or misreporting AUC/CDSM information. <See *Medicare One Time Notification Transmittal 2404*>
 - a. Even though claims will not be denied, the ordering practitioner is required to consult the CDSM and the performing provider is required to report AUC/CDSM information on claims, effective January 1, 2020. <See *Medicare One Time Notification Transmittal 2404*; 42 C.F.R. § 414.94(j) and (k)>
 - b. There are no payment consequences associated with the AUC program during the Testing Period. CMS is encouraging stakeholders to use this period to learn, test and prepare for the AUC program. Advanced imaging services with dates of service on and after January 1, 2023, however, must include relevant AUC/CDSM information in order to be paid.

Link: Appropriate Use Criteria Program under Medicare Related Sites – Physician/Practitioner

III. Multiple Outpatient Imaging Services Performed by Professionals in a Method II CAH

- A. A CAH paid under Method II may receive a reduced payment (MPPR) for certain diagnostic imaging procedures when reporting revenue codes 96X, 97X or 98X for services furnished by physicians and non-physician practitioners. <Medicare Claims Processing Manual, Chapter 4 § 250.16>
 1. For the diagnostic imaging procedure code with the highest amount listed in the MPFS, payment will be 100% of the allowed amount.

2. Payment for the subsequent diagnostic imaging code(s) will be 95% of the allowed amount listed in the MPFS.
3. The diagnostic MPPR applies when diagnostic services are furnished by the same physician to the same patient on the same day.
 - a. It is not necessary to report a modifier on the subsequent diagnostic service to initiate the payment reduction.

The beneficiary's deductible and coinsurance are based on the actual amount paid under MPFS for each imaging code.

B. Imaging Services Payment Reduction with Certain Modifiers

1. A CAH is paid under the cost-based methodology when billing the technical component of imaging services and the payment reductions associated with certain modifiers that follow will not apply.
2. Under Method II, the professional component of imaging services is paid under the MPFS and the payment reduction associated with certain modifiers that follow will not apply.
3. Attachment of the following modifiers by OPSS hospitals in appropriate circumstances will result in certain payment reductions described below:
 - a. Modifier -CT (OPSS only)
 - i. A hospital paid under OPSS must report modifier -CT when specified computed tomography (CT) scans are furnished on equipment that does not meet the NEMA Standard. If a CT scan reported with modifier -CT is paid separately, the OPSS payment is reduced by 15%. <Medicare Claims Processing Manual, Chapter 4 § 20.6.13>
 - b. Modifier -FX (OPSS only)
 - i. For dates of service from 2018 – 2022, a hospital paid under OPSS must report modifier -FX to indicate x-rays were obtained using film. If an x-ray reported with modifier -FX is paid separately, the OPSS payment is reduced by 7%. <Medicare Claims Processing Manual, Chapter 4 § 20.6.14>
 - c. Modifier -FY (OPSS only)

- i. For dates of service from 2018 – 2022, a hospital paid under OPPS must report modifier -FY to indicate an x-ray was taken using computed radiography technology/cassette-based imaging. If an x-ray reported with modifier -FY is paid separately, the OPPS payment is reduced by 7%. <Medicare Claims Processing Manual, Chapter 4 § 20.6.15>

IV. Billing Topics Related to Outpatient Clinical Diagnostic Laboratory Services

A. Date of Service

1. The date of service should be the specimen collection date rather than the date the test was performed. <42 C.F.R. 414.510(a); Medicare Claims Processing Manual, Chapter 16 § 40.8>
 - a. Exceptions
 - i. The date of service is the date the collection ended for a specimen collection that spans two calendar days. <42 C.F.R. 414.510(b)(1); Medicare Claims Processing Manual, Chapter 16 § 40.8>
 - ii. 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>
 - iii. The date of service should be the date the test was performed for a specimen that is stored for 30 calendar days or less and chemotherapy sensitivity tests performed on live tissue when all requirements at Medicare Claims Processing Manual, Chapter 16 § 40.8 are met.
 - iv. Molecular pathology performed by a laboratory other than a blood bank or blood center and Advanced Diagnostic Laboratory Tests (ADLTs)
 - a) The date of service should be the date the test was performed if 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); *Medicare Claims Processing Manual*, Chapter 16 § 40.8 C>
- b) When these requirements are met, the performing laboratory, rather than the hospital who collected the sample, is required to bill Medicare for payment of ADLTs and molecular pathology tests. <82 *Fed. Reg.* 59397; see *Medicare Claims Processing Manual* Transmittal 4481>
 - c) CMS updates the list of codes subject to this policy quarterly.

Link: *Laboratory Date of Service Policy under Medicare-Related Sites – Hospital*

See Downloads Section for Frequently Asked Questions and Enforcement Discretion Updates

B. Repeat Tests on the Same Day

1. Limitations on payment for repeat tests

- a. Laboratory tests repeated on the same day are covered and billable “when it is necessary to obtain multiple results for clinical reasons”. <*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.

2. Modifier usage

- a. Repeat laboratory tests should be reported with modifier -91 (repeat clinical diagnostic laboratory services). <Program Memorandum AB-02-030>
 - i. 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>

- b. Laboratory tests performed on specimens from distinct anatomical areas or wounds should be reported with modifier -XS (separate structure/organ) or modifier -59 (distinct procedural services). <MLN Matters 1783722>

C. Organ/Disease Panels

1. Definition

- a. "Panels" are groups of lab tests performed together – typically using automated testing equipment. <Medicare Claims Processing Manual, Chapter 16 § 90>
- b. If all tests described by a panel are performed, the CPT panel code must be reported. <Medicare Claims Processing Manual, Chapter 16 § 90.2; National Correct Coding Initiative Policy Manual for Medicare Services, Chapter 1, Section N>
 - i. The claim will be returned to the provider if all components of a panel are performed and billed separately. <Medicare Claims Processing Manual, Chapter 16 § 90.2>
- c. If a test included in a panel is repeated for medically necessary reasons on the same date of service, it should be reported separately with modifier -91. <National Correct Coding Initiative Policy Manual for Medicare Services, Chapter 1, Section N>

2. Panel not covered by Medicare

- a. 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 or panels included in this code if they are medically necessary. To ensure patients aren't charged personally for covered services, tests or panels included in this code should be billed individually to ensure proper application of medical necessity policies. Modifier -GY may be appended to tests or panels that are purely screening/preventative and do not fit a covered screening.

V. Payment for Laboratory Services in a CAH

A. Outpatient Laboratory Services

1. A CAH is paid 101% of its reasonable costs for clinical diagnostic laboratory tests provided to an outpatient. < *Medicare Claims Processing Manual*, Chapter 4 § 250.6; *Medicare Claims Processing Manual*, Chapter 16 § 40.3>
 - a. To be considered an outpatient of the CAH, the patient must be receiving services directly from the CAH on the same day the specimen is collected, or the specimen must be collected by an employee of the CAH.
 - b. Outpatient laboratory tests are billed on type of bill 085X.

B. Reference Laboratory Services

1. Laboratory services provided to non-patients (commonly called reference lab services) are paid separately under the clinical laboratory fee schedule (CLFS). < *Medicare Claims Processing Manual*, Chapter 4 § 250.6; *Medicare Claims Processing Manual*, Chapter 16 § 40.3.1>
 - a. A non-patient is a patient who has a specimen sent to the hospital for testing that was not collected by an employee of the CAH and is not an inpatient or considered to be an outpatient at the CAH. < *Medicare Benefit Policy Manual*, Chapter 6 § 70.5; *Medicare Claims Processing Manual Transmittal 2845*>
 - i. A non-patient (i.e., reference lab) test is billed as an outpatient test 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>
 - b. Non-patient laboratory tests are billed on type of bill 014X. < *Medicare Claims Processing Manual*, Chapter 4 § 250.6; *Medicare Claims Processing Manual*, Chapter 16 § 40.3.1; *Official UB-04 Data Specifications Manual*>
 - c. CMS no longer requires hospitals to collect Medicare secondary payer information for "reference laboratory services." < *MLN Matters Article MM3064*>
2. Payment under CLFS for Non-patient Laboratory Services Billed on TOB 014X

[Link: Clinical Diagnostic Laboratory Fee Schedule – Overview Page under Medicare-Related Sites – General](#)

- a. The payment rate for a Clinical Diagnostic Laboratory Test (CDLT) is set at the weighted median private payor rate. <42 C.F.R. 414.507 (a), (d)>
 - i. For CDLTs, except ADLTs, the weighted median private payor rate is recalculated every three years, based on a three-year data collection cycle. <42 C.F.R. 414.507(a); 42 C.F.R. 414.504>
- b. Transition to Weighted Median Private Payor Rates
 - i. In calendar years 2018-2020, the payment rate under the CLFS was limited to a 10% reduction from the prior year's rate. <42 C.F.R. 414.507(d)>
 - ii. Implementation of median private payor rates has been extended by two years and there is a 0.0% reduction to laboratory rates in CY2022 CY2023. <42 C.F.R. 414.507(d); *Protecting Medicare and American Farmers from Sequester Cuts Act*>
 - iii. In calendar years 2023-2025, the payment rate under the CLFS is limited to a 15% reduction from the prior year's rate. <42 C.F.R. 414.507(d)>
- c. Diagnostic and screening pap smear codes performed as non-patient reference lab tests, are paid the lesser of the local fee amount or National Limitation Amount but not less than the national minimum amount, capped by the actual charges, per statute. <*Medicare Claims Processing Manual Transmittal 4182*; Social Security Act § 1833(h)(7)>
 - i. The national minimum amount for CY2023 is \$17.31. <*Medicare Claims Processing Manual Transmittal 11186*>

Applicable pap smear codes are: 88142, 88143, 88147, 88148, 88150, 88152, 88153, 88164-88167, 88174, 88175, G0123, G0143, G0144, G0145, G0147, G0148, Q0111, Q0115, and P3000.

- d. Unlisted clinical diagnostic laboratory codes (CPT codes 81099, 84999, 85999, 86849, and 87999) do not have a fee schedule amount and instead are priced by the MAC. <*Medicare Claims Processing Manual, Chapter 16 § 100.4*>

C. Deductible and Coinsurance

1. In a CAH, the Medicare deductible and coinsurance do not apply to laboratory HCPCS codes paid on a reasonable cost basis (TOB 085X) or paid under CLFS for non-patient laboratory services (TOB 014X). < *Medicare Claims Processing Manual*, Chapter 4 § 250.6; *Medicare Claims Processing Manual*, Chapter 16 § 30.3 >
 - a. Presumably “laboratory HCPCS codes” are laboratory services listed in the CLFS file.
2. Medicare deductible and coinsurance will apply to codes in the 80000 series of the CPT manual that are non-clinical diagnostic laboratory services (e.g., pathology, blood product services). < *Medicare Claims Processing Manual Transmittal 2581* >

Case Study 1

Facts: A patient presents to the emergency department of a CAH on February 1 at 11:00 p.m. experiencing an exacerbation of longstanding congestive heart failure. The patient is placed in observation and blood is drawn at 11:30 p.m. Laboratory tests that were ordered by the physician include a comprehensive metabolic panel (80053) and complete blood count (85027). The physician receives the results of the tests at 12:15 a.m. The physician orders IV drugs and hydration with certain laboratory tests to be repeated at 6:00 a.m. The additional tests are sodium (84295), carbon dioxide (82374), and potassium (84132). The additional tests are also included in the comprehensive metabolic panel. The lab tests are within normal limits and the patient is discharged home at 10:00 a.m.

- What HCPCS codes, modifiers if applicable, and date of service should be reported for the laboratory tests?
- How will the laboratory tests be paid by Medicare?
- Will the patient be responsible for any coinsurance on the laboratory services?

VI. Blood, Blood Products, and Blood Processing and Storage

A. Blood Processing and Storage

1. 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 >

2. Billing for Blood Processing and Storage

- a. Blood processing and storage is billed using revenue codes 0392 (Blood Storage and Processing) or 0399 (Blood Storage and Processing/Other Processing and Storage). <Medicare Claims Processing Manual, Chapter 4 § 231.1>
 - i. In email correspondence, a CMS representative has indicated that the correct revenue code for billing blood processing and storage is the more specific revenue code of 0392. <Email correspondence from Fred Rooke>
 - ii. Revenue codes 0390 and 0399 are excluded from inpatient Part B claims; however, 0392 would be accepted. <Medicare Claims Processing Manual, Chapter 3 § 240.1>
- b. 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>
- c. 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>

B. Blood and Blood Products

1. 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>
2. 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.

3. Billing for Blood Products

- a. Blood products are billed using Revenue Code series 038X (Blood) with a final digit corresponding to the nature of the blood product. *<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>*
 - i. Modifier -BL should also be appended to the HCPCS code for the storage and processing. *<Medicare Claims Processing Manual, Chapter 4 § 231.2>*
 - a) For an OPPS hospital, 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, Sections 5.8, 5.8.1>*
 - b) Edit 73 does not apply to a CAH. *<IOCE Specifications: 6.2 Edit Descriptions and Reason for Edit Generation Table, Edit 73>*
- c. The line item date of service for blood products is the date of the transfusion. *<Medicare Claims Processing Manual, Chapter 4 § 231.2>*

C. Blood Administration (Transfusion)

1. 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>*

The transfusion/blood administration code is billed on a per date of service basis and not by the number of units of blood product transfused. Presumably, administration charges may be "tiered" in order to bill for the costs of transfusing multiple units over a longer period.

D. Processing and Storage for Unused Blood and Blood Products

1. 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>
 - a. 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>
 - b. Exception for frozen, thawed, split or irradiated blood
 - i. 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.
 - 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 freezing, thawing, splitting or irradiating service. <Medicare Claims Processing Manual, Chapter 4 §§ 231.6 and 231.7>
 - b) 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>

E. Payment for Blood Services

1. A CAH is paid 101% of its reasonable costs for blood administration, blood products, and blood processing and storage provided to an outpatient. <42 CFR 413.70>

2. Medicare deductible and coinsurance will apply to codes that are non-clinical diagnostic laboratory services (e.g., HCPCS codes for blood product and related services not listed in the CLFS). < *Medicare Claims Processing Manual Transmittal 2581*>

VII. Coverage of Outpatient Drugs

Medicare covers outpatient drugs under three circumstances:

- *Statutorily covered drugs*
- *Drugs incident to a physician's service and NOT usually self-administered*
- *Drugs integral to a procedure*

A. Statutorily Covered Drugs

1. The following drugs are covered by Medicare as specifically authorized by statute:
 - a. Blood clotting factors for hemophilia patients;
 - b. Drugs used in immunosuppressive therapy;
 - 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>

B. Drugs Provided Incident to a Physician's Service

1. Medicare covers drugs provided incident to a physician's or NPP's service that are not usually self-administered by the patient. <See *Medicare Benefit Policy Manual*, Chapter 15 § 50>
2. The local MAC makes the determination if a particular drug is usually self-administered or not by applying the following guidelines: <See *Medicare Benefit Policy Manual*, Chapter 15 § 50.2.A>
 - a. 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.A>

- b. 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.

- c. Drugs administered by subcutaneous injection are presumed to be usually self-administered. <See *Medicare Benefit Policy Manual*, Chapter 15 § 50.2.C.3>
- d. 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>
3. Each MAC publishes a Self-Administered Drug (SAD) Exclusion List with the injectable drugs the MAC has determined to be usually self-administered and not covered. The MAC SAD Exclusion Lists are posted on the Medicare Coverage Database.

Link: Coverage Database (NCDs, NCAs, LCDs) under Medicare-Related Sites – General

C. Drugs Integral to Procedures

1. Medicare covers certain SADs if the drug is:
- An integral component of the procedure; or,
 - Directly related to the procedure; or,
 - Facilitates the performance of or recovery from the procedure. <See *Medicare Benefit Policy Manual*, Chapter 15 § 50.2.M>

Examples of drugs integral to a procedure:

- *Sedatives administered in a pre-operative area*
- *Eye drops and certain other drugs related to eye procedures*
- *Barium and low osmolar contrast media*
- *Antibiotic ointment such as bacitracin*

2. A CMS representative has indicated the “overwhelming majority” of self-administered drugs are non-covered. The representative recommended comparing other items to the list above to determine if they may be covered. <Hospital Open Door Forum, August 23, 2011>

- a. The representative used the example of insulin given to control a patient's blood sugar as a non-covered drug, stating it would not be integral to a procedure because its purpose was to control a patient's blood sugar and not to be used as part of a procedure. <Hospital Open Door Forum, August 23, 2011>

Caution: *In the past, there was an exception for insulin when administered in an emergency, but current instructions do not allow payment for a drug administered on an emergency basis if the drug is excluded as usually self-administered.*

3. A drug will not be considered covered if the drug itself is the treatment rather than being an integral component of or facilitating the performance or recovery from the procedure. <See *Medicare Benefit Policy Manual*, Chapter 15 § 50.2.M>

Examples of drugs considered a treatment and not integral to a procedure:

- *Drugs given to a patient for continued use at home*
- *Oral pain medication given to an outpatient who develops a headache while receiving a chemotherapy treatment*
- *Daily routine insulin or hypertension medication given preoperatively*
- *A fentanyl patch or oral pain medication given to an outpatient presenting with pain*
- *A laxative for constipation given to a patient waiting for an unrelated x-ray*

4. Handout 14 is an algorithm of the coverage of self-administered drugs that are integral to a procedure.

D. Non-covered Self-Administered Drugs

1. Non-covered self-administered drugs may be billed to Medicare for a denial under the revenue code 0637 ("Self-administrable Drugs"), with or without a HCPCS code. <*NUBC Official UB-04 Specifications Manual; IOCE Specifications*, Section 7.2, Edit 48 (Supplement)>
 - a. If no drug HCPCS code is available for the self-administered drug and the provider wishes to bill with a modifier (e.g., -GX indicating a voluntary ABN was provided to the patient), the provider may use HCPCS A9270 ("Non-covered Item or Service"). <*Medicare Claims Processing Manual*, Chapter 1 § 60.4.2>
2. The DHHS Office of Inspector General (OIG) has stated hospitals will not be subject to administrative sanctions if they discount or waive amounts owed for non-covered self-administered drugs, subject to the following conditions:

- a. The discounts or waivers are for drugs received for ingestion or administration in outpatient settings;
 - b. The policy is uniformly applied without regard to diagnosis or type of treatment;
 - c. The policy is not marketed or advertised; and
 - d. 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. <See 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>
3. The OIG's policy statement does not affect the OIG's prior guidance on the ability of a hospital to discount or waive any amounts owed by Medicare beneficiaries on the basis of a good-faith, individualized determination of a beneficiary's financial need. <See 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>
 4. Handout 15 contains a diagram of the options for coverage, billing, and payment of drugs.

Case Study 2

Facts: A patient presents to the CAH's emergency department at 7:00 a.m. complaining of a severe headache. The patient usually administers Imatrex® at home; however, she had run out of her medication. The ED physician prescribes her usual dose of Imatrex® and the nurse administers the drug intramuscularly through a pre-loaded syringe. The patient also receives IV hydration and is ready for discharge at noon. Prior to billing, an edit notifies the billing staff that their MAC has identified intramuscular Imatrex® as a SAD.

- Is Imatrex® considered to be a covered drug when administered in the emergency department?

VIII. Billing and Payment for Outpatient Drugs

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

B. Revenue Codes

1. Drugs with HCPCS codes should be reported with revenue code 636 "Drugs Requiring Detailed Coding", except radiopharmaceuticals. < *Official UB-04 Data Specifications Manual*, Program Memorandum A-02-129>
 - a. Diagnostic radiopharmaceuticals are reported with revenue code 343 and therapeutic radiopharmaceuticals are reported with revenue code 344.
2. Drugs 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. < *Official UB-04 Data Specifications Manual*>
3. When self-administered drugs are integral to a procedure and are considered to be a "supply", the drugs are reported "under the revenue code associated with the cost center under which the hospital accumulates the costs of the drugs", presumably revenue code 0250. < See *Medicare Benefit Policy Manual*, Chapter 15 § 50.2 M>
 - a. Revenue code 0637 "Self-administrable Drugs" should not be reported for covered self-administered drugs because the OCE identifies it as an excluded revenue code.

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

- i. 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>
 - ii. 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>
 - i. 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>
 - i. 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>
- b. 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>

D. Modifiers Related to the 340B Drug Program

1. Definition

- a. 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. <See Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS), Frequently Asked Questions, Q1>

2. Mandatory reporting

- a. Specified drugs acquired in certain hospitals through the 340B drug discount program² are reported with either modifier -JG or -TB. <82 *Fed. Reg.* 59368; see Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS), Frequently Asked Questions, Q2, Q3>
 - i. Mandatory reporting of either modifier is limited to hospitals paid under OPPS.
 - ii. Modifier -JG must be reported on 340B acquired drugs with status indicator K (non-pass through drug) furnished by OPPS hospitals, *except* children's hospitals, PPS-exempt cancer hospitals, and rural sole community hospitals. <83 *Fed. Reg.* 59021-22; See Billing 340B Modifiers under the Hospital Outpatient Prospective Payment Systems (OPPS) Frequently Asked Questions, April 2, 2018, Q1, Q8>

Caution: *Effective January 1, 2019, drugs provided at non-excepted provider-based departments are subject to the reporting of the -JG modifier.*

- iii. For all OPPS hospitals, 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) Status indicator G (pass-through) drugs furnished by OPPS hospitals *including* children's hospitals, PPS-exempt cancer hospitals, and rural sole community hospitals; and,

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.

- b) Status indicator K (non-pass-through) drugs furnished at children's hospitals, cancer hospitals, rural sole community hospitals, and non-expected provider-based departments that are paid under the MPFS.

3. Voluntary reporting

- a. CAHs are not subject to the 340B payment policy mandatory modifier reporting because they are reimbursed under the cost methodology. <See Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS), Frequently Asked Questions, Q3>
 - i. CAHs have the option of reporting modifier -TB on a voluntary basis for drugs that were acquired under the 340B program.

Modifiers -JG and -TB do not apply to drugs not purchased through the 340B program or vaccines with status indicators F, L, or M.

E. Drug Administration

- 1. Drug administration HCPCS codes should be billed in addition to the HCPCS code for the drug administered, when appropriate. <Medicare Claims Processing Manual, Chapter 4 § 230.2; Medicare Claims Processing Manual, Chapter 17 § 10>

F. Pricing

- 1. Acquisition cost, pharmacy overhead, and nuclear medicine handling costs should be reported in the line-item charge for the drug. <Medicare Claims Processing Manual, Chapter 17 § 90.2>

G. Discarded Drugs and Biologicals

- 1. Unused portions of a single-use vial or other single use package are billable to Medicare if a portion of the drug or biological is administered to the patient and the remainder is discarded. <Medicare Claims Processing Manual, Chapter 17 § 40>

- a. A single-use vial is defined by the CDC as a vial of liquid medication intended for injection or infusion that is meant for use in a single patient for a single case/procedure/injection. Single-use vials are labeled as such by the manufacturer and typically lack an antimicrobial preservative. <CDC Injection Safety Provider FAQs, "Questions about Single-dose/Single-use Vials">

Providers can confirm whether a drug is a single use vial on the FDA approved label or package insert available on the FDA website:

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

2. Unused portions of multi-use vials may not be billed to Medicare. <Medicare Claims Processing Manual, Chapter 17 § 40>
 - a. A multi-dose vial is defined by the CDC as a vial of liquid medication intended for injection or infusion that contains more than one dose of medication. Multi-dose vials are labeled as such by the manufacturer and typically contain an antimicrobial preservative to help prevent the growth of bacteria. CDC recommends a multi-dose vial be dedicated to a single patient whenever possible. <CDC Injection Safety Provider FAQs, "Questions about Multi-dose vials">
3. Providers must document the amount of the discarded drug or biological in the patient's medical record. <Medicare Claims Processing Manual Transmittal 3538>
 - a. Discarded amounts may be automatically calculated and documented by software, if the amount is documented accurately. <See "JW Modifier: Drug/Biological Amount Discarded/Not Administered to Any Patient Frequently Asked Questions", August 26, 2016>
4. Providers must report unused, discarded drugs and biologicals on a separate line with modifier -JW, when possible to do so. <Medicare Claims Processing Manual Transmittal 3538>
 - a. This policy applies to providers and suppliers, physician's offices and hospital outpatient settings, who buy and bill drugs and is intended to track discarded amounts of drugs that occur as a result of the preparation of a drug dose for administration to a beneficiary. <See "JW Modifier: Drug/Biological Amount Discarded/Not Administered to Any Patient Frequently Asked Questions", August 26, 2016>
 - i. Reporting modifier -JW for discarded drugs is required in a CAH since most drugs are separately payable in that setting.

- a) Under OPPS, modifier -JW only applies to separately payable drugs with status indicators G (Pass-Through Drugs and Biologicals) or K (Non-pass-Through Drugs and Non-implantable Biologicals, Including Therapeutic Radiopharmaceuticals) when there is an unused or discarded amount. Modifier –JW does not apply to drugs assigned status indicator N (Items and Services Packaged into APC Rates) under the OPPS. <See “JW Modifier: Drug/Biological Amount Discarded/Not Administered to Any Patient Frequently Asked Questions”, August 26, 2016>
 - b) Modifier -JW does not apply to drugs reported on inpatient Part A claims.
5. The provider is limited to billing total units of both the administered and discarded drug up to the smallest vial available for purchase from the manufacturer that could have provided the appropriate dose for the patient. <MLN Matters Article SE1316, Revised>

Case Study 3

Facts: A patient presents to the CAH's oncology center for an injection of bortezomib (HCPCS code J9041 is reported for 0.1 mg of bortezomib). 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. The patient requires 2.7 mg of bortezomib and the hospital was unable to use the remainder for another patient and had to dispose of it.

- Will Medicare pay separately for the unused portion of this drug?
- How should this drug be billed to Medicare?

H. Payment for Covered Outpatient Drugs

1. When a drug is considered to be covered by Medicare, a CAH is paid 101% of its reasonable costs for the drug and the related administration. <42 CFR 413.70; Medicare Claims Processing Manual, Chapter 17 § 10>

CASE STUDIES WITH ANALYSIS

Case Study 1

Facts: A patient presents to the emergency department of a CAH on February 1 at 11:00 p.m. experiencing an exacerbation of longstanding congestive heart failure. The patient is placed in observation and blood is drawn at 11:30 p.m. Laboratory tests that were ordered by the physician include a comprehensive metabolic panel (80053) and complete blood count (85027). The physician receives the results of the tests at 12:15 a.m. The physician orders IV drugs and hydration with certain laboratory tests to be repeated at 6:00 a.m. The additional tests are sodium (84295), carbon dioxide (82374), and potassium (84132). The additional tests are also included in the comprehensive metabolic panel. The lab tests are within normal limits and the patient is discharged home at 10:00 a.m.

- What HCPCS codes, modifiers if applicable, and date of service should be reported for the laboratory tests?
- How will the laboratory tests be paid by Medicare?
- Will the patient be responsible for any coinsurance on the laboratory services?

Analysis:

The following lab tests would be billed to Medicare:

- 80053 DOS 020120
- 85027 DOS 020120
- 84295 DOS 020220
- 82374 DOS 020220
- 84132 DOS 020220

The laboratory test drawn on February 1 and performed on February 2 should be billed with the line item date of service of February 1 because that is the date of the specimen collection. The laboratory tests drawn and resulted on February 2 should be billed with date of service February 2. Even though the lab tests that were repeated on February 2 were also performed as part of the initial panel, modifier -91 would not be necessary since the edit is based on the line item date of service.

The CAH would be paid their cost reimbursement for the laboratory tests and the patient would not be responsible for any deductible and coinsurance.

Case Study 2

Facts: A patient presents to the CAH's emergency department at 7:00 a.m. complaining of a severe headache. The patient usually administers Imatrex® at home; however, she had run out of her medication. The ED physician prescribes her usual dose of Imatrex® and the nurse administers the drug intramuscularly through a pre-loaded syringe. The patient also receives IV hydration and is ready for discharge at noon. Prior to billing, an edit notifies the billing staff that their MAC has identified intramuscular Imatrex® as a SAD.

- Is Imatrex® considered to be a covered drug when administered in the emergency department?

Analysis: No. Each MAC publishes a Self-Administered Drug (SAD) Exclusion List with the injectable drugs the MAC has determined to be usually self-administered and not covered by Medicare when administered in an outpatient setting. A drug will not be considered covered if the drug itself is the treatment rather than being an integral component of or facilitating the performance or recovery from the procedure. In this scenario, the drug was not part of a procedure and an "emergency" exception does not exist. Even though the drug is given intramuscularly by the nurse, the non-coverage decision is based on the usual method of administration for all Medicare beneficiaries who use the drug.

Case Study 3

Facts: A patient presents to the CAH's oncology center for an injection of bortezomib (HCPCS code J9041 is reported for 0.1 mg of bortezomib). 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. The patient requires 2.7 mg of bortezomib and the hospital was unable to use the remainder for another patient and had to dispose of it.

- Will Medicare pay separately for the unused portion of this drug?
- How should this drug be billed to Medicare?

Analysis: Yes, unused portions of a single-use vial or other single use package are billable to Medicare if a portion of the drug or biological is administered to the patient and the remainder is discarded. The hospital should report revenue code 0636, J9041 with 27 units on one line and revenue code 0636, J9041-JW with 8 unit on a separate line.

Version 02/21/2023
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Displaying title 42, up to date as of 1/20/2022. Title 42 was last amended 1/18/2022.

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

EDITORIAL NOTE ON PART 410

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 the appropriate level of physician supervision specified by CMS in accordance with the definitions in this paragraph and in § 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii). 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. In addition -
 - (1) 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 must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room where the procedure is performed. During a Public Health Emergency, as defined in § 400.200 of this chapter, the presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.
 - (2) For services furnished under arrangement in nonhospital locations, "direct supervision" means the definition specified in § 410.32(b)(3)(ii).
- (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]



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EDITORIAL NOTE ON PART 410

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

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

- (a) **Ordering diagnostic tests.** Except as otherwise provided in this section, all diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary (see § 411.15(k)(1) of this chapter).
- (1) **Mammography exception.** A physician who meets the qualification requirements for an interpreting physician under section 354 of the Public Health Service Act as provided in § 410.34(a)(7) may order a diagnostic mammogram based on the findings of a screening mammogram even though the physician does not treat the beneficiary.
 - (2) **Application to nonphysician practitioners.** Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.
 - (3) **Public Health Emergency exceptions.** During the Public Health Emergency for COVID-19, as defined in § 400.200 of this chapter, the order of a physician or other applicable practitioner is not required for one otherwise covered diagnostic laboratory test for COVID-19 and for one otherwise covered diagnostic laboratory test each for influenza virus or similar respiratory condition needed to obtain a final COVID-19 diagnosis when performed in conjunction with COVID-19 diagnostic laboratory test in order to rule-out influenza virus or related diagnosis. Subsequent otherwise covered COVID-19 and related tests described in the previous sentence are reasonable and necessary when ordered by a physician or nonphysician practitioner in accordance with this paragraph (a), or when ordered by a pharmacist or other healthcare professional who is authorized under applicable state law to order diagnostic laboratory tests. FDA-authorized COVID-19 serology tests are included as covered tests subject to the same order requirements during the Public Health Emergency for COVID-19, as defined in § 400.20 of this chapter, as they are reasonable and necessary under section 1862(a)(1)(A) of the Act for beneficiaries with known current or known prior COVID-19 infection or suspected current or suspected prior COVID-19 infection.
- (b) **Diagnostic x-ray and other diagnostic tests -**
- (1) **Basic rule.** Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act or, to the extent that they are authorized to do so under their scope of practice and applicable State law, by a nurse practitioner, clinical nurse specialist, physician assistant, certified registered nurse anesthetist, or a certified nurse-midwife. Services furnished without the required level of supervision are not reasonable and necessary (see § 411.15(k)(1) of this chapter).
 - (2) **Exceptions.** The following diagnostic tests payable under the physician fee schedule are excluded from the basic rule set forth in paragraph (b)(1) of this section:
 - (i) Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.
 - (ii) Diagnostic tests personally furnished by a qualified audiologist as defined in section 1861(II)(3) of the Act.
 - (iii) Diagnostic psychological and neuropsychological testing services when -
 - (A) Personally furnished by a clinical psychologist or an independently practicing psychologist as defined in program instructions; or
 - (B) Furnished under the general supervision of a physician or clinical psychologist; or under the general supervision of a nurse practitioner, clinical nurse specialist, physician assistant, certified registered nurse anesthetist or certified nurse-midwife, to the extent they are authorized to perform the tests under their scope of practice and applicable State laws.
 - (iv) Diagnostic tests (as established through program instructions) personally performed by a physical therapist who is certified by the American Board of Physical Therapy Specialties as a qualified electrophysiologic clinical specialist and permitted to provide the service under State law.

- (v) Diagnostic tests performed by a nurse practitioner or clinical nurse specialist authorized to perform the tests under applicable State laws.
 - (vi) Pathology and laboratory procedures listed in the 80000 series of the Current Procedural Terminology published by the American Medical Association.
 - (vii) Diagnostic tests performed by a certified nurse-midwife authorized to perform the tests under applicable State laws.
 - (viii) During the COVID-19 Public Health Emergency as defined in § 400.200 of this chapter, diagnostic tests performed by a physician assistant authorized to perform the tests under applicable State law.
 - (ix) Diagnostic tests performed by a physician assistant authorized to perform the tests under their scope of practice and applicable State laws.
- (3) **Levels of supervision.** Except where otherwise indicated, all diagnostic x-ray and other diagnostic tests subject to this provision and payable under the physician fee schedule must be furnished under at least a general level of supervision as defined in paragraph (b)(3)(i) of this section. In addition, some of these tests also require either direct or personal supervision as defined in paragraph (b)(3)(ii) or (iii) of this section, respectively. When direct or personal supervision is required, supervision at the specified level is required throughout the performance of the test.
- (i) **General supervision** means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, 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 physician.
 - (ii) **Direct supervision** in the office setting means the physician (or other supervising 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 other supervising practitioner) must be present in the room when the procedure is performed. 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 other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).
 - (iii) **Personal supervision** means a physician must be in attendance in the room during the performance of the procedure.
- (4) **Supervision requirement for RRA or RPA.** Diagnostic tests that are performed by a registered radiologist assistant (RRA) who is certified and registered by the American Registry of Radiologic Technologists or a radiology practitioner assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants, and that would otherwise require a personal level of supervision as specified in paragraph (b)(3) of this section, may be furnished under a direct level of physician supervision to the extent permitted by state law and state scope of practice regulations.
- (c) **Portable x-ray services.** Portable x-ray services furnished in a place of residence used as the patient's home are covered if the following conditions are met:
- (1) These services are furnished under the general supervision of a physician, as defined in paragraph (b)(3)(i) of this section.
 - (2) These services are ordered by a physician as provided in paragraph (a) or by a nonphysician practitioner as provided in paragraph (a)(2) of this section.
 - (3) The supplier of these services meets the requirements set forth in part 486, subpart C of this chapter, concerning conditions for coverage for portable x-ray services.
 - (4) The procedures are limited to -
 - (i) Skeletal films involving the extremities, pelvis, vertebral column, or skull;
 - (ii) Chest or abdominal films that do not involve the use of contrast media; and
 - (iii) Diagnostic mammograms if the approved portable x-ray supplier, as defined in subpart C of part 486 of this chapter, meets the certification requirements of section 354 of the Public Health Service Act, as implemented by 21 CFR part 900, subpart B.
- (d) **Diagnostic laboratory tests -**
- (1) **Who may furnish services.** Medicare Part B pays for covered diagnostic laboratory tests that are furnished by any of the following:
 - (i) A participating hospital or participating RPCH.
 - (ii) A nonparticipating hospital that meets the requirements for emergency outpatient services specified in subpart G of part 424 of this chapter and the laboratory requirements specified in part 493 of this chapter.
 - (iii) The office of the patient's attending or consulting physician if that physician is a doctor of medicine, osteopathy, podiatric medicine, dental surgery, or dental medicine.
 - (iv) An RHC.
 - (v) A laboratory, if it meets the applicable requirements for laboratories of part 493 of this chapter, including the laboratory of a nonparticipating hospital that does not meet the requirements for emergency outpatient services in subpart G of part 424 of this chapter.

- (vi) An FQHC.
 - (vii) An SNF to its resident under § 411.15(p) of this chapter, either directly (in accordance with § 483.75(k)(1)(i) of this chapter) or under an arrangement (as defined in § 409.3 of this chapter) with another entity described in this paragraph.
- (2) **Documentation and recordkeeping requirements -**
- (i) **Ordering the service.** Except for tests described in paragraph (a)(3) of this section, the physician (or qualified nonphysician practitioner, as defined in paragraph (a)(2) of this section), who orders the service must maintain documentation of medical necessity in the beneficiary's medical record.
 - (ii) **Submitting the claim.** Except for tests described in paragraph (a)(3) of this section, the entity submitting the claim must maintain the following documentation:
 - (A) The documentation that it receives from the ordering physician or nonphysician practitioner.
 - (B) The documentation that the information that it submitted with the claim accurately reflects the information it received from the ordering physician or nonphysician practitioner.
 - (iii) **Requesting additional information.** The entity submitting the claim may request additional diagnostic and other medical information to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.
- (3) **Claims review.**
- (i) **Documentation requirements.** Except for tests described in paragraph (a)(3) introductory text, upon request by CMS, the entity submitting the claim must provide the following information:
 - (A) Documentation of the order for the service billed (including information sufficient to enable CMS to identify and contact the ordering physician or nonphysician practitioner).
 - (B) Documentation showing accurate processing of the order and submission of the claim.
 - (C) Diagnostic or other medical information supplied to the laboratory by the ordering physician or nonphysician practitioner, including any ICD-9-CM code or narrative description supplied.
 - (ii) **Services that are not reasonable and necessary.** If the documentation provided under paragraph (d)(3)(i) of this section does not demonstrate that the service is reasonable and necessary, CMS takes the following actions:
 - (A) Provides the ordering physician or nonphysician practitioner information sufficient to identify the claim being reviewed.
 - (B) Requests from the ordering physician or nonphysician practitioner those parts of a beneficiary's medical record that are relevant to the specific claim(s) being reviewed.
 - (C) If the ordering physician or nonphysician practitioner does not supply the documentation requested, informs the entity submitting the claim(s) that the documentation has not been supplied and denies the claim.
 - (iii) **Medical necessity.** The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.
- (4) **Automatic denial and manual review.**
- (i) **General rule.** Except as provided in paragraph (d)(4)(ii) of this section, CMS does not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation that is submitted with the claim (for example, justifications prepared by providers, primary and secondary diagnoses, and copies of medical records).
 - (ii) **Exceptions.** CMS may automatically deny a claim without manual review if a national coverage decision or LMRP specifies the circumstances under which the service is denied, or the service is specifically excluded from Medicare coverage by law.
- (e) **Diagnostic laboratory tests furnished in hospitals and CAHs.** The provisions of paragraphs (a) and (d)(2) through (d)(4) of this section, inclusive, of this section apply to all diagnostic laboratory test furnished by hospitals and CAHs to outpatients.

[62 FR 59098, Oct. 31, 1997, as amended at 63 FR 26308, May 12, 1998; 63 FR 53307, Oct. 5, 1998; 63 FR 58906, Nov. 2, 1998; 64 FR 59440, Nov. 2, 1999; 66 FR 58809, Nov. 23, 2001; 69 FR 66421, Nov. 15, 2004; 72 FR 66398, Nov. 27, 2007; 75 FR 73615, Nov. 29, 2010; 77 FR 69361, Nov. 16, 2012; 83 FR 60073, Nov. 23, 2018; 85 FR 19286, Apr. 6, 2020; 85 FR 27620, May 8, 2020; 85 FR 54871, Sept. 2, 2020; 85 FR 85026, Dec. 28, 2020]

Attachment - One-Time Notification

Pub. 100-20	Transmittal: 2404	Date: December 6, 2019	Change Request: 11268
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Transmittal 2323, dated July 26, 2019, is being rescinded and replaced by Transmittal 2404, dated, December 6, 2019. This correction removes codes that are not available for 2020. In addition, codes have been added to the attachment that serves to replace some of the expired codes. Removed codes include: 77058, 77059, 78205, 78206, 78270, 78271, 78272, 78320, 78607, 78647, 78710, 78805, 78806, 78807. Added codes include: 77048, 77049, 78429, 78430, 78431, 78432, 78433, 78434, 78830, 78831, 78832, 78835. All other information remains the same.

SUBJECT: Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging – Educational and Operations Testing Period - Claims Processing Requirements

EFFECTIVE DATE: January 1, 2020

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: January 6, 2020

I. GENERAL INFORMATION

A. Background: The Protecting Access to Medicare Act (PAMA) of 2014 section 218(b) established a new program to increase the rate of appropriate advanced diagnostic imaging services furnished to Medicare beneficiaries. Examples of advanced imaging services include computed tomography, positron emission tomography, nuclear medicine, and magnetic resonance imaging. Under this program, at the time an advanced imaging service is ordered for a Medicare beneficiary, the ordering professional will be required to consult a qualified clinical decision support mechanism (CDSM). 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 during the patient workup. There may be modules within or available through certified electronic health record (EHR) technology, private sector mechanisms independent from certified EHR technology, or those established by the CMS. The CDSM will provide the ordering professional with a determination of whether that order adheres to AUC, does not adhere to AUC, or if there is no AUC applicable (e.g., no AUC is available to address the patient's clinical condition) in the CDSM consulted.

Priority clinical areas are defined in 42 CFR 414.94(b) as clinical conditions, diseases or symptom complexes and associated advanced diagnostic imaging services identified by CMS through annual rulemaking and in consultation with stakeholders. Please note that AUC consultation is required for all advanced diagnostic imaging services, not just those within the priority clinical areas.

Current Priority Clinical Areas

- Coronary artery disease (suspected or diagnosed)
- Suspected pulmonary embolism
- Headache (traumatic and non-traumatic)
- Hip pain
- Low back pain
- Shoulder pain (to include suspected rotator cuff injury)
- Cancer of the lung (primary or metastatic, suspected or diagnosed)

- Cervical or neck pain

 When this program is fully implemented, a consultation must take place for any applicable imaging service ordered by an ordering professional that would be furnished in an applicable setting and paid under an applicable payment system. (Note the applicable setting is where the imaging service is furnished, not the setting where the imaging service is ordered.) Applicable settings include: physician offices, hospital outpatient departments (including emergency departments), ambulatory surgical centers (ASCs), and independent diagnostic testing facilities. Applicable payment systems include: the physician fee schedule (PFS), the hospital outpatient prospective payment system, and ASCs.

Voluntary participation was established for this program from July 1, 2018 through January 1, 2020. CR 10481 discusses the voluntary participation period. This CR (11268) discusses the Educational and Operations Testing Period for calendar year (CY) 2020 (see additional information below).

Full program implementation is expected January 1, 2021. At that time, information regarding the ordering professional's consultation with CDSM, or exception to such consultation, must be appended to the furnishing professional's claim in order for that claim to be paid.

Exceptions to consulting CDSMs include: the ordering professional having a significant hardship exception, situations in which the patient has an emergency medical condition, or, an applicable imaging service ordered for an inpatient and for which payment is made under Part A.

Ultimately, PAMA requires that the program result in prior authorization for ordering professionals that are identified as having outlier ordering patterns. Before the prior authorization component of this program begins there will be notice and comment rulemaking to develop the outlier methodology.

B. Policy: Regulatory language for this program is in 42 CFR 414.94 titled Appropriate Use Criteria for Advanced Diagnostic Imaging Services. In the CY 2018 PFS Final Rule, CMS- said this program will be implemented in 2020 with an Educational and Operations Testing Period.

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 (e.g., failure to include one of the below modifiers and/or one of the below G codes or reporting modifiers on the wrong line or wrong service), but inclusion is encouraged. In addition, the claims processing systems will be prepared by January 1, 2020, to accept claims that contain a Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) C code for advanced diagnostic imaging along with a line item HCPCS modifier to describe either the level of adherence to AUC or an exception to the program and a G-code to identify the qualified CDSM consulted.

During CY 2020 we expect ordering professionals to begin consulting qualified 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. Even though claims will not be denied during this Educational and Operations Testing Period inclusion is encouraged as it is important for CMS to track this information.

HCPCS modifiers have been established for this program for placement on the same line as the CPT code for the advanced diagnostic imaging service. These codes are available in the Attachment.

Claims that report HCPCS modifier ME, MF, or MG should additionally contain a G code to report which qualified CDSM was consulted. The G codes are available in the Attachment.

A subsequent CR will follow at a later date that will further operationalize this AUC policy.

Number	Requirement	Responsibility									
		A/B MAC			D M E	Shared-System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
	The Group Code is CO. NOTE: The beneficiary is not responsible for the denied charge.										
11268.5	Contractors shall refer to Attachment 1 for a list of HCPCS procedure codes that constitute advanced diagnostic imaging services subject to the Medicare appropriate use criteria program, HCPCS modifiers to be placed on the same line as any listed or unlisted procedure code and G codes for reporting the clinical decision support mechanism.	X	X								IOCE
11268.5.1	Contractors shall be notified of updates to Attachment 1 through the quarterly issuance of a Technical Direction letter.	X	X								IOCE

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility					
		A/B MAC			D M E	C E D I	
		A	B	H H H			M A C
11268.6	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	X	X				

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

Version 02/27/2023
Check for Updates

Attachment - Business Requirements

Pub. 100-04	Transmittal: 4481	Date: December 20, 2019	Change Request: 11574
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SUBJECT: Internet Only Manual Update to Pub 100-04, Chapter 16, Section 40.8 – Laboratory Date of Service Policy

EFFECTIVE DATE: January 1, 2020

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: January 23, 2020

I. GENERAL INFORMATION

A. Background: The date of service (DOS) is a required field on all Medicare claim types. A laboratory service may take place over a period of time. That is, for a given laboratory test, the date the physician orders the test, the date the specimen is collected from the patient, the date the laboratory accesses the specimen, the date of the test, and the date results are produced may occur on different dates. In most cases, the DOS for a laboratory test is the date the specimen was collected, unless certain conditions are met as set forth in 42 CFR 414.510(b). The laboratory DOS exception at § 414.510(b)(5) previously stated that, for a molecular pathology test or a test designated by CMS as an Advanced Diagnostic Laboratory Test (ADLT) under paragraph (1) of the definition of an ADLT in § 414.502, the DOS of the test must be the date the test was performed only if:

- (i) the test was performed following a hospital outpatient’s discharge from the hospital outpatient department;
- (ii) the specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2);
- (iii) it was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
- (iv) the results of the test do not guide treatment provided during the hospital outpatient encounter; and
- (v) the test was reasonable and medically necessary for the treatment of an illness.

In the calendar year (CY) 2020 Medicare hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) proposed rule published on August 9, 2019, CMS sought comments on excluding blood banks and blood centers from the laboratory DOS exception at 42 CFR 414.510(b)(5). In response to comments, CMS finalized excluding blood banks or centers from the laboratory DOS exception at 42 CFR 414.510(b)(5) in the CY 2020 OPPS/ASC final rule published on November 12, 2019. CMS also adopted a definition of “blood bank or center” and clarified that this policy change categorically excludes molecular pathology testing performed by laboratories that are blood banks or blood centers from the laboratory DOS exception at 42 CFR 414.510(b)(5).

B. Policy: In the case of a molecular pathology test performed by a laboratory other than a blood bank or center, or a test designated by CMS as an ADLT under paragraph (1) of the definition of an advanced diagnostic laboratory test in 42 CFR 414.502, the date of service of the test must be the date the test was performed only if the following conditions are met: (1) The test is performed following a hospital outpatient’s discharge from the hospital outpatient department; (2) The specimen was collected from a hospital outpatient during an encounter (as both are defined 42 CFR 410.2); (3) It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient 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.

Molecular pathology testing performed by laboratories that are blood banks or blood centers are categorically excluded from the laboratory DOS exception at 42 CFR 414.510(b)(5). That is, molecular pathology testing, when performed by blood banks or centers, are never subject to the laboratory DOS exception at 42 CFR 414.510(b)(5). For purposes of the laboratory DOS exception at 42 CFR 414.510(b)(5), a “blood bank or center” means an entity whose primary function is the performance or responsibility for the performance of, the collection, processing, testing, storage and/or distribution of blood or blood components intended for

transfusion and transplantation.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility									
		A/B MAC			D M E	Shared-System Maintainers				Other	
		A	B	H H H		F I S	M C S	V M S	C W F		
11574.1	Contractors shall be aware that molecular pathology testing performed by laboratories that are blood banks or centers are not subject to the laboratory DOS exception in Pub. 100-04, Chapter 16, Section 40.8.C of the Medicare claims processing manual.	X	X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility					
		A/B MAC			D M E	C E D I	
		A	B	H H H			M A C
11574.2	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	X	X				

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
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40.8 - Date of Service (DOS) for Clinical Laboratory and Pathology Specimens

(Rev. 4481; Issued: 12-20-19, Effective: 01-01-20, Implementation: 01-23-20)

The DOS policy for either a clinical laboratory test or the technical component of physician pathology service is as follows:

General Rule: The DOS of the test/service must be the date the specimen was collected.

Variation: If a specimen is collected over a period that spans two calendar days, then the DOS must be the date the collection ended.

Exceptions: The following three exceptions apply to the DOS policy for either a clinical laboratory test or the technical component of physician pathology service:

A. DOS for Tests/Services Performed on Stored Specimens:

In the case of a test/service performed on a stored specimen, if a specimen was stored for less than or equal to 30 calendar days from the date it was collected, the DOS of the test/service must be the date the test/service was performed only if:

- The test/service is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test/service do not guide treatment provided during the hospital stay; and
- The test/service was reasonable and medically necessary for treatment of an illness.

If the specimen was stored for more than 30 calendar days before testing, the specimen is considered to have been archived and the DOS of the test/service must be the date the specimen was obtained from storage.

B. DOS for Chemotherapy Sensitivity Tests/Services Performed on Live Tissue:

In the case of a chemotherapy sensitivity test/service performed on live tissue, the DOS of the test/service must be the date the test/service was performed only if:

- The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;

- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test/service do not guide treatment provided during the hospital stay; and
- The test/service was reasonable and medically necessary for treatment of an illness.

For purposes of applying the above exception, a “chemotherapy sensitivity test” is defined as a test that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents. CMS identifies such tests through program instructions issued to the Medicare Administrative Contractors (MACs).

C. DOS for Advanced Diagnostic Laboratory Tests and Molecular Pathology Tests:

In the case of a molecular pathology test *performed by a laboratory other than a blood bank or center*, or a test designated by CMS as an ADLT under paragraph (1) of the definition of advanced diagnostic laboratory test in 42 CFR 414.502, the DOS must be the date the test was performed only if:

- The test was performed following a hospital outpatient’s discharge from the hospital outpatient department;
- The specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2);
- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
- The results of the test do not guide treatment provided during the hospital outpatient encounter; and
- The test was reasonable and medically necessary for the treatment of an illness.

For the purpose of section 40.8.C, a “blood bank or center” means an entity whose primary function is the performance or responsibility for the performance of, the collection, processing, testing, storage and/or distribution of blood or blood components intended for transfusion and transplantation.

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

Version 02/21/2015
Check for Updates

April 2, 2018 *Editor's note:* The CY2019 OPSS Final Rule applied the JG modifier and 340B discount to drugs purchased at nonexcepted provider based departments, effective January 1, 2019. At the time of publishing, CMS has not updated these FAQs to reflect this change.

Medicare-FFS Program

Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS)

Frequently Asked Questions

Overview: The purpose of this document is to address frequently asked questions about billing 340B-acquired drugs under the OPSS in Calendar Year (CY) 2018.

General

1. What is Medicare's payment policy for 340B-acquired drugs provided by a hospital outpatient department?

Beginning January 1, 2018, Medicare pays an adjusted amount of the average sales price (ASP) minus 22.5 percent for certain separately payable drugs or biologicals (hereafter referred to as drug or drugs) that are acquired through the 340B Program and furnished to a Medicare beneficiary by a hospital paid under the OPSS that is not excepted from the payment adjustment policy. For purposes of this policy, "acquired through the 340B Program" means the drug was purchased at or below the 340B ceiling price from the manufacturer and includes 340B drugs purchased through the Prime Vendor Program (PVP).

Medicare will continue to pay for separately payable drugs that were not acquired through the 340B Program and furnished by a hospital paid under the OPSS at ASP+6 percent.

For CY 2018, CMS designated rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals are excepted from the 340B payment adjustment. For more details about which hospitals are designated as rural SCHs, please refer to Question 4.

2. What modifiers did CMS establish to report 340B-acquired drugs?

CMS established two Healthcare Common Procedure Coding System (HCPCS) Level II modifiers to identify 340B-acquired drugs:

- Modifier "JG" *Drug or biological acquired with 340B drug pricing program discount.*
- Modifier "TB" *Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes.*

When applicable, providers are required to report either modifier "JG" or "TB" on OPSS claims (bill type 13X) beginning January 1, 2018. Though modifier "TB" is an informational modifier, reporting is mandatory for applicable providers. See Question 8 below for additional information about these modifiers.

April 2, 2018

 **3. Are Critical Access Hospitals (CAHs) subject to the 340B payment policy? Should CAHs report the informational modifier “TB”? What about hospitals located in Maryland that are paid under a cost containment waiver?**

No, CAHs are not subject to the 340B payment policy because CAHs are not paid under the OPSS. Neither modifier “JG” nor modifier “TB” is required to be reported by CAHs. However, CAHs have the option of reporting informational modifier TB on a voluntary basis for drugs that were acquired under the 340B Program.

Likewise, hospitals paid under the Maryland waiver are excluded from the OPSS and are not subject to the payment policy change. These hospitals, as well as any other hospitals that are excluded from the OPSS, are similarly not required to report the JG modifier, but have the option to report the TB modifier on a voluntary basis.

4. How does CMS define rural sole community hospitals (SCHs)?

Rural SCHs receive a 7.1 percent add-on adjustment under the OPSS. These providers either meet the definition of an SCH under the regulations at 42 CFR § 412.92 or are EACHs (essential access community hospitals), which are considered to be SCHs under section 1886(d)(5)(D)(iii)(III) of the Act, and that meet the definition in the regulations at 42 CFR § 412.109. These providers must also be located in a rural area, as defined under section 412.64(b) of the regulations, or be treated as being located in a rural area under section 412.10 of the regulations.

If a provider is unsure of its status as a Rural SCH, it may check with its Medicare Administrative Contractor (MAC) or review the CY 2018 OPSS final rule impact file to determine whether the hospital is designated a rural SCH under the OPSS for CY 2018. Rural SCHs are defined in the impact file where Rural Sole Community and Essential Access Hospitals indicator flag is ‘1’ [column D] and where Urban/Rural Geographic Location is ‘rural’ [column G]. The CY 2018 OPSS impact file is available at <https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1678-FC-2018-OPSS-FR-Facility-Specific-Impacts.zip>.

5. My hospital has a dual designation such that it is listed in the HRSA database as a disproportionate share hospital (DSH) but paid under the OPSS as a rural SCH. Which designation determines whether my hospital is excepted or not excepted from the 340B payment policy in CY 2018?

The Medicare hospital type designation determines applicability of the 340B drug payment adjustment, regardless of how the hospital is enrolled in the 340B Program. For example, a hospital enrolled in the 340B program as a DSH but paid under the OPSS as a rural SCH would be excepted from the 340B payment reduction in CY 2018 and would bill the informational modifier “TB” for each 340B-acquired drug furnished to a hospital outpatient.

April 2, 2018

6. Are non-excepted off-campus provider-based departments of hospitals required to report modifier “TB” for 340B-acquired drugs?

See Editor's note on page one for modification to this policy 1/1/19

Yes. Non-excepted off-campus provider-based departments of hospitals that are participating in the 340B Program are required to report modifier “TB” for 340B-acquired drugs in addition to modifier “PN” (*Nonexcepted service provided at an off-campus, outpatient, provider-based department of a hospital*).

As stated in the CY 2018 OPSS/ASC final rule with comment, we intend to consider changes to the payment policy for 340B-acquired drugs furnished in non-excepted off-campus provider-based departments of hospitals in CY 2019 rulemaking.

7. Are hospital-owned retail pharmacies that bill 340B eligible claims under Part B impacted by the 340B payment policy?

No. The 340B payment policy adopted in the CY 2018 OPSS/ASC final rule with comment period applies to certain hospitals paid under the OPSS. Pharmacies do not bill under the OPSS and therefore are not affected by this policy.

8. Which hospital types should report the modifier “JG”? Modifier “TB”?

The following chart describes the modifier a hospital should report depending upon its hospital type and the pertinent OPSS drug status indicator (SI) for the 340B-acquired drug being furnished.

Hospital Type (determined by CMS)	Pass-through Drug (SI “G”)	Separately Payable Drug (SI “K”)	Vaccine (SI “F” “L” or “M”)	Packaged Drug (SI “N”)
Not Paid under OPSS				
CAH	TB, Optional	TB, Optional	N/A	TB or JG, Optional
Maryland Waiver Hospital	TB, Optional	TB, Optional	N/A	TB or JG, Optional
Non-Excepted Off-Campus PBD	TB	TB See note below	N/A	TB or JG, Optional
Paid under the OPSS, Excepted from the 340B Payment Adjustment for 2018				
Children’s Hospital	TB	TB	N/A	TB or JG, Optional
PPS-Exempt Cancer Hospital	TB	TB	N/A	TB or JG, Optional

Editor's note: Effective 1/1/19, the 340B discount applies to non-excepted PBDs; they should use modifier -JG for 340B purchased drugs.

April 2, 2018

Rural Sole Community Hospital	TB	TB	N/A	TB or JG, Optional
Paid under the OPPS, Subject to the 340B Payment Adjustment				
DSH Hospital	TB	JG	N/A	TB or JG, Optional
Medicare Dependent Hospital	TB	JG	N/A	TB or JG, Optional
Rural Referral Center	TB	JG	N/A	TB or JG, Optional
Non-Rural Sole Community Hospital	TB	JG	N/A	TB or JG, Optional

N/A= Not Applicable

9. How are Medicare Advantage (MA) plans impacted by the new payment policy for 340B-acquired drugs?

MA Payment of contracted providers / facilities: MAOs that contract with a facility/provider eligible for 340B drugs can negotiate the terms and conditions of payment with the provider / facility. CMS cannot interfere in the payment rates that MA organizations and providers enter into through contracts.

MA payment of non-contract providers / facilities: When paying a facility/provider eligible for 340B drugs, on a non-contract basis the MA plan pays the non-contract provider / facility the amount they would have received under Original Medicare payment rules less the plan allowed cost sharing collected from the MA enrollee.

Billing

10. To which drugs does the 340B payment adjustment apply? How can a provider identify a drug that must be billed with modifier “JG”?

Beginning January 1, 2018, the 340B payment adjustment applies to separately payable OPPS drugs (assigned status indicator “K”) that meet the definition of “covered outpatient drug” as defined in the section 1927(k) of the Act and that are acquired through the 340B Program or through the 340B PVP, but does not apply to vaccines

April 2, 2018

(assigned status indicator “F”, “L” or “M”) and does not apply to drugs on pass-through payment status (assigned status indicator “G”).

Providers should refer to the quarterly update of Addendum B for a listing of drugs paid under the OPSS and their assigned status indicator. The Addendum B updates are posted quarterly to the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html>.

The 340B payment reduction does not apply to OPSS separately payable drugs (assigned status indicator “K”) that are not acquired through the 340B Program. This means that if a participating 340B hospital did not purchase a 340B eligible drug at a 340B discounted price, then the hospital should not bill the drug with modifiers “JG” or “TB”.

11. Will CMS accept modifier “JG” on packaged drugs (i.e., status indicator “N” drugs)?

Yes. For administrative ease, providers may report modifier “JG” on packaged drugs (assigned status indicator “N”) although such modifier will not result in a payment adjustment. However, modifier “JG” is not required to be reported for these packaged drugs.

12. Are hospitals required to bill the informational modifier “TB” for pass-through drugs?

Yes. The use of informational modifier “TB” for pass-through drugs (assigned status indicator “G”) acquired with a 340B discount is required by all hospitals except for CAHs and Maryland Waiver Hospitals.

13. How are providers to bill using the “JG” and “TB” modifiers on claims?

Each separately payable, non-pass through 340B-acquired drug should be billed on a separate claim line with the appropriate 340B modifier. The use of modifier “JG” will trigger a drug payment rate of ASP minus 22.5 percent. The use of modifier “TB” will have no effect on the drug payment rate.

For a claim with multiple drug lines, the appropriate 340B modifier is required on each line of a 340B-acquired drug. A 340B modifier is not required on claim lines of a non 340B-acquired drug (regardless of status indicator), a vaccine (assigned status indicator “F”, “L” or “M”), or a packaged drug (assigned status indicator “N”), but could be appended if a hospital chooses.

14. How are providers to bill for the discarded drug amount on 340B-acquired drugs? How does this affect modifiers that are already required for off-campus departments of a hospital?

The discarded drug amount should be billed on a separate claim line with the JW

April 2, 2018

modifier and the appropriate 340B modifier. Modifier “PO” or “PN” is also required if the 340B-acquired drug is furnished in an off-campus outpatient provider-based department of a hospital, in which case three modifiers will be reported on the drug HCPCS line. For example, a 340B-acquired drug (assigned status indicator “K”) furnished in an excepted off-campus department of a hospital, would bill one claim line with the drug HCPCS code and modifiers “JG” and “PO”, and another claim line with the drug HCPCS code and modifiers “JG”, “JW”, and “PO”. As a reminder, when multiple modifiers are reported, providers should report pricing modifiers first followed by descriptive modifiers.

Please refer to the JW modifier FAQ document for more information available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf>.

15. What happens if a provider inadvertently does not use the “JG” modifier on claims that include 340B-acquired drugs? What happens if a provider mistakenly reports modifier “JG” instead of “TB”?

Providers are advised that reporting modifier “JG” on a claim line with an OPPTS separately payable drug HCPCS code (assigned status indicator “G” or “K”) will trigger a payment adjustment of ASP minus 22.5 percent. It is the provider’s responsibility to submit correctly coded claims. We note again that there is no circumstance under which a provider should report the “JG” modifier on a claim line with status indicator “G;” although the provider should use the informational modifier “TB” on claims for pass-through drugs.

Federal law permits Medicare to recover its erroneous payments. Medicare requires the return of any payment it erroneously paid as the primary payer. Providers are required to submit accurate claims, maintain current knowledge of Medicare billing policies, and ensure all documentation required to support the validity of the services reported on the claim is available upon request.

16. Do hospitals need to report a 340B modifier if the drug or biological was purchased at wholesale acquisition cost (WAC) but not through the 340B program at a discounted rate?

We recognize that not all covered outpatient drugs acquired by a 340B hospital are purchased through the 340B Program. Participating 340B hospitals are responsible for knowing whether a 340B eligible drug was obtained under the 340B Program and for maintaining documentation. As discussed in Question 9 above, a 340B modifier is not required for a 340B-eligible drug that was not purchased under the 340B Program.

17. My hospital is unable to upgrade its billing software by January 1, 2018 to include modifiers “JG” and “TB” and because of cash flow concerns cannot hold claims. What recourse do I have?

April 2, 2018

Under section 1835(a) of the Act, providers have 12 months after the date of service to timely file a claim for payment. If a hospital believes that it will not be able to properly identify and bill accurately for 340B acquired drugs, it should contact its MAC to discuss whether holding claims or rebilling claims may be an option. Again, hospitals are required to be in compliance with all applicable 340B Program requirements and Medicare billing requirements.

18. How are providers to bill the 340B modifiers for drugs administered to dual-eligible beneficiaries? Is the “UD” modifier required for Medicaid?

When Medicare is either the primary or secondary payer, the appropriate 340B modifier is required in accordance with the OPPS 340B payment policy. Because Medicaid billing requirements vary by state, providers should contact the applicable State Medicaid Program for guidance on billing 340B drugs. Normal CMS policy and procedures and trading partner agreement requirements for coordination of benefits (COB) claims will be followed.

Version 02/27/2018
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Medicare Program
JW Modifier: Drug/Biological Amount Discarded/Not Administered To Any Patient
Frequently Asked Questions

Policy: Effective January 1, 2017, providers and suppliers are required to report the JW modifier on Part B drug claims for discarded drugs and biologicals. Also, providers and suppliers must document the amount of discarded drugs or biologicals in Medicare beneficiaries' medical records.

Resources:

MLN Matters MM9603 <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9603.pdf>; and

Chapter 17 of the CMS Medicare Claims Processing Manual (Section 40) - <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf>

General

Q1. What is the JW modifier?

A1. The JW modifier is a Healthcare Common Procedure Coding System (HCPCS) Level II modifier used on a Medicare Part B drug claim to report the amount of drug or biological (hereafter referred to as drug) that is discarded and eligible for payment under the discarded drug policy. The modifier shall only be used for drugs in single dose or single use packaging.

Q2. What is Medicare Part B's payment policy for discarded drugs?

A2. As described in Chapter 17, Section 40.1 of the Medicare Claims Processing Manual, in addition to paying for the amount of drug that has been administered to a beneficiary, Medicare Part B also pays for the amount of drug that has been discarded, up to the amount that is indicated on the vial or package label. The discarded drug amount is the amount of a single use vial or other single use package that remains after administering a dose/quantity of the drug to a Medicare beneficiary.

Q3. Why did CMS establish a national policy for the JW modifier?

A3. CMS is establishing a consistent policy among all MAC jurisdictions for the use of the JW modifier for discarded drugs that are associated with separately paid Part B drug claims. Prior policy allowed the MACs to choose whether to require the JW modifier. MACs were also able to issue jurisdiction-specific instructions for the use of the modifier.

Q4. Is the JW modifier required on claims for single-dose drugs and biologicals?

A4. Effective January 1, 2017, the modifier must be used in order to obtain payment for a discarded amount of drug in single dose or single use packaging under the Medicare discarded drug policy. The modifier is not required if no discarded drug is being billed to any payer. (Overfill is discussed in question #7.)

Q5. In which settings is the JW modifier required?

-  **A5.** This policy applies to providers and suppliers who buy and bill drugs and is intended to track discarded amounts of drugs that occur as a result of the preparation of a drug dose for administration to a beneficiary. We anticipate that the JW modifier will be used mostly in the physician's office and hospital outpatient settings for beneficiaries who receive drugs incident to physicians' services. The JW modifier requirement also applies to Critical Access Hospitals (CAHs) since drugs are separately payable in the CAH setting.

The modifier may also apply to some drugs furnished by suppliers such as pharmacies. However, we believe that those suppliers, particularly those who dispense drugs and do not actually administer the drug, or sell partial vials of sterile products, would not have discarded amounts to report on claims. Similarly, entities such as outsourcing facilities or pharmacies that prepare doses of sterile drugs that are administered and billed by other practitioners would not be subject to the requirements for using the JW modifier or documenting discarded drug quantities for a specific beneficiary because they would not be billing for these drugs. Also, in certain situations where sterile product repackaging or compounding is carried out, for example in a hospital pharmacy, and the drug is separately payable under Part B after administration incident to a physician's services, it may not be possible to quantify discarded quantities of drugs and associate them with a beneficiary, particularly when batch preparation of products is being done.

-  The JW modifier does not apply to drugs or biologicals administered in a Rural Health Clinic (RHC) or a Federally Qualified Health Center (FQHC). Drugs and biologicals 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. Exceptions are the influenza, pneumococcal, and Hepatitis B vaccines which are paid separately at cost through an RHC's or FQHC's cost report and not via a claim.

Finally, the JW modifier is not intended for use on claims for hospital inpatient admissions that are billed under the Inpatient Prospective Payment System. (See question #21 for additional information).

-  **Q6. To which drugs does the policy apply? How can a provider or supplier identify a drug that must be billed using the JW modifier?**

A6. In general, the modifier policy applies to all separately payable Part B drugs that are designated as single-use or single dose on the FDA-approved label or package insert. Accordingly, use of the modifier is not appropriate for drugs that are from multiple dose vials or packages. Package inserts are available on the FDA website at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>.

However, the JW modifier is not required for:

- Drugs that are not separately payable, such as packaged OPSS drugs or drugs administered in the FQHC or RHC setting.
- Drugs paid under the Part B drug Competitive Acquisition Program (CAP). The CAP remains on hold and there is no current list of CAP medications.

Q7. Does the JW modifier apply to drug overfill?

A7. The JW modifier must not be used to report overfill wastage. Beginning January 1, 2011, Medicare issued regulations 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) available at <https://www.federalregister.gov/articles/2010/11/29/2010-27969/medicare-program-payment-policies-under-the-physician-fee-schedule-and-other-revisions-to-part-b-for>.

Q8. Is the JW modifier applicable when the dose administered is less than the HCPCS billing unit?

A8. CMS does not use fractional billing units to pay for Part B drugs. Therefore, the JW modifier should not be used when the actual dose of the drug administered is less than the HCPCS billing unit.

Q9. Does a provider or supplier have the option to bill using the JW modifier now or should they wait until January 1, 2017?

A9. Providers and suppliers may report the JW modifier prior to January 1, 2017.

Q10. What happens if a provider or supplier does not use the JW modifier on claims that include discarded drugs?

A10. Claims for drugs furnished on or after January 1, 2017 containing billing for discarded drugs that do not use the JW modifier correctly may be subject to review.

Billing, Claims, and Documentation

Q11. How are providers and suppliers to bill using the JW modifier on claims?

A11. The drug discarded should be billed on a separate line with the JW modifier. The unit field should reflect the amount of drug discarded. Please refer to the example in the Medicare Claims Processing Manual Chapter 17, section 40 located at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf>.

Q12. Instead of reporting a second line with the discarded amount and price, may a provider/supplier report one line with the amount used and the adjusted price?

A12. No. To identify and monitor billing and payment for discarded drugs under Medicare Part B, CMS requires the use of the JW modifier on a separate claim line.

Q13. When using the JW modifier, should the dollar amount be included on the wastage line or should the line reflect units only?

A13. General billing rules may require a charge be included on each line on the claim. Also, each MAC that processes claims may have specific billing policies or guidance for certain items or services where there is not national billing guidance from CMS. Please contact your local MAC for further billing information.

Q14. Does CMS have specific requirements regarding documentation for discarded 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 kept? Is there a specific area in the medical record where the administered/discarded amount should be documented?

A14. CMS expects 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 Medicare. General guidance on documentation is available in MLN Matters SE 1316 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1316.pdf>). 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.

Q15. Will CMS accept an “automatic” calculation of waste, for example a calculation done by software, as documentation of waste within the medical record?

A15. As long as the amount of wastage is accurately documented, the CMS does not dictate how it is calculated.

Hospital Outpatient Prospective Payment System (OPPS)

Q16. When billing for services furnished in the hospital outpatient setting, does the JW modifier apply to all Part B claims including Part B inpatient (Type of Bill 12X)? Are eligible and participating 340B providers exempt from the JW modifier reporting?

A16. The JW 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 an unused or discarded amount. Eligible and participating 340B providers are not exempt from reporting the JW modifier.

Q17. Are hospitals required to report the JW modifier only when the applicable drug is billed with revenue code 636?

A17. The requirements for using the JW modifier are independent of revenue codes reporting. Providers should always use the most appropriate revenue code that applies to the service they are reporting.

Q18. Does the JW modifier apply to drugs (as well as skin substitutes and implantable biologicals) administered in the operating room to hospital outpatients?

A18. The JW modifier requirement applies 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 OPPS for which there is an unused or discarded amount.

Q19. Will the JW modifier be required on hospital outpatient claims for single-dose drugs and biologicals?

A19. The JW modifier is intended to quantify the amount of drug from a single-use or single-dose package that is discarded by the provider, and the modifier must be used in order to obtain

payment for a discarded amount of drug. In many cases, drugs are administered almost immediately after a single-use or single-dose package is opened by the provider. However, we recognize that in certain situations, for example when a hospital pharmacy's sterile preparation area prepares multiple doses of a drug in advance of when they are needed, discarded amounts of drug may not be possible to quantify. In such situations, where the quantity of discarded drug cannot be quantified, the JW modifier is not required. The JW modifier is also not required if the amount of drug that is discarded is less than the amount described by one HCPCS billing unit. See question #4 for additional information.

Q20. Does the JW modifier apply to OPPS drugs with status indicator N?

A20. No. The JW modifier does not apply to drugs assigned status indicator N (Items and Services Packaged into APC Rates) under the OPPS.

Q21. Are hospitals required to transfer the charges related to waste 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?

A21. In circumstances where the 3-day/1-day payment window applies, all hospital outpatient services (and associated charges), including drugs and biologicals, 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 and biologicals are not separately payable under the inpatient prospective payment system (IPPS) the JW modifier will not be required in this situation.

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