



Medicare Hospital Version

KEY CONCEPTS OUTLINE

Module 10: Outpatient Diagnostic Services

- 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 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.
 - B. Location
 1. The service must be furnished directly or under arrangement by the hospital and must be furnished in the hospital, a department of the hospital, or a non-hospital setting. <See 42 C.F.R. 410.28(a)(1); see *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)>
 - a) During the COVID-19 PHE, a physician's order is not required for one COVID-19 laboratory test and one test for influenza or similar respiratory condition in conjunction with the COVID-19 laboratory testing to rule out influenza. Subsequent test require a physician's order to be covered. <42 C.F.R. 410.32 (a) (3)>

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. Radiology and nuclear medicine services

- i. 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)>

d. Bone Mass Measurement

- i. 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)>

e. Limitations on Ordering Diagnostic Services

- i. Regulations at 42 C.F.R. 410.32 contain limitations on coverage of diagnostic services and require an order from the patient's treating physician. This requirement does not apply to hospital diagnostic services, other than clinical diagnostic laboratory tests. <See 42 C.F.R. 410.32(a); 62 Fed. Reg. 59057>
- ii. *Medicare Benefit Policy Manual* Section 80.6 contains further limitations restricting the ability of the interpreting physician and/or facility to change a diagnostic test order or order additional tests. These limitations do not apply to hospital diagnostic services. <Medicare Benefit Policy Manual, Chapter 15 § 80.6>

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. 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; See 42 C.F.R. 410.28(e)>

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

- a. Supervision for diagnostic services must be provided by a physician or a non-physician practitioner (NPP) to the extent they are authorized to do so under their scope of practice and applicable State law. <See 42 C.F.R. 410.28(e)>
 - i. NPPs able to provide supervision for diagnostic services are physician assistants, nurse practitioners, clinical nurse specialists, certified nurse-midwives, or certified registered nurse anesthetists. <See 42 C.F.R. 410.28(e)>
- b. General supervision, indicated by a “01” on the MPFS, requires the service be furnished under the overall direction and control of the physician or NPP, but they need not be present during the performance of the procedure. <See 42 C.F.R. 410.28(e)(1)>
 - i. Training of the non-physician personnel who perform the diagnostic procedure and the maintenance of the equipment and supplies are the continuing responsibility of the hospital. <See 42 C.F.R. 410.28(e)(1); see *Medicare Benefit Policy Manual*, Chapter 6 § 20.4.4>
- c. Direct supervision, indicated by a “02” on the MPFS
 - i. For services provided in the hospital or a hospital department, direct supervision requires the physician or NPP be immediately available to provide assistance and direction throughout the performance of the procedure. <See 42 C.F.R. 410.28(e)(2)(i); see *Medicare Benefit Policy Manual*, Chapter 6 § 20.4.4>
 - a) The physician or NPP 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>

- ii. For services furnished under arrangement by the hospital in non-hospital locations, direct supervision requires the physician or NPP be present in the office suite and immediately available to provide assistance and direction throughout the performance of the procedure. <See 42 C.F.R. 410.28(e)(2)(ii)>
- iii. Until the end of the calendar year the COVID-19 PHE ends, the presence of the physician or NPP for purposes of direct supervision includes virtual presence through audio/video real-time communications technology. <See 42 C.F.R. 410.28(e)(2)(iii)>
- iv. The physician or NPP 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 or NPP 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 or NPP 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>
- d. Personal supervision, indicated by a “03” on the MPFS, requires the physician or NPP be in the room during the performance of the procedure. <*Medicare Benefit Policy Manual*, Chapter 15 § 80; see 42 C.F.R. 410.28(e)(3)>
- e. Under MPFS regulations, non-physician practitioners may personally perform diagnostic tests with the level of supervision required for general coverage of that NPPs services. <See *Medicare Benefit Policy Manual*, Chapter 6 § 20.4.4; 42 C.F.R. 410.32(b)(2); 85 *Fed. Reg.* 84590-592>

The technical portion of a test that is personally performed by an NPP eligible to supervise the test within their scope of practice would presumably be provided under personal supervision of the NPP, meeting the highest level of supervision required for coverage of hospital diagnostic services.

f. 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. 410.28(f); 42 C.F.R. 410.32(b)(2)(vi)>

Case Study 1

Facts: A patient presents to an off-campus provider based urgent care clinic several miles from the hospital. The clinic is staffed by nurse practitioners, who are the only providers at the location. A nurse practitioner orders a chest x-ray for suspected pneumonia. The patient receives the chest x-ray in the provider-based radiology department next door, which is staffed by radiology technicians. The radiologists are located at the main campus of the hospital and are available by phone to provide supervision to the radiology technicians while the off-campus radiology department is open. A chest x-ray has a supervision indicator of “1” in the Medicare Physician Fee Schedule. Is the chest x-ray covered?

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

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

B. Implementation

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

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

- a. Even though claims will not be denied, the ordering practitioner is required to consult the CDSM and the rendering providers are required to report AUC/CDSM information on claims effective January 1, 2020. <Medicare One Time Notification Transmittal 2404; 42 C.F.R. § 414.94(j) and (k)>

C. Ordering Practitioner Requirements

1. The ordering physician must consult a CDSM, unless an exception applies, when ordering applicable advanced imaging services that will be furnished in an applicable setting and paid under an applicable payment system. <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; 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. <Medicare One Time Notification Transmittal 2404>

E. Applicable Settings

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

F. Applicable Payment Systems

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

G. Reporting Requirements

1. An applicable advanced imaging service must be reported with an appropriate informational modifier -MA through -MH indicating if a CDSM was consulted, if the order adheres to the AUC of the CDSM or if a special circumstance applies (e.g., a hardship exception). <Medicare One Time Notification Transmittal 2404; see MLN Matters SE20002>
 - a. If modifiers -ME (the order adheres to AUC), -MF (the order does not adhere to AUC), or -MG (the service does not have AUC) are reported, a G code representing the CDSM consulted must also be reported. <Medicare One Time Notification Transmittal 2404; see MLN Matters SE20002>
 - i. CMS has provided a list of G-codes corresponding to various approved CDSMs, including G1011 for CDSM not otherwise specified for newly approved CDSM products. The current list is included in the materials behind the outline. <Medicare One Time Notification Transmittal 2404; see MLN Matters SE20002>
 - ii. The CDSM G codes are reported with the same date of service as the advanced imaging service, a revenue code corresponding to the advanced imaging service (i.e. the same revenue code as the advanced imaging service or the corresponding XXX9 revenue code), and a nominal charge of \$.01. For claims examples see MLN Matters SE20002. <See MLN Matters SE20002>
 - b. If the ordering practitioner does not provide the furnishing provider AUC related information, modifier -MH is reported. <Medicare One Time Notification Transmittal 2404; see MLN Matters SE20002>
 - i. Modifier -MH will not be accepted after the Educational and Operational Testing Period and claims without appropriate AUC modifiers will be returned to the provider for correction. <86 Fed. Reg. 65241>

2. Each line with an applicable advanced imaging service must be reported separately in the K3 segment with the ordering provider's NPI, using the AUC indicator and LX to indicate the service line per the format and claims examples in *MLN Matters SE20002* included in the materials behind the outline. <See *MLN Matters SE20002*>
 - a. If the same ordering provider is associated with multiple lines (i.e. they ordered multiple applicable advanced imaging services), each line must be reported separately, resulting in the same ordering provider's NPI being reported multiple times in the K3 segment. <*Medicare One Time Notification Transmittal 2425*>

III. Imaging Family Composites

- A. There are three imaging families and five imaging family composite APCs. The codes included in each imaging family and composite are published in Table 3 of the CY2023 OPPS Final Rule, included in the materials behind the outline. <See 87 *Fed. Reg.* 71774-71777>

1. Imaging Families:

- a. Ultrasounds of the chest, pelvic and abdominal area;
- b. CT/CTA of the head, neck, spine, pelvis, colon, and upper and lower extremities; and
- c. MRI/MRA of the head, spine, chest, heart, pelvis, and upper and lower extremities. <See 87 *Fed. Reg.* 71774-71777; see *IOCE Specifications*, Section 5.5.8 (Supplement)>

2. Multiple Imaging Family Composite APCs:

- a. APC 8004, Ultrasound Composite;
- b. APC 8005, CT and CTA without Contrast Composite;
- c. APC 8006, CT and CTA with and without Contrast Composite;
- d. APC 8007, MRI and MRA without Contrast Composite;
- e. APC 8008, MRI and MRA with and without Contrast Composite. <See 87 *Fed. Reg.* 71774-71777; see *IOCE Specifications*, Section 5.5.8 (Supplement)>

B. Mechanics of the Imaging Family Composite APCs

1. Composite payment is made when two or more imaging procedures from a single “imaging family” are performed on a single date of service. <73 Fed. Reg. 68566; IOCE Specifications, Section 5.5.8 (Supplement)>
 2. If multiple imaging procedures from the same family are performed, and at least 1 is performed with contrast, the “with and without Contrast” APC will be paid. <73 Fed. Reg. 68566; IOCE Specifications, Section 5.5.8 (Supplement)>
- C. The multiple imaging family composites have a status indicator S, meaning they will not be reduced if they are on the same claim with other procedures or services. <73 Fed. Reg. 68566>

IV. Special Radiology Payment Modifiers

A. Modifier -CT

1. Specified computed tomography (CT) scans furnished on equipment that does not meet the NEMA Standard¹ must be reported with modifier –CT. <Medicare Claims Processing Manual, Chapter 4 § 20.6.13>
 - a. Modifier –CT applies to CT scan codes specified in the IOCE Quarterly Data Files, Report-Tables folder, “DATA_HCPCS”, column CS “NON_STANDARD_CT_SCAN” available on the IOCE homepage.
2. If a CT scan reported with modifier –CT is paid separately, the payment is reduced by 15%. <Medicare Claims Processing Manual Transmittal 3685>
3. If a CT scan is paid as part of an Imaging Family Composite APC (APCs 8005 and 8006), the APC Composite payment is reduced by 15%. <Medicare Claims Processing Manual Transmittal 3685; IOCE Specifications, Section 5.5.8 (Supplement)>
 - a. No reduction is applied to CT scans reported with modifier –CT, that are packaged into payment for other services (i.e. composite or comprehensive APCs). <IOCE Specifications, Section 5.5.8 (Supplement)>

B. Modifier -FX

1. An x-ray taken using film must be reported with modifier -FX. <Medicare Claims Processing Manual, Chapter 4 § 20.6.14>

¹ National Electrical Manufacturers Association (NEMA) Standard XR-29-2013 (“Standard Attributes on CT Equipment Related to Dose Optimization and Management”)

- a. Modifier –FX applies to radiology codes specified in the IOCE Quarterly Data Files, Report-Tables folder, “DATA_HCPCS”, column CT “FILM_XRAY” available on the IOCE homepage.
- 2. If an x-ray reported with modifier -FX is paid separately, the payment is reduced by 7%. <Medicare Claims Processing Manual, Chapter 4 § 20.6.14>
 - a. The payment reduction for x-rays reported with modifier -FX will increase to 10% in 2023. <Medicare Claims Processing Manual, Chapter 4 § 20.6.14>

C. Modifier -FY

- 1. An x-ray taken using computed radiography technology/cassette-based imaging must be reported with modifier -FY. <Medicare Claims Processing Manual, Chapter 4 § 20.6.15>
- 2. If an x-ray reported with modifier -FY is paid separately, the payment is reduced by 7%. <Medicare Claims Processing Manual, Chapter 4 § 20.6.15>
 - a. The payment reduction for x-rays reported with modifier -FY will increase to 10% in 2023. <Medicare Claims Processing Manual, Chapter 4 § 20.6.14>

V. Radiation Therapy

A. Intensity Modulated Radiation Therapy (IMRT)

- 1. Certain specified treatment planning codes are included in and should not be reported in addition to IMRT planning code 77301 (“Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications”) when provided prior to or as part of the IMRT plan. <Medicare Claims Processing Manual, Chapter 4 § 200.3.1; MLN Matters Article SE 18013>
 - a. The list of specified treatment planning codes that should not be reported with IMRT planning (CPT code 77301) is provided in *Medicare Claims Processing Manual*, Chapter 4 § 200.3.1, included in the materials behind the outline.
 - b. This reporting limitation applies whether the services described by the specified treatment planning codes are provided on the same or a different date of service as the IMRT planning (CPT code 77301). <Medicare Claims Processing Manual, Chapter 4 § 200.3.1>

2. Simple, intermediate and complex simulated field settings (CPT codes 77280, 77285 and 77290) should not be reported for verification of the treatment field during a course of IMRT. <Medicare Claims Processing Manual, Chapter 4 § 200.3.1>

B. Stereotactic Radiosurgery (SRS)

1. Reporting of SRS

- a. Delivery of SRS is differentiated between the type of equipment use for single session cranial SRS and delivery of fractionated (multiple session) SRS for either cranial or other lesions. <Medicare Claims Processing Manual, Chapter 4 § 200.3.2>
 - i. A single session of cranial SRS delivered with multi-source cobalt-60 based equipment should be reported with CPT code 77371 (“Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multisource cobalt 60 based”). <Medicare Claims Processing Manual, Chapter 4 § 200.3.2>
 - ii. A single session of cranial SRS delivered with linear accelerator (“Linac”) based equipment should be reported with CPT code 77372 (“Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based”). <Medicare Claims Processing Manual, Chapter 4 § 200.3.2>
 - iii. For any fractionated (multiple session) SRS deliver, including multiple session cranial SRS, each fraction or session, including the first, is reported with CPT code 77373 (“Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions”) <Medicare Claims Processing Manual, Chapter 4 § 200.3.2>
- b. In addition to treatment delivery, SRS planning services should also be reported as appropriate. <Medicare Claims Processing Manual, Chapter 4 § 200.3.2>

2. Payment for SRS

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

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

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

- a) The list of the 10 specific planning codes that will be paid separately from the C-APC for SRS is provided in the OPPS Final Rule, included in the materials behind the outline.

VI. Billing Issues Relating to Outpatient Clinical Diagnostic Laboratory Services

A. Date of Service

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

a. Exceptions

i. Specimens Stored for More than 30 days

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

ii. Specimens Stored for 30 Days or Less and Chemotherapy Sensitivity Tests Performed on Live Tissue

- a) The date of service should be the date the test was performed if all the following criteria are met:
 - 1) The specimen was collected during a hospital surgical procedure and it would have been medically inappropriate to have collected the specimen in another way;

- 2) The test was ordered or the decision regarding the chemotherapeutic agent was made at least 14 days following discharge from the hospital;
 - 3) The results of the test did not guide treatment during the hospital stay; and
 - 4) The test was reasonable and medically necessary for treatment of an illness. <42 C.F.R. 414.510 (b)(2)(i), and (b)(3); *Medicare Claims Processing Manual*, Chapter 16 § 40.8>
- iii. Molecular pathology tests, Advanced Diagnostic Laboratory Tests (ADLTs), and cancer-related protein based Multianalyte Assays with Algorithmic Analysis (MAAA)
- a) The date of service should be the date the test was performed if all of the following are met:
 - 1) The test was performed following discharge from a hospital outpatient department encounter;
 - 2) The specimen was collected from a hospital outpatient during the encounter;
 - 3) It was medically appropriate to collect the sample from the outpatient during the encounter;
 - 4) The results of the test do not guide treatment provided during the hospital outpatient encounter; and
 - 5) The test was reasonable and medically necessary for the treatment of an illness. <42 C.F.R. 414.510(b)(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>
 - c) Molecular pathology tests performed by blood banks or blood centers are excluded from this policy. A blood bank or center is 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. <*Medicare Claims Processing Manual*, Chapter 16 § 40.8 C>

- d) CMS updates the list of codes subject to this policy quarterly as needed and the most current list is available on the CMS website.

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

2. The date of service for a specimen collection that spans two calendar days is the date the collection ended. <42 C.F.R. 414.510(b)(1); *Medicare Claims Processing Manual*, Chapter 16 § 40.8>

Case Study 2

Facts: A Medicare patient presents to the emergency department of a hospital on Monday, February 1, at 11 pm 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 are performed on the blood at 12:15 a.m. on Tuesday, February 2. Drugs are administered to the patient and the lab test is repeated at 6 a.m. The patient is discharged home at 8 a.m. What line item date of service should be used for the laboratory tests? How is the laboratory test paid?

Modified Facts: The patient is later admitted to the same hospital on Friday, February 5 for repair of a broken hip following a fall in their home. Should the laboratory tests performed during the emergency department encounter for congestive heart failure be billed on the claim for the inpatient admission or separately on the outpatient claim for the emergency department visit?

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”, but payment is generally packaged into other services on the claim. <*Medicare Claims Processing Manual*, Chapter 16 § 100.5.1; 80 *Fed. Reg.* 70350>

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

2. Modifier Usage

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

C. Organ/Disease Panels

1. What is an Organ/Disease Panel?

- a. “Panels” are groups of lab test 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, it should be reported separately with modifier -91. <National Correct Coding Initiative Policy Manual for Medicare Services, Chapter 1, Section N>
- d. Code 80050 (General Health Panel) is assigned status indicator E1 (Not covered by any Medicare outpatient benefit category/Statutorily excluded/Not reasonable and necessary).

Caution: Medicare may cover one or more of the individual tests or panels included in 80050 if they are medically necessary. In order 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 don’t fit a covered screening /preventative benefit.

D. Add-on Codes for High-Throughput CDLT for Detection of COVID-19

1. CMS makes a \$75 payment for high-throughput COVID-19 tests billed with HCPCS codes U0003 and U0004, and an additional \$25 add-on payment when add-on code U0005 is billed. <CMS Ruling CMS-2020-1-R2>
 - a. In order to bill the add on code U0005, the hospital must meet the following two criteria:
 - i. The CDLT must be completed within 2 days of the specimen collection; and
 - ii. The laboratory must have completed the majority of the high throughput CLDTs for all patients in the prior calendar month in 2 calendar days or less from specimen collection. <CMS Ruling CMS-2020-1-R2>
 - b. Code U0005 must be billed on the same day as U0003 or U0004 or IOCE Edit 115 will trigger a line item denial. <IOCE Specifications, Section 4.2.1 (Supplement)>

VI. Payment for Clinical Diagnostic Laboratory Services

Medicare makes separate payment for clinical diagnostic laboratory services under the Clinical Laboratory Fee Schedule (CLFS) for:

- Molecular pathology, Advanced Diagnostic Laboratory Tests (ADLTs) and covered screening /preventative services
- Laboratory services billed on a claim without other outpatient services
- Non-patient (reference lab) tests

A. Molecular Pathology, ADLTs² and Certain Screening/Preventative Services

1. Laboratory services with a status indicator A, including molecular pathology, ADLTs and certain screening/preventative services, are paid separately on the CLFS. <See *IOCE Specifications*, Section 5.4.5 (Supplement)>

B. Only Clinical Diagnostic Laboratory Services on the Claim

² Advanced Diagnostic Laboratory Tests (ADLT) are offered and furnished by a single laboratory that designed the test, is not sold for use by other laboratories, and is an analysis of DNA, RNA or protein biomarkers giving the probability of developing specific conditions or responding to particular therapies.

1. Laboratory services, with status indicator Q4, are paid separately under the CLFS when no other services with status indicators J1, J2, S, T, V, Q1, Q2 or Q3 are provided and billed on the same claim as the laboratory service. <80 Fed. Reg. 70350, *Medicare Claims Processing Manual*, Transmittal 3425>

C. Reference Laboratory Services

1. Laboratory services, regardless of status indicator, provided to non-patients (commonly called reference lab services) are paid separately on the CLFS. <*Medicare Claims Processing Manual*, Transmittal 2845>
2. Non-patient reference laboratory services should be billed on TOB 14X. <*Medicare Claims Processing Manual Transmittal 734*, *Medicare Claims Processing Manual Transmittal 2845*, *Official UB-04 Data Specifications Manual*>
 - a. A non-patient is a patient who has a specimen sent to the hospital for testing but is not an inpatient or outpatient and is not physically present at the hospital. <*Medicare Benefit Policy Manual*, Chapter 6 § 70.5; *Medicare Claims Processing Manual*, Transmittal 2845>
 - b. An otherwise non-patient (i.e., reference lab) test is billed as an outpatient test (i.e., on TOB 013X) if the patient receives other outpatient services on the same day as the specimen collection and laboratory test. <*Medicare Benefit Policy Manual*, Chapter 6 § 70.5>
 - c. If a hospital, other than a CAH or Maryland hospital, only collects or draws a specimen and the patient does not have any other outpatient services that day, the hospital may choose to bill the specimen collection on an outpatient claim (TOB 013X) or a non-patient claim (TOB 014X). <*Medicare Benefit Policy Manual*, Chapter 6 § 70.5>
3. Medicare Secondary Payer Information for Non-Patients
 - a. CMS does not require hospitals to collect Medicare secondary payer information for “reference laboratory services.” <*Medlearn Matters Article MM3064*>

Case Study 3

Facts: General Memorial Hospital receives a blood sample for Martha Smith for testing related to congestive heart failure. The sample was drawn that morning during Martha's visit to her cardiologist, who's practice is a freestanding practice not related to General Memorial Hospital. Later that day Martha trips and injures her ankle. She presents to General Memorial Hospital's urgent care clinic and the urgent care clinic physician orders an x-ray of the ankle. She is diagnosed with a sprained ankle and discharged home. Is the laboratory test billed as an outpatient lab test or non-patient reference lab test? What bill type should be used to bill the test? How would this laboratory test be paid?

VII. The Clinical Lab Fee Schedule

Link: Clinical Diagnostic Laboratory Fee Schedule – Overview Page under Medicare-Related Sites – General

- A. The payment rate for a Clinical Diagnostic Laboratory Tests (CDLT), including ADLTs paid under the CLFS prior to January 1, 2018, is set at the weighted median private payor rate. <42 C.F.R. 414.507 (a), (d)>
 1. 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>
 2. For ADLTs, the weighted median private payor rate is recalculated every year, based on a one-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
 1. Implementation of median private payor rates has been extended and there is a 0.0% reduction to laboratory rates in CY2023. <42 C.F.R. 414.507(d); Consolidated Appropriations Act of 2023, Sec 4114>
 2. In calendar years 2024-2026, 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); Consolidated Appropriations Act of 2023, Sec 4114>
- C. Diagnostic and screening pap smear codes, by statute, 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. <Medicare Claims Processing Manual Transmittal 4182; Social Security Act § 1833(h)(7)>

1. The national minimum amount for CY2023 is \$17.31. <Medicare Claims Processing Manual Transmittal 11186>
 2. 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>
- E. Exceptions to the CLFS:
1. Critical Access Hospitals (CAHs)
 - a. Clinical diagnostic laboratory services provided to patients of the CAH are paid at 101% of reasonable cost. <Medicare Claims Processing Manual, Chapter 16 § 30.3>
 - b. Non-patient lab services, however, are reimbursed based on the fee schedule methodology. <Medicare Claims Processing Manual, Chapter 16 § 30.3>
 2. Waiver Hospitals
 - a. For hospitals granted a waiver from Medicare payment principles for outpatient services (i.e., Maryland waiver hospitals), most clinical diagnostic lab services are reimbursed on a reasonable charge basis. <Medicare Claims Processing Manual, Chapter 16 § 30.3>
 - b. Non-patient lab services, however, are reimbursed based on the fee schedule methodology. <Medicare Claims Processing Manual, Chapter 16 §§ 10.2 and 30.3>
- F. Deductibles and Coinsurance
1. Medicare deductibles and coinsurance do not apply to services paid for under the CLFS. <Medicare Claims Processing Manual, Chapter 16 § 30.3>
 2. Medicare deductibles and coinsurance do not apply to laboratory HCPCS paid on a reasonable cost basis to CAHs. <Medicare Claims Processing Manual, Chapter 16 § 30.3>
 - a. Presumably “laboratory HCPCS codes” are laboratory services paid on the CLFS to OPPS hospitals.

3. Medicare deductible and coinsurance apply to diagnostic lab services (except for non-patient lab services) provided by waiver hospitals and paid under the waiver plan. <Medicare Claims Processing Manual, Chapter 16 § 30.3>

VIII. 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 039X (Administration, Processing and Storage for Blood and Blood Components); General Classification (0390), Processing and Storage (0392), Other Blood Handling(0399). <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, but 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). <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) 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, Section 5.8, 5.8.1 (Supplement)>
- 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>

Tip: 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 of time.

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>

Version 01/09/2023
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CASE STUDIES WITH ANALYSIS

Case Study 1

Facts: A patient presents to an off-campus provider based urgent care clinic several miles from the hospital. The clinic is staffed by nurse practitioners, who are the only providers at the location. A nurse practitioner orders a chest x-ray for suspected pneumonia. The patient receives the chest x-ray in the provider-based radiology department next door, which is staffed by radiology technicians. The radiologists are located at the main campus of the hospital and are available by phone to provide supervision to the radiology technicians while the off-campus radiology department is open. A chest x-ray has a supervision indicator of “1” in the Medicare Physician Fee Schedule. Is the chest x-ray covered?

Analysis: Yes. Even though a nurse practitioner cannot provide supervision of diagnostic services, only general supervision is required for diagnostic services with a supervision indicator of “1”. The availability of the radiologist by phone will satisfy this requirement. <Medicare Benefit Policy Manual, Chapter 6 § 20.4.4; 42 C.F.R. 410.32(b)(3)(i)>

Case Study 2

Facts: A Medicare patient presents to the emergency department of a hospital on Monday, February 1, at 11 pm 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 are performed on the blood at 12:15 a.m. on Tuesday, February 2. Drugs are administered to the patient and the lab test is repeated at 6 a.m. The patient is discharged home at 8 a.m. What line item date of service should be used for the laboratory tests? How is the laboratory test paid?

Analysis: 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 the sample was drawn on February 1, even though the test was performed on February 2. The laboratory test drawn and performed on February 2 should be billed with the line item date of service of February 2. The laboratory tests will be packaged and no separate payment will be made.
<Medicare Claims Processing Manual, Chapter 3 § 40.3>

Modified Facts: The patient is later admitted to the same hospital on Friday, February 5 for repair of a broken hip following a fall in their home. Should the laboratory tests performed during the emergency department encounter for congestive heart failure be billed on the claim for the inpatient admission or separately on the outpatient claim for the emergency department visit?

Analysis: The laboratory test billed with the date of service of February 1 should be billed separately on the claim for the emergency department visit because it occurred outside the three-day window. The laboratory test billed with the date of service of February 2 should be billed on the inpatient claim even though it is unrelated to the admission because all outpatient diagnostic tests performed in the three days before admission should be combined to the inpatient claim regardless of whether they are related.
<Medicare Claims Processing Manual, Chapter 3 § 40.3>

Case Study 3

Facts: General Memorial Hospital receives a blood sample for Martha Smith for testing related to congestive heart failure. The sample was drawn that morning during Martha's visit to her cardiologist, who's practice is a freestanding practice not related to General Memorial Hospital. Later that day Martha trips and injures her ankle. She presents to General Memorial Hospital's urgent care clinic and the urgent care clinic physician orders an x-ray of the ankle. She is diagnosed with a sprained ankle and discharged home. Is the laboratory test billed as an outpatient lab test or non-patient reference lab test? What bill type should be used to bill the test? How would this laboratory test be paid?

Analysis: The laboratory test is an outpatient lab test because the patient received other outpatient services from the hospital on the same day as the specimen was received by the hospital for testing. The test would be billed on a type of bill 0131 along with the urgent care clinic and x-ray. The laboratory test is packaged to the other services on the claim. <Medicare Benefit Policy Manual, Chapter 6 § 70.5; Medicare Claims Processing Manual, Transmittal 2845>

Medicare Benefit Policy Manual, Chapter 6, Excerpt

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

20.5.1 - Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After August 1, 2000, and Before January 1, 2010

(Rev. 128, Issued: 05-28-10, Effective: 07-01-10, Implementation: 07-06-10)

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

Title 42 - Public Health

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

Subchapter B - Medicare Program

Part 410 - Supplementary Medical Insurance (SMI) Benefits

Subpart B - Medical and Other Health Services

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

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

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

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

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

Hospital or CAH diagnostic services furnished to outpatients:...

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

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

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

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

Computerized Tomography

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

Single-Photon Emission Computed Tomography

76390

Nuclear Medicine

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

C codes

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

HCPCS Modifiers

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

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

G codes

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

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

MLN Matters Number: SE20002

Related Change Request (CR) Number: N/A

Related CR Release Date: January 9, 2020

Effective Date: N/A

Related CR Transmittal Number: N/A

Implementation Date: January 1, 2020

PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

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

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

Key Points

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

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

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

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

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

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

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

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

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

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

K3 Examples:

Reporting 1 Ordering Professional NPI

K3*AUC LX1DK111111111~

Reporting 5 Ordering Professional NPIs

K3*AUC LX1DK111111111 LX11DK999999999 LX22DK111111111 LX433DK222222222~

K3*AUC LX444DK444444444~

Qualified CDSM specific HCPCS not yet available

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

2400 — SERVICE LINE

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

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

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

2400 — SERVICE LINE

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

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

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

Multiple consultations of the same CDSM

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

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

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

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

Option One

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

0351 test 1 unit

0352 test 2 unit

0359 CDSM 2 units

-or use the alternate approach -

Option Two

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

0351 test 1 unit

0351 CDSM 1 unit

0352 test 1 unit

0352 CDSM 1 unit

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

Option One

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

0351 test 1 unit

0359 CDSM 1 units

0611 test 1 unit

0619 CDSM 1 unit

-or use the alternate approach -

Option Two

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

0351 test 1 unit

0351 CDSM 1 units

0611 test 1 unit

0611 CDSM 1 unit

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

0351 test 1 unit with contrast

0351 test 1 unit without contrast

0351 CDSM 2 units

0611 test 1 unit with contrast

0611 test 1 unit without contrast

0611 CDSM 2 units

Claim Examples

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

ADDITIONAL INFORMATION

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

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

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

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

DOCUMENT HISTORY

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

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

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

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

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

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

BILLING CODE 4120-01-C

3. Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

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

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

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

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

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

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

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

200.3.1 - Billing Instructions for IMRT Planning and Delivery

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

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

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

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

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

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

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

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

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

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

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

200.4 - Billing for Amniotic Membrane

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

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

200.5 - Reserved

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

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

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

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

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

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

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

These codes were removed from the geometric mean cost calculations for C-APC 5627. In addition, for CY 2016 and CY 2017, we provided separate payment for the 10 planning and preparation services adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC-based technology, even when the planning service was included on the same claim as the primary “J1” SRS treatment service. The use of the modifier “CP” was not required to identify these 10 planning and preparation codes.

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

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

For CY 2018, we also proposed to continue to make separate payments for the 10 planning and preparation services adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC-based technology when furnished to a beneficiary within 1 month of the SRS treatment. The continued separate payment of these services will allow us to complete our analysis of the claims data including modifier “CP” from both CY 2016 and CY 2017 claims. As stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583), we will consider in the future whether repackaging all adjunctive services (planning, preparation, and imaging, among others) back into cranial single session SRS is appropriate.

We invited public comments on these proposals.

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

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to make separate payments for the 10 planning and preparation services adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC-based technology when furnished to a beneficiary within 1 month of the SRS treatment.

(5) Complexity Adjustment for Blue Light Cystoscopy Procedures

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



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

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

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

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

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

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

should therefore be excluded from OPPS packaging policy and subject to the laboratory DOS exception at § 414.510(b)(5) as described in section II.A. of this final rule. We intend to continue to study the list of laboratory tests included the laboratory DOS exception policy and to determine whether any additional changes are warranted and may consider proposing future changes to this policy through notice-and-comment rulemaking. For these reasons and in light of the commenters' suggestions, we are revising the current laboratory DOS exception at 42 CFR 414.510(b)(5) to include cancer-related protein-based MAAAs, such as CPT codes 81500, 81503, 81535, 81536, 81539, as well as the test described by CPT code 81490. We are also finalizing that we will exclude cancer-related protein-based MAAAs that do not currently exist, but that are developed in the future, from the laboratory DOS policy.

XIX. Physician-Owned Hospitals

A. Background

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

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