



## KEY CONCEPTS OUTLINE

### Module 12: 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); *Medicare Benefit Policy Manual*, Chapter 6 § 20.4.4>
  - C. Order
    - 1. The service must be furnished on the order of a physician or NPP as discussed below:
      - a. Clinical Diagnostic Laboratory Tests
        - i. Clinical diagnostic laboratory tests must be provided only on the order of a physician or NPP who is treating the patient and uses the results in the management of the beneficiary's specific medical problem. <See 42 C.F.R. 410.28(f); see 42 C.F.R. 410.32(a)>
      - b. Mammogram exception
        - i. A beneficiary may self-refer themselves for a screening mammogram without an order from a treating physician. <*Medicare Benefit Policy Manual*, Chapter 15 § 280.3>

c. 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). <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); 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); 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. <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. Through December 31, 2024, 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. <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. <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. <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. <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 would consult a Clinical Decision Support Mechanism (CDSM) before ordering advanced imaging services for a Medicare patient, and information about the CDSM, or an exception, were to be reported on the claim for the advanced imaging service in order for the claim to be paid.

### B. Permanent Delay

1. CMS has rescinded the AUC regulations and providers and suppliers should no longer submit AUC information on their claims. Additionally, CMS will no longer quality CDSMs. See the Appropriate Use Criteria Program website.

Link: Appropriate Use Criteria Program under Medicare-Related Sites – General

## 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 CY2024 OPPI Final Rule, included in the materials behind the outline. <See 88 Fed. Reg. 81568-72>

### 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 88 *Fed. Reg* 81568-72; see *IOCE Specifications*, Section 6.5.7 (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 88 *Fed. Reg* 81568-72; see *IOCE Specifications*, Section 6.5.7 (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 6.5.7 (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 6.5.7 (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 Standard<sup>1</sup> 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 6.5.7 (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 6.5.7 (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>
  - 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 10%. <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 10%. <Medicare Claims Processing Manual, Chapter 4 § 20.6.15>

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

## 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 or in the *IOCE Specifications*, Section 6.20 in the Supplement.
  - 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>
  - c. If the specified codes are reported on the same claim as the IMRT planning code 77301, edit 125 of the IOCE will cause the claim to be returned to the provider. <IOCE Specifications, Section 6.20 (Supplement)>
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 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>
2. 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 as 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

### 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.

## 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, ADLTs<sup>2</sup> 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 6.4.5 (Supplement)>

### B. Only Clinical Diagnostic Laboratory Services on the Claim

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>

<sup>2</sup> 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.

- 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) is set at the weighted median private payor rate, based on payment data from providers on a three-year data collection cycle, except for ADLTs on a one year data collection cycle. <42 C.F.R. 414.507 (a), (d); 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 CY2024 and no more than a 15% reduction from the prior year’s rate in CY2025-CY2027. <42 C.F.R. 414.507(d); Further

*Continuing Appropriations and Other Extensions Act of 2024, Section 502;  
Medicare Claims Processing Manual Transmittal 12389>*

- 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 CY2024 is \$17.76. *<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 6.9 (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>

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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>

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## Title 42 — Public Health

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

#### Subchapter B — Medicare Program

#### Part 410 — Supplementary Medical Insurance (SMI) Benefits

#### Subpart B — Medical and Other Health Services

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

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

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

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

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

- (i) For services furnished directly or under arrangement in the hospital or in an on-campus or off-campus outpatient department of the hospital, as defined in § 413.65 of this chapter, “direct supervision” means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room where the procedure is performed.
  - (ii) For services furnished under arrangement in nonhospital locations, “direct supervision” means the physician or nonphysician practitioner must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed.
  - (iii) Through December 31, 2024, 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; 88 FR 82177, Nov. 22, 2023]

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

<b>Family 1 – Ultrasound</b>	
<b>CY 2024 APC 8004 (Ultrasound Composite)</b>	<b>CY 2024 Approximate APC Geometric Mean Cost = \$314.27</b>
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 <sup>st</sup> target lesion
<b>Family 2 - CT and CTA with and without Contrast</b>	
<b>CY 2024 APC 8005 (CT and CTA without Contrast Composite) *</b>	<b>CY 2024 Approximate APC Geometric Mean Cost = \$231.39</b>
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

<b>CY 2024 APC 8006 (CT and CTA with Contrast Composite)</b>	<b>CY 2024 Approximate APC Geometric Mean Cost = \$439.51</b>
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.	
<b>Family 3 - MRI and MRA with and without Contrast</b>	
<b>CY 2024 APC 8007 (MRI and MRA without Contrast Composite) *</b>	<b>CY 2024 Approximate APC Geometric Mean Cost = \$537.26</b>
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
<b>CY 2024 APC 8008 (MRI and MRA with Contrast Composite)</b>	<b>CY 2024 Approximate APC Geometric Mean Cost = \$854.60</b>
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 4150-28-P

## 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 payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage

their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which may occur if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the

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.

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

As instructed in the CY 2014 OPPI/ASC final rule, CPT code 77371 is to be used only for single session cranial SRS cases performed with a Cobalt-60 device, and CPT code 77372 is to be used only for single session cranial SRS cases performed with a linac-based device. The term “cranial” means that the pathological lesion(s) that are the target of the radiation is located in the patient’s cranium or head. The term “single session” means that the entire intracranial lesion(s) that comprise the patient’s diagnosis are treated in their entirety during a single treatment session on a single day. CPT code 77372 is never to be used for the first fraction or any other fraction of a fractionated SRS treatment. CPT code 77372 is to be used only for single session cranial linac-based SRS treatment. Fractionated SRS treatment is any SRS delivery service requiring more than a single session of SRS treatment for a cranial lesion, up to a total of no more than five fractions, and one to five sessions (but no more than five) for non-cranial lesions. CPT code 77373 is to be used for any fraction (including the first fraction) in any series of fractionated treatments, regardless of the anatomical location of the lesion or lesions being radiated. Fractionated cranial SRS is any cranial SRS that exceeds one treatment

session and fractionated non-cranial SRS is any non-cranial SRS, regardless of the number of fractions but never more than five. Therefore, CPT code 77373 is the exclusive code (and the use of no other SRS treatment delivery code is permitted) for any and all fractionated SRS treatment services delivered anywhere in the body, including, but not limited to, the cranium or head. 77372 is not to be used for the first fraction of a fractionated cranial SRS treatment series and must only be used in cranial SRS when there is a single treatment session to treat the patient's entire condition.

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

<b>CPT Code</b>	<b>Long Descriptor</b>
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 OPPS/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

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