Chapter Six
Medicare Policies Affecting Diagnostic Imaging Services

Since 2005, Congress and the Centers for Medicare and Medicaid Services (CMS) have instituted a range of policies affecting the reimbursement and utilization of diagnostic imaging services, especially “advanced diagnostic imaging services,” such as MRI, CT, PET/CT and other nuclear procedures (including SPECT).

In general, these policies have been adopted in response to the growth in the utilization prior to 2006 and to the perception that some of the procedures were medically unnecessary. Although utilization has leveled-off or declined since then, this perception has persisted among many policy leaders. The result has been continued efforts to reduce or otherwise limit reimbursement and utilization. This chapter summarizes the most significant changes affecting Medicare reimbursement for imaging.

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Background

Medicare pays for imaging services through several different payment systems.

- **Physician Fee Schedule**: Medicare uses this system to reimburse providers for interpreting diagnostic imaging tests in all delivery settings and facilities. It also uses this system to reimburse providers for the cost of equipment, non-physician clinical personnel (such as RTs), supplies, and overhead in non-hospital facilities. These include physicians’ offices and diagnostic imaging centers. In Medicare parlance, such equipment, staff, and services are referred to as “Technical Component” (or “TC”) physician fee schedule services.

- **Hospital Outpatient Prospective Payment System (HOPPS)**: Medicare uses this system to pay for the equipment, non-physician clinical staff, supplies, and overhead associated with diagnostic imaging services that are provided in hospital outpatient departments and “provider-based” facilities.

- **Inpatient Prospective Payment System**: Medicare makes payment for diagnostic imaging services for hospital inpatients as part of the payment made for the hospital admission.
Policy Changes in Non-Hospital Settings

Cap on Technical Component Payments

The Deficit Reduction Act of 2005 set a cap on the technical component of diagnostic imaging services performed in physician offices and independent diagnostic testing facilities (IDTFs). Specifically, the law limited the TC in these settings to the amount paid for comparable services provided in hospital outpatient facilities. The cap applies to virtually all radiology services, including MRI and CT.

*Effective Date:* January 1, 2007.

*Impact:* The cap primarily affects MRI, CT, PET and certain ultrasound services (especially vascular ultrasound), but not myocardial perfusion imaging (SPECT) imaging. Although the cap is still in place, over time the TC allowances for many of the services that were initially affected decreased to an amount that is now below the hospital outpatient rate for comparable services, making the cap inapplicable. Thus, the impact of this cap on Medicare allowances for imaging services overall has decreased.

Mandatory Accreditation for MRI, CT, and Nuclear Facilities

All non-hospital providers of MRI, CT, PET and other nuclear procedures (including PET/CT and nuclear cardiology procedures) are required to be accredited by the Joint Commission, the American College of Radiology (ACR), or the Intersocietal Accreditation Commission (IAC). All of these accreditation organizations maintain quality standards that address the safety of the equipment as well as the safety of the patients and staff.

*Effective Date:* January 1, 2012.

*Impact:* The accreditation requirements vary depending on which of the three approved accreditation organizations is used, but the accreditation process may include:
Unannounced, random site visits;
Review of phantom images;
Review of staff credentialing records and maintenance records;
Review of beneficiary complaints and patient records;
Review of quality data and ongoing data monitoring; and
Triennial surveys

For additional Q & A, see Summary of Final Rule Provisions for Accountable Care.

Multiple Procedure Payment Reductions on Technical Component Services

Medicare reduces payment for the second and subsequent TC of MRI, CT and certain (non-cardiology) ultrasound services by 50% when two or more of these services are provided to the same patient during a single session. This reduction applies even if the two procedures do not use the same modality (e.g., when an ultrasound and an MRI are performed in the same session).

For certain ophthalmic and cardiology procedures (including SPECT and echocardiography procedures), the TC for the second and subsequent TC is reduced by 25%, rather than 50%.

Effective Date: The 50% reduction in the TC of the second and subsequent CT, MRI and certain ultrasound services became effective on January 1, 2011. The 25% reduction in the TC of the second and subsequent cardiology and ophthalmic procedures became effective on January 1, 2013.

Impact: This “multiple procedure payment reduction” or “MPPR” discourages the performance of more than one study on the same date of service in non-hospital settings. The initial impact was especially harsh for CT services. However, some of that impact has been mitigated by the creation of new codes that include procedures commonly performed together (e.g. abdominal and pelvic CTs), thus making the MPPR inapplicable.
As for cardiology procedures, the primary service combination affected by this limitation appears to be myocardial perfusion (SPECT) and transthoracic echocardiography (TTE) performed on the same date of service. In addition, other relatively common service combinations affected by the MPPR include vascular and other ultrasound services performed on the same date of service as echocardiography.

**Restrictions on Physician Self-Referral**

The federal physician self-referral law (commonly called the “Stark Law”) precludes a physician from sending patients who need diagnostic imaging and radiation therapy services to facilities in which the physician has a financial relationship. However, an exception in the law allows physicians that provide MRI, CT, or PET to make such self-referrals if they:

- inform the patient *in writing* that the patient may obtain the service from a clinician other than the referring physician, and
- provide the patient with a list of suppliers that furnish the service in the area.

*Effective Date:* Disclosure of alternative facility requirements became effective on January 1, 2011.

*Impact:* To date, no formal studies have been done on the impact of the disclosure policy on physician practices. However, the Stark Law generally remains a constraint on the types of ventures that can provide diagnostic imaging, radiation therapy, and many other services.

**Equipment Utilization Rate Assumption**

The formula for determining the technical component amount for MRI and CT services in non-hospital settings assumes that such equipment is used 90% of the time—an increase from 75% which had been used in the formula for many years. The net effect of this change is a *substantial decrease* in Medicare reimbursement for technical component services for MRI and CT in non-hospital settings.
Effective Date: January 1, 2014

Impact: Implementation of the 90% utilization assumption will reduce Medicare payment for the TC of MRI and CT procedures by approximately $800 million in 2014, according to Congressional Budget Office. It is important to recognize that the 90% equipment utilization rate assumption is not used in determining Medicare payment for CT or MRI services provided by hospital outpatient departments.
Policy Changes in Hospital and Non-Hospital Settings

National Coverage Determination for FDG PET and FDG CT/PET

Although Medicare coverage policy for FDG PET and FDG PET/CT services was initially limited, CMS decided in 2009 to expand it for Medicare beneficiaries diagnosed with cancer. The ruling covered PET scans used in the initial evaluation of patients with most types of solid tumors and allowed for PET in subsequent evaluations for several cancer types. However, the 2009 coverage decision also required providers to participate in a device registry—the National Oncologic PET Registry (NOPR)—as a condition of coverage for a number of different cancer types and for subsequent evaluations.

In 2013, CMS eliminated the NOPR participation requirements. It also determined that it would allow PET scans under specific circumstances for certain cancer types that had not been included in its 2009 expansion of coverage. Specifically, it determined that Medicare would cover three FDG PET scans when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anticancer therapy. Coverage of any additional FDG PET scans (that is, beyond three) used in this way would have to be determined by local Medicare administrative contractors.

Effective Date: Effective for claims with dates of service on and after June 11, 2013, the chart below summarizes national FDG PET coverage for oncologic conditions:

<table>
<thead>
<tr>
<th>FDG PET for Solid Tumors and Myeloma Tumor Type</th>
<th>Initial Treatment Strategy (formerly “diagnosis” &amp; “staging”)</th>
<th>Subsequent Treatment Strategy (formerly “restaging” and “monitoring response to treatment”)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Esophagus</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Head and Neck (not thyroid or CNS)</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Cancer Type</td>
<td>Coverage Status</td>
<td>Notes</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>---------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Non-small cell lung</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Ovary</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Brain</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Cervix</td>
<td>Cover with exceptions *</td>
<td><strong>Cervix:</strong> Nationally non-covered for the initial diagnosis of cervical cancer related to initial anti-tumor treatment strategy. All other indications for initial anti-tumor treatment strategy for cervical cancer are nationally covered.</td>
</tr>
<tr>
<td>Small cell lung</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Soft tissue sarcoma</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Pancreas</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Testes</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Prostate</td>
<td>Non-cover</td>
<td><strong>Breast:</strong> Nationally non-covered for initial diagnosis and/or staging of axillary lymph nodes. Nationally covered for initial staging of metastatic disease. All other indications for initial anti-tumor treatment strategy for breast cancer are nationally covered.</td>
</tr>
<tr>
<td>Thyroid</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Breast (male and female)</td>
<td>Cover with exceptions *</td>
<td><strong>Melanoma:</strong> Nationally non-covered for initial staging of regional lymph nodes. All other indications for initial anti-tumor treatment strategy for melanoma are nationally covered.</td>
</tr>
<tr>
<td>Melanoma</td>
<td>Cover with exceptions *</td>
<td>Cover</td>
</tr>
<tr>
<td>All other solid tumors</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Myeloma</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>All other cancers not listed</td>
<td>Cover</td>
<td>Cover</td>
</tr>
</tbody>
</table>

*Notes:*

- **Cervix:** Nationally non-covered for the initial diagnosis of cervical cancer related to initial anti-tumor treatment strategy. All other indications for initial anti-tumor treatment strategy for cervical cancer are nationally covered.

- **Breast:** Nationally non-covered for initial diagnosis and/or staging of axillary lymph nodes. Nationally covered for initial staging of metastatic disease. All other indications for initial anti-tumor treatment strategy for breast cancer are nationally covered.

- **Melanoma:** Nationally non-covered for initial staging of regional lymph nodes. All other indications for initial anti-tumor treatment strategy for melanoma are nationally covered.
Value Based Modifier and Impact on Diagnostic Imaging

The ACA requires that, by 2015, CMS must implement a system to adjust physician payment to reflect performance on the value of services physicians provide to patients. Under the system CMS established to implement this “Value-Based Modifier,” both the cost and the quality of services provided to a physician group’s Medicare patients are considered. Physicians in groups of 100 or more eligible professionals who submit claims to Medicare under a single tax identification number will be subject to the value modifier in 2015, based on their performance in calendar year 2013. CMS has extended the system to smaller groups based on their performance in 2014.

Effective Date: January 1, 2015, for groups of 100 or more eligible professionals (with adjustments based on 2013 performance); January 1, 2016, for groups of 10 or more eligible professionals (based on 2014 performance).

Impact: Under the Value-Based Modifier, CMS determines a “Cost Composite Score” for the Medicare beneficiaries attributable to a physician group. This score summarizes the group’s performance on costs based on two equally weighted domains: “Per Capita Costs for All Attributed Beneficiaries” and “Per Capita Costs for Beneficiaries with Specific Conditions (diabetes, coronary artery disease, chronic obstructive pulmonary disease, and heart failure).” The costs both of hospital outpatient services (including imaging services performed in hospital outpatient departments) and ancillary services (including imaging services performed in non-hospital settings) are included in each group’s cost profile for the purposes of determining the group’s Cost Composite Score. Thus, under this program, each physician group whose payment is subject to the “Value Based Modifier” has a general incentive to minimize the Medicare costs (including imaging costs) of beneficiaries.
Meaningful Use of Electronic Health Records

The Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs provide incentive payments and penalties to encourage eligible professionals, eligible hospitals, and critical access hospitals to demonstrate meaningful use of certified EHR technology. CMS has established the objectives for “meaningful use” that providers must meet in order to receive incentive payments and avoid penalties.

The requirements are staged in three steps, with increasing demands at each level. All providers must meet Stage 1 requirements for a 90-day period during their first year of meaningful use and, during the second, they must meet the requirements for the entire year. Providers are then required to meet Stage 2 requirements for two full years.

Effective dates: Providers must begin participation in the Medicare EHR Incentive Program no later than 2014. Beginning in 2015, those who do not successfully demonstrate meaningful use will be subject to a payment reduction. The payment reduction starts at 1% and increases each year to a maximum of 5%.

Impact: Meaningful use Stage 2 for “eligible professionals” (including radiologists and other imagers) includes a “core”—or mandatory—measure requiring computerized physician order entry for at least 30% of radiology procedures. In addition, clinical decision support must be used for “high priority” health conditions.

Among the optional measures is a requirement that imaging studies and reports be accessible through the Electronic Health Record. This does not require that EHRs store radiology images, but it does mandate that referring physicians or attending physicians in hospitals be able to access at least 10% of their patients’ studies (the image plus accompanying text) via links in the EHR. The imaging measures for hospitals are similar.
Policy Changes in Hospital Settings

Packaging Imaging-Related Services in Hospital Outpatient Payment System

In 2008, Medicare decided to “package” payment for seven categories of ancillary items and services in the hospital outpatient payment classifications they support. The seven categories are:

1. guidance services;
2. image processing services;
3. intraoperative services;
4. imaging supervision and interpretation services;
5. diagnostic radiopharmaceuticals;
6. contrast media; and
7. observation services.

Many of these are imaging services or items used in conjunction with imaging procedures, such as diagnostic radiopharmaceuticals and other drugs. For 2014, Medicare expanded the list of packaged items to include additional drugs and biologicals, certain clinical laboratory tests, and certain add-on and ancillary services, such as stress tests and stress agents used in conjunction with stress imaging procedures.

Effective Date: Calendar year 2014 for stress tests and stress agents and additional drugs and biologicals.

Impact: Medicare’s policies are intended to eliminate the financial incentive for providing ancillary and supportive services except as necessary for patient care. It is unclear whether these policies have, in fact, affected utilization of such services.
Composite APCs for Multiple Imaging Procedures

Medicare makes a single, composite payment when a hospital performs more than one imaging procedure on the same day from an “imaging family” of services. The intent is to promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session. The five multiple imaging composite APCs established in 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

Effective Date: January 2009

Impact: While this policy is intended to encourage efficiency in providing multiple imaging services on the same date of service, it may have the effect of encouraging hospitals to refrain from scheduling necessary multiple imaging services on the same date of service.
Hospital Quality Reporting Program for Outpatient Services

Medicare pays hospitals an additional fee for reporting their performance on a wide range of quality measures for care provided in hospital outpatient departments. These may include measures of process, structure, outcome, and efficiency. As part of this, CMS has adopted six measures to reduce unnecessary exposure to contrast materials and/or radiation, ensure adherence to evidence-based medicine and practice guidelines, and promote efficiency defined as "absence of waste."

Effective Date: Varies by measure

Impact: This policy is intended to reduce unnecessary utilization of contrast materials, multiple procedures, imaging of pre-operative patients undergoing minor surgery, and other practices that are not consistent with medical guidelines. Hospitals failing to meet these requirements are subject to a 2% reduction in hospital outpatient payment. The vast majority of hospitals meet the requirements.