



American Association of Physicists in Medicine

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Office of the President

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Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1525-FC
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: Comments regarding Intraoperative Radiation Therapy Codes 77424 and 77425 assigned comment indicator “NI”; 2012 Hospital Outpatient Prospective Payment System Final Rule (CMS-1525-FC)

The American Association of Physicists in Medicine¹ (AAPM) respectfully submits the following comments regarding the assignment of status indicator ‘N’ to new CPT codes for Intraoperative Radiation Therapy (IORT) treatment delivery: 77424 *Intraoperative radiation treatment delivery, x-ray, single treatment session*; and 77425 *Intraoperative radiation treatment delivery, electrons, single treatment session* effective January 1, 2012.

In the 2012 Hospital Outpatient Prospective Payment System (HOPPS) Final Rule published in the November 30, 2011 *Federal Register*, CMS assigned status indicator “N” to CPT codes 77424 and 77425 in both the hospital outpatient and ambulatory surgical care setting, indicating that these procedures would be packaged with the primary procedure and receive no separate payment.

Intraoperative radiation therapy is a method of delivering an entire course of radiation therapy in a single fraction (treatment). This procedure is performed during surgery, typically after a cancerous tumor is removed by a surgeon. Historically, this procedure required transport of an anesthetized patient to a radiation oncology department shielded radiation vault. Recent improvements have allowed this equipment to be located in a surgical environment that meets radiation safety guidelines.

¹The American Association of Physicists in Medicine (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 7,000 medical physicists.

IORT requires the presence of a radiation oncologist and a qualified medical physicist. In addition, IORT utilizes specialized equipment that is not used to perform or support a surgical procedure. The equipment must be registered by a state regulatory department and follow the guidelines in place for other radiation producing systems.

Currently, CMS considers IORT treatment delivery to be an ancillary or supportive part of a surgical procedure and proposes to package this service with associated surgical services. However, this proposed policy is incorrect as IORT is a standalone radiation therapy procedure that is completely separate from the surgical procedure. In fact, surgeons do not perform IORT, as it is not in their scope of practice. This modality is therapeutic in nature with potential benefit, but due to the high doses of radiation delivered also carries significant risk to both the patient and the operator. Other "intraoperative" services currently packaged under the HOPPS utilize staff and equipment normally present in the operative suite. IORT treatments are delivered by staff using equipment that is outside the typical surgical process.

Prior to the creation of CPT 77424 and 77425, IORT services were reported using a variety of codes including CPT 77412-77416 electron beam therapy, 77799 unlisted procedure for clinical brachytherapy, and 0182T high dose rate electronic brachytherapy. The work effort provided by the medical physicist in the process of the delivery of this radiation is not captured by other codes. Medical physicist work includes:

- Patient-specific calibration of the x-ray source, including verification of probe alignment to within 0.1mm, radiation mapping of source symmetry, and the absolute calibration of source output. For electron delivery systems, calibration of electron energies prior to delivery for each individual patient.
- Setup and disassembly of the high intensity delivery system used for treatment delivery in the surgical suite. This involves positioning of the unit and console for use inside the operating room, placement of protective shielding and signage, verification, and recording of data for personnel requiring radiation monitoring during the procedure.
- Consultation with the radiation oncologist on the positioning of the treatment device and fields based on the patient's anatomy at the time of treatment delivery and any pre-treatment CT or ultrasound based planning.
- Verification of all radiation oncologist-entered prescription parameters in the radiation delivery system and coordination of the technical operation of the radiation delivery.
- Maintenance and validation of all calibration and patient-specific treatment records.

The IORT procedure is not ancillary to the standard surgical procedure, but rather is a separate, resource intensive, specialized service that is provided in the surgical suite and should receive separate payment in addition to the surgical procedure.

AAPM recommends that CMS remove status indicator "N" and correctly apply status indicator "S" or "X" to IORT treatment delivery codes 77424 and 77425 before January 1, 2012. In addition, CPT codes 77424 and 77425 codes should be reassigned to a New Technology APC with an appropriate payment level while CMS collects claims data.

In summary, AAPM strongly recommends that the work effort represented by medical physicists, as well as the expense associated with specialized IORT equipment, be acknowledged in the treatment delivery of this important new technology. IORT is clearly not an ancillary or supportive service and should not be classified as a "packaged" service by CMS.

We hope that CMS will take this issue under consideration and make the necessary changes prior to January 1, 2012. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (561) 637-6060.

Sincerely,

A handwritten signature in cursive script that reads "J. Anthony Seibert". The signature is written in black ink and is positioned above the typed name.

J. Anthony Seibert, Ph.D., FAAPM
President