

Advanced Medical Strategies
Winter 2011 Newsletter

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Spotlight On: Intraoperative Radiation Therapy

Intraoperative radiation therapy (IORT) is designed to increase the intensity of radiation directly delivered to tumors. The tumor volume and associated tissues at risk for micrometastatic spread are directly visualized at the time of the surgery. IORT is delivered directly to the tumor volume, and normal or uninvolved tissues are not exposed to radiation because they are removed or shielded from the treatment field.

IORT is performed with applicators and cones that attach to the treatment head of high-energy medical linear accelerators and that are designed to direct radiation to defined surface structures.

This is performed by different techniques including intraoperative electron beam techniques and high-dose rate brachytherapy. IORT is usually given in combination with external-beam radiation therapy with or without chemotherapy and surgical resection.

Typically, IORT is used for:

- Recurrent, noncentral cervical cancer with positive or close margins
- Recurring uterine/endometrial cancer confined to the pelvis
- Retroperitoneal/intraabdominal sarcoma with positive or close margins
- Colon cancer with T4 or recurrent cancer
- Rectal cancer with positive or close margins with T4 or recurrent cancer

The addition of IORT to conventional treatment methods has improved local control as well as survival in many disease sites in both the primary and locally recurrent disease settings. Some major payors only cover it for rectal cancer, others for cervical cancer, colon cancer, and uterine cancer. More recently, there has been interest in the use of IORT as a technique of partial breast irradiation for women with early breast cancer but no major payors cover it for breast cancer. It has traditionally been considered experimental for that. IORT has been shown to be slightly more cost-effective than external beam radiation therapy when it is used alone. As there is wide coverage variation, its used should be reviewed for medical necessity.

Guidant to pay the US Government \$9.25 M for False Claims Act Allegations

In September 2011, Guidant LLC, a wholly owned subsidiary of Boston Scientific Corp., agreed to pay the United States \$9.25 million to resolve False Claims Act allegations. The government alleges that the company inflated the cost of replacement pacemakers and defibrillators to federal health care programs by knowingly failing to grant warranty credits and rebates to hospitals for pacemakers and defibrillators that were explanted while covered under a product warranty or another credit program.

The settlement resolves allegations that Guidant actively promoted the longevity and reliability of its pacemakers and defibrillators to physicians in an effort to convince them to purchase Guidant products over competing devices. Guidant reinforced these claims by touting the generous credits available should a device need to be replaced while covered under warranty. At the same time, Guidant allegedly was fully aware that it failed to grant an appropriate credit to the purchaser of the device in a large number of cases where a product failed while still under warranty. As a result, the United States contends that Guidant submitted invoices to Department of Veterans Affairs

hospitals and Department of Defense facilities that overstated the cost for a replacement pacemaker or defibrillator. In addition, Guidant's alleged submission of inflated invoices for pacemakers and defibrillators to private hospitals caused these hospitals to overstate the cost of these devices on hospital cost reports, resulting in Medicare paying more for pacemakers and defibrillators than it otherwise should have.

The civil settlement resolves allegations contained in a whistleblower lawsuit filed in federal court in the Middle District of Tennessee under the qui tam provisions of the False Claims Act, which allow for private citizens to bring civil actions on behalf of the United States and share in any recovery. As part of the resolution, the whistleblower will receive more than \$2.3 million from the settlement amount. This resolution is part of the government's emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative.

Harvard Pilgrim Plan Seeks To Reduce Costs

Told they need a routine medical test, such as a colonoscopy or a mammogram, most patients go wherever the doctor recommends. But under a program being rolled out January 2012 by Harvard Pilgrim Health Care, they could be paid to seek care somewhere else. The health insurer plans to introduce a rewards program through which its Massachusetts members who have been given referrals will be asked to call a "clinical concierge" service that can direct them to hospitals or medical facilities that charge less for the same tests. In return, they will receive a check from Harvard Pilgrim, ranging from \$10 to \$75.

The program, called SaveOn, is intended to help patients make smarter health care choices, according to Harvard Pilgrim, and to rein in the runaway prices of imaging tests and other procedures that have contributed to steadily rising premiums. "It's the kind of decision patients aren't making today because they don't have the information," said Eric H. Schultz, chief executive of Harvard Pilgrim, the state's second-largest health insurer. "Doctors are still referring patients for diagnostics based on the way they've always done it, without regard for the cost. But we can't sit around and accept behavior that drives costs up with little or no impact on quality."

But some doctors are skeptical of anything that would take away from them decisions about where to refer patients. They say they are in the best position to vouch for the quality of medical test providers and have longstanding relationships with testing companies that get them data quickly and accurately. Dr. Rick Lopez, a primary care internist and chief medical officer of Newton's Atrius Health stated "When I refer a patient for a test or an imaging, I'm taking into account what the patient needs and I'm referring the patient to a place where there's quality. And I know that from experience."

Harvard Pilgrim officials were expected to meet with regulators from the state Division of

Insurance, which must approve the program before it can be marketed as an add-on to the insurance products the company sells to businesses and other employers. If the program succeeds in moderating reimbursements for everything from MRIs and CT scans to ultrasounds and sleep studies, employers will likely want their own financial reward.

Immune Globulin Therapy Not Effective For Neonatal Sepsis

Neonatal sepsis is a major cause of death and complications despite antibiotic treatment. More Effective adjunctive treatments are needed. Newborn infants are relatively deficient in endogenous immunoglobulin so this has been looked at as a potential therapy. Meta-analyses of trials of intravenous immune globulin for suspected or proven neonatal sepsis suggest a reduced rate of death from any cause, but the trials have been small and have varied in quality.

In September 2011, the New England Journal of Medicine published results for this therapy from a multi-center trial. At 113 hospitals in nine countries, the authors enrolled 3493 infants receiving antibiotics for suspected or proven serious infection and randomly assigned them to receive two infusions of either polyvalent IgG immune globulin (at a dose of 500 mg per kilogram of body weight) or matching placebo 48 hours apart. The primary outcome was death or major disability at the age of 2 years. There was no significant between-group difference in the rates of the primary outcome, which occurred in 686 of 1759 infants (39.0%) who received intravenous immune globulin and in 677 of 1734 infants (39.0%) who received placebo. Similarly, there were no significant differences in the rates of secondary outcomes, including the incidence of subsequent sepsis episodes. In follow-up of 2-year-old infants, there were no significant differences in the rates of major or non-major disability or of adverse events. Based on this, the authors concluded that Therapy with intravenous immune globulin had no effect on the outcomes of suspected or proven neonatal sepsis.

Immunoglobulin therapy can be extraordinary costly, even at only two doses. It is also likely to see the therapy be given for longer than the authors' duration. If claims are received with this treatment, reimbursement should be pended until further medical review is completed to assess the medical necessity of the therapy.

FDA Approves New Drug for Myelofibrosis

In November 2011, the FDA Approved Jakafi (ruxolitinib) for myelofibrosis. Jakafi is indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis. Myelofibrosis is an increase of abnormal red blood cells inside the bone marrow resulting in extensive scarring. This causes anemia, fatigue, pain, night sweats, and swelling of the spleen.

Currently, the disease is treated with chemotherapy or bone marrow transplantation, and some patients are ineligible for the procedures. Jakafi is the first and only product to be approved by the FDA for myelofibrosis, and the first in a new class of drugs, known as JAK inhibitors, to be approved for any indication. Jakafi is an oral JAK1 and JAK2 inhibitor. The FDA approved the drug based on two studies that included 528 patients with the disease. Patients were randomly assigned to receive a placebo or Jakafi. More patients in the drug group saw a significant reduction in the size of their spleen as well as a 50 percent decrease in symptoms.

The starting dose of Jakafi is 20 mg given orally twice daily for patients with a platelet count greater than $200 \times 10^9/L$, and 15 mg twice daily for patients with a platelet count between $100 \times 10^9/L$ and $200 \times 10^9/L$. The dose is increased based on response and as recommended to a maximum of 25 mg twice daily. It should be discontinued after 6 months if there is no spleen reduction or symptom improvement.

The drug's maker, Delaware-based Incyte, stated that Jakafi will cost \$7,000 a month, or \$84,000 for a year's supply. It is only available through specialty pharmacies.

From The Claims Files-A Case Study

A recent AMS case illustrates the benefit of the physician input that is a routine part of our claims process and how a proactive TPA worked with AMS to maximize the value of the claim screen process and achieve a highly desirable outcome.

In the case at hand, a 1350 gram premature infant was born at 28.5 weeks. The infant was critically ill at birth with suspected pulmonary hypoplasia. An echocardiogram documented PPHN (persistent hypertension of newborn), and she was treated with high frequency ventilation and inhaled nitric oxide. Despite 29 days of treatment on high levels of support, her condition deteriorated and ultimately led to her death.

Overall charges for this claim totaled \$1,452,564 million, and our client requested a claim review to assess the charges and see if there were cost containment opportunities.

Our screening physician questioned the use of inhaled nitric oxide for this patient, which accounted for \$559,649 of the total charges. Our screening physician recommended that a neonatal specialist review the case to determine whether or not treatment with inhaled nitric oxide was medically necessary and whether or not the treatment was considered experimental or investigational. Our client agreed to proceed with the specialist review.

The physician specialist's review determined that the treatment was not medically necessary and was considered experimental. According to the plan language, this \$559,649 was therefore non-reimbursable. This enormous savings for the client would not have been discovered in a financial

audit.

Upon our recommendations, the client then proceeded with a financial audit of the remaining \$892,915, finding additional savings of 43% above the PPO discount. The net savings from the audit amounted to \$382,838. The client's overall responsibility for this claim dropped from \$1,016,794 million to just \$242,203.

Within the industry, our physician-driven claims reviews are unique. This case illustrates how substantially clients can benefit from our routine medical assessments of all claims that are submitted to AMS.

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