



the medical Review

Spotlight On: *MammoSite Therapy For Breast Cancer*

In 2002, the FDA approved MammoSite therapy for early stage breast cancer. MammoSite is a form of brachytherapy where the device delivers radiation directly to the area where a breast tumor has been surgically removed via lumpectomy. Standard breast brachytherapy involves surgically implanting up to 24 catheters into the breast, where MammoSite requires only a single catheter to perform the therapy. The system consists of a balloon catheter that is inserted into the area of the breast where the tumor was removed. Once inserted, the balloon is expanded and radiation is delivered through a tiny bead attached to a wire, irradiating the area surrounding the cavity. The seed stays inside the balloon for about 5-10 minutes and is then removed. The treatment is given twice a day over 5 consecutive days then the catheter is removed. External beam radiation therapy is usually given over a period of 5-7 weeks, so the treatment

duration is significantly reduced for the patient. This is also performed on an outpatient basis.

The American Society of Breast Surgeons and the American Brachytherapy Society have both outlined guidelines for patient selection. Both agree that MammoSite is effective for invasive ductal carcinoma but disagree as to the effectiveness for ductal carcinoma in situ. Both require tumor size of three centimeters or less, negative microscopic surgical margins of excision and negative lymph nodes. There is some disagreement in age with one recommending patients be over 45 years old and the other recommending this treatment for patients greater than 50 years old. Results have been very promising with this treatment when compared to external beam radiation therapy. The total cost for MammoSite treatment is approximately \$15,000-\$20,000.

NEWS IN BRIEF...

Patients suffering from conditions such as stroke, blindness, deafness, incontinence, glaucoma or hydrocephalus will be the first to benefit from a range of new medical devices. A consortium of 27 universities, research centers, hospitals, technology companies and manufacturers is developing new micro-technologies for implantable medical devices of the future.

New Radiation Software Given FDA Approval

A medical software company, CMS Inc., has won FDA approval for a new cancer treatment computer program. Monaco software is used in a cancer treatment method known as Intensity-Modulated Radiation Therapy (IMRT), where oncologists destroy tumors in patients with precise doses of radiation delivered with computer-controlled X-ray accelerators. Monaco helps radiation oncologists accurately model a radiation plan to treat cancer in patients.

IMRT accuracy is very important when trying to approach a tumor located in a difficult area. Too much radiation can damage unaffected surrounding organs and too little radiation would not

destroy the tumor. The program is based on the Monte Carlo Method, a technique of solving complex mathematical problems with computational algorithms. Monaco is a stand-alone program and it can be loaded on ordinary computers.

The software costs more than \$100,000 and the manufacturer has plans to distribute it nationally. Currently, 21 medical institutions have ordered Monaco and CMS Inc. expects it will bring in \$10 million in revenue next year. These costs will most likely be passed onto payors in escalating IMRT billed charges. IMRT billed charges range from \$1,800-\$3,000/session and will likely increase.

Manufacturer prices for a cardiac defibrillator range from \$18,000 to \$30,000.

THE BOTTOM LINE



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Sudden cardiac death accounts
for 50% of deaths due to coronary
artery disease.

Current Treatment Trend: Remicade

Remicade is a relatively new treatment available in the arsenal to treat many autoimmune disorders. The immune system protects the body by responding to bacteria and viruses by producing antibodies and putting them into action to fight off infections. In autoimmune disorders like psoriasis, rheumatoid arthritis, Crohn's disease, ulcerative colitis, and ankylosing spondylitis, TNF causes the immune system to attack healthy tissues resulting in inflammation and damage. Remicade is a protein that binds to tumor necrosis factor (TNF) and prevents TNF from performing its natural immune functions. Remicade will not cure the underlying disorder but its action reduces inflammation in patients.

Remicade is given as an intravenous infusion and its dosage and frequency varies depending on the disorder it is being given for. In most indicated autoimmune disorders, patients are given

an initial treatment with Remicade then are placed on maintenance infusions to prevent further "flare-ups". The recommended dose of Remicade generally is 5 mg/kg given as an intravenous induction regimen at 0, 2 and 6 weeks followed by a maintenance regimen of 5 mg/kg every 8 weeks. In rheumatoid arthritis, Remicade should only be given in combination with Methotrexate. It can be given either alone or in combination with Methotrexate for psoriatic arthritis.

Remicade is quite expensive in comparison to other drugs that have similar FDA approved indications (Enbrel and Humira). This is likely due to the fact that Remicade is given as an intravenous infusion while both Enbrel and Humira can be self administered with subcutaneous injection. Although average wholesale price for Remicade is \$671/100mg, the billed charges can be over \$15,000/dose.

Bill Introduced To Release Device Pricing

In October 2007, Senator Arlen Specter (R-PA) introduced a congressional bill that would require device manufacturers to disclose prices. The companies that make implantable medical devices including defibrillators and artificial joints would report prices to the government each quarter and that information would be released to the public.

A recent lawsuit between PA based health care research firm ECRI Institute and Guidant over whether hospitals can be required to keep price information confidential ended fittingly with a confidential settlement. ECRI had sued for the right to gather price information from hospitals and then share average and low prices. Guidant countersued arguing that its deals with hospitals were confidential. The case would have gone

to Federal Court in December 2007 had the parties not reached an agreement and it does not appear that price data will be released in the near future.

The Specter bill argues that high device prices are passed on to the government and other payors and that price negotiations are currently one sided due to the lack of information available. The bill's primary purpose is to allow smaller hospitals to have more leverage when negotiating with manufacturers since most currently invoke a confidentiality clause. This bill is another step towards price transparency allowing the market to become competitive and create a fair playing field. This would clearly allow payors more information about true hospital costs which could be utilized in contract and claim negotiations.

