

Debate surrounds new prostate-cancer treatment

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CyberKnife radiosurgery -- which uses narrow beams of radiation to kill several types of cancer -- is marketed as a less invasive, more convenient way to treat prostate cancer, a pitch that has proved convincing for about 3,000 men over the last six years.

But some <u>prostate-cancer</u> experts have reservations. Because prostate cancer grows slowly and because radiation side effects can emerge after many years, they say it is too soon to call the treatment a success.

And those concerns have unleashed a battle over insurance payments that may soon leave thousands of men unable to afford this increasingly popular option.

Highmark <u>Medicare</u> Services Inc., which administers payments for 4.2 million Medicare subscribers in Pennsylvania, New Jersey, Delaware, Maryland, and Washington, D.C., is considering dropping most coverage for the treatment. It plans to make a decision later this month.

Medicare has not set a national standard. The treatment is covered in 36 states.

Private insurers often follow Medicare's lead. Locally, Independence Blue Cross covers the <u>radiation treatment</u> _ known generically as stereotactic body radiotherapy (SBRT) -- for prostate cancer when "medically necessary," but it is also reevaluating its policy. A November decision is expected.



Philadelphia-based Cigna Corp. does not cover SBRT for prostate cancer.

The debate pits doctor against doctor and raises tough questions about when insurance should pay for promising new techniques, especially when technology is a key driver of rising costs.

In prostate cancer, new treatments delivered by expensive machines have been embraced without large head-to-head comparisons of effectiveness. To further complicate matters, doctors on both sides say the arguments are clouded by ownership interests in various machines and other financial incentives.

"There's a lot of politics involved in this. There's a lot of self-interest. There's a lot of greed," said Mark Brenner, chief of radiation oncology at Sinai Hospital in Baltimore and a CyberKnife supporter.

Convenience is the big attraction. Men who choose radiation often get about 40 treatments of intensity modulated radiation therapy (IMRT) over eight weeks. SBRT offers five higher doses over a week or two.

Though more than one machine can deliver this kind of therapy, CyberKnife, made by Accuray Inc., is the one most associated with prostate SBRT. Accuray has hired a public relations firm to campaign against the proposed Highmark Medicare rule change, saying that "a change in Highmark's policy would be devastating to local men."

It certainly would be hard on owners of CyberKnife machines, which cost about \$5 million.

At Philadelphia CyberKnife in Havertown, one of the region's three machines, 19 percent of patients have prostate cancer, administrator Rick Habacivch said. Luther Brady, a well-known radiation oncologist



who is the center's medical director, said losing Medicare coverage would be a "dramatic blow."

In South Jersey, about one-tenth of patients treated with Cooper University Hospital's year-old CyberKnife machine have prostate cancer, said Tamara LaCouture, chief of the department of radiation oncology. She said she thought she would have more patients if her center was not competing with a new IMRT facility owned by a large group of urologists, the specialists who typically refer patients for prostate treatment.

Without insurance coverage, LaCouture said, few patients would pick SBRT: "To expect a patient in today's financial climate to choose this over a covered modality, that's just not realistic."

Fox Chase Cancer Center, which has a new CyberKnife, plans to use the machine only for prostate-cancer patients enrolled in clinical trials.

Highmark, which pays for SBRT for about 100 prostate patients a year, says it based its proposal to drop coverage on reports from ASTRO, the American Society for <u>Radiation Oncology</u>. That group's emerging-technology committee released a report last year that called SBRT promising, but not yet well proven.

"What the report said, essentially, is that early data, very immature data, suggest that it may be tolerated and may be effective," said Paul Wallner, a radiation oncologist who co-chaired the panel. "It's interesting. It's clearly seductive. ... We don't think there is yet any mature data."

Prostate-cancer treatment is a big business. Prostate is the second-most-common cancer in men; the American Cancer Society estimates that more than 192,000 will be diagnosed with it this year, and 27,000 will



die. Daniella Perlroth, a Stanford University researcher who has studied treatments and their cost, estimates \$3 billion a year is spent in the United States.

The cancer has long been controversial because many men die with it, not of it. But doctors have trouble identifying the most dangerous cases, and patients are reluctant to leave well enough alone. Compared with many other cancer patients, men with prostate cancer can choose from a cornucopia of effective treatments, but they also risk side effects such as urinary and bowel problems and impotence.

Medicare cannot consider cost in coverage decisions; a spokeswoman said she could not supply payment data.

In her studies, Perlroth found that, for men with cancer confined to the prostate, the cost of treatment over two years was \$23,000 for surgery, \$50,000 for IMRT, and almost \$29,000 for brachytherapy, in which tiny radioactive seeds are implanted in the prostate.

Especially for men older than 65, she is partial to watchful waiting, which costs \$2,436. "Doing nothing is pretty good," she said.

Because SBRT is so new, Perlroth could not get data for it or an even more expensive and controversial emerging technology, proton-beam therapy. (Highmark also has a proposed policy on protons that would allow the treatment for some men with prostate cancer when "reasonable and necessary." The University of Pennsylvania plans to open its new Roberts Proton Therapy Center in late fall.)

Proponents of SBRT say it is cheaper than IMRT by thousands of dollars. LaCouture said that, according to her analysis of Medicare payment codes, the government pays about \$21,700 for hospital and physician fees for CyberKnife treatment. Regular IMRT is about



\$25,100, and a variation, image-guided radiation therapy (IGRT), gives doctors another \$3,500.

Pro-SBRT forces also point to a recent Agency for Healthcare Research and Quality study, which found that no prostate-cancer treatment was superior to the others. The report also noted the lack of good comparative studies.

"My societal hat tells me that we should be using in health care what works and not simply what patients want and not simply the latest technology, so I'm a believer in comparative-effectiveness research," said Wallner, who is vice president for medical affairs at 21st Century Oncology, which develops and operates radiation-treatment centers. Patients treated with SBRT by his company are told it is experimental.

Wallner has served on the board of a company that sought to develop proton-beam centers. He said he quit earlier this year and thinks that approach also needs further study.

The idea of giving bigger doses of radiation over fewer days is attractive, but the important thing is giving the right dose, Wallner said.

Think about having a headache and a bottle of aspirin, he said: If you take the whole bottle, "your headache will clearly go away, but you'll end up in the hospital getting your stomach pumped."

Philadelphia CyberKnife's Brady said that his center had treated about 150 prostate-cancer patients and that his results were similar to those of patients treated with IMRT.

Sinai Hospital's Brenner has treated 70 to 80 patients over the last 18 months, with few side effects and not "even a hint of a failure." He said he did not have an ownership interest in the machine, but he owns some



Accuray stock.

Richard Vanderveer, a 61-year-old Gwynedd Valley psychologist who runs a company that does medical-marketing research, was diagnosed with prostate cancer earlier this year. He rejected surgery because he had "no great interest in being filleted." And, he said, getting radiation therapy every day for weeks "does not fit in smoothly with my lifestyle."

He saw an ad for CyberKnife, recognized Brady's name, and started researching. Soon, he was sold.

"It looked like the future," Vanderveer said. He knew he was trying something with a short track record. "You can't have long-term data on leading therapy," he said.

Vanderveer, who said he had never worked for Accuray, said he thought he made the right choice.

"As I sit here today, I could not be more satisfied."

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