Spinal Fusion for Back Pain Retains CMS Coverage

BY ALICIA AULT
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A Medicare advisory panel has concluded that it has low confidence in spinal fusion as a treatment for lower-back pain, but for now, the federal insurance program has no plans to deny coverage for the procedure.

The Medicare Coverage Advisory Committee met in late 2006 to weigh the available evidence on spinal fusion, and voted on six questions. It said that the available data provide an intermediate level of confidence in addressing the outcomes needed to determine whether fusion is effective for low-back pain resulting from degenerative disk disease.

For all the other questions posed, which all pertained to degenerative disk disease, MCAC found that the evidence fell below the intermediate level of confidence for determining improved outcomes— compared with conservative treatment— for both the first 2 years post surgery and beyond 2 years. They said the data were similarly lacking for fusions both with and without instrumentation. The panel said the results in the literature are reasonably likely to apply to the Medicare population.

The Centers for Medicare and Medicaid Services decided to hold a meeting to explore fusions after it denied coverage for the Charité artificial disk, according to an agency spokesman.

"It was also to identify where the holes are so that medical societies and industry and others could start to develop better data on those areas," said Eric Muehlbauer, executive director of the North American Spine Society, in an interview.

Mr. Muehlbauer said that CMS is essentially wielding its clout to spur better data collection.

The North American Spine Society is considering three proposals on how to improve the evidence base on fusion, he said. There is an especially glaring need for data specific to the Medicare population, partly because fusions are rarer in that age group, Mr. Muehlbauer said.

Medical device makers, represented by the Advanced Medical Technology Association (AdvaMed), said that access should not be restricted during the evidence-gathering process.

"We encourage [CMS] to allow Medicare patients access to spinal fusion surgery as a treatment option as the body of clinical evidence develops over time," said AdvaMed president and CEO Stephen J. Ubl in a statement.

The American Academy of Neurological Surgeons and the Congress of Neurological Surgeons are starting the second year of a pilot program to collect outcomes data on patients who have operations for lumbar stenosis at 15 practices, said Dr. Daniel Resnick, of the department of neurological surgery at the University of Wisconsin, Madison, in an interview.

There are several obstacles to getting good data, Dr. Resnick said. "We're hampered by an imperfect understanding of the physiology of pain in many patients," he noted. And most patients will not enroll in a study in which there's a 50% chance they would get conservative treatment instead of surgery, he said, as most U.S. patients have already tried many therapies before they undergo fusion.

Both he and Mr. Muehlbauer said there is evidence that fusions work in the right patient. But they said they weren't surprised that CMS is examining the procedure, given the increase in fusions since the introduction of instrumentation.

A study on trends estimated that lumbar fusion increased 250% from 1992 to 2003 (Spine 2006; 31:2707-14). Medicare payments for fusion rose from $75 million in 1992 to $482 million in 2003, estimated the authors, who are affiliated with Dartmouth Medical School and Dartmouth-Hitchcock Medical Center, Hanover, N.H. They also found huge geographic variations.

Dr. Resnick said fusions have increased because there are new technologies and techniques and because surgeons want to help patients who previously were not thought to be surgical candidates. ■

Medicare Part D Drug Prices: Let's Make a Deal

BY JOEL B. FINKELSTEIN
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WASHINGTON — Rhetoric aside, it's not clear whether lifting restrictions on the government's ability to negotiate pharmaceutical prices for the Part D benefit will have any real impact, experts said at a forum on the future of Medicare sponsored by the Association of Health Care Journalists.

In January, the House of Representatives passed H.R. 4, which would require the Secretary of Health and Human Services to negotiate drug prices directly with manufacturers, as is currently done by the Veterans Affairs system. Over in the Senate, Sen. Edward Kennedy (D-Mass.), who chairs the powerful Health, Education, Labor, and Pension Committee, placed this legislation near the top of the committee's agenda.

"I'm a little perplexed at how this issue is going to play out," said Paul Ginsburg, Ph.D., president of the Center for Studying Health System Change. "In a sense, if you really want the government to negotiate with manufacturers, you might as well repeal, not the benefit, but the whole structure of delivering it."

The Part D program is based on the concept that the different plans would compete with each other based on price, said Marilyn Moon, Ph.D., vice president and director of the health program at the American Institutes for Research.

"If you hand them a price list, there's really no reason for them to be there. It's very difficult to imagine how you would do this," she said. "This is going to be much more of a morass than people think."

Medicare already sets prices for many services and procedures, but setting prices for prescription drugs is far more complicated, Dr. Ginsburg said.

"Setting prices for pharmaceuticals, given the fact that the actual production costs of pharmaceuticals are a very small part of the total cost of pharmaceuticals—most of it is in R&D for that drug and for the drugs that didn't make it—that's a much more challenging job to do well," he said. However, Democrats argue that negotiating drug prices will help solve other problems with Part D.

Giving the government the ability to negotiate discounted drug prices will lower expenses for seniors and yield savings for Medicare that can be used to fill the gap in coverage known as the doughnut hole, said a statement from Sen. Kennedy's office.

"My concern about the doughnut hole is that who it really hits are the people who are taking maintenance drugs, who are also the main ones who can save costs over time" by keeping their health problems in check, Dr. Moon said. ■