Endoluminal Devices to Treat GERD Are Lacking

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LAS VEGAS — Not long ago, Dr. C. Daniel Smith showed a slide at an American College of Surgeons meeting that proclaimed endoluminal approaches to gastroesophageal reflux disease were "here to stay."

A mere 2 years later, he's not so sure. "We're already reading obits for several of these procedures," said Dr. Smith, chairman of surgery at the Mayo Clinic in Jacksonville, Fla., at the spring meeting of the ACS.

The curtain closed rapidly on several of the new stars in endoluminal GERD technology, sharply reducing the number of devices and procedures available for use in the United States.

Back in 2005, four devices had been approved and were being marketed for U.S. use and one—the Gatekeeper—appeared to be nearing Food and Drug Administration approval.

But in the interim between then and now, there have been several new developments:

- ► Medtronic Inc. withdrew its application for the Gatekeeper device because of concerns over efficacy.
- ► Boston Scientific Inc. voluntarily recalled the Enteryx liquid chemical polymer augmentation system in response to reports of serious adverse events, including deaths.
- ► Curon Medical Inc., maker of the Stretta device, declared bankruptcy, ending sales of that radiofrequency system, at least for now.

The endoluminal GERD device market now includes only the EndoCinch suturing system and the Plicator device, which uses jaws to create a "pleat" of tissue at the gastroesophageal junction.

For reasons that are both economic and practical, it would make sense to have a safe, predictable, and efficacious minimally invasive procedure for GERD, said Dr. Smith. Each year, 700,000 GERD-related endoscopies are performed and 200,000 patients are evaluated for possible antireflux surgery (although only about 70,000 patients undergo such a procedure).

But any endoluminal approach involves challenges, including the question of whether it would be reimbursed as an endoscopic procedure or as a more lucrative surgical procedure, which specialists would perform it, and whether it would prove truly efficacious in the long term.

Insurer Starts Paying for OTC Omeprazole

Blue Cross Blue Shield of Michigan now is covering Prilosec OTC for heartburn and acid reflux disease, reflecting increasing attention from insurers to over-the-counter drugs as vehicles for savings.

Patients who switch from prescription proton pump inhibitor Nexium (esomeprazole) to Prilosec OTC or generic omeprazole will receive their first prescription or supply for free and will pay their normal generic drug copay on subsequent refills, the insurer announced.

Officials at Blue Cross Blue Shield of Michigan (BCBSM) estimate that members of the plan will save $9 million in out-of-pocket costs because of the switch; 1.5 million patients are insured by BCBSM, whose customer groups have agreed to the program.

Some patients may save about $130 a year using Prilosec OTC instead of Nexium, according to the company, which added that employers could save nearly $20 million in the first year.

"The majority of our members will find that over-the-counter or generic Prilosec will provide the same benefit as the brand name," said James Lang, vice president for pharmacy services. "We encourage them to discuss making this change with their doctor."

The coverage decision builds on previous strategies employed by BCBSM and other insurers to drive patients toward lower-cost drug options such as generics and OTCs.

—Christopher Walker, *"The Tan Sheet"*

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