

What Is the Future of EVAR With Health Care Reform?

Declining reimbursement may affect this procedure and the medical device industry.

BY SEAN P. LYDEN, MD

When I finished this article on Christmas Eve 2012, our government had adjourned for the holidays. Our President and Congress still had not negotiated a compromise to avoid the “fiscal cliff” that was slated to occur on January 1, 2013. I would bet that many of you had never heard of the fiscal cliff before the 2012 presidential election, but all of us were bombarded with this term by the news media in December. Hopefully, change and compromise will occur, but we as health care providers need to understand the important effect these issues have on the diseases and patients we treat. One area the changes may affect negatively is endovascular aneurysm repair (EVAR).

CUTS TO REIMBURSEMENT

Health care reform is here to stay and is now being implemented. The Affordable Care Act, better known as “Obamacare,” was upheld as a tax by the Supreme Court in 2012, and most of the sweeping changes took effect on January 1, 2013. With increased individual coverage and growth in the Medicare population, more people will seek medical care in the years to come. However, will physicians be willing to take care of patients with Medicare? For more than a decade, physicians have been haunted by the Medicare Sustainable Growth Rate (SGR). This is the method used by the Centers for Medicare & Medicaid Services (CMS) in the United States to control spending by Medicare on physician services. SGR was passed in

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the Balanced Budget Act of 1997. Most of us never paid attention to the SGR because the implementation of the physician fee schedule update to meet the target SGR was usually suspended or adjusted by Congress in the past. When President Obama signed the Middle Class Tax Relief and Job Creation Act of 2012 on February 22, 2012, the implementation of the conversion factor was again delayed until January 1, 2013, when the cut was estimated to be 27.4%. As a consequence, physicians and practices may decide to opt out of Medicare.

Each time the SGR cut approached in the past, many physicians wrote to congressional leaders to stress the financial consequences to medical practices. Furthermore, the press and general public recognized that only a short-term fix was going to be implemented. Congress has not found a long-term solution to this flawed formula or accepted the budgetary increase in spending that would occur. This time, avoiding the SGR

cut was not so simple as we approached the fiscal cliff at the end of 2012 (*see postscript on page 71*).

THE FISCAL CLIFF

The formation of the fiscal cliff problem began with our government spending more money than tax revenue generated, creating and running up the national debt. Since 1962, the country reached a debt ceiling 76 times; each time, Congress raised the debt ceiling. The Budget Control Act of 2011 increased our debt ceiling and required the federal government to make billions in spending cuts to reduce debt. The Joint Select Committee on Deficit Reduction was appointed to come up with a recommendation by November 23, 2011, for at least \$1.5 trillion in additional deficit reduction steps to be undertaken over a 10-year period. This was a bipartisan group comprising 12 members of Congress—six from the House of Representatives and six from the Senate—with each delegation evenly divided between Democrats and Republicans. The Joint Select Committee on Deficit Reduction failed to compromise and recommend cuts from the budget, so mandatory broad-based cuts were required to begin on January 1, 2013. This process of mandatory cuts is known as *sequestration* and will reduce funding for most federal agencies across the board. The press has termed this sequestration process the “fiscal cliff.”

How does sequestration affect health care? For one, physicians and hospitals will face a 2% cut in CMS reimbursement in 2013 alone due to this process. This cut does not include the 27.4% pay cut the SGR will impose on physician reimbursement in the future. Why is this so important, and how does this affect the future of EVAR? Today, more than 61% of physicians in the United States are no longer independent (private practice) and are employees of large groups or hospitals. The American Hospital Association and American Medical Association noted in a joint statement that many health care and health care-related jobs will be lost if cuts are allowed to stand. This pay cut will push many large hospital and health system budgets into the red and make hospitals look critically at areas of high spending where physician-preference items predominate. Cardiology, orthopedic surgery, cardiac surgery, and vascular surgery practices all consume high-dollar implants, the choice of which is dominated by physician preference.

THE EFFECT ON EVAR

Let's take a look at EVAR from the hospital perspective before the fiscal cliff. EVAR typically falls under MS-DRG 237 major cardiovascular procedures with major complication and comorbidity (MCC) conditions and MS-DRG

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238 major cardiovascular procedures without MCC. A typical case mix would be 9% MS-DRG 237 and 91% MS-DRG 238, and a national base reimbursement for 2013 would be \$29,547 and \$18,398, respectively, with an average of \$19,401. Current list prices for EVAR devices average from \$14,000 to \$15,000. Some EVAR devices are designed as two-piece devices, whereas others are designed as three-piece devices. Extensions are frequently needed and are not included in this price. A 2008 article from the University of Florida noted an average of 1.9 extensions per case for the AneuRx graft (Medtronic, Inc., Minneapolis, MN), 1.19 for Excluder (Gore & Associates, Flagstaff, AZ), and 0.21 for Zenith (Cook Medical, Bloomington, IN).¹ A 2012 article from Stanford looked at the use of extensions in EVAR over a 4-year period and found a 30% increase in overall mean device-related cost when using extensions versus the standard number of pieces.² It becomes easy to see how EVAR device extension usage and case mix can easily lead to financial losses for hospitals. With tighter hospital budgets and little evidence to justify one product over another, many hospitals will start to dictate which implants will fill the shelves.

Declining physician and hospital reimbursement are not the only pressures on the future of EVAR. The Affordable Care Act authorized a 2.3% tax on medical device manufacturers' sales, which is set to begin in 2013; this will put significant financial constraints on the medical device industry and pressure the industry to reduce costs and increase revenue to offset the effect of the tax. While research and development may not be significantly affected in the short term because pipeline development is necessary to survive, sales, marketing, and device pricing are prone to short-term effects. We are likely to see a drastic reduction in personnel by many companies as a first effort to save money. According to the Advanced Medical Technology Association, the tax will cause the loss of 43,000 medical device jobs.³ Stryker Corporation, a maker of orthopedic and neurovascular implants, implemented plans to lay off 1,000 people by the end of 2012 to prepare for losses when this tax is implemented. Because a large

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number of physicians rely on support from medical device companies for case planning and implantation, we will see a reduction in the number of EVAR cases performed when this is lost.

Recently, chief executive officers of multiple medical device manufacturers jointly lobbied Congress to emphasize the potential crippling economic effect of the tax. The rules for implementing the tax have been poorly defined, and little guidance has been given on how to calculate the amount owed. In the near future, I find it unlikely that the tax will be repealed.

Hopefully, with avoidance of the “fiscal cliff,” some compromise will occur over the financial pressures we face. If not, we may see a landslide change in health care that will adversely affect the future of EVAR. ■

Postscript: A Look Back and Ahead

I am not surprised the fiscal cliff was temporarily avoided. The term has once again faded out of our news media. How did this happen? On January 1, 2013, the American Tax Payer Relief Act was passed, which delayed many of the financial impact issues of the fiscal cliff. The act stopped activation of the budget sequestration provisions of the Budget Control Act of 2011, and the Medicare “doc fix” for the SGR was extended again for 1 year. But some new things will affect us. The tax bracket for single Americans making more than \$400,000 will rise to 39.6%, which may affect many physicians performing EVAR. The medical device tax was also not addressed. Finally, spending that continues under the American Tax Payer Relief Act will increase the national debt, bringing all of these issues into the limelight as we once again reach the debt ceiling. Republicans and Democrats will undoubtedly fight their respective positions regarding raising new taxes and creating new spending cuts. Many of the fiscal cliff issues will return as we work for a solution to reduce our national debt. So the train is still coming—just a little farther down the track until it arrives.

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1. Feezor RJ, Huber TS, Berceli SA, et al. Impact of endograft design and product line on the device cost of endovascular aneurysm repair. *J Vasc Surg.* 2008;47:499-503.

2. Chandra V, Greenberg JJ, Al-Khatib WK, et al. Cost impact of extension cuff utilization during endovascular aneurysm repair. *Ann Vasc Surg.* 2012;26:86-92.

3. IRS Final Device Tax Regulations Underscore Urgent Need for Action. Accessed December 31, 2012. Available at: <http://advamed.org/news/8/irs-final-device-tax-regulations-underscore-urgent-need-for-action>.