The Case Of CT Angiography: How Americans View And Embrace New Technology

The Centers for Medicare and Medicaid Services attempted to control the proliferation of computed tomography angiography through its coverage determination process—and lost.

by Julie Appleby

Dur ing his career as a cardiologist, Jason Cole of Alabama has seen thousands of patients with suspected heart disease. When he first started practicing several years ago, he’d send an average of four or five patients each day to a lab for a cardiac catheterization test—an invasive procedure to see if blockages threatened their hearts. For the test, patients have a thin catheter pushed up through a groin artery and into the heart. Contrast dye is injected, and x-ray pictures show if narrowing or blockages impede the flow of blood. For patients with blockages, various medical and surgical treatments typically follow, including angioplasties, possibly with insertion of stents, or heart bypass operations. Cardiac catheterization poses some risk of bleeding and a tiny risk for major complications, such as heart attack, stroke, even death.

Now, when certain patients with suspected heart disease—say, a fifty-year-old woman who smokes and has some chest pain and whose echocardiogram shows inconclusive results—come to see Dr. Cole, he has a far more attractive option. The patient can simply lie on a table and let a $1.3 million computed tomography (CT) scanner snap hundreds of pictures of her heart. The newest of the machines, the 64-slice scanner, became commercially available in 2005 and rapidly replaced earlier 4-, 8-, and 16-slice machines that were slower. The state-of-the-art machines produce eerily beautiful three-dimensional color pictures of the heart, which doctors can manipulate with a computer, turning them this way and that, for an unparalleled look into the innermost recesses of the heart.

The test, called CT angiography, or CTA, is painless. At the same time, it does deliver a tiny dose of radiation—feeding worries that overexposure to CT over a lifetime could raise the risk of cancer. The test is also convenient. Because the more than two dozen physicians at Dr. Cole’s Cardiology Associates group practice in Mobile bought one of the machines in 2005, the procedure can be done right in their offices. Finally, in the high-cost calculus of modern medicine, the test is practically cheap. Insurers reimburse Dr. Cole about $600 for the test. Those same insurers would pay about $4,000 for a cardiac cath done at a local hospital, Dr. Cole says.

For many patients, the conventional stress test is still the appropriate first-line test. But Dr. Cole and many other physicians say CT angiography is an alternative for others with heart disease symptoms—ruling out those who don’t need further intervention and sparing them the more invasive cardiac cath test.
Nowadays, Dr. Cole says he only sends about one patient out of the thirty he sees each day for a cardiac cath. About two to four of the these thirty have CT angiography. A few end up having both tests.

That might make going with CTA seem like a slam-dunk—but of course, in medicine, things are rarely that simple. Various studies have yielded mixed evidence that the technology is truly effective in diagnosing heart disease. Beyond that, there is no conclusive evidence that CT angiography leads to treatment that saves lives. In other words, there is no clear-cut sign that the technology is a clear advance over cardiac catheterization by perhaps the most important metric: whether or not it really reduces deaths.

In addition, an increasing number of physicians own or lease their own CT machines for their office-based practices—in which case they’re not governed by Medicare’s prohibitions on self-referral. There’s evidence that many doctors thus have an inherent conflict of interest: too much financial incentive to order and perform all manner of CT scans. And with the tests proliferating, there’s also reason to fear that many patients could be harmed by the low but real risks of excess radiation.

These issues confronted Medicare late last year, when the agency proposed sharp limits on coverage for CTA under a so-called national coverage determination: a formal decision on whether and under what circumstances it would pay. In so doing, it launched the first salvo in what ultimately became a war. In the end, Medicare lost—and CT angiography remained a covered benefit for a broad range of patients with possible heart disease. Among other winners: imaging manufacturers and hundreds of cardiologists who’ve invested in CT machines.

Benefits Versus Costs

The episode represents a case study in the pull of new health care technologies—and, in the broadest sense, how American society awkwardly balances the costs and benefits of technological innovation in health care. Much of this innovation is now coming in medical imaging, from CT to magnetic resonance imaging (MRI) to positron emission tomography (PET). A critically important medical advance, imaging allows physicians to detect disease with far less risk than with more invasive techniques of yesteryear—often translating into care with fewer complications and shorter hospital stays.

Yet the boom in imaging also carries a hefty price tag. Medicare alone saw its payments to physicians for imaging services double to about $14 billion from 2000 to 2006, according to a U.S. Government Accountability Office (GAO) report issued in June 2008.³ Sales of imaging equipment in the United States are expected to grow from $7.8 billion in 2007 to $11.6 billion by 2012.⁴

Constraints Versus Innovation

In the view of many, much of the money going to imaging is also going down a rat hole. The nation’s health insurers released a report in July 2008 saying billions of dollars are wasted annually on unnecessary or duplicative imaging tests.⁵ Many of these insurers now require doctors to seek approval in advance of ordering imaging tests before insurers will agree to pay for them.

Elliott Fisher, director of the Center for Health Policy Research at Dartmouth Medical School, says the imaging boom illustrates how doctors and patients too often embrace new technology before its actual benefits—and drawbacks—are truly clear. “We have to change the idea that new is good until proven otherwise,” says Fisher. “We have to flip that and say, ‘Let’s be cautious until it’s proven to be good.’”

Critics of imposing such constraints on new technologies say that doing so could stifle ongoing innovation. “Holding back on technology is not costless,” says Harvard Business School economist Regina Herzlinger. “Unless
you get a technology out, ways to improve it are not discovered.” Herzlinger adds that experts can often come to vastly different conclusions about the value of new technology—an argument for letting the broad market ultimately decide its value. Other critics point to the fact that once CT scanners were on the market, competition led to improvements that made the machines faster and able to produce much more detailed images. They say limits would deter manufacturers from improving their products or inventing new ones. What’s more, they say, limiting new technology to research facilities or for use only in carefully designed clinical trials won’t show how the products work in the often messier “real world.”

**CTA And Medicare**

Enthusiasm for CT angiography grew rapidly after the 64-slice scanners came to market in 2005. The Web site for Dr. Cole’s medical group brags that it was the first private practice to buy one of the state-of-the-art devices from its manufacturer, General Electric. Others quickly followed, part of a trend of doctors doing more tests and procedures in-house, rather than referring patients to a hospital lab or a separate testing facility. Indeed, the GAO report found that the proportion of Medicare Part B spending on in-office imaging rose from 58 percent of total imaging spending in 2000 to 64 percent in 2006. Nearly one-third of doctors submitting claims for MRIs and about one-fifth of those seeking payment for CT or PET scans either owned the imaging equipment or had some other type of financial arrangement with the owners, according to a study published in *Health Affairs*.

By last year, Medicare officials had become concerned about CT angiography’s rapid adoption “despite the lack of clinical evidence to demonstrate improved patient health outcomes.” The agency wanted answers to key questions: Is CT angiography a diagnostic advance over cardiac catheterization or simply an add-on test that exposes patients to additional radiation? Which patients benefit the most? Do the tests save lives?

Under Medicare’s rules, the agency has to reach a national coverage decision over a new technology when it receives requests from its own staff or a member of the public that are deemed legitimate. Alternatively, new procedures and technologies can be used without a national coverage determination if Medicare’s local contractors—the carriers and intermediaries—allow it and agree to pay for it. And, by mid-2007, all of the local contractors in the United States were paying for CTA. That left Medicare only one option if it was to follow through on its doubts: it would have to reach a national coverage decision determining that Medicare would pay for CTA for only a limited group of patients.

To understand the choices facing Medicare, think of groups of patients along a spectrum. At one end are the “worried well,” or patients with no obvious symptoms of heart disease. There’s broad agreement that these patients fall into the “red light” category: They should not get CTA. At the other extreme are “high-risk” patients—people with known coronary artery disease who are clearly suffering symptoms such as severe unstable angina. For them, there’s a swift green light: Go directly to the cath lab.

Then there’s the middle group: patients who are suffering symptoms such as angina and who are deemed at “intermediate risk” of coronary artery disease because they have elevated cholesterol or blood pressure levels or other possible markers of disease. It’s over CTA coverage for this group that the struggle took place.

In a December 2007 report, Medicare proposed to pay for CT angiography for only two types of these “intermediate risk” patients with symptoms. These included patients who had chronic stable angina—the type of chest pain or discomfort that occurs with activity or stress—and those with unstable angina. That’s the type of chest pain or discomfort that occurs when a blood clot forms on a plaque in the coronary arteries and causes a degree of blockage that places the patient at low risk of death in the short term. It’s the condition Vice President Dick Cheney found himself in when he...
was rushed to a Washington, D.C., hospital in 2000 and got treatment that forestalled a massive heart attack.

In limiting the group of patients who could receive paid CTA, the Centers for Medicare and Medicaid Services (CMS) also proposed another condition: patients who received the exam would have to be enrolled in clinical trials aimed at determining if the procedure was more effective than cardiac catheterization. The double-barreled limitation triggered a firestorm of protest—and within months, Medicare backed down. In the end, it allowed CT angiography to remain a covered benefit for a wide range of Medicare patients under rules that would be set regionally by Medicare’s “intermediaries” and “carriers”—the insurance companies that process Medicare claims.

Although it is Medicare’s policy not to consider cost when making a national coverage decision, the agency’s budget is inevitably in the background. The Medicare Payment Advisory Commission (MedPAC) had already warned Congress in 2005 of the growing expense and use of medical imaging. In response, the CMS reduced payments to doctors for certain imaging procedures. Specifically targeting physician-owned imaging facilities, Congress also made some changes, using the Deficit Reduction Act of 2005 to limit payment for medical images taken in doctors’ offices. Beginning in January 2007, the technical component of CT angiography—the largest component of Medicare reimbursement—performed in physicians’ offices is capped at the amount paid under the hospital outpatient prospective payment system (PPS). That change caused Medicare spending on physician imaging services to decline an estimated 11.1 percent in 2007, according to a GAO report.

To further address the overall growth in CT angiography despite a paucity of supporting evidence, in December 2007 the CMS issued its proposal to limit CT angiography to certain patients—mainly those at intermediate risk of heart disease—and to require clinical trials. Marcel Salive, a physician and division director in the Coverage and Analysis Group at the CMS, says the agency was mainly interested in intermediate-risk patients because of the uncertainty surrounding whether or not they might have actual heart disease. By contrast, low-risk patients probably didn’t need CTA, and high-risk patients should probably go right to the cath lab. “In intermediate risk, there’s some probability they have heart disease and some reasonable probability that they don’t,” he says. “So, in that group, a negative result [on a CTA] might lead you to just drop it at that point and not do a cath.” A positive result, on the other hand, could suggest the presence of disease and lead to follow-up measures, including a cath, that could be important in saving lives.

Before making its proposal, the agency waded through a raft of often-conflicting medical studies about the effectiveness of CTA as a diagnostic tool. One study by researchers at Duke found “limited evidence” of the performance of CTA and MRI in diagnosing coronary artery disease. Others reached different conclusions. One study cited by the agency looked at the newest generation of CT scanners and said the scans “provided very promising results,” in that they helped identify patients who needed further interventions, such as stents or cardiac bypass surgery.

Ultimately, the CMS concluded that none of the studies proved that the tests saved lives—because the studies hadn’t looked at patient outcomes. There was simply no evidence one way or another that the tests saved lives.

Physicians’ Response

Specialty societies representing radiologists and cardiologists were outraged—and they launched a letter-writing campaign seek-
ing to block the national coverage determination. In letter after letter, doctors said the agency failed to consider many of the most promising recent studies of 64-slice scanner CT angiography. More than 100 of those who wrote also criticized Medicare for using as its bottom line for the national coverage determination whether or not CT angiography saved lives. A typical example was a letter sent in January to Medicare by the six specialty societies, including the American College of Cardiology, the American College of Radiology, and the Society of Cardiovascular Computed Tomography. “It has been well established in medicine that no diagnostic test improves health outcomes by itself; only the resulting therapeutic interventions may do so,” the letter read.

In fact, there’s widespread disagreement over which questions are most important when evaluating a new medical technology—and especially a diagnostic one. “The outcomes we should measure are these: How many more patients did we save? Did patients have a better quality of life? Did patients have less pain? Those are the things that matter,” says Jerome Hoffman, a professor of medicine at the University of California, Los Angeles (UCLA), and an emergency department physician who was not involved with the Medicare decision. Comparing one diagnostic technology with another also poses difficulties, since they typically have different pluses and minuses. Cardiac catheterization, for example, produces better spatial resolution than CTA and thus more clear-cut results. Older patients may have more calcium deposits in their hearts that also obstruct the views from CTA.

But Alabama cardiologist Cole says a key advantage to CTA is the value of a noninvasive test—not only in sparing patients risk and a longer recovery, but also because it’s cheaper than cardiac catheterization and could also lead to relatively low-cost treatment options. He cites a study done by his cardiology group in Mobile during April–August 2005. Of 204 patients with abnormal or equivocal findings on various heart tests who then went on to have CT angiograms, Dr. Cole and his colleagues found that two-thirds could be managed with prescription drugs or lifestyle changes, with no need for cardiac cath, stenting, or other invasive procedures. What’s more, Dr. Cole’s study showed savings of nearly $1,500 per patient compared with cardiac catheterization, even accounting for those patients who eventually had both tests.

Industry’s Response

Physicians weren’t the only group who resisted Medicare’s conclusions. General Electric, one of the world’s largest makers of medical imaging equipment—including the million-dollar-plus CT scanners—urged the CMS not to move forward with its national coverage determination proposal. CT angiography, wrote Michael Becker, general manager, Global Reimbursement, for GE, “provides vital information for physicians to improve their decision making, enables more prompt diagnosis and reduces complications and risks associated” with alternative diagnostic methods.

All told, Medicare’s proposal drew more than 670 comments. The overwhelming majority were opposed; a scattering took no position. And only ten—including that from America’s Health Insurance Plans (AHIP), the insurance industry’s trade association—agreed with agency’s proposed decision to limit coverage. “This technology is viewed by some as having great clinical value and as such is being eagerly adopted; but there remain important gaps in knowledge about its risks, benefits, and costs, particularly for patients at intermediate risk of coronary artery disease,” wrote Carmella Bocchino, an executive vice president at AHIP.

Congress’s Response

Eventually, even Congress got involved. On 7 March 2008, a letter signed by seventy-nine members of the House of Representatives was sent to Kerry Weems, acting administrator of the CMS. In language similar to the specialty societies’ letter, the Democrat and Republican representatives said Medicare had made its decision without considering some data from
two large studies showing the effectiveness of CTA that had only been published in initial form in the fall of 2007. Denying coverage “will limit beneficiaries’ access to this valuable technology, which will ultimately require more costly invasive procedures,” the letter to Weems said. Five days later, Medicare backed down.

Current Status And Stance

In its official decision memorandum, the CMS announced that it would not move forward with its proposed national coverage determination, despite what it called continued uncertainty about the tests’ usefulness. It noted tersely that the evidence was still not in: “It is our hope that future studies will evaluate health outcomes so that the health benefits of cardiac CTA to the patient and their balance against the risk of radiation exposure can be demonstrated.”

And so today, CT angiography remains a covered benefit in Medicare, broadly available for symptomatic “intermediate risk” patients and above. For Kim Allen Williams, a professor of medicine and radiology and the director of nuclear cardiology at the University of Chicago, the growth of imaging is a natural, market-based phenomenon—one that will eventually tail off as the technology becomes almost universal. “By the mid-1970s, no cardiology practice or internal medicine practice was without an EKG [electrocardiogram] machine,” says Williams, and CT imaging seems likely to follow suit. Technology spreads “until it saturates all the office and people understand when it should be used and when not.” Then growth flattens out and is perceived as less of a problem. And in the meantime, says Williams, “it’s actually providing more capability of saving people’s lives.”

Many private health insurers aren’t so sanguine. Stung by double-digit increases in spending on all types of medical imaging, many are increasingly regulating the use of CTA. Some demand preapproval, while others are counting more on education, training, and accreditation programs to slow the rise in use.

Donald Ryan is chief executive officer of CareCore National, one of the four largest radiology benefit management (RBM) firms in the United States. His firm reviews about four million preauthorization requests a year for most types of outpatient medical imaging tests, including CTA, from about twenty-five insurer clients including Blue Cross/Blue Shield plans, Aetna, CIGNA, and Health Net. He says about 15–20 percent of the requests for prior authorization “don’t meet the evidence-based criteria” and are turned down—much to the consternation of the doctors who order the tests.

“Physicians don’t like prior authorization, and from their perspective, you can understand that,” says Ryan. “But it’s a necessary evil when you look at runaway utilization.”

Many cardiologists protest the use of these RBMs. Among other criticisms, they argue that the RBMs are often not transparent in reporting their reasons for rejecting imaging requests. “They make doctors who are trying to take care of patients very unhappy,” agrees Jack Lewin, chief executive officer of the American College of Cardiology. But he acknowledges that some use of CTA is clearly unwarranted. “There are abuses going on with imaging—places where too many images are ordered, or the wrong image is ordered,” he says. He says that taking more steps to force doctors to get permission from insurers is not the best solution. Better, he says, to use electronic medical records and special software to help physicians decide which test to order, relying on criteria set by specialty societies such as his own.

The college has drawn up such appropriateness guidelines, outlining which types of patients will benefit from the test. The guidelines spell out that CT angiography should not...
be done on the “worried well”—those patients who don’t have symptoms but are afraid that they might have heart disease. Very high-risk patients should probably go straight to a cardiac cath lab, because they are likely to need stents or other interventions that can be done at the same time as the catheterization. The guidelines support the use of CT angiography for the patients in the middle, with “intermediate risk”—some symptoms, or with equivocal findings on other heart tests.

And that, of course, is where the CMS still disagrees.

Salive, the Medicare analyst, says the agency remains unconvinced that paying for many more CT angiographies will ultimately save lives. And in its June 2008 report to Congress, the GAO recommended that the CMS consider similar preauthorization policies for CT angiography and many other imaging tests that many private insurers now employ.

CMS officials, bearing the scars of the battle over the national coverage determination, responded that implementing such procedures would be difficult.

NOTES
14. Ibid.