Medicare Expands Coverage of CPAP Devices

BY MARY ELLEN SCHNEIDER
New York Bureau

Medicare has expanded its coverage of continuous positive airway pressure therapy for obstructive sleep apnea to include patients who were diagnosed using home sleep tests.

Officials at the Centers for Medicare and Medicaid Services handed down their final decision, after first proposing the change last December.

The new coverage policy is a significant departure from the agency's 2005 policy, which provided coverage for continuous positive airway pressure (CPAP) devices when the diagnosis was made using polysomnography in an attended sleep laboratory. The new policy will add coverage for CPAP following a clinical evaluation in combination with a positive result on an unattended home sleep monitoring device of type II, type III, or type IV measuring at least three channels.

CPAP therapy prescribed based only on a clinical evaluation or a test that is not specified by the CMS will be covered only in the context of a clinical study, according to the new coverage policy.

The CMS has also eliminated the requirements that individuals have moderate to severe obstructive sleep apnea and that surgery is a likely alternative, to be covered for CPAP therapy. The agency also eliminated its requirement for a minimum of 2 hours of continuous record sleep to make a diagnosis of obstructive sleep apnea.

But CMS officials are limiting coverage of CPAP devices to an initial 12-week trial period. Only those beneficiaries who improve on the devices will be able to continue to receive coverage.

In the short run, the policy could cause a lot of durable medical equipment vendors to jump into the market without providing adequate support to patients.

The agency will also continue monitoring use of home testing for obstructive sleep apnea to detect potential fraud.

"[The] policy provides more options for Medicare beneficiaries and their treating physicians. At the same time, we remain vigilant to ensure that Medicare payments for these services do not create incentives for inappropriate use," Kerry Weems, CMS acting administrator, said in a statement.

While experts say the revised policy does a lot to improve access, it could have unintended consequences for the more than 4 million Medicare beneficiaries who have some form of obstructive sleep apnea.

Dr. Robert Thomas, sleep medicine fellowship director at Beth Israel Deaconess Medical Center, Boston, said the final policy is an improvement over last year's proposal because it specifies that any type IV sleep test used must have at least three channels. Single-channel devices have numerous problems including false negative results, he said.

While the policy allows for greater access to CPAP therapy, there is no guarantee it will be followed by appropriate care, said Dr. Thomas, who holds patents for technology to estimate sleep quality from an ECG and for CO_2 use in mixed sleep apnea treatment. "Sleep apnea management is not simple and many patients with sleep apnea have comorbid sleep disorders."

Dr. Alex Chediak, president of the American Academy of Sleep Medicine, and a sleep specialist based in Miami, said that in the short run the policy could cause a lot of durable medical equipment vendors to jump into the market to reap the financial benefits without providing the proper level of support to patients. The equipment will show up on the patients' doorsteps but they won't know what to do with it and "physicians will be left holding the bag." But in the long run, the policy will improve access and outcomes, he predicted.

Guidelines issued last year from the American Academy of Sleep Medicine outline the appropriate use of unattended portable monitors in diagnosing obstructive sleep apnea. They recommend that unattended portable monitors be used only for obstructive sleep apnea diagnosis in conjunction with a comprehensive sleep evaluation (J. Clin. Sleep. Med. 2007;3:737-47).

They also state that portable monitoring is not appropriate for the diagnosis of obstructive sleep apnea in patients with significant comorbid medical conditions that may interfere with the accuracy of the home test. Portable home tests are also inappropriate for diagnosing patients who may have comorbid sleep disorders. ■

The national coverage determination is available online at www.cms.hhs.gov/center/coverage.asp.

CMS Updates Oversight of Outpatient Dialysis Centers

BY MARY ELLEN SCHNEIDER
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A new regulation on Medicare coverage at outpatient dialysis centers aims to bring the requirements in line with new technology and scientific advances.

The final regulation, published in the Federal Register last month, also directs dialysis centers to focus more on patient needs. The final rule includes updated requirements for safety, patients' rights, quality reporting, and patient assessment.

The changes are so significant that the Centers for Medicare and Medicaid Services is granting centers 180 days to come into compliance with the new requirements instead of the standard 60 days.

"It's a cultural change in many ways as much as it is having to build new processes or implement new equipment," Dr. Barry M. Straube, director of the CMS Office of Clinical Standards and Quality, said during a press briefing to announce the publication of the final rule.

The new requirements set a minimum standard that dialysis centers must comply with to be certified as Medicare providers. Under the final rule, centers must conduct a comprehensive assessment of the patient's health condition when they start dialysis and create a personalized care plan for each patient. That care plan should be developed by an interdisciplinary team made up of the treating physician, a registered nurse, a social worker, and a dietician.

The regulation also includes new patient rights protections. For example, patients must be informed of their right to have advance directives, and they must be given 30-day written notice before their dialysis services can be terminated involuntarily.

Centers will also be required to establish a center-level quality assessment and performance improvement program to show how the facility plans to improve quality of care.

The final rule also includes a requirement for dialysis centers to submit performance data through the Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) system starting next year. Facilities will have until Feb. 1, 2009, to develop or enhance their systems to begin submitting end-stage renal disease clinical performance data electronically.

The final rule has been in the works for some time and officials at the CMS have sought significant input from the end-stage renal disease community since the proposed rule was issued in 2005. There are unlikely to be surprises in the regulation, he said.

CMS officials do not expect the regulation to be a major financial burden on dialysis facilities. Most costs associated with new requirements should be offset by the elimination of other resource-heavy requirements, Dr. Straube said. ■

Coverage of Computed Tomographic Angiography Decided Case by Case

BY ALICIA AULT
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Medicare reimbursement for computed tomographic angiography will not be limited, according to the Centers for Medicare and Medicaid Services.

The federal agency never had a formal policy on CTA, but the majority of local Medicare contractors had been covering the procedure. In July 2007, the CMS said it was starting a formal analysis of CTA with an eye toward potentially limiting its coverage. In December 2007, the CMS posted a formal proposal to do just that.

Under the proposal, Medicare would have covered only CTA for symptomatic patients with chronic angina at intermediate risk of coronary artery disease, and symptomatic patients with unstable angina at low risk of short-term death or intermediate risk of CAD.

Reimbursement would be made only for patients getting CTA as part of a CMS-approved clinical trial.

After reviewing the current literature, however, the CMS said that it had decided that "coverage should be determined by local contractors through the local coverage determination process or case-by-case adjudication."

The decision applies only to use of CTA for evaluation of coronary arteries in patients with symptomatic coronary artery disease, according to the CMS. CTA for asymptomatic patients would not be covered under Medicare, as it is considered a screening test.

The American College of Cardiology, which submitted comments opposing the CMS proposal, said it was pleased with the agency's decision. "Medicare beneficiaries can continue to have the access they deserve to an advanced, noninvasive clinical tool that has been clinically proven to be effective in diagnosing coronary artery disease," Jack Lewin, ACC CEO, said in a statement.

The ACC, along with five other professional societies—the American Society of Nuclear Cardiology, the American College of Radiology, the Society for Cardiovascular Angiography and Interventions, the North American Society for Cardiac Imaging, and the Society of Cardiovascular Computed Tomography—argued that the CMS had relied on studies of older technology, such as 4-, 8-, and 16-slice imaging.

According to the ACC, 64-slice or higher machines are now considered the clinical standard for diagnosing CAD.

The CMS received 670 comments after the proposed decision was published. According to the CMS, 649 of the comments were opposed.

There were 10 comments in favor, and the rest provided no direction for coverage. Among those who backed the CMS' proposal to limit CTA reimbursement: America's Health Insurance Plans.

Even so, Aetna, Humana, UnitedHealth Group, and 14 Blue Cross Blue Shield plans, currently cover CTA, according to the American College of Radiology.

Almost half of those who submitted comments to the CMS said that CTA would save money and reduce the number of invasive tests done. The agency said it generally does not consider cost when weighing a national coverage determination, but that it would be interested in knowing whether CTA prevented the need for additional procedures. The CMS could not find any such evidence, however. ■