HCFA tries to clear up confusion over Medicare coverage decisions

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Agency hopes publication will clarify procedures

Drug and device manufacturers got a glimpse into the internal workings of the Health Care Financing Administration last month when the agency for the first time outlined how it decides to grant Medicare reimbursement for new technologies and services. Industry advocates praised HCFA for making its operations clearer, but also voiced concern about the scope and quality of the notice. Medicare coverage can often make the difference between success or failure for new medical technologies and the companies that developed them. Following several high-profile struggles over Medicare coverage decisions, industry advocacy groups have asked HCFA to clarify the seemingly Byzantine process the agency uses in its coverage decisions. After more than a year of consultation between HCFA and representatives of the medical community, the agency made its response in the form of guidelines published in the April 27 edition of the Federal Register.

The document delineates how interested parties may request national coverage decisions. It also outlines the time lines HCFA follows for reviewing requests, how it uses technology assessments, and the roles of HCFA staff and the Medicare Coverage Advisory Committee. That committee was formed last year to provide advisory opinions to HCFA on coverage proposals for controversial or important technologies.

Although most Medicare coverage decisions are made locally by HCFA contractors, the agency makes coverage policies that apply nationwide. HCFA hopes the notice will contribute to a more streamlined and understandable administrative process for national decisions. Under HCFA’s new protocol, interested parties must submit written requests to the agency for national coverage decisions on new technologies. The requests must include a description of the item or service and any appropriate clinical trials, medical, and scientific information available about the service, and the item or service’s Food and Drug Administration clearance status. HCFA will launch national coverage reviews in four situations:

- when local coverage policies conflict;
- when the item or service to be reviewed is a notable medical advance and no similar procedure is covered;
- when there is significant dispute among medical experts about an item or service’s efficacy; and
- when a service is covered but thought to be ineffective or out of date.

In addition to setting forth more specific criteria for Medicare coverage decisions, the notice establishes time frames in which HCFA must reply to requests for coverage. Once a request has been accepted, HCFA will respond in written form within 90 calendar days. If a requestor submits further information about an item or service, however, the agency starts a new 90-day period. HCFA’s response can take many forms, ranging from a national coverage decision with no limitations on coverage, to referrals to the Medicare Coverage Advisory Committee, or a request for further information. The agency plans to post on its Web site the coverage issues under review, the phase each review is in, and when the next action is expected. Although HCFA has not formally established a comment process for the coverage notice, it does invite comments.

Most medical device industry advocates applauded HCFA’s notice, praising the attempt to clarify its decision-making. Since HCFA’s administrative process for coverage decisions has been for the most part a private process, the fact that the document was published at all is a positive development, according to Ted Mannen, executive vice president of healthcare systems for the Health Industry
Manufacturers Association (HIMA) in Washington, DC.

"HCFA's having issued the notice is certainly a step in the right direction," Mannen said. "We and many groups have been calling for some time for greater openness in this whole area of coverage, so the fact that they wrote the rules down is a good step."

The document didn’t contain many surprises, although it did raise some red flags, Mannen said. HIMA is concerned that the document does not cover decision-making processes for local coverage or establish a process for appealing coverage decisions. HIMA had also recommended to HCFA that the agency publish its administrative process as a rule rather than a notice, which would hold HCFA to a greater level of accountability to the public, Mannen said.

"We expected the notice to look as it did, and not to contain a local (protocol), but local coverage process is still a concern for us," he said. "Another area we’ll be paying close attention to is the time frames that HCFA has sketched out."

The Institute for Clinical PET, a nuclear medicine advocacy organization in Foothill Ranch, CA, shared some of HIMA’s concerns. It also plans to respond to the document.

"We’ve gone through this national coverage policy as a (nuclear medicine) community several times, first with getting rubidium approved, then working through FDG and trying to get that approved for Medicare," said Jennifer Keppler, executive director of ICP. "So it’s nice to see that they’ve formalized the process, because before this there really wasn’t a road map. But there are several things we’d like to see added to the policy, like guidelines as to what data would be considered acceptable, a more defined sense of the (administrative) pathways that HCFA would take for a new technology, and an appeals process."

The agency isn’t finished with its policy disclosures. HCFA plans to publish a proposed rule this summer that will explain the criteria used to evaluate medical items and services for national coverage decisions. The proposed rule will have a public comment period, and will clarify criteria used to determine whether items and services are reasonable and necessary, as well as the types of evidence needed for a national coverage decision.

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