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Client Alert Commentary

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10 Strategic Considerations for Tackling Medicare's Revised National Coverage Determination Process

CMS's August 2013 notice establishes a new internal review process, signalling increased agency-initiated activity

The Centers for Medicare & Medicaid Services (CMS or the Agency) has initiated an automatic, internally-generated, periodic review process of existing national coverage determinations (NCDs), through which the Agency plans to evaluate the continued need for older NCDs that have not been reviewed for 10 years or more. The new process is designed to retire old policies where either the subject technology, the policy, or the rationale behind it has changed. The new process presents increased risks to established, older products and technologies. Technology companies can mitigate these risks and increase opportunities by better understanding the process and preparing response strategies early.

Revised NCD process: Implications for technology companies

Determining how to position technologies for Medicare coverage at the national level can be daunting. Yet, technology companies can learn many lessons through an examination of the policy statements developed by CMS, as the Agency issues new or reconsidered NCDs or decides not to revise existing NCDs. These policy statements, published in the form of decision memoranda and guidance documents, provide a roadmap for approaching Medicare coverage for both new and established technologies. A new layer of uncertainty follows CMS's recently-articulated review process, however. Published in August 2013, CMS's new process document (the 2013 Notice[1]), signals that the Agency will take a more active role with respect to agency-generated reviews of existing NCDs.

The 2013 Notice essentially left in place CMS's 10-year old NCD process, but announced a new, expedited review process for older NCDs, which the Agency describes as an administrative procedure to periodically review all existing NCDs that have not been reviewed in at least 10 years and to determine whether there is continued need for those policies to remain active nationally. CMS will now more formally engage in reviews triggered by scientific and technological changes and may lift barriers to allow access to more beneficial technologies. CMS would not create a new NCD, but instead remove the old, existing NCD, allowing Medicare contractors to use their discretion to make coverage decisions regarding the particular item or service previously covered by the old, removed NCD. Consistent with its prior procedures, CMS may also determine that the NCD should be retained or formally reconsidered.

Subject to the removal process are NCDs for which there have been:

1. Changes in technology/age of data, including any of the following:
    - Information in the NCD is no longer clinically pertinent or current.

- A once experimental item or service covered by a noncoverage NCD is no longer considered experimental.

- The technology behind the item or service covered by the NCD is generally acknowledged to be obsolete and is no longer marketed.

2. Changes in NCD specific policy determinations, including any of the following:

   - The items or services covered by the NCD are used infrequently by beneficiaries.

   - The evidence base reviewed when the NCD was initially made has evolved to support other policy conclusions.

   - Eliminating a national noncoverage NCD would permit access to technologies that may be beneficial for some limited uses.

   - Allowing local contractor discretion over the item or service would better serve the needs of the Medicare program and its beneficiaries.

3. Changes in program level policies or rules, including any of the following:

   - The NCD has been superseded by subsequent Medicare policy.

   - The national policy in the NCD does not meet the definition of an "NCD" as defined in sections 1862(l) or 1869(f) of the Social Security Act.

   - The benefit category determination in the NCD is no longer consistent with a category in the Act.

Drawing on the new process and the past 10 years of coverage policies, we include below the top 10 issues that companies should consider when looking to the Medicare program for coverage at the national level. This list includes the import of the changes in CMS's 2013 Notice, which retained much of the same process used to develop NCDs since the last notice in 2003 (the 2003 Notice[2]). Also included are hot button issues implicated by the 2013 Notice and approaches companies may want to consider. By drawing from CMS's body of precedent in the context of the 2013 Notice, companies seeking new Medicare coverage or those interested in ensuring that their existing coverage is retained, may position their technologies strategically.

Top 10 strategic considerations for mitigating the risks of the revised process

#10. Become familiar with CMS's tracking systems

CMS utilizes a web-based tracking system[3] called the "Medicare Coverage Database," which contains various NCD information, including: all active NCDs, proposed NCD decisions, National Coverage Analyses, and Medicare coverage guidance documents. The website's search feature provides real-time updates on national coverage information intended to enable interested stakeholders to participate in and monitor the progress of CMS's review. Information available via the tracking system includes a reference number and name of the issue under consideration and summaries of significant actions that CMS has taken on the issue. Actions include acceptance of a complete, formal NCD request and subsequent actions thereon.

Companies should take advantage of the CMS database in light of CMS's goal for transparency in the 2013 Notice. This includes subscribing to CMS's listserve to monitor new additions to the tracking system or updates on existing issues and items.

#9. Become familiar with the process and timeframes of CMS's new, internally generated, expedited process to remove older NCDs

CMS plans to periodically publish on its website a list of NCDs proposed for removal, along with CMS's rationale explaining why that particular NCD is being considered for removal. CMS will solicit public comments for 30 days on whether the NCD should be removed or retained, after which, the Agency will either retain the NCD, follow the proposal to remove the NCD, or formally reconsider the NCD and post a tracking sheet to that effect on its website.

Under the new process, the Agency expects the amount of time to be reduced "significantly" from the nine to 12 month formal reconsideration process, which previously was the only way for an existing NCD to be removed or amended. The 2013 Notice, however, contains no expected timeline for CMS once there is a proposal to remove the NCD and comments have been submitted. Companies should monitor this timeline process in order to prepare adequately for possible future CMS initiatives.

#8. Proactively prepare for retention or challenge of older NCDs

Companies interested in existing, older NCDs should (i) take an inventory of these NCDs immediately so that they understand which older NCDs CMS may target, (ii) collect data as soon as possible in preparation of positions to either remove or retain the NCD, and (iii) actively monitor the CMS website for a possible 30 day public comment window.

Once an NCD relating to a company's specific products or services is identified to be an "at risk" NCD, companies may elect to collect scientific data to include such things as clinical trial and patient populations information. Companies should not discount the importance of economic and social policy data (*e.g.*, the number of beneficiaries actually using the product or service covered by the NCD and the costs of the product or service versus the benefit to beneficiaries). Though CMS does not factor cost data into its NCD decisions themselves, because CMS is tasked with utilizing its finite resources to ensure adequate coverage to a large and rapidly growing beneficiary population, such data may inform possible risks.

#7. Remain vigilant of changing circumstances and opportunities for new NCDs, and removals or reconsiderations of existing NCDs

Although the expedited removal process for old NCDs is the most significant change from the existing process, CMS nonetheless may internally generate or reconsider any policy or entire NCD, regardless of its age, if the Agency identifies evidence supporting a new NCD or becomes aware of new evidence that could support a material change in coverage to an existing NCD. CMS has provided specific examples that would prompt it to internally generate a new NCD, include any of the following:

- Practitioners, patients, or other members of the public have raised significant questions about the health outcomes attributable to the use of the items or services for the Medicare beneficiary population.
- New evidence or reasonable re-interpretation of previously available evidence indicates that a national coverage review may be warranted.

- Local coverage policies on a particular item or service may vary in language or implementation.

- The health technology represents a substantial clinical advance and is likely to result in a significant improvement in patient health outcomes or positive impact on the Medicare program.

- When rapid diffusion of an item or service is anticipated.[4]

Companies should utilize the same techniques discussed above in #s 8 through 10 to monitor NCDs of strategic interest and prepare readily available defensive or offensive scientific, economic, and social policy data should CMS propose a new NCD or target an existing NCD for modification or removal.

#6. Be prepared before requesting a new NCD or reconsideration of existing NCDs

Companies should evaluate fully the opportunities for new NCDs and reconsideration of any existing NCDs. These processes are the same, and CMS will consider accepting a formal request for a new NCD or reconsideration of an existing NCD at any time. With respect to a reconsideration, however, CMS will only do so if the request is accompanied by at least one of the following:

- Additional scientific evidence that was not considered by CMS during the most recent review along with a sound premise by the requester that new evidence may change the NCD decision

- Plausible arguments that CMS's conclusion materially misinterpreted the existing evidence at the time the NCD was decided[5]

Once the formal request is considered complete, CMS will generally make a decision within 60 days whether to accept or reject the external NCD reconsideration request.

#5. Meet informally with CMS, including before submitting a "Formal Request"

Informal discussions with CMS are encouraged under the 2013 Notice and highlighted for two main reasons. First, informal contacts allow companies to crystallize the issues to be considered and avoid delays. Indeed, CMS specifically notes in the 2013 Notice that a submission of a "formal request" without any prior conversation with the Agency generally requires additional clarification and discussion before such a request can move forward. Second, the informal discussions often clarify whether the request will be successful, thereby preventing premature reviews that unnecessarily expend resources. CMS specifically notes in the 2013 Notice that, following informal discussions with the Agency, a significant proportion of potential requesters have either withdrawn or substantially amended their initial requests.

The Coverage and Analysis Group within the Center for Clinical Standards and Quality — responsible for NCD development, including reconsidered decisions — may respond to stakeholder inquiries by conference call or in-person meeting. Staff routinely meet with companies to learn about technologies, provide feedback on clinical data, and discuss the types of information necessary for a successful formal request.

Companies that expect to submit a request for a new or reconsidered NCD may use this opportunity to (i) clarify the ultimate NCD request (*e.g.*, the scope of coverage); (ii) ensure that all the relevant materials, such as clinical studies, meet any preliminary expectations for coverage; and (iii) ensure that the company understands and can access all information to be included in the formal request.

#4. Submit complete information with any formal request

Both the 2003 Notice and 2013 Notice emphasize the need to submit a complete, formal request. A single missing piece of required information may render the request incomplete, and delay timelines for CMS action.

The following information is required for a complete formal request:

- The request must be in writing.
- The request must clearly identify the statutorily-defined benefit category to which the requester believes the item or service applies and contains enough information for CMS to make a benefit category determination.
- The request must be accompanied by sufficient, supporting evidentiary documentation and preferably robust, peer-reviewed studies.
- The information provided must address relevance, usefulness, or the medical benefits of the item or service to the Medicare population.
- The information must fully explain the design, purpose, and method of using the item or service for which the request is made.[6]

#3. Understand the differences between FDA and CMS requirements

While FDA approvals or clearances are a prerequisite for a technology receiving Medicare coverage, meeting such requirements alone does not entitle a technology to Medicare coverage. As noted in both the 2013 Notice and the 2003 Notice, CMS and FDA review scientific evidence through different lenses, notwithstanding the likely overlap in the evidence itself. For example, if a company is pursuing CMS approval for a product or service, the following FDA-required data must also be submitted to CMS: (i) the integrated summary of safety data, (ii) the integrated summary of effectiveness data, (iii) the identification of predicate device to which the item or service is claimed to be substantially equivalent, and (iv) the use of an item or service (including labelling) subject to FDA regulation as well as the status of the current FDA regulatory review of the item or service involved.

Despite this overlap in evidence, FDA reviews are to determine whether a product is “safe and effective,” whereas CMS reviews evidence to determine whether or not the item or service is “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”[7] Further, CMS may recognize coverage for certain services not otherwise evaluated by the FDA, such as off-label uses supported by clinical data and accepted by the medical community as a standard of care. Examples include the use of chemotherapies for conditions not otherwise approved by the FDA and coverage for certain devices used for new indications under FDA-approved investigational device exemption trials.

Finally, companies going through the FDA review process may want to consider participating in the pilot program for concurrent review of FDA premarket review submissions and CMS NCD requests. This is a voluntary program designed to bring certain innovative device technologies to Medicare beneficiaries on an expedited basis.[8] The parallel review program does not change the distinct review standards by FDA and CMS.

#2. Ensure your product or related service fits a recognized benefit category

Because the Medicare program is a statutorily-defined benefit program, regardless of the breakthrough, life-improving or prolonging properties of a company's technology, CMS cannot establish coverage through an NCD or otherwise unless the technology is an "item" or "service" that is recognized in the Medicare statute. An NCD (defined as "a determination by the Secretary with respect to whether or not a particular item or service is covered nationally"[9]) must be based on a Medicare Part A or Part B benefit category or categories. An NCD request is not considered formal unless the request clearly identifies the statutorily-defined benefit category to which the requester believes the item or service applies and contains enough information for CMS to make a benefit category determination.

CMS has not developed a formal, all-inclusive list of benefit categories. In many instances, companies may need to review the Medicare statute, regulations and manual provisions.[10] Identifying a benefit category or categories is also important because the category defines which payment methodology and policies are applicable for the particular technology.

#1. Obtain data to show relevancy to the Medicare population

Companies should ensure that evidence supporting their technologies includes data either directly addressing individuals covered by Medicare or must otherwise demonstrate how existing data impacts this population. Because CMS is most concerned with its target population, companies should consider including this population in clinical studies, for example, by including adequate numbers of individuals aged 65 or older, disabled, or suffering from end stage renal disease. If data for the Medicare population is not available, companies must be prepared to explain applicability of the data to this population. Without such data, a company will be unable to meet the requirement for a complete, formal request for a new NCD (or formal reconsideration of an existing NCD) discussed in #4 above that the information provided address relevance, usefulness, or the medical benefits of the item or service to the Medicare population.

Conclusion

As Medicare's population grows larger and continues to age, and as budget issues remain in the political spotlight, CMS has announced its intent to closely examine and weigh the benefits of technologies to be covered under the Medicare program. With the 2013 Notice signalling CMS's increased focus on continuous re-evaluation of NCDs to ensure that they reflect current science and medical practice, companies more than ever must understand and meaningfully participate in CMS's processes. The on-going monitoring of available resources to address opportunities and risks, including any proposed removals, will help to ensure appropriate policies are established and NCDs remain relevant.

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Endnotes

1 78 Fed. Reg. 48164 (Aug. 7, 2013).

2 68 Fed. Reg. 55634 (Sept. 26, 2003).

3 http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

4 78 Fed. Reg. 48164 at 48167.

5 *Id.*

6 *Id.* at 48166.

7 42 U.S.C § 1395y(a)(1).

8 76 Fed. Reg. 62808 (Oct. 11, 2013)

9 42 U.S.C § 1395ff(f)(2)(B).

10 See, e.g., *id.* at § 1395x (listing definitions of various items and services).