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Client Alert

FDA & Life Sciences and Healthcare Practice Groups

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CMS Updates Policies and Procedures for National Coverage Determinations and Announces a New Expedited Process for Removing Certain Older NCDs

On August 7, 2013, the Centers for Medicare & Medicaid Services (CMS) published in the Federal Register[1] a notice that updated the processes that CMS uses for opening, deciding or reconsidering National Coverage Determinations (NCDs) for items and services under the Medicare program. The notice supersedes the 2003 Federal Register notice[2] that had been utilized for almost ten years in which CMS announced the procedures for considering NCD requests and issuing NCDs. The 2013 notice does not alter or amend the regulations governing the administrative appeals of NCDs, however.

In a major departure from past practice, CMS also established an expedited administrative process for removing certain older NCDs, thereby enabling local Medicare contractors to independently determine coverage for items and services addressed by NCDs rescinded under the new process. Manufacturers and other advocates of older technologies should be prepared for CMS to actively reassess its previous coverage determinations and take steps to ensure that those decisions are based on clinical evidence that is scientifically sound. This increased scrutiny of coverage decisions by CMS may also present manufacturers with opportunities to introduce CMS to newer products that are innovations of the older technologies under review.

The August 7, 2013 notice became effective upon publication in the Federal Register.

Background on NCDs

NCDs are determinations by the Secretary of Health and Human Services (through CMS) with respect to whether or not a particular item or service is covered nationally under Title XVIII of the Social Security Act. They are controlling authorities for Medicare contractors and administrative bodies that adjudicate disputes in the Medicare program. In the absence of an NCD, Medicare contractors may establish Local Coverage Determinations (LCDs) or analyze coverage

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and medical necessity on a claim-by-claim basis. The following is an analysis of the updated policies and procedures contained in CMS's 2013 notice.

External NCD Requests: Informal Contacts Prior to Submission

Any individual or entity can submit an NCD request, which may seek to establish, limit, or entirely remove coverage for an item or service under the Medicare program.[3] CMS encourages, but does not require, potential NCD requesters to communicate, via conference call or meeting, with staff in the Coverage and Analysis Group (CAG) within the Center for Clinical Standards and Quality at CMS before submission of a formal request. Requesters may present a summary of the item or service and supporting documentation, as well as identify clinical trial protocols whose results may later be submitted to support an NCD request. Such informal discussions permit CMS to advise the requester of additional information that might be needed or helpful, as well as discuss potential issues that could affect CMS's review and implementation of coverage of the item or service.

External NCD Requests: Submission of a Complete Formal Request

An NCD request is not accepted until a complete formal request in writing is received by CMS. The request must include the following:

- A final letter of request that is clearly identified as "A Formal Request for a National Coverage Determination."
- A full and complete description of the item or service in the request, including its design, method of use, the target Medicare population, the medical indication(s) for which it can be used, and whether it is intended for use by health care providers or beneficiaries. The relevance, usefulness or medical benefits of the item or service to the Medicare population must be identified.
- Scientific evidence supporting the clinical indication(s) for the item or service.
- If the requester has submitted an application to the FDA for premarket approval or 510(k) clearance, a copy of the "integrated summary of safety data" and "integrated summary of effectiveness data," or the combined "summary of safety and effectiveness data" portions of the FDA application.
- If the items or services are eligible for 510(k) clearance, identification of the predicate devices to which the item or service is claimed to be substantially equivalent.
- The status of current FDA regulatory review of the item or service at the time that the formal request is submitted. The requester must notify CMS of any changes to that status during the pendency of review.

- The labeling submitted to FDA or approved by FDA for the item or service, indicating whether the item or service for which review is being requested is covered under the labeled indication(s). The requester should submit the labeling in effect at the time that the formal request is submitted, although it must notify CMS of any changes to the labeling during the pendency of review.

- The Medicare Part A or Part B benefit category or categories in which the requester believes the item or services fall.

With one exception, CMS will not accept a coverage request for a device or pharmaceutical that has not been approved or cleared for marketing by the FDA for at least one indication. The exception is for Category B Investigational Device Exemption (IDE) devices,[4] which may be covered by Medicare when used in the context of a clinical trial even though they are not approved or cleared for marketing by the FDA.

External NCD Requests: Process for CMS Consideration

Upon acceptance of a complete formal request, CMS "opens" the NCD review by publishing a "tracking sheet" on the CMS website, which provides public notice of the opening of the NCD process.[5] Generally, CMS allows a 30-day public comment period on the NCD review topic. CMS then engages in a formal evidence review to determine whether or not an unbiased interpretation of the available evidence base supports or refutes the requested coverage in whole or in part. CMS issues a proposed decision within 6 months of opening the NCD review. More time is allotted if a technology assessment from an outside entity is commissioned or a meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) is convened. If so, then CMS will issue a proposed decision within 9 months of opening the NCD.[6] Once the proposed decision is published, CMS will allow another 30-day public comment period on the proposal. No later than 60 days after the end of the 30-day public comment period, CMS issues a final NCD and decision memorandum. A formal review may result in an NCD, a noncoverage NCD, or an NCD with limitations. CMS may also determine that no NCD is required, permitting local Medicare contractors to make the initial determination of coverage. The NCD is effective for claims with dates of service beginning with the effective date of the NCD, which is the same date as the publication date of the final decision memorandum.

Internal NCD Requests

CMS may also internally initiate the NCD process. The following are examples of circumstances that may lead to an NCD review initiated by CMS:

- Practitioners, patients or other members of the public have raised significant questions about the health outcomes attributable to the use of items or services for the Medicare beneficiary population.

- New evidence or reasonable reinterpretation 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 (although variability is not a *de facto* sign of inappropriate local policy).

- 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, the evidence may inadequately address questions regarding impact on the Medicare population, target subgroup populations, practitioner or facility qualifications, beneficiary health outcomes, etc.

Requests for Reconsideration

When an NCD currently exists, any individual or entity may request that CMS reconsider any provision of the NCD by filing a complete formal request for reconsideration. Requests for reconsideration will only be accepted if documentation of one of the following is provided: (1) additional scientific evidence that was not considered during the most recent review along with a sound premise by the requester that new evidence may change the NCD decision; or (2) plausible arguments that CMS's conclusion materially misinterpreted the existing evidence at the time the NCD was decided. In a change from previous policy, CMS will determine within 60 days whether it will accept the request for reconsideration. If accepted, CMS will post a tracking sheet opening the NCD review. If declined, CMS will send a letter to the requester rejecting the request.

CMS may also internally open a reconsideration of an NCD. Generally, CMS opens NCD reconsiderations when it has become aware of new evidence that could support a material change in coverage and seeks public comment on relevant questions arising as a result.

New Expedited Process for Removing Certain Older NCDs

Previously, the removal of an NCD required a formal reconsideration process that generally took 9 to 12 months. In the 2013 Federal Register notice, CMS created a new expedited administrative process for periodic review of NCDs that have not been reviewed for at least 10 years in order to evaluate the continued need for those policies to remain active on a national scale. As part of this process, CMS will periodically publish on its website a list of NCDs proposed for removal and the rationale for proposed removal. CMS will then solicit public comment for 30 calendar days on whether it should remove the NCD, retain the policy as an NCD, or formally reconsider the NCD. After considering the comments, CMS will post a final list of NCDs for removal, which will be effective immediately. At that time, local Medicare contractors would be able to independently determine coverage for the items and services previously addressed by those NCDs.

CMS indicated that it may consider an older NCD for removal if any of the following circumstances applies:

- Allowing local contractor discretion better serves the needs of the Medicare program and its beneficiaries.
- The technology is generally acknowledged to be obsolete and is no longer marketed.
- In the case of a noncoverage NCD based on the experimental status of an item or service, the item or service in the NCD is no longer considered experimental.
- The NCD has been superseded by subsequent Medicare policy.
- The national policy 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 is no longer consistent with a coverage category in the Social Security Act.

According to CMS, future utilization for items and services addressed by certain older NCDs is limited, so allowing local contractor discretion in such cases better serves the needs of the Medicare program and its beneficiaries. Further, the expedited procedure allows CMS to regularly identify and remove NCDs that no longer contain clinically pertinent and current information or that involve items or services that are used infrequently by beneficiaries. CMS noted that, in some circumstances, the effect of removing national noncoverage policies may permit access to technologies that are beneficial for some limited uses.

Considerations

Although the processes and procedures that CMS uses for opening, deciding or reconsidering NCDs are more streamlined, but remain largely unchanged, as a result of the 2013 Federal Register notice, the new expedited process for removing certain older NCDs announced by CMS is a major departure from prior practice. Manufacturers and other advocates of technologies that are subject to NCDs that have not been reviewed for at least 10 years should be prepared for these NCDs to be reconsidered in the near future. If NCDs are removed, national coverage for these technologies will no longer be assured. Coverage questions will then be decided by local Medicare contractors, each of which may reach different conclusions. Interested parties should start immediately considering how to marshal clinical and other support for coverage of older items and services that may once have been certain, but will soon be subject to reconsideration and potential upheaval. Manufacturers of newer products that are innovations of the older technologies subject to review may also find opportunities to introduce their newer products to CMS and make a case for coverage.

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The August 7, 2013 Federal Register notice may be found **here**.

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[1] 78 Fed. Reg. 48164 (Aug. 7, 2013).
[2] 68 Fed. Reg. 55634 (Sept. 26, 2003).
[3] Section 1869(f)(4) of the Social Security Act establishes expedited timeframes for CMS review of NCD requests for items and services for which there is no national coverage or noncoverage decision by "aggrieved persons"—individuals entitled to Part A benefits, or enrolled under Part B, or both, who are in need of the item or service.
[4] A Category B IDE device is a non-experimental/investigational device for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval or clearance for that device type. 42 C.F.R. § 405.201(b).
[5] In rare situations, CMS may issue a proposed decision concurrently with the opening of an NCD. This generally occurs when CMS determines that an expedited NCD is required to manage an unforeseen health-related issue or program need that must be resolved quickly. CMS may also use its discretion to expedite a final NCD for requests that are accepted in the FDA-CMS Parallel Review Pilot Program.
[6] CMS appears to suggest that issuance of an NCD may be further delayed if "a clinical trial is requested"—presumably by the CAG or the MEDCAC—however, certain statutory deadlines exist for the issuance of NCDs. The process by which CMS intends to issue NCDs in such circumstances is not addressed in the 2013 notice.