

recommend one or more benefit categories for the item or service and must submit supporting documentation justifying the recommendation. We must have all information, both from the requestor and internally, to make a benefit category determination, before the request can be considered complete. If an item or service can fit into more than one benefit category, we have the discretion to assign it to the most appropriate benefit category.

- The requestor must submit adequate supporting documentation along with the formal letter, including the following:
 - A full and complete description of the item or service in question.
 - A specific, detailed description of the proposed use of the item or service, including the target Medicare population and the medical condition(s) for which it can be used.
 - A compilation of the supporting medical and scientific information currently available that measures the medical benefits of the item or service. This may include portions of primary study data that have been separately submitted to the FDA as part of its submission package and are deemed most relevant for our review.
 - If the requestor has submitted an application to the FDA for market approval of the product for which coverage is sought, then 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 should be included in the request for an NCD. These documents will ensure that our review is comprehensive.
 - An explanation of the design, purpose, and method of using the item or equipment, including whether the item or equipment is for use by health care practitioners or patients.
 - A statement from the requestor (in cases in which there is an aggrieved party, the statement must be from that party) containing the following:
 - ++An explanation of the relevance of the evidence selected.
 - ++Rationale for how the evidence selected demonstrates the medical benefits for the target Medicare population.
 - ++Information that examines the magnitude of the medical benefit.
 - ++Reasoning for how coverage of the item or service will help improve the medical benefit to the target

population.

- ++In the case of an aggrieved party, how that party is “in need” of the item or service.
- A description of any clinical trials or studies currently underway that might be relevant to a decision regarding coverage of the item or service.
- Information involving the use of a drug or device subject to FDA regulation as well as the status of current FDA regulatory review of the drug or device involved. An FDA regulated article would include the labeling submitted to the FDA or approved by the FDA for that article, together with an indication of whether the article for which a review is being requested is covered under the labeled indication(s). (We recognize that the labeling on FDA-approved products sometimes changes. For purposes of our review, we are interested in the labeled indications at the time a requestor submits a formal request. If, during our review, the labeled indication or status of a pending FDA approval or clearance changes, we expect the requestor to notify us.)
- In the case of items that are eligible for a 510(k) clearance by the FDA, identification of the predicate device to which the item is claimed to be substantially equivalent.

C. When a National Coverage Determination Request or Reconsideration Request Is Not Considered Complete and Formal

When a requestor submits a request for an NCD or reconsideration, we will review the materials to determine if it meets the definition of a complete, formal request as defined in section IV.B of this notice. If the request lacks adequate supporting documentation to enable us to conduct our review, we will notify the requestor and explain our rationale. If we accept the request, we will notify the requestor of the acceptance. We will also post our acceptance on our Web site under our list of pending coverage issues.

As we previously stated, we will not consider a request to be a complete, formal request if any of the following occur:

- Request is not in writing.
- Request is not accompanied by sufficient, supporting documentation.
- Information provided does not address relevance, usefulness, or the medical benefits of the item or service to the Medicare population.
- Information does not fully explain the design, purpose, and method of

using the equipment for which the request is made.

- Information provided is not supported by scientific or clinically relevant data.
- Information provided is not relevant to the item or service for which the request is made.
- Request does not clearly identify the statutorily defined benefit category to which the requestor believes the item or service applies and does not contain enough information for us to make a benefit category determination.
- Request is considered an informal contact described in section IV.A.

D. Acceptance of a Complete, Formal National Coverage Determination or Reconsideration Request

In the rare event that we have a large volume of NCD requests to review at once, we retain the flexibility to prioritize these requests based on the magnitude of the impact on the Medicare program and beneficiaries. This flexibility will enable us to ensure that we can pay priority attention to those requests that have potential for significant impact on our beneficiaries—a life-saving cancer treatment, a breakthrough in cardiac pacing, etc. In order to do so, we may have to temporarily suspend or diminish our review of other issues that, while important, do not have the same profound potential. We expect to use any such authority infrequently.

For these cases, two lists, an accepted list and lower priority list (based on impact) will be maintained and available on our Web site; the lower priority list will be processed based on the order of acceptance as resources become available. Requestors can use this public priority list to verify whether the request has been accepted, the status of the request, and where the requestor is in the order of priorities.

Upon acceptance of a request, we will notify the requestor and post a tracking sheet announcing our review of this issue on the list of pending coverage issues on the coverage Web site. Posting of the tracking sheets permits interested individuals to participate and monitor the progress of the NCD process. This is a key element in making our NCD process more efficient, open, and accessible to the public. Once a formal request is posted, there will be an opportunity for public participation and submission of additional evidence. (If after accepting the request, we decide that the request does not fall under a benefit category, we will issue a noncoverage NCD.)