

### *E. Review of a Complete, Formal Request for a National Coverage Determination*

Development of a complete, formal request for an NCD can be initiated in one of three ways:

**Track #1:** Request for New National Coverage Determinations Initiated by Any Party, Including Beneficiaries, Manufacturers, Providers, or Suppliers.

A request to make an NCD can be received from an individual or entity who identifies an item or service as a potential benefit (or to prevent potential harm) to the Medicare population; this requestor can be either an aggrieved party as defined by section 522 of BIPA, or a nonaggrieved party. This may include a manufacturer, provider, supplier, or party who requests our consideration of a particular issue for an NCD. All requests must meet the requirements in this notice. An initial request can only be made if we have not previously issued an NCD for a particular item or service.

If an individual or other entity initiates a request, we expect to generally issue a decision memorandum within a 90-day period. More complex issues, or issues that require referral to the Medicare Coverage Advisory Committee or for a Technology Assessment, would generally take longer than 90 days. Generally, we expect to make a payment change effective within 180 calendar days of the next full calendar quarter that follows the date we issue the decision memorandum.

Though the 90-day clock in this option is not as strict as the process used only for aggrieved parties, this track offers a more collaborative process than track two. The opportunities for greater collaboration will flow from the more flexible approach to the 90-day clock. Requestors and other interested parties will be able to provide additional information, clarify issues, and engage in dialogue as questions arise. The ability to follow this path is necessarily constrained when we are under a strict, narrowly-framed 90-day response timeline.

**Track #2:** Request by an Aggrieved Party for New National Coverage Determinations Where There Were No National Coverage or Noncoverage Determinations.

Aggrieved parties are defined in section 1869(f)(5) of the Act as "individuals entitled to benefits under Part A, or enrolled under Part B, or both, who are in need of the items or services that are the subject of the coverage determination." Section 1869(f)(4) of the Act permits these individuals to make a

request that the Secretary issue a national coverage or noncoverage determination with respect to a particular type or class of items or services, if the Secretary had not previously made a coverage or noncoverage determination. Thus, this track can be invoked only for an initial request if we have not issued a coverage or noncoverage NCD.

As noted in section E, track 1, generally we expect to make a payment change effective within 180 calendar days of the first day of the next full calendar quarter that follows the date we issue a decision memorandum. This time is necessary to identify and make any necessary coding, payment, and systems changes. However, if an aggrieved party initiates a request under track 2, we expect to issue a decision memorandum and an NCD (that is, the manual instruction or other appropriate document) to our contractors by no later than the end of the 90-day period, in accordance with the statutory timeframe. The NCD will include the effective date of the policy. In cases where we are not able to complete our review within this 90-day timeframe, the law requires that we issue a notice that includes an identification of the remaining steps in the review process and a deadline by which we will complete that review.

A decision memorandum will include a clear statement of the basis for the determination including our responses to comments we receive from the public. The actual effective date of the NCDs will depend on whether we must make changes to our claims processing systems to allow Medicare payment; this step is not included in the 90-day clock. However, whether systems changes are needed and how long they may take to implement will be reflected in the effective date contained in the NCD.

**Track #3:** Internally Generated Request.

We may generate a request to make an NCD in the interest of the general health and safety of Medicare beneficiaries. Generally, this process is similar to the externally generated request process.

### *F. NCD Reconsideration Process*

When an NCD currently exists, any individual or entity may request that we reconsider any provision of that NCD by filing an acceptable request for an NCD reconsideration. We will consider a request to revise an existing NCD at any time, but only if the requestor presents documentation that meets either of the following criteria:

- Additional material medical and/or scientific information that was not

considered during the initial review, that is, results from new clinical trials, new scientific or medical publications, or studies supporting the request.

- Arguments that our conclusion materially misinterpreted the existing evidence at the time the NCD was made.

- If the request is for reconsideration of the benefit category determination, the requestor must recommend a benefit category and, in support of the recommendation, submit either (1) new information that was not considered during the initial benefit category determination, or (2) arguments that our determination decision materially misinterpreted the applicable statutory provisions, the applicable regulatory provisions, or the existing evidence at the time the benefit category determination was made.

We will not accept a request for reconsideration that is not submitted in writing, identified as "A Formal Request for Reconsideration," and accompanied by the required, additional, supporting information as described more fully in sections IV.B and IV.C. Upon receipt of the additional information as outlined above, we will consider this a formal request for an NCD reconsideration and initiate the reconsideration process. We generally expect to complete the reconsideration process and issue a decision memorandum within 90 calendar days. Our current NCD will remain in effect during the reconsideration process until we issue a revised NCD, if applicable.

A reconsideration of an NCD must be distinguished from a challenge to an existing NCD. Under section 522 of BIPA and section 1869(f)(1) of the Act, aggrieved parties may elect to challenge an existing NCD. On August 22, 2002, we published a proposed rule (67 FR 54534) that addresses procedures for the Departmental Appeals Board (Board) review process under section 522 of BIPA.

A request for review of new clinical and scientific evidence that was published or available only after the date the initial NCD was issued may be submitted as a request for reconsideration. The reconsideration of an existing NCD is part of our coverage determination process so that our medical and scientific experts have an opportunity to examine this new evidence. Thus, a reconsideration of an NCD is separate and distinct from an initial NCD request and separate from the Board review process under section 522 of BIPA.

As noted above, because reconsiderations are outside of the strict BIPA timeline, they offer several alternative opportunities for individuals