DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Departmental Appeals Board
Appellate Division, MS-6127
Room G-644, Cohen Building
330 Independence Avenue, SW
Washington, D.C. 20201

BY CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Mr. _____ [Beneficiary]
[Beneficiary's address]

and

Ms. Linda Keyser
Office of the General Counsel
Centers for Medicare & Medicaid
Services Division
330 Independence Avenue, S.W., Room 5309
Washington, D.C. 20201

Re: NCD Complaint – Carcinoembryonic Antigen
DAB Docket No. A-07-106

RULING ON MOTION TO DISMISS NCD COMPLAINT

On July 9, 2007, [Beneficiary] filed a complaint asking the Departmental Appeals Board (Board) to review a Medicare national coverage determination regarding the clinical laboratory diagnostic test for carcinoembryonic antigen (CEA). The Centers for Medicare & Medicaid Services (CMS) has filed a motion to dismiss the complaint, claiming that [Beneficiary] is not entitled to challenge the national coverage determination in this forum because he lacks standing as an "aggrieved party."

For the reasons discussed below, we grant CMS's motion to dismiss [Beneficiary's] complaint. We also advise [Beneficiary] of other potential avenues of relief, including his right to appeal the denial of any individual claim for coverage of CEA testing, as well as his right to petition CMS directly to reconsider the national coverage determination.

Legal Background

Medicare is a health insurance program, established under title XVIII of the Social Security Act (Act), for persons 65 years and older and for other classes of eligible "beneficiaries."[1] Medicare covers broad categories of medical care (such as hospital care and physician services) but generally excludes from coverage any item or service that is "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]"[2]

Medicare is administered nationally by CMS, a component of HHS. Claims for Medicare benefits are processed by private insurance companies under contract with CMS. These contractors either approve or deny claims based on coverage criteria set out in the Medicare statute, program regulations, and CMS policies.

When a Medicare beneficiary receives a medical item or service, a claim for Medicare benefits is typically submitted to a CMS contractor on the beneficiary's behalf. If the contractor denies the claim, the beneficiary may appeal by first asking the contractor to make a redetermination, and, if redetermination is denied, then requesting a second "independent" contractor (called a Qualified Independent Contractor, or QIC) to reconsider the denial.[3] If still dissatisfied, the beneficiary may seek further review by an independent ALJ. If dissatisfied with the ALJ's decision, the beneficiary may appeal to the Medicare Appeals Council, an independent body within the Department of Health and Human Services. Once these administrative avenues of relief are exhausted, the beneficiary may seek judicial review by a United States District Court. CMS refers to this multi-step appeal

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[1] Title XVIII of the Social Security Act can be found on the internet at www.ssa.gov/OP_Home/ssact/comp-ssa.htm.

[2] Act § 1862(a)(1)(A).

[3] The Medicare claims appeal process is for beneficiaries who participate in the original or "fee-for-service" Medicare program, which has two parts: Part A, which covers inpatient hospital care, inpatient care in skilled nursing facilities, home health services, and other services; and Part B, which covers certain physicians' services, outpatient hospital care, and some other services that are not covered under Part A. A different appeals process is available to beneficiaries who elect to receive Medicare benefits from managed care organizations under Medicare Part C.

process as the "Medicare claims appeal process."[4] This process, which is governed by regulations at 42 C.F.R. part 405, subpart I, permits the beneficiary to submit any medical or other information relevant to his individual claim for benefits.[5]

In 2000, Congress created a new and separate appeals process that enables certain Medicare beneficiaries to challenge national coverage determinations in a proceeding before the Board.[6] A national coverage determination (NCD) is a policy statement that identifies the circumstances under which a medical item or service will be considered covered, or not covered, by Medicare on a nationwide basis.[7] Under the NCD appeal process, a Medicare beneficiary who needs a medical item or service may, if certain criteria are met, challenge an NCD that would deny Medicare coverage for that item or service.[8]

The Medicare claims appeal process and the NCD appeal process differ in several respects, the most significant being their subject matter. The subject of an appeal in the Medicare claims appeal process is the merit of the coverage claim initially denied by the CMS contractor.[9] Such an appeal focuses on whether the contractor's coverage denial was justified given the beneficiary's clinical condition and other circumstances unique to his claim for benefits. The merit of a particular coverage

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[4] Descriptions of this process can be found on CMS's internet website at http://www.cms.hhs.gov/OrgMedFFSAppeals as well as on the Medicare.gov website at http://www.medicare.gov/basics/appeals.aspn.

[5] Federal regulations may be found on the internet at www.gpoaccess.gov/cfr.

[6] *Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000*, Pub. L. No. 106-554, § 522, 114 Stat. 2763A-463, 2763A-543.

[7] Section 1869(f)(1)(B) of the Act defines an NCD as "a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title [title XVIII], but does not include a determination of what code, if any, is assigned to a particular item or service covered under this title or a determination with respect to the amount of payment made for a particular item or service so covered."

[8] Final Rule, *Medicare Program: Review of National Coverage Determinations and Local Coverage Determinations*, 68 Fed. Reg. 63,692, 63,693-94 (Nov. 7, 2003).

[9] 68 Fed. Reg. at 63,693-94.

claim is not at issue in the NCD appeal process. In that process, the issue to be resolved is the validity of the NCD, a nationwide policy that governs the handling of all claims that fall within its purview.[10] In judging whether the NCD is valid, the Board must determine whether the factual findings, legal conclusions, and "applications of fact to law" made by CMS in adopting the NCD were "reasonable."[11]

The conditions under which a beneficiary may challenge an NCD are spelled out in the Medicare statute and in CMS regulations at 42 C.F.R. Part 426, subparts C and E. One of the conditions is that the Medicare beneficiary be an "aggrieved party."[12] An "aggrieved party" is defined in the regulations as a Medicare beneficiary (or the estate of such a beneficiary) who "[i]s in need of coverage for a service that is denied based on" an NCD.[13] CMS regulations require the Board to dismiss a complaint if the person who files it is not an aggrieved party.[14]

Case Background

Carcinoembryonic antigen is a protein found in some carcinomas.[15] CEA is an effective biochemical marker for monitoring the response of some cancers to treatment.[16]

On November 23, 2001, CMS published a rule in the Federal Register regarding a negotiated rulemaking on coverage and administrative policies for certain clinical diagnostic laboratory tests, with an addendum containing NCDs including one involving the CEA test.[17] CMS republished the appended NCDs in the Medicare National Coverage Determinations Manual (NCD

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[10] 68 Fed. Reg. at 63,693-94.

[11] 42 C.F.R. §§ 426.110 (definition of "reasonableness" standard), 426.525.

[12] 42 C.F.R. § 426.320(a).

[13] 42 C.F.R. § 426.110.

[14] 42 C.F.R. § 426.544(b)(3).

[15] Final Rule, *Medicare Program; Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services* 66 Fed. Reg. 58,788, 58,867 (Nov. 23, 2001).

[16] 66 Fed. Reg. at 58,867.

[17] 66 Fed. Reg. at 58,788.

Manual).[18] The NCD for CEA testing is found in section 190.26 of the NCD Manual.[19]

[Beneficiary] has a diagnosis of medullary thyroid cancer. In connection with the treatment for this disease, [Beneficiary] had CEA tests on October 10, 2006, December 14, 2006, and January 27, 2007. Cigna, a Medicare contractor, denied the claim for Medicare coverage of these tests.

In his July 9, 2007 complaint, [Beneficiary] asserted that NCD 190.26 permits CEA testing for some types of cancer but not for medullary thyroid cancer. Although he stated that calcitonin (a type of hormone) is the "primary marker for the progression of his cancer," he contended that the medical literature accompanying his complaint showed the medical necessity of testing for CEA as a "secondary marker" of medullary thyroid cancer and as an indicator of significant changes in the ratio of the markers guiding treatment choices.

Discussion

As noted, the Medicare statute and regulations provide that only "aggrieved parties" may pursue an NCD appeal. An aggrieved party includes a person who is in need of Medicare coverage for a service for which payment is "denied based on an applicable . . . NCD" (emphasis added). There is no question that Mr. ____ is a Medicare beneficiary who has medullary thyroid cancer and that his doctor has identified him as in need of coverage for an item or service that is the subject of an NCD. The crucial issue here is whether NCD 190.26 denies Medicare coverage of the item or service for the population of patients with medullary thyroid cancer.

NCD 190.26 states in relevant part (with emphasis added) as follows:

> **Indications**
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> The CEA may be medically necessary for follow-up of patients with colorectal carcinoma. It would however only be medically necessary at treatment decision-making points. In some clinical situations (e.g., adenocarcinoma of the lung, small cell carcinoma of the

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[18] The NCD Manual (CMS Pub. 100-03) is available on CMS's website at http://www.cms.hhs.gov/Manuals/IOM/list.asp.

[19] CMS Pub. 100-3, Ch. 1, Part 3, § 190.26 (Rev. 17, Issued July 2, 2004).

lung, and some gastrointestinal carcinomas) when a more specific marker is not expressed by the tumor, CEA may be a medically necessary alternative marker for monitoring. Preoperative CEA may also be helpful in determining the post-operative adequacy of surgical resection and subsequent medical management. **In general, a single tumor marker will suffice in following patients with colorectal carcinoma or other malignancies that express such tumor markers.**

In following patients who have had treatment for colorectal carcinoma, ASCO guideline suggests that if resection of liver metastasis would be indicated, it is recommended that post-operative CEA testing be performed every two to three months in patients with initial stage II or stage III disease for at least two years after diagnosis.

For patients with metastatic solid tumors, which express CEA, CEA may be measured at the start of the treatment and with subsequent treatment cycles to assess the tumor's response to therapy.

Limitations

Serum CEA determinations are generally not indicated more frequently than once per chemotherapy treatment cycle for patients with metastatic solid tumors which express CEA or every two months post-surgical treatment for patients who have had colorectal carcinoma. **However, it may be proper to order the test more frequently in certain situation, for example, when there has been a significant change from prior CEA level or a significant change in patient status which could reflect disease progression or recurrence.**

Testing with a diagnosis of an in situ carcinoma is not reasonably done more frequently than once, unless the result is abnormal, in which case the test may be repeated once.

To summarize, NCD 190.26 provides, under the heading "Indications," that a CEA test "may be medically necessary," and thus covered by Medicare, for two broad groups of patients: (1) patients with colorectal cancer; and (2) patients with other types of cancer when the cancer tumor does not express a "more specific marker." The NCD goes on, however, to state:

> In general, a single tumor marker will suffice in following patients with colorectal carcinoma or other malignancies that express such tumor markers.

By using the words "in general," the NCD implies that there may be circumstances in which a single tumor marker may not suffice, in which case the test for CEA as a secondary marker might be medically reasonable and necessary. In other words, Medicare might, in appropriate circumstances, cover a CEA test for a type of cancer, such as medullary thyroid cancer, for which CEA is a secondary marker, depending on individualized showings of medical need.

CMS represents in the present case that this reading is precisely what NCD 190.26 contemplates. In NCD 190.26, CMS specified three categories of diagnostic codes associated with the NCD. (A diagnostic code represents a disease, health condition, or clinical finding.) The first category, labeled "ICD-9-CM Codes Covered by Medicare Program," includes codes for medical diagnoses or conditions for which the CEA test is presumptively "reasonable and necessary" and thus covered.[20] The second category, entitled "ICD-9-CM Codes Denied," lists diagnostic codes that are never covered.[21] The third category, entitled "ICD-9-CM Codes That Do Not Support Medical Necessity," lists or describes "generally non-covered codes for which there are only limited exceptions."[22] Regarding codes identified in NCDs in this third category, the Federal Register publication explained that "additional documentation could support a determination of medical necessity in certain circumstances."[23]

CMS has acknowledged in this proceeding that medullary thyroid cancer falls into this third category of diagnoses — the category of diagnoses for which coverage is not categorically precluded and which may be covered upon a showing that the CEA test is medically reasonable and necessary.[24] The general requirement for evidence of medical necessity is a statutory requirement, not

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[20] 66 Fed. Reg. at 58,810, 58,867.

[21] 66 Fed. Reg. at 58,810, 58,867-68.

[22] 66 Fed. Reg. at 58,810, 58,689.

[23] 66 Fed. Reg. at 58,810.

[24] CMS states: "Although CMS has issued an NCD regarding the CEA lab test, that NCD does not include a nationwide bar of coverage for CEA testing for appellant's diagnosis of medullary thyroid carcinoma ("MTC")." CMS Motion to Dismiss at 10-11.

a limitation imposed by the NCD.[25] Thus, NCD 190.26 does not deny Medicare coverage of CEA testing for persons with medullary thyroid cancer. Because the NCD does not deny Medicare coverage of CEA testing for that patient population, [Beneficiary] is not an aggrieved party.

[Beneficiary] correctly asserts that the Board earlier determined that he had filed an "acceptable complaint," which is a complaint filed by an aggrieved party. However, we made that determination because the record at the time indicated that [Beneficiary's] claim for coverage had been denied on the basis of the NCD. CMS has since submitted evidence and argument persuading us that the NCD does not deny Medicare coverage of CEA testing for persons with medullary thyroid cancer. Any indication previously conveyed to [Beneficiary] that the NCD prevented coverage of his claim, as opposed to simply providing that coverage for his condition had to be based on an individual showing of medical necessity, was erroneous. In other words, CMS has now clarified that its NCD does not deny coverage for CEA testing for [Beneficiary]'s condition but rather obliges the contractor to review documentation which he and/or his healthcare providers may submit on why he needs CEA testing. Given this new information, we conclude that we are legally bound to dismiss the complaint because we determine that the complainant is not, in fact, an aggrieved party.

Alternatives for further review

[Beneficiary] has other options for appealing the denial of Medicare coverage of CEA testing. First, he may submit a coverage claim for a CEA test to the appropriate Medicare Part B contractor and present medical evidence to demonstrate that the

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[25] In its "Forward," the NCD Manual explains that when a NCD like NCD 190.26 permits coverage for some indications but does not expressly exclude coverage for others, the program will make a coverage decision regarding an unmentioned or unspecified indication based, not on the NCD, but on other laws and policies and the beneficiary's individual clinical situation:

> Where coverage of an item or service is provided for specified indications or circumstances but is not explicitly excluded for others . . . the Medicare contractor is to make the coverage decision, in consultation with its medical staff, and with CMS when appropriate, based on the law, regulations, rulings and general program instructions.

NCD Manual, Ch. 1, Part 1, *Forward*.

test is reasonable and necessary for his circumstances. In that process, he is free to present this ruling and the submissions of CMS in this matter to clarify the relevance and effect of the NCD. If the claim is denied, [Beneficiary] may appeal the coverage denial via the Medicare claims appeal process.

Second, [Beneficiary] may ask CMS directly to reconsider NCD 190.26. The "NCD reconsideration" process is distinct from the NCD appeal process. The reconsideration process allows any person, not just aggrieved parties, to petition CMS to revise an existing NCD based on argument and evidence submitted by the petitioner. A reconsideration request may include a request that the identification of conditions for which coverage is presumptively approved be expanded based on current medical evidence. For example, [Beneficiary] could offer evidence through that process to request CMS to include medullary thyroid cancer as a condition for which CEA testing is indicated.

In order to initiate the NCD reconsideration process, a person must submit to CMS a complete, formal request for reconsideration that meets certain requirements specified by CMS. These requirements, and a fuller description of the NCD reconsideration process, can be found in the September 26, 2003 Federal Register. See Notice: *Medicare Program; Revised Process for Making Medicare National Coverage Determinations,* 68 Fed. Reg. 55,634, 55,636-37 (Sept. 26, 2003). (The Federal Register is available online at http://origin.www. gpoaccess.gov/fr.)

A formal reconsideration request or an informal request for guidance in the reconsideration process may be submitted by email to cms caginquiries@cms.hhs.gov. Alternatively, [Beneficiary] may write to the Director, Coverage and Analysis Group, CMS, MS C1-09-06, 7500 Security Boulevard, Baltimore, MD 21244, or call the Medicare Service Center at 800-MEDICARE (800-633-4227) for further information about how and where to file a request for NCD reconsideration.

Conclusion

Because [Beneficiary] is not an aggrieved party, the Board hereby dismisses his July 9, 2007 complaint seeking review of NCD 190.26.

/s
Sheila Ann Hegy

/s
Constance Tobias

/s
Leslie A. Sussan
Presiding Board Member

cc: CMS Acting Administrator

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Medicare Appeals Council

[dated 4/15/08]