

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DEPARTMENTAL APPEALS BOARD

ORDER OF MEDICARE APPEALS COUNCIL  
REMANDING CASE TO ADMINISTRATIVE LAW JUDGE  
Docket Number: M-12-648

In the case of

Claim for

Caris MPI, Inc.  
\_\_\_\_\_  
(Appellant)

Supplementary Medical  
Insurance Benefits (Part B)  
\_\_\_\_\_

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\_\_\_\_\_  
(Beneficiary)

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\_\_\_\_\_  
(HIC Number)

Noridian Administrative  
Services, LLC  
\_\_\_\_\_  
(Contractor)

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\_\_\_\_\_  
(ALJ Appeal Number)

**INTRODUCTION**

The Administrative Law Judge (ALJ) issued a fully favorable decision, dated December 12, 2011. The ALJ found that the appellant was entitled to payment for molecular diagnostic laboratory testing services provided to the beneficiaries on the dates of service listed on Attachment 1. The Centers for Medicare & Medicaid Services (CMS) has referred the ALJ's decision to the Medicare Appeals Council (Council) for its own motion review, pursuant to a memorandum filed on February 10, 2012. The appellant filed exceptions to the referral, which the Council received on February 27, 2012. The Council has audited the recording of the ALJ hearing, held on October 13, 2011.

The Council has decided, on its own motion, to review the ALJ's decision, because there are errors of law material to the outcome of the claims. The Council admits the referral memorandum and appellant's exceptions into the administrative record as Exhibits (Exhs.) MAC-1 and MAC-2. For the reasons set forth below, the Council vacates the hearing decision and

remands this case to an ALJ for further proceedings, including a new decision. See 42 C.F.R. § 405.1110(d).

### BACKGROUND

#### *Overpayment Determinations and Redeterminations*

The appellant submitted claims for multiple laboratory services provided to the beneficiaries on the dates of service and billed to Medicare with the Current Procedural Terminology (CPT) codes listed and described on Attachments 1 and 2.<sup>1</sup> The contractor initially paid the claims, then subsequently issued individual overpayment determinations. The contractor upheld the overpayment determinations in individual redetermination decisions. See individual claims files.

#### *QIC Reconsideration*

On July 7, 2011, the Qualified Independent Contractor (QIC) consolidated the individual claims and issued an unfavorable decision which (1) found that a majority of the services were not covered by Medicare; and (2) dismissed the requests for reconsideration of the remaining services as untimely or duplicative of previously issued dismissals. Exh. 25.<sup>2</sup> The QIC stated the contractor's reason for denying coverage was that the services were "investigational." *Id.* at 5.

The QIC then stated that, based on the reconsideration request, the appellant's "Target Now molecular profiling service is an evidence-based technology platform that utilizes established molecular diagnostic technologies with a decision support system which aids oncologists with therapeutic guidance resulting in a better therapeutic selection, thereby potentially improving progression-free survival and avoiding ineffective therapeutic agents." Exh. 25, at 5. The QIC also stated, "As the literature evolves, Target Now will evolve." *Id.* The QIC

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<sup>1</sup> CMS has developed the Healthcare Common Procedural Coding System (HCPCS) to establish "uniform national definitions of services, codes to represent services, and payment modifiers to the codes." 42 C.F.R. § 414.40(a). CPT codes are Level I HCPCS codes and are 5-position numeric codes primarily representing physician services.

<sup>2</sup> The attachment to the reconsideration indicates that the claims at issue involved 13 beneficiaries for a total of 95 CPT codes billed. Of the 95 codes billed, 24 were the subject of dismissals of the requests for reconsideration. Exh. 25, at 7-16.

evaluated the evidence submitted, which included an affidavit by Dr. D.S. *Id.* The QIC stated that Dr. D.S.'s affidavit indicated that "the use of genetic biomarkers, while promising, is at the cusp of a new age in oncology, with the science developing and improving daily. This conclusion concurs with the research noted by the QIC." *Id.* The QIC concluded that, although promising, technology for the "personalized and customized cancer treatment based on the genetic composition of the tumor . . . is still in the investigational phase." *Id.*

The QIC noted that available studies consisted of small samples and that Caris Life Sciences was currently conducting further studies of the Caris Target Now molecular tumor profiling with institutions and cancer centers. Exh. 25, at 5. The QIC then determined that "[t]he application of the services ha[s] not yet been proven to be clinically effective and [is] still considered to be investigational." *Id.* The QIC concluded that the services were not reasonable and necessary and that the appellant was responsible for the overpayment. *Id.* at 6. The QIC also dismissed 17 requests for reconsideration as untimely filed or as duplicates of previously dismissed requests. Exh. 25, at 5-6, 7-16.

#### *ALJ Hearing*

On July 26, 2011, the appellant filed a request for ALJ hearing "to challenge the QIC decision," arguing that the services provided were medically necessary, not investigational or experimental, and were ordered by the patients' physicians and required for the beneficiaries' conditions. Exh. 26, at 1. On August 29, 2011, the ALJ issued a Notice of Hearing, scheduling a hearing for October 13, 2011. Exh. 27. The Notice of Hearing was sent to the QIC and the Medicare contractor and was served on counsel to the appellant. *Id.* at 5. The ALJ framed the issue for decision as follows:

Whether there is sufficient information and medical documentation to prove that it was medically reasonable and necessary for the Appellant to provide the Beneficiaries (*See Attachment A*) with laboratory services (molecular profiling tests), pursuant to Sections 1833(e) and 1862(a)(1)(A) of the Social Security Act ("the Act") and Medicare regulations.

*Id.* at 2.

On October 13, 2011, the ALJ conducted an in-person hearing, at which appellant was represented by counsel and the ALJ heard testimony from appellant's witness Dr. A.W. and from the ALJ's independent expert witness, Dr. A.F. Dec. at 2. Dr. A.W. testified as an employee of Caris Life Sciences, which he described as a healthcare company that provides multiple services, including gastrointestinal (GI) pathology, dermatopathology, and hematopathology services. Dr. A.W. also testified that the appellant Caris MPI is a business component of Caris Life Sciences and provides molecular testing for molecular oncology under the brand name "Target Now." CD at 10:20-10:25.<sup>3</sup>

Dr. A.W. testified that molecular oncology is a rapidly evolving field and that a "great deal of innovation" is occurring. He asserted that the appellant's molecular oncology laboratory in Phoenix was "CLIA" certified and received referrals from ordering physicians around the country. According to Dr. A.W., oncologists provided the majority of referrals, while gynecologic oncologists, oncologist surgeons, and pathologists also made referrals. CD at 10:20-10:25.

Dr. A.W. testified that the molecular diagnostic testing involved taking a sample (or biopsy) from a cancerous tumor and then performing a variety of tests on that sample. Dr. A.W. stated that all of the laboratory tests were available in "the community" and some had been in use for an extended period. He testified that "molecular diagnostics" was a "catch-all phrase," but meant the identification of particular targets or biomarkers that influence therapy or that are useful in diagnosis. He stated that, from a laboratorian perspective, molecular diagnostic laboratory testing "would be using new molecular techniques manipulating the genes," but without necessarily using traditional anatomical pathology tests. He indicated that the testing involved some "very traditional anatomical pathology techniques and to a lesser extent, some of newer molecular genetic techniques." He stated that the terms "markers," "targets," "genes," and "proteins" were used interchangeably in relation to molecular diagnostic testing. CD at 10:25-10:30.

In response to a question from counsel, Dr. A.W. agreed that molecular diagnostic testing involved the identification of

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<sup>3</sup> Caris Life Sciences is headquartered in Irvine, Texas, and has a laboratory in Phoenix, Arizona, where molecular testing is performed. Dr. A.W. also testified that the company has laboratories in Dallas, Texas; Annapolis, Maryland; Newton, Massachusetts; and Lausanne, Switzerland. *Id.*

certain genes or proteins that may or may not be receptive to a particular course of treatment. He stated that the concept of "personalized medicine" in oncology differs from the "histologic meaning like microscope assessment of the tumor" and, unlike microscope assessment, seeks to determine the "actual genes that are driving the tumor to grow out of control." Dr. A.W. clarified that "Target Now is a brand name of the service" and "doesn't embody a specific test." He stated that the beneficiaries were cancer patients, some of whom received a single test, while others received a broad array by physicians desperately seeking therapeutic options. CD at 10:30-10:35.

Dr. A.W. testified that certain tests were ordered as the result of FDA label information, the National Comprehensive Cancer Network (NCCN) Guidelines, the American Society of Clinical Oncology Guidelines, and some tests provided were covered in the Local Coverage Determination (LCD) issued by the Medicare contractor Noridian Administrative Services.<sup>4</sup> He also indicated that a particular "test" could actually be comprised of several different laboratory tests, which were billed consistent with the CMS National Correct Coding Initiative. Dr. A.W. stated that he did not know why the contractor had denied payment for the laboratory tests billed. CD at 10:35-10:45.

Dr. A.W. then considered the record for the services provided to beneficiaries B.B. and J.K. CD at 10:35-10:49. During this testimony, Dr. A.F., the independent medical expert, stated that she reviewed all files and that it was her opinion that there was sufficient documentation to establish that the laboratory services were medically reasonable and necessary. *Id.* at 10:42-10:44, 10:48-10:49. Dr. A.F. did not provide an underlying analysis to support her opinion.

#### *ALJ Decision*

On December 12, 2011, the ALJ issued a fully favorable decision. In the Findings of Fact, the ALJ listed each of the 13 beneficiaries, "CPT Code: 88381-7659," and the date of service. Dec. at 2-5. In each finding, the ALJ stated that "The Target Now test was performed" on the date of service. *Id.* The ALJ recounted the appellant's contention that "the Target Now testing panel was not a duplicate procedure but a distinct claim for a manual micro dissection, a diagnostic test for cancer," that it "was not experimental or investigational," and that "the

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<sup>4</sup> Contractor LCDs can be located in the Medicare Coverage Database at <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>.

Appellant stated that the Target Now test should be paid because the test was crucial to developing crucially appropriate treatment decision for cancer patients." *Id.* at 5. In support, the ALJ provided a block quote that is consistent with Dr. A.W.'s testimony. *Id.*, citing Exhs. 26 (request for ALJ hearing) and 29 (Prehearing Statement).<sup>5</sup> The ALJ found that the Clinical Dossier in the record, prepared by the appellant, was consistent with Dr. A.W.'s testimony. *Id.*, citing Exh. 25, at 29-50. The ALJ also found that the record contained a letter from Dr. D.S. endorsing "molecular profiling offered through Target Now" and "medical articles regarding the use of molecular profiling." *Id.*, citing Exhs. 24, at 2-5; 22.

The ALJ then found that "[b]ased on a review of the evidence, I find that the Appellant is entitled to payment" for molecular profiling services provided to the 13 beneficiaries from March 10, 2010, to August 27, 2010 (sic). Dec. at 8. The ALJ found that the services were not experimental or investigational and were necessary for therapy decisions, based on a block quotation that duplicates appellant's contentions (*compare* Dec. at 5, 8):

Based on the aforementioned, I find that Target Now is certainly effective in that it allows doctors to make educated decisions on how best to treat their patients on a long-term basis and potentially minimize their exposure to unnecessary drugs. I also find the testimony in record by Dr. [A.W.] to be credible as substantiated by the Clinical Dossier, medical articles regarding the use of molecular profiling, and the medical records specific to the 13 Beneficiaries in appeal.

*Id.* at 8.

#### *CMS Referral*

On February 10, 2012, CMS submitted a referral memorandum for the Council's own motion review. Exh. MAC-1. Generally, CMS presents four bases for ALJ legal error. First, CMS argues that the ALJ erred in "ordering Medicare reimbursement for the twenty-four services for which the QIC dismissed Appellant's request for reconsideration." Exh. MAC-1, at 1-2. Next, CMS argues that the ALJ erred in failing to adjudicate all issues brought out in the initial determination, redetermination, and reconsideration not decided entirely in the appellant's favor by

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<sup>5</sup> The Council cannot locate the statement cited. Dec. at 5, 8; Exhs. 26, 29.

addressing coverage only for the claims involving CPT code 88381. *Id.* at 2. Further, CMS argues that the ALJ erred in finding that the "molecular profiling services were medically reasonable and necessary" without considering the administrative standards set forth in the Medicare Program Integrity Manual (MPIM)(Pub. 100-08). *Id.*, citing MPIM Ch. 13, § 13.7.1.<sup>6</sup> Finally, CMS argues that the ALJ erred in failing to consider the coverage standards set forth in the contractor LCD for CPT codes 83890, 83891, 83898, 83904, 83909, and 83912. *Id.*, citing 42 C.F.R. §§ 410.32, 405.1062(a). CMS concludes by stating that the contractor's Medical Director requested to participate in any further adjudication in this case. *Id.* at 18.

### *Appellant Exceptions*

On February 27, 2012, the appellant filed exceptions to the referral. Exh. MAC-2. Generally, the appellant argues that the ALJ decision is correct, except for the claims previously dismissed by the QIC. *Id.* at 2. The appellant asserts that CMS, through the Administrative Qualified Independent Contractor (AdQIC), did not consider the entire record before the ALJ, that the ALJ "considered all of the issues now being raised" by the AdQIC, and that the AdQIC is seeking to "relitigate issues that were considered and correctly decided by the ALJ." *Id.* at 2.

The appellant also argues that the ALJ gave notice of the hearing to the contractor, who did not participate in the hearing, and now seeks a second chance at litigating decided issues. Exh. MAC-2, at 2-3. The appellant further argues that CMS did not consider the testimony of the ALJ's independent medical expert in its referral, that "it is simply not the case that the LCD was not considered," and that it is also incorrect "that the ALJ did not consider each of the tests that was provided to each of the patients. The fact that her decision refers only to CPT code 88381 reflects nothing more than the ALJ's method of organizing her discussion. It does not mean she did not consider coverage for each test." *Id.* at 4. The appellant concludes, "With the exception of correcting the procedural denials, this Council should deny the request to review the outcome of the substantive issues presented to the ALJ . . . ." *Id.* at 5.

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<sup>6</sup> Manuals issued by CMS can be found at <http://www.cms.hhs.gov/manuals>.

## AUTHORITIES

### *ALJ Review of QIC Reconsideration*

The issues before an ALJ "include all the issues brought out in the . . . reconsideration that were not decided entirely in a party's favor." 42 C.F.R. § 405.1032(a). A party has a right to ALJ review of a QIC dismissal of a request for reconsideration when it files a written request for review within 60 days following receipt of the notice of dismissal. 42 C.F.R. § 405.1004(a)(1). If the ALJ determines that the dismissal was incorrect, the ALJ vacates the dismissal and remands the case to the QIC for reconsideration. 42 C.F.R. § 405.1004(b). "An ALJ's decision regarding a QIC's dismissal of a reconsideration request is binding and not subject to further review." 42 C.F.R. § 405.1004(c).

### *Local Coverage Determinations (LCDs) and Other Policies Not Binding on ALJs*

A local coverage determination (LCD) is a decision by a Medicare contractor on whether to cover a particular service on a contractor-wide basis pursuant to section 1862(a)(1)(A) of the Act, i.e., a decision on whether or not a particular service is "reasonable and necessary." MPIM, Ch. 13, § 13.1.3. An ALJ is not bound by an LCD or CMS program guidance, including program memoranda and administrative manuals, "but will give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062(a) (emphasis supplied). "If an [ALJ] declines to follow a policy in a particular case, the [ALJ] decision *must* explain the reasons why the policy was not followed. An [ALJ] decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect." 42 C.F.R. § 405.1062(b) (emphasis supplied). CMS makes clear in a regulation that an ALJ "*may not* set aside or review the validity of an [LCD] for purposes of a claim appeal. An ALJ or the DAB *may* review or set aside an [LCD] in accordance with part 426 of this title." 42 C.F.R. § 405.1062(c) (emphasis supplied).

*Reasonable and Necessary Determinations - Experimental  
and Investigational Services*

Section 1862 of the Act provides that:

(a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items and services -

(1)(A) which . . . are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.

Historically, in making coverage determinations, CMS has interpreted the terms reasonable and necessary to mean that the item or service in question is safe and effective and not experimental. CMS has further determined that the relevant tests for applying these terms are whether the item or service has been proven safe and effective based on authoritative evidence, or alternatively, whether the item or service is generally accepted in the medical community as safe and effective for the condition for which it is used. 54 Fed. Reg. 4304 (Jan. 30, 1989); 60 Fed. Reg. 48417 (Sept. 19, 1995); see also 52 Fed. Reg. 15560 (Apr. 29, 1987). Although an FDA-regulated product must receive FDA approval or clearance (unless exempt from the FDA premarket approval review process) for at least one indication to be eligible for Medicare coverage, except for certain Category B devices, FDA approval/clearance alone does not generally entitle a device to Medicare coverage. 68 Fed. Reg. 55634, 55636 (Sept. 26, 2003).

The Act vests in the Secretary the authority to make coverage decisions. Under that authority, CMS issues National Coverage Determinations (NCDs) that state whether specific medical items, services, treatment procedures, or technologies may be paid for by Medicare. In the absence of a specific NCD, the Medicare contractor is responsible for determining whether an item or service is reasonable and necessary. (See preface to Coverage Issues Manual (reprinted at 54 Fed. Reg. 34555 (Aug. 21, 1989).) The Medicare contractor provides coverage determinations on a contractor-wide basis by issuing an LCD. In the absence of an applicable LCD, when determining whether an item or service is medically reasonable and necessary, individual adjudicators, including ALJs and the Council, take into account the same issues that CMS and its contractors consider when they make

coverage determinations, including, when appropriate, factors that contractors use when they develop LCDs.

CMS has provided guidance for making "reasonable and necessary" determinations in developing LCDs in the MPIM. The MPIM instructs contractors that, "[i]n order to be covered under Medicare, a service shall be reasonable and necessary." MPIM, Ch. 13, § 13.5.1. The MPIM contemplates that, in making a determination as to whether an item or service is reasonable and necessary, contractors will analyze whether the item or service is safe and effective, and not experimental or investigational:

Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational . . . ;  
and
- Appropriate, including the duration and frequency that is considered appropriate for the service . . . .

*Id.*

The MPIM further instructs contractors to base LCDs on the strongest evidence available at the time the determination is issued. In the order of preference, this includes:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standards of practice), supported by sound medical evidence based on:
  - Scientific data or research studies published in peer-reviewed medical journals;
  - Consensus of expert medical opinion (i.e., recognized authorities in the field); or

- Medical opinion derived from consultations with medical associations or other health care experts.

*Id.* at § 13.7.1. The manual further explains:

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

*Id.*

### **DISCUSSION**

The Council has considered the record, the agency referral, and the appellant's exceptions, and finds that the ALJ erred in three respects. First, the ALJ did not review the QIC's dismissals of the requests for reconsideration. Second, the ALJ did not afford substantial deference to Local Coverage Determination (LCD) for Genetic Testing (L24308) or provide reasons for not doing so in the decision. Third, the ALJ did not determine whether services not specified in the LCD's coverage requirements are reasonable and necessary, and not experimental and investigational, as set forth in the MPIM. The Council therefore vacates the ALJ's decision and remands this case for supplementary proceedings.

#### *1. ALJ Review of QIC Dismissals*

CMS first argues that the ALJ erred "in ordering Medicare reimbursement for the twenty-four services for which the QIC dismissed [the] request for reconsideration." Exh. MAC-1, at 1. The reconsideration decision states that the QIC dismissed some requests for reconsideration, and the attachment indicates that the dismissal involved 24 of 95 services. Exh. 25, at 5-6, 7-16.

The appellant's request for hearing states that the appellant filed "the request for a hearing . . . to challenge the QIC

decision" and argues that it disagrees with the QIC's decision because the non-covered services are reasonable and necessary, are not investigational or experimental, and were ordered by the treating physician. Exh. 26, at 1. The appellant's pre-hearing statement also states that "Caris timely requested a hearing with an administrative law judge to challenge the QIC Decision." Exh. 29, at 3. Like the request for hearing, the pre-hearing statement acknowledges that "[i]n a few cases the QIC dismissed the appeals because of untimely submission or some other alleged procedural failure. This Prehearing Statement and the hearing, itself, however, will focus on the investigational denials." *Id.* In its exceptions to the agency referral, the appellant argues that the Council should decline the referral as "the ALJ's Decision is correct in all respects except for that portion of the ALJ's Decision which pertains to certain claims that had been previously dismissed by the QIC on procedural grounds . . . ." Exh. MAC-2, at 2. The appellant concludes that the Council should decline the referral "with the exception of correcting the procedural denials . . . ." *Id.* at 5.

The ALJ made no findings concerning the dismissals, and the attachment to the ALJ's decision lists only the beneficiary name, Health Insurance Claim Number (HICN), and the date of service. The attachment thus does not specify the services that the ALJ actually considered in the fully favorable decision. The Findings of Fact also mention only CPT code 88381-7659. Dec. at 2-5. The ALJ's decision does not mention multiple services billed to Medicare under CPT codes listed on the attachment to this action. See Attachment 2.

The Council finds that the ALJ erred in failing to consider the dismissals. The appellant requested an ALJ hearing on the QIC's decision, which included both coverage determinations and dismissals of the requests for reconsideration. While the appellant's arguments in the request for hearing "focused on" the coverage determinations, neither the request for hearing nor the pre-hearing statement indicates that the appellant requested a hearing only on the QIC's coverage determinations. The appellant's exceptions further support that the appellant sought ALJ review of the dismissals.

## 2. *Application of Local Coverage Determination (LCD) for Genetic Testing (L24308)*

CMS next argues that the ALJ committed legal error in only adjudicating the claims involving CPT code 88381, without

addressing "the other eleven services at issue." Exh. MAC-1, at 2. CMS also argues that the ALJ erred in failing to consider the application of the LCD to the six CPT codes that fall under its coverage provisions. *Id.*

Contractor Noridian Administrative Services issued an LCD for genetic testing that addresses whether laboratory services billed to Medicare by the appellant under some CPT codes at issue are reasonable and necessary.<sup>7</sup> The LCD generally discusses genetic testing in relation to patients with hereditary breast and ovarian cancer and hereditary colorectal and endometrial cancer syndromes. Exh. MAC-3, at 3-7. Under indications and limitations of coverage, the LCD lists six CPT/HCPCS codes at issue in this case (CPT codes 83890, 83891, 83898, 83904, 83909, and 83912). *Id.* at 8-9. The LCD also lists ICD-9-CM diagnosis codes that support medical necessity for BRCA1 and BRCA2 gene mutation testing; hereditary colorectal cancer (HNPCC) and Familial Adenomatous Polyposis (FAP) testing including APC, MYH, and HNPCC syndromes; KRAS testing; and JAK2 testing. *Id.* at 9-12. Diagnoses that do not support medical necessity are all ICD-9-CM codes not listed in the LCD. *Id.* at 12.

The laboratory or billing provider must make supporting documentation available upon request, which "must include personal and family history information consistent with this policy, and a signed informed consent indicating that the patient was informed of" issues and information associated with genetic testing. Exh. MAC-3, at 12 (underline in original). "The laboratory or billing provider must have on file the physician requisition which sets forth the diagnosis or condition (ICD-9-CM code) that warrants the test." *Id.*

The LCD also explains how to request "a formal reconsideration" of the LCD from the contractor, which "must be accompanied by complete copies of relevant peer-reviewed literature that support the recommendation. Abstracts are not sufficient for this purpose." Exh. MAC-3, at 13. In response to provider input, the contractor states, "We continue to review submitted literature on other examples of this emerging genetic testing field and will consider adding coverage of new disease-specific tests if and as literature support warrants." *Id.* at 16.

Contrary to the appellant's exceptions, the ALJ's decision does not reflect that the ALJ considered the LCD in reaching her findings. Exh. MAC-2, at 3. The ALJ does not mention the LCD or

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<sup>7</sup> The Council enters the LCD into the record as Exhibit MAC-3.

its requirements in the Findings of Fact, Principles of Law (although the ALJ provides a brief discussion of general Medicare regulations concerning LCDs), Analysis, or Conclusions of Law. Dec. at 2-9. Medicare regulations require that an ALJ afford substantial deference to an LCD when applicable in a case or explain the reasons for not doing so. 42 C.F.R. § 405.1062. The ALJ erred in failing to do so in this case.

### 3. *Experimental and Investigational Services*

CMS has determined that services that are experimental and investigational are not "reasonable and necessary" and are not covered by Medicare. MPIM Ch. 13, § 13.5.1. In this case, the contractor based its overpayment determinations on grounds that the services billed were "investigational." Exh. 25, at 5.

Each of the ALJ's findings of fact refers to the "Target Now test." Dec. at 2-5. In the case of beneficiary C.B., the ALJ cites to an appellant form captioned "Caris Dx Tumor Profiling Requisition," which contains multiple information fields, including patient information, client information (ordering physician), and a field captioned "TEST REQUESTED (REQUIRED) Caris Dx pathologists will select the stains, antibodies, markers, FISH/ISH probe(s) needed based on their medical judgments." *Id.* at 2; C.B. Exh. 21, at 31.<sup>8</sup> This field contains six "fill in the circle" options, and the circle selected for this service is:

TARGET NOW™ COMPLETE MOLECULAR PROFILING ANALYSIS  
 IMMUNOHISTOCHEMISTRY (IHC) AND DNA MICROARRAY ANALYSIS  
 (Both formalin fixed paraffin-embedded and fresh flash  
 frozen tissue is required)

*Id.* Other options include the appellant's immunohistochemistry (HCD) analysis (up to 44 antibodies/markers); DNA microarray analysis (up to 81 druggable targets); *KRAS* mutational analysis; fluorescence in situ hybridization (FISH), with subsidiary options for EGFR and HER2; and H&E stain (consult only). *Id.*

The Council finds that the ALJ's findings of fact concerning the "Target Now test" are unclear, as the findings for each beneficiary indicate that all beneficiaries received the same "Target Now test," although the appellant submitted claims with multiple and differing CPT codes. Attachment 1. The lack of

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<sup>8</sup> Citations to individual beneficiary claims files shall be preceded by the beneficiary's initials.

clarity is compounded by Dr. A.W.'s testimony that "Target Now is a brand name of the service. It doesn't embody a specific test." CD at 10:30-10:35. Dr. A.W. further testified that the concept of "personalized medicine" in the field of oncology involved "get[ting] beyond that broad histologic meaning like microscope assessment of the tumor and let's see what actual genetic causes are driving the tumor to grow out of control." *Id.* Dr. A.W. stated that the testing in the cases at issue use "very traditional anatomical pathology techniques and to a lesser extent, some of newer molecular genetic techniques." CD at 10:25-10:30. Dr. A.W. conceded at the outset of his testimony that there was a "great deal of innovation" taking place in the field of molecular oncology and that Caris Life Sciences sought to use his background to deliver tests and services "that were grounded in evidence and were routinely used in the community." CD at 10:20-10:25.

The Executive Summary in the Caris Life Sciences Clinical Dossier on Target Now Molecular Profiling explains:

There is now a rapidly expanding peer-reviewed medical literature [sic] describing the correlation between protein or biomarker expression and therapeutic response. Therefore, a detailed biomarker assessment should be performed before embarking on desperately needed and often very expensive therapy. Target Now meets this need.

The *Target Now Molecular Profiling service* has several key features.

- The medical literature that correlates chemotherapy drugs and biomarkers to response or lack of response has been reviewed, rated for level of evidence, and summarized.
- When a patient with a refractory tumor is referred for Target Now molecular profiling, a customized panel of biomarkers is selected based on the patient's clinical characteristics and the medical literature.
- The panel of biomarkers indicated typically include several technologies including immunohistochemistry (IHC), Fluorescent In-Situ Hybridization (FISH) microarray (MA) and polymerase chain reaction (PCR).
- *The test specified by the best evidence is the test that is performed by Caris Life Sciences.*

- All testing techniques are established and accepted by the general laboratory community. None of the individual tests are investigational or research use only (RUO).
- The biomarker assays are performed at the Caris Life Sciences CLIA-certified laboratories.
- The results of the biomarker panel are summarized in a report to the treating physician that includes a list of potential drugs with anticipated clinical benefit, as well as those associated with a lack of clinical benefit.
- *The Target Now program* includes an outcome focused registry that will provide important data to the medical community.
- The cost of *the Target Now program* is based on those biomarkers assayed. For a typical patient this is approximately \$3,000, far less than the cost of the majority of chemotherapy regimens being considered for the patient.

The evidence which supports *Target Now molecular profiling service* is the continuously updated world literature on cancer chemotherapy drugs and biomarkers as correlated with response or lack of response. A recent prospective study published in the Journal of Clinical Oncology demonstrated that drug choices based on Target Now molecular profiling improved progression-free survival compared with the patient's prior regimen.

Exh. 25, at 31-32 (emphasis supplied).

In sum, Dr. A.W. testified that Target Now is a brand name, while the Clinical Dossier describes Target Now Molecular Profiling as a service, a test, and/or a program. Moreover, Dr. A.W. testified that the terms "markers, targets, genes, and proteins" are used interchangeably in discussing laboratory testing in the field of oncology. CD at 10:25-10:30. Although unclear, it appears that the appellant generally provides gene testing of tumor samples of beneficiaries who have various cancer diagnoses. It is thus necessary to determine whether the claims submitted are "reasonable and necessary" in each case under the applicable authority.

The Council notes that the LCD addresses the subject of this appeal, i.e., genetic testing for forms of cancer. For example, the "KRAS" test is both discussed in the LCD and listed on the appellant's tumor requisition form. Compare Exh. MAC-3, at 7 with C.B. Exh. 21, at 31. Six CPT codes at issue are listed in the LCD with accompanying coverage requirements (CPT codes 83890, 83891, 83898, 83904, 83909, 83912), while the appellant billed six CPT codes that are not listed in the LCD (CPT codes 83902, 83907, 88360, 88368, 88381, 88385). Attachment 2. Consistent with Dr. A.W.'s testimony, the LCD clearly recognizes that the field of genetic testing is rapidly changing, and the contractor updated the LCD in response to provider recommendations. Exh. MAC-3, at 14-16. The LCD also states that the contractor "continue[s] to review submitted literature on other examples of this emerging genetic testing field and will consider adding coverage of new disease-specific tests if and as literature support warrants." *Id.* at 16.

The CMS referral lists each of the medical articles of the administrative record. Exh. MAC-1, at 20-21, citing Exh. 22. CMS also encloses the complete article from an excerpt in the administrative record published by the Journal of the National Cancer Institute on December 29, 2010. Exh. MAC-1, at 24-27; see Exh. 22, at 9. In relevant part, the article describes "[o]ne vital goal of cancer research" as being "a test that profiles individual tumors at the molecular level in order to guide treatment. Some single-marker predictive tests are now standard, as are two well-validated genomic prognostic tests for breast cancer." Exh. MAC-1, at 24. The article then states, "But for most tumors, such personalized tests are still viewed as futuristic." *Id.* (emphasis supplied). The article also discusses "genomic test methods" (commercial tumor profiling tests) presented by three companies at a recent cancer molecular diagnostics conference, including one by Caris Life Sciences. *Id.* at 24. The article refers to "all of them [as] strictly experimental" (*id.*) and states:

[T]hese tests . . . have not yet proven better at guiding cancer treatment than standard methods. Their effectiveness has not been validated, and no randomized trials have taken place. Claims for their worth hinge on the argument that molecular profiling information should translate to better treatment decisions, but no one knows yet whether that assumption is true. Critics argue that the tests should be used only to direct patients to clinical

trials until the tests prove utility in their own randomized clinical trials. *Such trials are planned, but these companies aren't waiting.*

*Id.* (emphasis supplied).

The article also includes Dr. A.W.'s observation, "Think of it more as a literature aggregation profiling platform than an isolated test." Exh. MAC-1, at 25. According to the article, one clinical trial has been conducted. The investigators, whose paper was published in the *Journal of Clinical Oncology*, concluded that "the molecular profiling approach is promising." However, the lead author of the paper and colleagues opined that "using patients as their own control subjects can introduce biases that can skew the results," and that "a randomized trial would be preferable." *Id.* at 25-26 (brackets omitted from quote).

As noted, in the absence of an applicable LCD, an ALJ and the Council make "reasonable and necessary" determinations using the standards applied by Medicare contractors in formulating LCDs. MPIM Ch. 13, § 13.5. In part, those standards include that the service provided must be safe and effective for the condition treated, and not experimental and investigational. *Id.* The determination is based upon published evidence based on definitive randomized clinical trials or other definitive studies and general acceptance within the medical community. *Id.* § 13.7.1. Acceptance by individual or a limited number of providers, or testimonials or "limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community." *Id.*

The ALJ based the fully favorable decision on the appellant's contentions in response to the QIC's reconsideration, "the testimony in the record by Dr. [A.W.] [as] substantiated by the Clinical Dossier, medical articles regarding the use of molecular profiling, and the medical records" of the beneficiaries. Dec. at 8. The Council finds this analysis insufficient, standing alone, to establish that the Target Now services provided are not experimental and investigational and are reasonable and necessary. The Council therefore remands this case to the ALJ for consideration under the applicable authority.

#### 4. LCD Challenge

The LCD includes coverage standards for some, but not all, of the laboratory services provided. The ALJ shall determine whether the appellant's request for hearing is in effect a request to set aside or review the validity of the LCD for Genetic Testing (L24308) in a claims appeal that should be filed under 42 C.F.R. part 426. 42 C.F.R. § 405.1062(c). As the contractor's local coverage policy is at issue on remand, the Council finds it reasonable for the ALJ to provide notice of the proceedings to the contractor's medical director, consistent with the request to the AdQIC.

#### REMAND ORDER

1. The ALJ shall offer the parties the opportunity for a hearing. The ALJ shall provide notice of the hearing to the medical director of the contractor at the address provided by the AdQIC. Exh. MAC-1, at 18.
2. The ALJ shall review the QIC's dismissals of the requests for reconsideration. 42 C.F.R. § 405.1004.
3. The ALJ shall determine whether the appellant's request for ALJ hearing, as to the billed codes that are not addressed in the LCD, is a request to set aside or review the validity of the contractor's LCD for Genetic Testing (L24308) in a claims appeal and should instead be filed under 42 C.F.R. part 426. 42 C.F.R. § 405.1062(c).
4. If the ALJ determines that the appellant's request for hearing, as to the billed codes that are not addressed in the LCD, is not a request to set aside or review the validity of the contractor's LCD for Genetic Testing (L24308), then the ALJ shall determine whether those services claimed are reasonable and necessary under section 1862(a)(1)(A) of the Act pursuant to the provisions of LCD L24308 and MPIM Ch. 13, §§ 13.5, 13.7.
5. For those claims made using the codes addressed in the LCD, the ALJ shall determine whether those claims were for services reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act and the LCD.

6. The ALJ shall also address the issue of liability for any overpayments found, under sections 1879 and 1870 of the Act.
7. The ALJ shall issue a decision with findings of fact and conclusions of law based upon record evidence. 42 C.F.R. §§ 405.1042(a), 405.1046(a).

The ALJ may take further action not inconsistent with this order.

MEDICARE APPEALS COUNCIL

/s/ Susan S. Yim  
Administrative Appeals Judge

/s/ Clausen J. Krzywicki  
Administrative Appeals Judge

April 24, 2012