CMS Referral for Own Motion Review by DAB/MAC

Appellant at ALJ Level	ALJ Appeal Number
Strand Analytical Laboratories	*1-921456878*
Beneficiary (if not the Appellant) ☒List attached	ALJ Decision Date *September 20, 2012*
Health Insurance Claim Number (HICN)*	Specific Item(s) OR Service(s) *DNA tests*
Provider, Practitioner OR Supplier *Strand Analytical Laboratories*	☐ **Part A** ☒ **Part B**

Basis for referral

Any Case	**CMS as a Participant**	**Pre-BIPA**
☒ Error of law material to the outcome of the claim	☐ Decision not supported by the preponderance of evidence	☐ Decision not supported by substantial evidence
☐ Broad policy or procedural issue of public interest	☐ Abuse of discretion	☐ Abuse of discretion

Rationale for Referral:

Strand Analytical Laboratories (Appellant) is a clinical laboratory that furnishes DNA Specimen Provenance Assignment (DSPA) testing for the purpose of confirming that surgical biopsy samples furnished to diagnose prostate cancer belong to the correct patient. The Medicare administrative contractor (MAC) paid the claims for the services initially but subsequently recouped $44,480.80 based on its review of multiple claims and services. The MAC found the services constituted quality assurance activities and were not separately reimbursable. The QIC affirmed the denial.

The administrative law judge (ALJ) reversed the denials, finding that evidence in the record demonstrates:

- that the DSPA testing fits the definition of diagnostic testing, as defined by Medicare;
- that the physician specifically ordered the DSPA testing based on the individual patient's biopsy results;
- that the tests were administered as billed, and the information was used by the physician to aid in the assessment of a medical condition or the identification of a disease; and
- that the DSPA tests were not part of a quality assurance program, and are not done for every patient, but for specific patients where the physician determined that specific information was required to diagnose and treat the patient

The ALJ erred as a matter of law in finding the DSPA testing is a separately reimbursable diagnostic test. "All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJs and the MAC." 42 C.F.R. 405.1063(a). Regulations governing clinical laboratories and laboratory tests require laboratories to meet certain quality standards described in 42 C.F.R. Part 493, Subpart K, including the requirement that, "[t]he laboratory must establish and follow written policies and procedures that ensure positive identification

and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results." 42 C.F.R. § 493.1232. Thus, "procedures that ensure positive identification and optimum integrity of a patient's specimen" constitute part of a laboratory's quality system requirements and may not be billed separately as diagnostic tests.

Additionally, § 1862(a)(1)(A) of the Act limits Medicare payment to items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 C.F.R. § 410.32(a) states all diagnostic tests must be ordered by the physician "who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." DSPA testing does not diagnose or treat an illness or injury, nor can its results be used to manage a specific medical problem. In particular DSPA testing cannot diagnose or treat either elevated PSA, the diagnosis for which DSPA testing was billed, or cancer. Tests that do not diagnose or treat an illness or disease do not constitute a covered Medicare benefit. Furthermore, such tests cannot be considered reasonable and necessary to diagnose treat the patients' cancer.

Background:

The Appellant, which describes itself "[a]s a comprehensive provider of identity confirmation testing services," offers a service called the Know Error system designed to reduce errors due to mislabeling and contamination of biopsy samples. Http://stranddiagnostics.com/. For purposes of Medicare payment and this referral, the central feature of the system is DSPA testing. The Appellant describes DSPA testing as "an integral component of the diagnostic test cycle which utilizes DNA microsatellite analysis to provide independent concordance of a cancer diagnosis, putatively assigned to a given patient based on histopathology examination." Exh 22 at P 045.[1] Stated more simply on the Know Error website, "The know error® system uses bar coding, forensic principles and DNA matching to confirm that surgical biopsy samples being evaluated belong exclusively to the patient being diagnosed, arming physicians with the critical information they need to proceed confidently with treatment recommendations." Http://knowerror.com/; *see also* http://knowerror.com/system-details/core-features/ ("Through the use of microsatellite analysis … DSPA testing virtually eliminates diagnostic mistakes due to [specimen provenance complications] by verifying the patient's identity at the molecular level.")

The Appellant provided testing for DNA matching to 28 Medicare beneficiaries between November 2, 2009 and April 28, 2010. The Appellant reported claims to Medicare with the following Current Procedural Terminology (CPT) codes:

[1] The binders are not paginated, so we cite the last three digits of the stamp in the lower left.

- 83890 – molecular diagnostics; molecular isolation or extraction, each nucleic acid type (i.e., DNA or RNA)
- 83900 – molecular diagnostics; amplification, target, multiplex, first 2 nucleic acid sequences
- 83901 – molecular diagnostics; amplification, target, multiplex, each additional nucleic acid sequence beyond 2 (list separately in addition to code for primary procedure)
- 83907 – molecular diagnostics; lysis of cells prior to nucleic acid extraction (eg, stool specimens, paraffin embedded tissue), each specimen
- 83909 – molecular diagnostics; separation and identification by high resolution technique (eg, capillary electrophoresis), each nucleic acid preparation
- 83912 – molecular diagnostics; interpretation and report

The Appellant typically billed the tests with ICD-9 code 790.93 (elevated prostate specific antigen (PSA)).[2] *See e.g.*, Attachment A. National Government Services (NGS), the MAC in the Appellant's jurisdiction, paid the claims initially. However, during post payment review, NGS requested documentation for services provided between November 1, 2009 and April 30, 2010. Exh 11 at P 553. On November 19, 2010, NGS notified the Appellant it had been overpaid $44,480.80. *Id.* at P 569. NGS explained 41 claims and 1,869 services were reviewed and all services should have been denied because "medical necessity for service(s) [was] not supported." *Id*. at P 570. NGS stated further, "The services billed have been determined to be a *quality assurance* activity and as such is not separately reimbursable. The payment for costs associated with normal specimen handling is included in the reimbursement for the diagnostic tests for which the specimen was obtained." *Id.* at P 570; emphasis added. NGS requested repayment of the overpayment on December 2, 1010. Exh 12 at P 536.

In its request for redetermination, the Appellant argued:

- DPSA is a molecular test ordered by the treating physician as an integral part of the inherently complex tissue biopsy—diagnosis—report test cycle (the "Test Cycle"). The results of the DSPA test are an integral component of the body of information obtained by the ordering physician to inform his or her accurate and timely diagnosis of certain cancers. Specifically, DSPA testing prevents misdiagnosis and inappropriate or unnecessary medical treatment which can result from undetected specimen provenance complications such as *specimen contamination or misidentification*. DSPA testing provides an objective, measurable assessment to accompany subjective histopathology, and improves quality of care, patient outcomes, and patient safety by enabling the physician to recommend the treatment that is most appropriate for a particular identified patient. As a physician ordered test which an increasing number of clinicians consider to be a reasonable and necessary component of the diagnosis and treatment of patients, we believe that DSPA is clearly consistent with Medicare coverage rules.

[2] Elevated PSA levels may indicate prostate cancer.

- In that DSPA provides independent concurrence of the attribution of a suspected cancer diagnosis to *a* patient, the policy supporting Medicare coverage of DSPA testing is similar to that which supports the unambiguous Medicare coverage of second opinions and special stains ordered by an interpreting physician.
- Furthermore, an outside review of our lab initiated in 2009 by CMS (pursuant to CLIA regulations) has confirmed that the testing performed by Strand does, in fact, impact diagnosis and treatment of patients, an assessment which we feel lends additional support to the position that DSPA testing is reimbursable by Medicare.

Exh 13 at P 498; emphasis added.

On April 7, 2011, NGS issued an unfavorable redetermination decision, explaining, "the facts received about the case in question have been carefully studied. The medical facts provided do not warrant payment for multiple procedures." Exh 14 at P 478. With the request for reconsideration, the Appellant's counsel submitted a position paper in which he argued:

1. The diagnostic laboratory services provided were medically necessary and appropriate for the care of the beneficiaries at issue and were properly ordered by the physician;
2. NGS improperly and illegally imposed a de facto LCD upon Strand without following proper notice and rule-making procedures and in contravention of 26 wholly favorable ALJ opinions finding the testing at issue to be medically necessary in identical cases;
3. [The Appellant] provided clinical laboratory services determined to be medically necessary and appropriate by the treating physician and Strand cannot, without inappropriately engaging in the practice of medicine, override, dispute or challenge the treating physician's determination of medical necessity;
4. Strand is a Provider Without Fault as defined by Section 1870 of the Social Security Act;
5. Strand is entitled to payment for the services rendered under the doctrine of Waiver of Liability.

Exh 15 at P 601 and P 615. The Appellant also argued that, as an independent clinical laboratory, it is not required to make individual medical necessity assessments. *Id.* at P 616. On February 24, 2012, the QIC affirmed the denials. Exh 18 at P 446. Noting "payment for costs associated with normal specimen handling is included in the reimbursement for the diagnostic tests for which the specimen was obtained," the QIC determined each "service was rendered as a confirmation of specimen handling, not to provide a diagnosis or treatment of the beneficiary's condition." *Id*. at P 450.

The Appellant submitted a pre-hearing brief to the ALJ in which it describes DSPA testing as an integral component of a so-called two-step "diagnostic testing cycle" that involves "conventional histopathology/microscopy" and DSPA testing. Exh 22 at P 045 – P 046. The Appellant states, "The DSPA portion of the diagnostic testing cycle

eliminates the potential for misdiagnosis that is inherent in conventional histopathology/microscopy." *Id*. at P 046. More specifically, the Appellant explains:

> In the past, physicians treating patients with a suspected cancer diagnosis were forced to accept the imprecise testing cycle that led to assignment of a final cancer diagnosis because the histopathology portion of the testing cycle necessarily involves passing the specimen with the suspected cancer cells through the custody of several different parties, and subjecting the specimen to various laboratory procedures during which the tissue and its various means of identification are necessarily estranged. Diagnostic errors are inherent in this process, for a number of reasons, including, by way of example, occult specimen transposition or contamination.

Id. at P 047. The Appellant argues further that DSPA testing cannot be considered "quality assurance measure" as characterized by the MAC and the QIC. *See* Appellant's "Pre-Hearing Brief," Exh 22 at P 052. To support its contention, the Appellant cited *College of American Pathologists v. Heckler*, a 1983 district court case addressing the distinction under § 1887(a)(1) of the Act between separately payable services "personally rendered for an individual patient by a physician and which contribute to the diagnosis or treatment of an individual patient" in a hospital setting, and those "constitut[ing] professional services which are rendered for the general benefit to patients in a hospital or skilled nursing facility and which may be reimbursed only on a reasonable cost basis." *Id*. at P 053, *citing College of American Pathologists v. Heckler,* 1983 U.S. Dist. LEXIS 16800 (D.D.C. May 20, 1983).[3] The court determined pathologists may not bill separately for laboratory tests furnished to hospital patients for quality assurance purposes, as those tests provided a general benefit to all hospital patients, rather than for the direct benefit of individual patients.

In his September 20, 2012 fully favorable decision, the ALJ correctly summarized the QIC's decision as stating:

> that the testing at issue was rendered to provide DNA confirmation between the patient and the biopsy tissue samples, and the service was rendered as a confirmation of specimen handling, not to provide a diagnosis or treatment of the beneficiary's condition. The QIC determined that the services were determined to be a quality assurance activity, and as such, were not separately reimbursable.

ALJ decision at 6. The ALJ determined:

> Here, the record establishes that the DSPA testing meets the definition of diagnostic testing, as the testing involves swabbing the patient's cheek, and performing testing on the materials derived from the patient. In addition, these tests are ordered by the physician, who uses the information to aid in the assessment of the patient's medical condition or identification of the patient's disease. The record contains medical records for the individual beneficiaries, which demonstrates that based on the results of the testing, the physician either ordered active surveillance or more radical treatment.

[3] A copy of the district court case is located at Exh 22 at P 235 – P 244.

…

In addition, the record supports the Appellant's argument that the DSPA tests should not be characterized as a quality insurance measure. According to the Appellant, DSPA testing is a test that a physician orders, as an integral part of the testing cycle, in order to ensure an accurate cancer diagnosis. The testing is initiated and ordered by the patient's treating physician for that specific patient. It is not a test that is initiated by a hospital or laboratory for general quality control purposes. The Appellant cited the case *College of American Pathologists v. Heckler,* as distinguishing diagnostic tests from quality assurance testing. In its opinion, the court stated that "quality assurance services are performed with no particular patient in mind and can only be said to benefit individual patients in the sense that any service which contributes to the smooth operation of the hospital improves the lot of the patients who happen to be there." *College of American Pathologists v. Heckler,* 1983 U.S. Dist. LEXIS 16800 (D.D.C. May 20, 1983). Here, the record demonstrates that the DSPA tests were not part of a quality assurance program, and are not done for every patient, but for specific patients where specific information is required to diagnose and treat the patient.

The Appellant also somewhat convincingly analogized DSPA testing to a second opinion, consultation, or special histopathology stain, all of which are covered by Medicare. The Appellant noted that Medicare provides coverage for secondary opinions because they afford a thorough evaluation of the patient's need for a procedure and an additional opportunity to receive an independent professional opinion or identify potential mistakes in the assignment of a given diagnosis to a patient. The Appellant argues that the DSPA test serves the same purpose the second opinions serve.

After careful review of the record and the Appellant's oral arguments, I find that Medicare payment can be made for the DSPA testing at issue. The testimony, studies, and journal articles submitted by the Appellant demonstrate that the DSPA testing fits the definition of diagnostic testing, as defined by Medicare. In addition, I am not aware of any NCD or LCD that prohibits this specific type of testing. The evidence in the record demonstrates that the physician specifically ordered the DSPA testing based on the individual patient's biopsy results. The record demonstrates that the tests were administered as billed, and the information was used by the physician to aid in the assessment of a medical condition or the identification of a disease. The record also demonstrates that the DSPA tests were not part of a quality assurance program, and are not done for every patient, but for specific patients where the physician determined that specific information was required to diagnose and treat the patient. While this is so, I am compelled to observe that there is a fine line between diagnostic testing and quality control in the context of an individual patient's tissue samples. Here, I find that the Appellant has demonstrated the diagnostic value of a test that seeks to confirm the accuracy and correct identification of the sampling in individual cases, and thus aids in the identification of treatment options. Based on the foregoing, I find that the record establishes that the test was medically necessary for the individual patients.

Id. at 6-8.

Applicable Law, Regulation, and Medicare Policy:

Except as specified by law, § 1862(a)(1)(A) of the Act limits Medicare payment to services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Diagnostic tests are covered by Medicare under § 1861(s)(3) of the Act and include "diagnostic x-ray tests … diagnostic laboratory tests, and other diagnostic tests." *See also* Medicare Benefit Policy Manual (MBPM) (CMS Pub. 100-02) Chapter 15, § 80.6.1.

42 C.F.R. § 410.32 sets forth the conditions for coverage of diagnostic tests under Medicare Part B. Specifically, § 410.32(a) provides, "All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." 42 C.F.R. § 410.32(a). Additionally, "[t]ests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." *Id*. Pertinent to this case, Medicare Part B pays for covered diagnostic laboratory tests furnished by "A laboratory, if it meets the applicable requirements for laboratories of part 493 of this chapter…." 42 C.F.R. § 410.32(d)(1)(v).

42 C.F.R. § 493.2 defines laboratory as "a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings." 42 C.F.R. Part 493, Subpart K sets forth requirements for the "Quality System for Nonwaived Testing."[4] 42 C.F.R. § 493.1200 states:

> (a) Each laboratory that performs nonwaived testing must establish and maintain written policies and procedures that implement and monitor a quality system for all phases of the total testing process (that is, preanalytic, analytic, and postanalytic) as well as general laboratory systems.
>
> (b) The laboratory's quality systems must include a quality assessment component that ensures continuous improvement of the laboratory's performance and services through ongoing monitoring that identifies, evaluates and resolves problems.
>
> (c) The various components of the laboratory's quality system are used to meet the requirements in this part and must be appropriate for the specialties and subspecialties of testing the laboratory performs, services it offers, and clients it serves.

[4] *Nonwaived test* means any test system, assay, or examination that has not been found to meet the statutory criteria specified at section 353(d)(3) of the Public Health Service Act. 42 C.F.R. § 493.2. Generally, waived tests include "laboratory examinations and procedures that have been approved by the Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result." Waived tests include those listed at 42 C.F.R. § 493.15(c) and updated in the federal register pursuant to 42 C.F.R. § 493.15(d).

Furthermore, “Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in §§ 493.1231 through 493.1236.” 42 C.F.R. § 493.1230. Quality standards described in 42 C.F.R. Part 493, Subpart K include the standard for specimen identification and integrity, which specifies, “[t]he laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.” 42 C.F.R. § 493.1232. This quality standard for specimen identification and integrity applies expressly to histopathology services. 42 C.F.R. § 493.1219. *See also* 42 C.F.R. § 493.1273, describing other quality standards specific to histopathology laboratory services.

Discussion:

The Know Error website explains DSPA testing works as follows:

> **Swab.**
> Before the biopsy procedure, a reference sample of DNA is taken by swabbing the inside of the patient’s cheek. The swab is then sent to an independent DNA lab.
>
> **Sample.**
> The patient’s biopsy tissue sample(s) are placed in bar-coded specimen containers included in the biopsy kit and sent to the pathology lab for evaluation.
>
> **DNA match.**
> If the biopsy results come back positive for cancer (malignant), the DNA lab performs a DNA Specimen Provenance Assignment (DSPA) test to compare the DNA profiles of the biopsy tissue and the reference sample. Concurrence of these profiles allows for absolute confirmation of patient identity.

Http://knowerror.com/process-overview/how-it-works/. On appeal, the Appellant argues DSPA testing is an integral component of a “diagnostic testing cycle” because it eliminates the potential for misdiagnosis that is inherent in conventional histopathology/microscopy.” Exh 22 at P 045 – P 046. The Appellant also argues that DSPA testing is not a “quality assurance measure.” *Id*. at P 052.

The ALJ agreed that the DSPA tests met the definition of diagnostic tests, were reasonable and necessary to diagnose the patient’s disease, and should not be considered a quality assurance measure. ALJ decision at 6-7. The ALJ erred in finding DSPA testing is a separately payable diagnostic test. NGS disallowed the claims because it deemed DSPA testing “to be a quality assurance activity and as such is not separately reimbursable.” Exh 11 at P 570. NGS stated, “The payment for costs associated with normal specimen handling is included in the reimbursement for the diagnostic tests for which the specimen was obtained.” *Id*. Pursuant to 42 C.F.R. Part 493, Subpart K – Quality System for Nonwaived Testing, it is the responsibility of the entity furnishing the underlying histopathology (biopsy) services to “establish and follow

written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results." 42 C.F.R. § 493.1232. Thus, "procedures that ensure positive identification and optimum integrity of a patient's specimen" are expressly required as part of the billing entity's quality system and not a separately billable service.

Furthermore, § 1862(a)(1)(A) of the Act provides that, aside from specified exceptions, Part A and B Medicare will not incur expenses for items and services that "are not reasonable and necessary *for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member*." Emphasis added. 42 C.F.R. § 410.32(a) states all diagnostic tests must be ordered by the physician "who furnishes a consultation or treats a beneficiary for a specific medical problem and who *uses the results in the management of the beneficiary's specific medical problem*. Emphasis added. DSPA testing does not diagnose or treat an illness or injury, nor can its results be used to manage a specific medical problem. The Appellant does not contend that DSPA testing diagnoses either elevated PSA, the diagnosis for which DSPA testing was billed, or prostate cancer. Rather, DSPA testing confirms that the biopsy sample belongs to the patient being diagnosed, which purportedly "allows for absolute confirmation of patient identity." Http://knowerror.com/process-overview/how-it-works/. Procedures confirming a biopsy specimen belongs to the correct patient do not diagnose or identify a disease and do not constitute a covered Medicare benefit.

In August of 2012, the Acting Administrator of CMS responded to a Congressman's inquiry regarding DSPA, explaining Medicare does not cover DSPA testing because:

> [t]he DSPA test does not provide diagnostic information that is used by a practitioner in treating a patient – it merely confirms that a biopsy specimen belongs exclusively to a particular patient.
>
> Since the writing of your letter, Strand Analytical Laboratories provided us with a detailed analysis of why it believes the DSPA test should be considered a diagnostic laboratory test for purposes of Medicare coverage. After a detailed review of their analysis, we concluded, and continue to believe, that the DSPA test does not fit within this, or any other, Medicare benefit category.

Attachment B.

Palmetto GBA, the jurisdiction 11 MAC, has issued a "Know Error Coding and Billing Guidelines Update" that states:

> The know error® DNA Specimen Provenance Assay is a forensic assay to confirm that a surgical specimen belongs to the patient evaluated for treatment. Although Palmetto GBA agrees the health care community should define and follow strict procedures regarding patient and patient specimen identification and handling, such quality assurance measures are not considered a Medicare benefit and therefore are not a covered service. Providers

supplying this test (directly or through a purchased service) should obtain a valid Advance Beneficiary Notice (ABN) prior to providing this service.

Available online at http://www.palmettogba.com/palmetto/palmetto.nsf/DocsCat/Home, *then click on* "J11 Part B MAC – NC, SC, VA, WV," *then* "Browse by Topic," *then* "Lab," *then* "J11 B: know error Coding and Billing Guidelines Update."[5] While not binding on the services at issue, the Acting Administrator's letter and Palmetto GBA's update are useful in analyzing whether the services are covered; to the extent CMS and its contractors have considered the Appellant's DSPA testing, they have clearly found it to be noncovered.

At the ALJ level, the Appellant argued that "in addition to providing confirmation that the cancer diagnosis is being assigned to the correct patient, it also provides concordance that the specific patient's cancer has been accurately characterized." *See* ALJ decision at 6; *see also* Appellant's "Pre-Hearing Brief," Exh 22 at P 046. This argument merely adds to the objective of patient identification that of identifying biopsy contamination, for example where a "particular core contained extraneous tissue." *Id*. As noted above, however, 42 C.F.R. § 493.1232 requires "procedures that ensure positive identification *and optimum integrity* of a patient's specimen." Emphasis added. Federal regulations consider both objectives part of the laboratory's quality system.

Finally, we note that CMS and contractor analyses have found DSPA testing to be not reasonable and necessary *and* not a covered benefit, sometimes in the same document. This appears to be less a result of careless decision making than of the unusual nature of the service at issue. That is, DSPA testing is not reasonable and necessary *because* it does not diagnose or treat an injury or illness. Since it is neither diagnostic nor therapeutic, it is not a covered benefit. However, it is likewise correct to state the DSPA test is not reasonable and necessary for diagnosing elevated PSA, the condition for which the tests were purportedly billed. For purposes of determining liability, it is sufficient that "procedures that ensure positive identification and optimum integrity of a patient's specimen" are considered quality system requirements and not separately billable services under 42 C.F.R. § 493.1232.

[5] The complete web address is http://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~Jurisdiction%2011%20Part%20B~Browse%20by%20Topic~Lab~8XWTYJ1378?open&navmenu=Browse^by^Topic||||.