CMS Referral for Own Motion Review by DAB/MAC

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<thead>
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<th>Field</th>
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<tr>
<td>Appellant at ALJ Level</td>
<td>K &amp; T Diagnostic, Inc.</td>
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<tr>
<td>ALJ Appeal Number</td>
<td>1-902902573</td>
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<td>Beneficiary (if not the Appellant)</td>
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<td>ALJ Decision Date</td>
<td>May 4, 2012</td>
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<tr>
<td>Health Insurance Claim Number (HICN)*</td>
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<tr>
<td>Specific Item(s) OR Service(s)</td>
<td>Duplex extracranial artery scan (93880)</td>
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<tr>
<td>Provider, Practitioner OR Supplier</td>
<td>K &amp; T Diagnostic, Inc.</td>
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<td>Part A Part B</td>
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### Basis for referral

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<th>Any Case</th>
<th>CMS as a Participant</th>
<th>Pre-BIPA</th>
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<tr>
<td>☑ Error of law material to the outcome of the claim</td>
<td>☐ Decision not supported by the preponderance of evidence</td>
<td>☐ Decision not supported by substantial evidence</td>
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<td>☐ Broad policy or procedural issue of public interest</td>
<td>☐ Abuse of discretion</td>
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### Rationale for Referral:

K & T Diagnostic, Inc. (Appellant), an independent diagnostic testing facility (IDTF) requested an Administrative Law Judge (ALJ) hearing to review the Qualified Independent Contractor’s, C2C Solutions, Inc. (QIC), unfavorable reconsideration decision, finding Appellant failed to submit sufficient documentation to establish the duplex extracranial artery scan. Appellant furnished the beneficiary on March 30, 2011, was medically reasonable and necessary. Following a consolidated hearing, the ALJ issued a fully favorable decision, finding Appellant substantially complied with Medicare criteria for coverage and the Medicare Administrative Contractor’s, Palmetto GBA (MAC), Local Coverage Determination (LCD) L28283. Noninvasive Cerebrovascular Studies, LCD L28283, effective Oct. 1, 2010, available at www.cms.gov/medicare-coverage-database.

The ALJ’s decision contains errors of law material to the outcome of this claim. First, the ALJ erred as a matter of law in failing to consider the requirements for Medicare coverage of diagnostic tests performed by IDTFs articulated in sections 410.32, 410.33, and 424.5 of Title 42 of the Code of Federal Regulations (CFR). Specifically, the ALJ erred in finding a written physician’s order, a copy of the test results, and an interpretation of the test results sufficient for Medicare coverage and reimbursement of the diagnostic test Appellant furnished the beneficiary. Additionally, the ALJ erred as a matter of law in failing to consider the documentation requirements articulated in LCD L28283, specific to CPT code 93880, requiring additional documentation indicating more common causes of syncope were ruled out before ordering CPT code 93880, when syncope is an indication. Noninvasive Cerebrovascular Studies, LCD L28283, effective Oct. 1, 2010, available at

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www.cms.gov/medicare-coverage-database. The ALJ also failed to consider the documentation requirement articulated in LCD L28283, stating “[t]he provider must ensure documentation showing reasonableness and necessity of the procedures are kept on file and made available upon request by the Medicare carrier.” Id.

To the extent the ALJ failed to consider or apply the requirements for Medicare coverage and reimbursement of IDTF services articulated in the Act and the CFR, the ALJ erred as a matter of law in violation of sections 405.1060(a)(4) and 405.1063 of Title 42 of the CFR, stating an ALJ is bound by statutes, regulations, National Coverage Determinations (NCD), and CMS rulings. To the extent the ALJ failed to consider the requirements for Medicare coverage and reimbursement of IDTF services articulated in the Medicare Benefit Policy Manual (MBPM) (CMS Pub. 100-02), the Medicare Program Integrity Manual (MPIM) (CMS Pub. 100-08), and LCD L28283, the ALJ erred as a matter of law in violation of section 405.1062(a) of Title 42 of the CFR, requiring ALJs to give LCDs, Local Medicare Review Policies (LMRP), and CMS program guidance such as program memoranda and manual instructions substantial deference. In the event the ALJ intended to deviate from the provisions of the LCDs and program guidance, the ALJ erred as a matter of law in violation of section 405.1062(b) of Title 42 of the CFR, requiring an ALJ to articulate an explanation for deviation in each particular case. These errors of law are material to the outcome of this claim because they result in the ALJ finding Medicare coverage exists for and in ordering Medicare reimbursement for IDTF services which do not comply with Medicare coverage and reimbursement criteria.

Background:

On March 30, 2011, Appellant provided the beneficiary with a duplex scan of extracranial arteries; complete bilateral study. ALJ at 1. Appellant submitted a claim seeking Medicare reimbursement to the MAC. Exh.12 at 59. The claim was initially denied because Medicare coverage does not extend to routine exams. Exh.12 at 42. Appellant sought a redetermination, arguing the “study was ordered by the patient’s [primary care physician]. Not a routine evaluation. Documents verifying medical necessity and signature authentication are attached.” Exh.12 at 54. On September 1, 2011, the MAC issued an unfavorable redetermination decision, indicating that following a review of the patient’s history, “the documentation does not show the service was reasonable and necessary for the care or treatment of the patient.” Exh.12 at 56. The decision explained a diagnosis of dizziness is not an indication noted in the relevant LCD, L28283. Id.

In Appellant’s October 4, 2011 request for reconsideration, Appellant reiterated the arguments made in its redetermination request--that the study was ordered by the patient’s primary care physician, the test was not routine, and submitted documentation supports coverage. Exh.12 at 40. In its December 19, 2011 unfavorable decision, the QIC explained that the record lacked documentation substantiating the need for the test in question:
The diagnostic order form on file reflects the beneficiary presented with diagnoses of vertigo, syncope and collapse. However, the record does not contain a physician’s order and/or treatment notes from the referring provider highlighting the beneficiary’s medical history, diagnoses and clinical indications to warrant the need for the service documented on the K & T diagnostic order form. Medical records such as office notes, progress notes, physician orders, operative notes, diagnostic test results, etc., must indicate the medical necessity and reasonableness for performing the service. Therefore, the record does not support the medical necessity for and the performance of the service(s) in question. Based upon the aforementioned, Medicare coverage criteria have not been met.

Exh.12 at 33. The decision also noted that because the claim was filed without the GA modifier and a valid Advanced Beneficiary Notice was not on file, Appellant remained liable for the denied services. Id.

In its request for ALJ hearing, Appellant asserted, “As an IDTF, we are liable for our own records. By regulations, we are required to have a signed order by the PCP for the procedure. There is not a singe [sic] request to the PCP to provide any medical records by the 1st or 2nd level of appeal.” Exh 12 at 11. Following a consolidated hearing, the ALJ issued a fully favorable decision, finding Appellant substantially complied with LCD L28283. ALJ at 12. The ALJ found “[t]he [administrative] record contains no progress notes from the referring provider.” ALJ at 3. Nevertheless, the ALJ found: “Appellant has provided sufficient documentation to establish compliance with national Medicare policy for IDTFs and LCD L28283 which address this type of study and is applicable to the current matter (93880).” ALJ at 12. With regard to the medical notes in the beneficiary’s case file, the ALJ determined:

Although the preferred treating/referring physician’s treating notes are not provided, it is the standard practice of Appellant to request treating records from the referring provider. Although the handwritten annotations of the order by the treating physician would be preferable, the findings of the order form of the treating physician and examination report by the evaluating physician include handwritten comments and indications for treatment that adequately document the medical reasons the testing was required and establish the medical necessity for these tests in this particular case.

Id. The ALJ concluded the test was “medically reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act and 42 C.F.R. § 411.15(k)(1). Medicare must pay for said items/services in their entirety.” ALJ at 13. This referral requesting the Council accept own motion review follows.

Applicable Law, Regulation, and Medicare Policy:

I. ALJ Review
A party dissatisfied with a reconsideration may request a hearing before an ALJ. 42 C.F.R. § 405.1000(a). The ALJ conducts a de novo review and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d). Further, an ALJ’s “decision must be based on evidence offered at the hearing or otherwise admitted into the record.” 42 C.F.R. § 405.1046(a); see also 42 C.F.R. § 405.1046(a) (“Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. The decision must be based on evidence offered at the hearing or otherwise admitted into the record.”). “The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party’s favor.” 42 C.F.R. § 405.1032(a).

An ALJ is bound by statutes, regulations, National Coverage Determinations (NCD), and the Centers for Medicare and Medicaid Services’s (CMS) rulings. 42 C.F.R. §§ 405.1060(a)(4), 405.1063. However, an ALJ is not bound by contractor Local Coverage Determinations (LCD), Local Medicare Review Policies (LMRP), or CMS program guidance such as program memoranda and manual instructions, “but will give substantial deference to these policies if they are applicable to a particular case.” 42 C.F.R. § 405.1062(a). An ALJ must explain its reasoning for deviating from a LCD, LMRP, or CMS’s program guidance in a particular case. 42 C.F.R. § 405.1062(b).

II. Medicare Coverage of IDTF Services

Title XVIII of the Social Security Act (the Act) explains Medicare payment may be allowed only for services considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Social Security Act § 1862(a)(1)(A). Additionally, section 1833(e) of the Act prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

All entities seeking Medicare reimbursement are responsible for furnishing sufficient documentation to demonstrate whether and how much payment is due. 42 C.F.R. § 424.5(a)(6); Medicare Program; Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services, 66 Fed. Reg. 58,788, 58,800-01 (Nov. 23, 2001) (“Presently, all entities that bill the Medicare program are held liable when they bill for services and are not able to produce documentation of the medical necessity of the service.”). See also, Friedman v. Sec’y of Dep’t of Health & Human Servs., 819 F.2d 42, 45 (2d. Cir. 1987) (“A claimant nevertheless has the burden of proving entitlement to Medicare benefits.”)

To determine whether services meet coverage guidelines, the Secretary may require the entities billing Medicare to submit medical documentation supporting coverage. Ch.3, § 3.11.1 of the Medicare Program Integrity Manual (MPIM) (CMS Pub. 100-08) (“For Medicare to consider coverage and payment for any item or service, the information submitted by the supplier or provider (e.g., claims and CMNs) must be corroborated by the documentation in the patient’s medical records that Medicare
coverage criteria have been met.”). See also, Gulfcoast Med. Supply, Inc., v. Leavitt, 468 F.3d 1347 (11th Cir. 2006) (“[W]e agree with the district court, and we conclude that when the Medicare Act is read as a whole, it unambiguously permits carriers and the Secretary to require suppliers to submit evidence of medical necessity beyond a CMN.”); Mackenzie Med. Supply, Inc. v. Leavitt, 506 F.3d 341 (4th Cir. 2007); Maximum Comfort, Inc., v. Leavitt, (9th Cir. 2007).

Diagnostic testing may be covered by Medicare pursuant to section 1861(s)(3) of the Act. Medicare regulations set forth the conditions for coverage of diagnostic tests under Medicare Part B in section 410.32 of Title 42 of the CFR. Specifically, section 410.32(a) of Title 42 of the CFR states in order to be eligible for coverage, diagnostic testing must be ordered by the treating physician, “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.” Additionally, the regulation states: “Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.” 42 C.F.R. § 410.32(a).

“A ‘diagnostic test’ includes all diagnostic x-ray tests, all diagnostic laboratory tests, and other diagnostic tests furnished to a beneficiary.” Ch. 15, § 80.6.1 of the Medicare Benefit Policy Manual (MBPM) (CMS Pub. 100-02). Similarly, a “treating physician” is a physician defined by section 1861(r) of the Act2 “who furnishes a consultation or treats a beneficiary for a specific medical problem, and who uses the results of the diagnostic test in the management of the beneficiary’s specific medical problem.” Id.

Section 410.33(d) of Title 42 of the CFR specifically addresses an IDTF’s responsibility in relation to furnishing diagnostic tests ordered by the beneficiary’s treating physician:

All procedures performed by the IDTF must be specifically ordered in writing by the physician who is treating the beneficiary, that is, the physician who is furnishing a consultation or who is treating a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary’s specific medical problem. (Nonphysician practitioners may order tests as set forth in § 410.32(a)(3).) The order must specify the diagnosis or other basis for the testing. The supervising physician for the IDTF may not order tests to be performed by the IDTF, unless the IDTF’s supervising physician is in fact the beneficiary’s treating physician. That is, the physician in question had a relationship with the beneficiary prior to the performance of the testing and is treating the beneficiary for a specific medical problem. The IDTF may not add any procedures based on internal protocols without a written order from the treating physician.

2 In pertinent part, section 1861(r) of the Act defines “physician” to include “a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action.”
In defining an order for diagnostic testing services, the MPBM provides:

An “order” is a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary. The order may conditionally request an additional diagnostic test for a particular beneficiary if the result of the initial diagnostic test order yields to a certain value determined by the treating physician/practitioner (e.g., if test X is negative, then perform test Y). An order may be delivered via the following forms of communication:

- A written document signed by the treating physician/practitioner, which is hand-delivered, mailed, or faxed to the testing facility; **NOTE:** No signature is required on orders for clinical diagnostic tests paid on the basis of the clinical laboratory fee schedule, the physician fee schedule, or for physician pathology services;
- A telephone call by the treating physician/practitioner or his/her office to the testing facility; and
- An electronic mail by the treating physician/practitioner or his/her office to the testing facility.

If the order is communicated via telephone, both the treating physician/practitioner or his/her office, and the testing facility must document the telephone call in their respective copies of the beneficiary’s medical records. While a physician order is not required to be signed, the physician must clearly document, in the medical record, his or her intent that the test be performed.

Ch. 15, § 80.6.1 of the MBPM (CMS Pub. 100-02).

In the context of diagnostic tests, the courts have explicitly found “order forms [identifying] the referring physician and include[ng] check boxes which identified symptoms and possible diagnoses” were insufficient to meet the requirements of section 410.33(d) of Title 42 of CFR and fail to establish the diagnostic testing services were reasonable and necessary. **KGV Easy Leasing Corp. v. Sebelius,** No.09-56393 (9th Cir. 2011) (“KGV never presented evidence that supplemented the information contained on its order forms or otherwise established medical necessity.”). **See also, In the Case of KGV Easy Leasing Corp.,** (Medicare Appeals Council, February 24, 2010)3 (”[T]he [IDTF] appellant had the burden to provide sufficient documentation, evidence and testimony that indicates the services provided are covered by Medicare.”).

In comments to the final rule governing diagnostic tests, CMS addressed the concern arguing the new rule would make “it possible for laboratories to be held liable for claims denial due to the lack of information supporting medical necessity.” 66 Fed. Reg. 58,800. In response, CMS explained:

The commenters do not seem to recognize that the March 10, 2000 proposed rule does not change the current provisions for liability on claims due to lack of

information supporting medical necessity. Section 1862(a)(1)(A) of the Act provides that, notwithstanding any other provision of the Act, payment may not be made for services that are not reasonable and necessary for the diagnosis or treatment of illness or injury. Presently, all entities that bill the Medicare program are held liable when they bill for services and are not able to produce documentation of the medical necessity of the service. Although the Committee discussed at length the special circumstances related to laboratories, which frequently do not have direct contact with the patient, the Committee recognized that the law does not provide the authority to exempt laboratories from the provision related to medical necessity.

In addition, we do not agree that the provision related to denial of claims for laboratory services when documentation is not provided is unfair. Rather, we believe it would be unfair to exempt laboratories from this provision while continuing to require it for other providers and suppliers. For example, durable medical equipment (DME) suppliers frequently do not have direct contact with beneficiaries but are dependent upon physician documentation of medical need in order to receive payment.


III. LCD L28283 – Noninvasive Cerebrovascular Studies

The MAC published an LCD, applicable to duplex extracranial artery scans, CPT code 93880, effective for tests administered on or after October 1, 2010. Noninvasive Cerebrovascular Studies, LCD L28283, effective Oct. 1, 2010, available at www.cms.gov/medicare-coverage-database. LCD L28283 provides the following guidance for CPT code 93880:

Indications for CPT Codes 93875, 93880 and 93882 for Cerebrovascular Evaluation:

2. Amaurosis fugax.
3. Focal cerebral or ocular transient ischemic attacks (i.e., localizing symptoms, weakness of one side of the face, slurred speech, weakness of a limb). Visual transient ischemic attacks are defined as retinal or hemispheric visual field deficits and not temporary blurred vision.
4. Drop attack or syncope is a rare indication primarily seen with vertebrobasilar or bilateral carotid artery disease. Incoordination or limb dysfunction should be grouped with unilateral weakness of the face or extremities.
5. Subclavian steal syndrome.
7. Follow-up after a carotid endarterectomy.
8. Re-evaluation of existing carotid stenosis.
10. **Preoperative evaluation of patients scheduled for major cardiovascular surgical procedures.**
11. Evaluation of nonhemispheric or unexplained neurologic symptoms.
13. Evaluation of suspected dissection

**Id.** (emphasis in original). Additionally, LCD L28283 provides:

All other codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section will be denied without additional information to warrant reasonableness and necessity. Studies will be denied if they are determined to be screening studies, were duplicative of other vascular studies or were not needed to make management decisions.

**Id.** The LCD includes the following diagnosis codes relevant to this case: 438.85 (Vertigo); 780.2 (Syncope and Collapse); 433.20 (Occlusion and Stenosis without Cerebral Infarction); and 369.9 (Unspecified Visual Loss). **Id.** LCD L28283 also provides the following documentation requirements:

The provider must ensure documentation showing reasonableness and necessity of the procedures are kept on file and made available upon request by the Medicare carrier.

When using syncope as an indication, it is necessary to document that other more common causes have been ruled out.

The accuracy of noninvasive vascular diagnostic studies depends on the knowledge, skills and experience of the technologist and physician performing and interpreting the study. It is recommended that noninvasive vascular studies either be rendered in a physician's office by/or under the direct supervision of persons credentialed in the specific type of procedure being performed or performed in laboratories accredited in the specific type of evaluation. Noninvasive vascular studies done in an IDTF facility or vascular laboratory are subject to the rules and regulations governing the facility. This A/B MAC is not a credentialing body; therefore, this LCD will recommend certification, but not recommend certifying bodies.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.
When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary.

When requesting a written redetermination (formerly appeal), providers must include all relevant documentation with the request.

Id.

Discussion:

The ALJ erred as a matter of law in finding Medicare coverage existed for and in ordering Medicare reimbursement for the duplex scan of extracranial artery Appellant furnished the beneficiary on March 30, 2011. Specifically, the ALJ erred in failing to consider the documentation requirements articulated in the Act, CFR, LCD L28283, the MBPM, and the MPIM. These errors of law are material to the outcome of the claim because they result in the ALJ finding Medicare coverage exists for IDTF services which do not comply with Medicare coverage and reimbursement guidelines.

The beneficiary’s medical documentation consists of a physician’s order for the diagnostic test, indicating the following diagnosis codes: 438.85 (Vertigo); 780.2 (Syncope and Collapse); 433.20 (Occlusion and Stenosis without Cerebral Infarction); 402.10 (Benign Hypertensive Heart Disease without Heart Failure); 428.1 (Left Heart Failure); and 369.9 (Unspecified Visual Loss). Exh.11 at 1, 11. Additionally, the administrative record contains the beneficiary’s personal and insurance information. Exh.11 at 2-4, 10-12. The test results and Appellant’s interpretation are also included in the beneficiary’s medical records. Exh.11 at 5-8, 13-16.

Here, the ALJ found “the findings of the order form of the treating physician and examination report by the evaluating physician include handwritten comments and indications for treatment that adequately document the medical reasons the testing was required and establish the medical necessity for these tests in this particular case.” ALJ at 12. The ALJ erred in determining the submitted physician orders, test results, and interpretations satisfied Appellant’s burden of proof for establishing the diagnostic tests were reasonable and necessary. As the entity billing Medicare, Appellant is responsible for furnishing sufficient documentation to show that services are covered. 42 C.F.R. § 424.5(a)(6); 66 Fed. Reg. 58,800-01. Section 410.33(d) of Title 42 of the CFR requires all tests furnished by IDTFs to be ordered by a physician “who uses the results in the management of the beneficiary’s specific medical problem.” Furthermore, in the context of diagnostic tests, the courts have explicitly found “order forms [identifying] the referring physician and include[ing] check boxes which identified symptoms and possible diagnoses” were insufficient to meet the requirements of section 410.33(d) of Title 42 of CFR and fail to establish the diagnostic testing services were reasonable and necessary.

4 The physician’s order also orders a transthoracic echocardiogram, CPT Code 93306. Exh.11 at 1, 11.
necessary. KGV Easy Leasing Corp. v. Sebelius, No.09-56393 (9th Cir. 2011) (“KGV never presented evidence that supplemented the information contained on its order forms or otherwise established medical necessity.”). See also, In the Case of KGV Easy Leasing Corp., (Medicare Appeals Council, February 24, 2010)\(^5\) (“[T]he [IDTF] appellant had the burden to provide sufficient documentation, evidence and testimony that indicates the services provided are covered by Medicare.”). As the ALJ repeatedly stated, the administrative record in this case does not include any of the treating physician’s treatment notes. Therefore, the administrative record does not include any documentation of the ordering physician treating the beneficiary for a specific medical problem and who would use the test results in the management of that specific medical problem. Accordingly, in failing to consider whether the administrative record contains sufficient information to determine whether the ordering physician would use the results of the diagnostics tests in the treatment of the beneficiary’s specific medical problem, the ALJ erred as a matter of law in failing to consider the requirements articulated in the CFR.

Additionally, the physician’s order form includes a diagnosis of syncope as a reason for the beneficiary’s need for CPT code 93880. Per LCD L28283, if syncope is an indication for the diagnostic test, “it is necessary to document that other more common causes have been ruled out.” Noninvasive Cerebrovascular Studies, LCD L28283, effective Oct. 1, 2010, available at www.cms.gov/medicare-coverage-database. As set forth above, the beneficiary’s medical documentation includes the physician’s order, the beneficiary’s personal and insurance information, the test results, and Appellant’s interpretation of the test result. Exh.11 at 1-16. The medical documentation included in the administrative record does not include any evidence of more common causes of syncope being ruled out prior to the beneficiary’s physician ordering this diagnostic test. Furthermore, the ALJ failed to address this particular coverage criterion in finding Medicare coverage existed for the CPT code 93880 test Appellant furnished the beneficiary. Specifically, the ALJ repeatedly stated none of the prescribing physician’s treatment notes were included in the administrative record. ALJ at 3, 12. Accordingly, the ALJ erred as a matter of law in failing to address the documentation requirement articulated in LCD L28283, requiring a provider to document more common causes of syncope have been ruled out when syncope is used as an indication of the beneficiary’s need for CPT code 93880.

Conclusion:

Based on the foregoing, we believe the ALJ’s decision contains errors of law material to the outcome of these claims. Therefore, we refer the ALJ’s decision to the Council and request own motion review.

\(^5\) Available at www.hhs.gov/dab/divisions/medicareoperations/macdecisions/case_kgvleasing.pdf.