**Basis for referral**

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**Rationale for Referral:**

IMIG SonoMed Diagnostics (Appellant), an Independent Diagnostic Testing Facility (IDTF), billed Medicare for five diagnostic tests furnished to each of three Medicare beneficiaries on February 8, 2010. The tests initially paid, but were later denied. The Appellant requested an appeal, arguing that an IDTF is not responsible for furnishing more than a physician’s order and test results. The denials were upheld because Medicare does not pay for routine exams or test that are not medically necessary. On appeal, the appellant argued the tests were performed as ordered by the referring physician and, as an IDTF, it is not responsible for furnishing patient evaluations.

Following a telephone hearing, the administrative law judge (ALJ) issued a fully favorable decision, finding the submitted documentation was sufficient to support the medical necessity and reasonableness of the tests, pursuant to § 1862(a)(1) of the Social Security Act. The ALJ determined:

- the Appellant has complied with all requirements established for all procedures performed by an IDTF as well as those of the LCDs. The services were specifically ordered in writing by the physician or practitioner who is treating the beneficiary. The order further specifies the diagnosis or other basis for the testing. The results of the tests ordered are included in the file. Therefore, Medicare payment is granted.

ALJ decision at 8. The ALJ concluded, “The Appellant has submitted adequate documentation pursuant to Section 1833(e) of the Social Security Act that it provided...
the subject services incident to a physician’s services. … The decision of the QIC is reversed.” *Id.* at 19.

The ALJ erred in finding a physician’s order and test results sufficient to satisfy an IDTF’s documentation requirements for purposes of Medicare payment. As the entity billing Medicare, the Appellant is responsible for furnishing sufficient documentation to show that services are covered. Section 1833(e) of the Social Security Act (the Act); 42 C.F.R. § 424.5(a)(6); 66 FR 58800-58801, Friday, November 23, 2001 (“[A]ll 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.”); *In the Case of KGV Easy Leasing Corp.* (Medicare Appeals Council, February 24, 2010) at http://www.hhs.gov/dab/divisions/medicareoperations/macdecisions/case_kgv_leasing.pdf (“[T]he [IDTF] appellant had the burden to provide sufficient documentation, evidence and testimony that indicates the services provided are covered by Medicare.”).

The ALJ also erred in finding the physician’s orders and test interpretations alone are sufficient to establish the diagnostic tests were reasonable and necessary in accordance with 42 C.F.R. §§ 410.32(a) and 410.33(d), which require that the tests be ordered in writing by “the physician who furnishes a consultation or treats the beneficiary for a specific medical problem and who uses the results in the management of the beneficiary’s specific medical problem.” *See also KGV Easy Leasing Corp. v. Sebelius*, No.09-56393 (9th Cir. 2011) (An IDTF’s preprinted “order forms [that] identified the referring physician and included check boxes which identified symptoms and possible diagnoses” were insufficient to meet the requirements of 42 C.F.R. § 410.33(d) and failed to establish that the services were reasonable and necessary.”) As the QIC noted, the administrative record lacks medical documentation indicating why the tests were ordered or explaining how the test results would be used to manage the beneficiaries’ care.

To the extent the ALJ determined the services to be covered because they were furnished as incident to a physician’s professional service, his decision is in error. Services furnished incident to a physician’s services constitute a distinct benefit category under the Social Security Act (the Act), defined at § 1861(s)(2)(A) of the Act and in federal regulations at 42 C.F.R. § 410.10(b) and § 410.26. Had the diagnostic tests been furnished incident to a physician’s services, they would have been furnished by the treating physician or by the physician’s staff while under the physician’s direct supervision, either in the physician’s office or a hospital outpatient setting. In such cases, the treating physician would bill for the tests. Section 1861(s)(2)(A) – (B) of the Act; 42 C.F.R. Sections 410.26(b). In this case, the services were furnished by an IDTF, not the treating physician. Specific to the circumstances in this case, the Medicare Benefit Policy Manual (MBPM) (CMS Pub. 100-02) clarifies that services covered under a separate benefit category, such as diagnostic tests, are not covered under the benefit for services furnished incident to a physician’s services. MBPM, Chapter 15, § 60.
Background:

The Appellant submitted three claims to Medicare for diagnostic tests furnished to Medicare beneficiaries on February 8, 2010. In each case, the Appellant billed with the following CPT codes:

- 93875 – noninvasive physiologic studies of extracranial arteries, complete bilateral study (eg, periorbital flow direction with arterial compression, ocular pneumoplethysmography, Doppler ultrasound spectral analysis)
- 93886 – transcranial Doppler study of the intracranial arteries; complete study
- 93923 – complete bilateral noninvasive physiologic studies of upper or lower extremity arteries, 3 or more levels (eg, for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental blood pressure measurements with bidirectional Doppler waveform recording and analysis, at 3 or more levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental volume plethysmography at 3 or more levels, or ankle brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental transcutaneous oxygen tension measurements at 3 or more level(s), or single level study with provocative functional maneuvers (eg, measurements with postural provocative tests, or measurements with reactive hyperemia)
- 93924 – noninvasive physiologic studies of lower extremity arteries, at rest and following treadmill stress testing, (ie, bidirectional Doppler waveform or volume plethysmography recording and analysis at rest with ankle/brachial indices immediately after and at timed intervals following performance of a standardized protocol on a motorized treadmill plus recording of time of onset of claudication or other symptoms, maximal walking time, and time to recovery) complete bilateral study
- 93965 – noninvasive physiologic studies of extremity veins, complete bilateral study (eg, Doppler waveform analysis with responses to compression and other maneuvers, phleborheography, impedance plethysmography)

The services initially paid. On May 16, 2011, however, the money was recouped. Four day later, the Appellant requested redeterminations, arguing:

We would like to remind you, that my company is an IDTF (Independent Diagnostic Testing Facility) and not a Primary Care Physician Office. According Medicare Program Integrity Manual (Chapter 10 Medicare Provider/Supplier Enrollment) 4.19.1 IDTF Standards Sec. 410.33 Independent diagnostic tests facility (d) ordering of tests: 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 treating a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary’s specific medical problem...All that information you will be able to find in the Order Form. My
company has performed a diagnostic evaluation after which has forward it all of the findings to the physician for further evaluation and treatment.

Exh 1 at 1. In its three July 14, 2011 redetermination letters, the Medicare administrative contractor upheld the denials, explaining “Medicare does not cover routine exams or related services.” Exh 2 at 1, 22, 41. On reconsideration, the qualified independent contractor (QIC) issued substantially identical denials in which it explained:

The provider ordering the tests could not be identified either through their signature or printed name, as they were both illegible. The history appears as though the patient filled out the questionnaire. Certificate of medical necessity indicated the need for a transcranial Doppler was dizziness and bruit. There was no indication of visual disturbance as typically the reason for the testing. Results of the testing should be expressed in the degree of stenosis not as ‘mild stenosis”. Ankle brachial indices did not support the medical need for further testing, should have been reported from the ordering physician and are not covered for payment. ABIs, as separate procedures, are not reimbursable. An abnormal ABI (i.e., <0.9 at rest) must be accompanied by another appropriate indication before proceeding to more sophisticated or complete studies, except in patients with severe elevated ankle blood pressure. The studies were all performed by another provider. Procedure code 93923 and 93924 cannot be billed together per Medicare guidelines and the Current Procedure Terminology (CPT) manual. Payment is excluded if the medical necessity for the service cannot be substantiated. Studies must be ordered by a treating physician and must be both reasonable and necessary for management of the patient. Results of these studies must be used in the management of the patient. Records indicate both a venous and arterial scans were ordered for the same day. A statement of medical necessity from the ordering physician supporting the medical need for both an arterial and venous scans was not provided. A strong statement of medical need should be provided to support why both exams were needed on the same day. This information can be viewed in Local Coverage Determination (LCD) L28284 and L28285. The information does not support the medical need for the service or the requirements found in LCD L28283. There was no indication of symptoms or physical findings that would support the performance of the service(s) in accordance with Medicare guidelines. An overpayment did occur.

Exh 4 at 4, 8-9, and 12-13. The QIC held the Appellant liable for the denied charges. Id. at 5, 9, and 13.

Following a March 22, 2012 telephone hearing, the ALJ issued his fully favorable decision in which he determined that submitted evidence supports coverage of the tests. The judge explained:

The Appellant asserted that his responsibility to produce documentation is limited to the physician order and test result. The IDTF’s regulatory requirements are limited to providing a valid physician’s order and test result. They are not required to provide copies of the referring physician’s documentation. Most LCDs do indicate the carrier has a responsibility to request medical documentation if it is needed to determine the medical necessity of the service. The redetermination level appropriation of medical documentation was not
ascertained, as is required and noted in the above references Medicare guidelines of Publication 100-04, Chapter 29, Section 3 10.4(B) when Appellant is an IDTF.

The Beneficiary … was a patient of Dr. Jackson. The documentation submitted for review included a physician order form for bilateral lower extremity testing due to pain in limb, swelling of limb, atherosclerosis of the extremities w/intermittent claudication, and spasm of artery. The record also included a physician order form for transcranial Doppler and carotid Doppler due to bruit and dizziness.

After careful consideration and review of the evidentiary record and all applicable rules and regulations, the undersigned finds there is sufficient evidence in the administrative record to establish that the services provided were medically reasonable and necessary pursuant to the provisions of Section 1862(a)(1) of the Social Security Act and 42 C.F.R. § 411.15(k). The undersigned has reviewed the underlying documentation and finds the documentation establishes a favorable finding for the Appellant. The documentation submitted for review included the physician order form that indicated clinical problems, specifically swelling of limb (729.81), pain in limb (729.5), atherosclerosis of the extremities w/intermittent claudication (440.21), and spasm of artery. As noted in the LCDs, these are covered diagnoses. The undersigned finds the Appellant has complied with all requirements established for all procedures performed by an IDTF as well as those of the LCDs. The services were specifically ordered in writing by the physician or practitioner who is treating the beneficiary, that is, the physician who is furnishing a consultation or treating a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary’s specific medical problem. The order further specifies the diagnosis or other basis for the testing. The results of the tests ordered are included in the file. Therefore, Medicare payment is granted.

ALJ decision at 7-8. The ALJ concluded:

The Appellant is eligible to receive reimbursement for the tests conducted for the beneficiaries and dates of services as identified herein, consistent with the subject decision. The Appellant has submitted adequate documentation pursuant to Section 1833(e) of the Social Security Act that it provided the subject services incident to a physician’s services. Therefore, the Appellant has met the conditions and limitations of payment pursuant to § 1861(s)(2) of the Social Security Act and 42 C.F.R. § 410.28(a).

Id. at 19.

Applicable Law, Regulation, and Medicare Policy:

Section 1862(a)(1)(A) of the Act explains that payment may be allowed only for those services that are considered reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

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 42 C.F.R. § 410.32. Specifically, § 410.32(a) provides that 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.” 42 C.F.R. § 410.32(a). Additionally, subsection (a) states “[t]ests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.” *Id.*

“A ‘diagnostic test’ includes all diagnostic x-ray tests, all diagnostic laboratory tests, and other diagnostic tests furnished to a beneficiary.” Medicare Benefit Policy Manual (MBPM) (CMS Pub. 100-02) Chapter 15, § 80.6.1. The MPBM defines an order for diagnostic testing services as “a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary.” *Id.* Similarly, a “treating physician” is a physician defined by section 1861(r) of the Act¹ “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.*

42 C.F.R. § 410.33(d) 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.

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); *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.”)

42 CFR § 405.1062 provides that while ALJs and the Medicare Appeals Council are not bound by LCDs, LMRPs, or CMS program guidance, they must give substantial deference to these policies if they apply to a case. If the ALJ does not follow an LCD, the ALJ must explain the reasons why the policy wasn’t followed. An ALJ’s decision not

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¹ In pertinent part, § 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....”
to follow a policy applies only to the specific claim on appeal and does not have precedential effect.

Section 1861(s)(2)(A) of the Social Security Act allows Medicare Part B coverage of “services and supplies … furnished as an incident to a physician’s professional service, of kinds which are commonly furnished in physicians’ offices and are commonly either rendered without charge or included in the physicians’ bills ….”

42 C.F.R. Section 410.26 explains in greater detail the benefit for items and services furnished “incident to a physician’s services” under Section 1861(s)(2)(A):

(b) Medicare Part B pays for services and supplies incident to the service of a physician (or other practitioner).

(1) Services and supplies must be furnished in a noninstitutional setting to noninstitutional patients.

(2) Services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.

(3) Services and supplies must be commonly furnished without charge or included in the bill of a physician (or other practitioner).

(4) Services and supplies must be of a type that are commonly furnished in the office or clinic of a physician (or other practitioner).

(5) Services and supplies must be furnished under the direct supervision of the physician (or other practitioner). The physician (or other practitioner) directly supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.

Emphasis added. Physicians’ services and services covered incident to physicians’ services are billed by the physician and payment is made under the Medicare physician fee schedule to the physician. Medicare Claims Processing Manual (MCPM) (CMS Pub 100-4), Chapter 23, § 30. Pertinent to this case, Chapter 15, § 60 of the MBPM distinguishes between services furnished incident to a physician’s services and services such as diagnostic tests that are covered under another benefit:

Medicare pays for services and supplies (including drug and biologicals which are not usually self-administered) that are furnished incident to a physician’s or other practitioner’s services, are commonly included in the physician’s or practitioner’s bills, of the Act. Carriers and intermediaries must not apply incident to requirements to services having their own benefit category. Rather, these services should meet the requirements of their own benefit category. For example, diagnostic tests are covered under §1861(s)(3) of the Act and are subject to their own coverage requirements.
Discussion:

The diagnostic tests at issue were denied because the record lacked documentation from the ordering physicians such as progress or medical notes to indicate the rationale for the test or otherwise support that the tests were medically reasonable and necessary. On appeal, the Appellant argued generally the tests were performed as ordered by the referring physician and, as an IDTF, it is not responsible for furnishing patient evaluations. The ALJ agreed, determining the test results and interpretations and the physician’s orders were sufficient to establish that services were reasonable and necessary.

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); Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services, Final Rule, 66 FR 58800-58801, Friday, November 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 that entities billing Medicare submit medical documentation to support coverage. See MPIM, Chapter 3, § 3.11.1 ("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).

In the context of diagnostic tests furnished by IDTFs, courts have explicitly found that "order forms [that] identified the referring physician and included check boxes which identified symptoms and possible diagnoses" were insufficient to meet the requirements of 42 C.F.R. § 410.33(d) and fail to establish that the 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) at http://www.hhs.gov/dab/divisions/medicareoperations/macdecisions/case_kgv_leasing.pdf ("[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 laboratory tests, CMS addressed the concern that 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.” *Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services*, Final Rule, 66 FR 58800, Friday, November 23, 2001. CMS responded:

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.

*Id.* at 58801.

The ALJ erred in determining the submitted physician orders, test results, and test interpretations satisfy an IDTF’s documentation requirements for purposes of Medicare payment. 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 FR 58800-58801, Friday, November 23, 2001. The ALJ also erred in finding the physician’s orders and test interpretations alone are sufficient to establish the diagnostic tests were reasonable and necessary in accordance with 42 C.F.R. § 410.32. The physician’s orders are the only physician records in these cases. However, these checklist forms, which contain undated and apparently digitally stamped or copied signatures, do not indicate the ordering physician had a prior relationship with the beneficiary, ordered the tests to treat a specific medical problem, or used the results to manage the beneficiary’s treatment. Notably, the ordering physician is never fully identified, designated in the administrative record only as “J. Jackson M.D.” or “Jackson.” See *e.g.* Exh 5 at 34-35, 38 and 81.

The ALJ concluded that the Appellant “provided the subject services incident to a physician’s services.” ALJ decision at 19. To the extent the ALJ found this to be a basis for allowing coverage, the decision contains an error of law material to the outcome of the case. Generally, services furnished incident to a physician’s services must be must be an integral, although incidental part of the physician’s professional service;
commonly furnished without charge or included in the physician’s bill; of a type that are commonly furnished in a physician’s offices; and furnished by the physician or by auxiliary personnel under the physician’s direct supervision. 42 C.F.R. § 410.26(b). The MBPM Chapter 15, § 60 further explains:

Medicare pays for services and supplies … that are furnished incident to a physician’s or other practitioner’s services, are commonly included in the physician’s or practitioner’s bills, of the Act. Carriers and intermediaries must not apply incident to requirements to services having their own benefit category. Rather, these services should meet the requirements of their own benefit category. For example, diagnostic tests are covered under §1861(s)(3) of the Act and are subject to their own coverage requirements.

Emphasis added. Diagnostic tests furnished by an IDTF based on written physicians’ orders do not meet the statutory and regulatory definition of supplies furnished incident to a physician’s services.