



**CMS Referral for Own Motion Review by DAB/MAC**

Appellant at ALJ Level <i>M. A. Hamed, M.D., Inc.</i>	ALJ Appeal Number <i>1-840363739 and three others</i>
Beneficiary (if not the Appellant) <input checked="" type="checkbox"/> List attached	ALJ Decision Date <i>June 8, 2012, June 10, 2012</i>
Health Insurance Claim Number (HICN)* <i>See attached</i>	Specific Item(s) OR Service(s) <i>Diagnostic tests</i>
Provider, Practitioner OR Supplier <i>M.A. Hamed, M.D., Inc.</i>	<input type="checkbox"/> Part A <input checked="" type="checkbox"/> Part B

Basis for referral		
<u>Any Case</u>	<u>CMS as a Participant</u>	<u>Pre-BIPA</u>
<input checked="" type="checkbox"/> Error of law material to the outcome of the claim	<input checked="" type="checkbox"/> Decision not supported by the preponderance of evidence	<input type="checkbox"/> Decision not supported by substantial evidence
<input type="checkbox"/> Broad policy or procedural issue of public interest	<input type="checkbox"/> Abuse of discretion	<input type="checkbox"/> Abuse of discretion

**Rationale for Referral:**

Between January 12, 2010 and January 19, 2010, M. A. Hamed, M.D. (Appellant), a physician, billed Medicare for multiple diagnostic tests furnished to four Medicare beneficiaries. The Appellant billed Medicare for miscellaneous diagnostic tests that are addressed in local coverage determinations (LCDs) L28230, L28283, L28284, L28285 and L28295.

The tests were paid initially. Later, Palmetto GBA, the Medicare administrative contractor (MAC) responsible for processing the claims recouped the money. The Appellant appealed the overpayment determinations, stating that the beneficiaries arrived at its facility for medical attention and received it. On redetermination the MAC upheld the overpayment determinations because the documentation did not show that the testing was reasonable and necessary for the care and treatment of the beneficiaries. The Qualified Independent Contractor (QIC) issued partially favorable decisions, finding only the office visits, echocardiograms and electrocardiograms covered. The QIC upheld the denials of the remaining tests generally because the symptoms and physical findings did not meet indications for coverage according to the relevant LCDs.

In its request for hearing before an administrative law judge (ALJ), the Appellant argued that all testing was carried out in accordance with Medicare regulations. On March 29, 2012, the QIC submitted written testimony for these hearings, posing several concerns, including whether the Appellant was treating the beneficiaries for specific ailments and whether the tests were ordered to diagnose specific conditions. Following an April 10, 2012 telephonic hearing, the ALJ reversed the unfavorable QIC decisions, because “there were clinical indications to warrant the ordering and rendering of tests performed. The case file included results of the procedures that were performed on the Beneficiary.” *E.g.*, appeal 1-840363739, ALJ decision at 12. The ALJ also found Section 1879 of the Social Security Act (the Act) was not applicable since the decision was fully

favorable to the Appellant. *Id.* In ordering coverage, the ALJ relied on the physician's progress notes, test order forms and test results, all dated on the date of service.

The ALJ's decision contains multiple errors of law and fact. First, the ALJ erred as a matter of law in failing to consider 42 CFR § 410.32(a), which requires that diagnostic testing be ordered and used 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." Medical documentation fails to indicate what specific medical problem the Appellant is treating, why he is ordering (or performing) the diagnostic tests, or how test results are to be used to manage the beneficiary's treatment. The Appellant apparently did not see the patient's either before or after the testing. As the QIC noted, the administrative record lacks medical documentation supporting the diagnosis or the need for the test or indicating the testing was used to treat the patient. *E.g.*, appeal 1-840363739, Exh 4 at 7.

Second, the ALJ erred as a matter of law in not considering coverage requirements in relevant LCDs L28230, *Abdominal and Retroperitoneal Ultrasound*, L28283, *Noninvasive Cerebrovascular Studies*, L28284, *Noninvasive Peripheral Arterial Studies*, L28285, *Noninvasive Peripheral Venous Studies* and L28295, *Pulmonary Function Testing*. 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 to follow a policy applies only to the specific claim on appeal and is not precedential. 42 C.F.R. § 405.1062.

Third, the ALJ erred in finding the evidence in the record sufficient to support that the services were reasonable and necessary. As will be discussed below, medical documentation is vague, inconsistent, and incomplete. Test orders are nonspecific or nonexistent, and it is never evident what specifically the Appellant is trying to diagnose or treat, why he orders a particular test, why he orders so many tests (including so many similar tests) or how he might use the results.

#### **Background:**

The Appellant ordered and/or performed<sup>1</sup> multiple diagnostic tests for four Medicare beneficiaries. The tests were administered on January 12, 2010, January 15, 2010 and January 19, 2010 and were billed to Medicare with the following Current Procedural Terminology (CPT) codes:

- 76700 – ultrasound, abdominal, real time with image documentation; complete

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<sup>1</sup> It is not clear which tests the Appellant performed himself, which were performed by his staff, and which were outsourced.

- 93000 – electrocardiogram, routine ecg with at least 12 leads; with interpretation and report
- 93306 – echocardiography, transthoracic, real-time with image documentation (2d), includes m-mode recording, when performed, complete, with spectral doppler echocardiography, and with color flow doppler echocardiography
- 93880 – duplex scan of extracranial arteries; complete bilateral 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 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)
- 93978 – duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; complete study
- 94200 – maximum breathing, capacity, maximal voluntary ventilation
- 94240 – functional residual capacity or residual volume: helium method, nitrogen open circuit method, or other method
- 94350 – determination of maldistribution of inspired gas: multiple breath nitrogen washout curve including alveolar nitrogen or helium equilibration time
- 94370 – determination of airway closing volume, single breath tests
- 94375 – respiratory flow volume loop
- 94720 – carbon monoxide diffusing capacity (eg, single breath, steady state)
- 94725 – membrane diffusion capacity

- 94750 – pulmonary compliance study (eg, plethysmography, volume and pressure measurements)
- 99204 – office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: a comprehensive history; a comprehensive examination; medical decision making of moderate complexity, counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient’s and/or family’s needs, usually, the presenting problem(s) are of moderate to high severity. Physicians typically spend 45 minutes face-to-face with the patient and/or family.

The MAC paid the claims initially. In March and April 2011, the MAC notified the Appellant “the claim[s were] processed incorrectly” and recouped the overpayment. Exh 2 at 26-27.<sup>2</sup>

The Appellant requested redeterminations, explaining, “the above patient arrived to [sic] our facility for medical attention regarding their complaints. Included is a copy of the Medical Records of all the services provided to them.” *Id.* at 15. In multiple redetermination decisions, Palmetto GBA found all services unfavorable because its “medical staff indicated the documentation did not show the medical need for the services.” *Id.* at 2, 8 and 11. Citing the Medicare Benefit Policy Manual (MBPM), (CMS Pub 100-3), Chapter 16, Section 90, the MAC explained, “Medicare does not cover routine exams or related services.” *Id.*

The QIC issued partially favorable decisions, finding the echocardiograms (93306), office visits (99204) and electrocardiograms (93000) covered, but the remaining tests noncovered, generally because the patient’s diagnosis (e.g., chronic obstructive pulmonary disease) was already known and thus the testing did not meet LCD criteria. The QIC found, “there was no indication of symptoms or physical findings that would document the medical necessity of the service(s) in accordance with Medicare guidelines.” Exh 3 at 6-7.

The Appellant requested an ALJ hearing, arguing “all procedures were performed according to CMS rules and regulations.” Exh 4 at 1. On March 29, 2012, the QIC submitted position papers specific to each of the four appeals. *E.g.*, Exh 17 at 4-8. The QIC’s papers reflect confusion regarding whether the Appellant was an IDTF that was self-referring its own patients. The QIC also noted inconsistencies between the physician progress notes and the physician order forms, explaining, for example, that:

[s]ome of the conditions noted on the order forms, such as intermittent claudication, chest pain, varicose veins, apnea, chronic cough, and shortness of breath, were not documented in the progress note, either as a patient complaint or an examination finding. Due to this discrepancy, the exact reason for ordering the testing was unknown. Additionally, if the

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<sup>2</sup> The case files are substantially similar. We have referred to the documentation in appeal 1-840363739 for beneficiary P.T. unless otherwise noted.

physician was able to diagnose COPD, peripheral vascular disease, and ASHD prior to testing, the need for testing was unclear.

*Id.* at 7-8. Finally, the QIC noted that the particular battery of tests could last up to four and a half hours, a “prolonged period of testing [that] did not seem reasonable or feasible” for an 88-year old patient described as being in physical distress. *Id.* at 8.

Following the April 10, 2012 telephone hearing, the ALJ issued four fully favorable decision letters in which he found the services medically reasonable and necessary under Section 1862(a)(1) of the Act. In reversing the QIC denials, the ALJ explained:

Contrary to the decision of the QIC, the ALJ finds that the multiple tests including an electrocardiogram, a pulmonary function study, and extremity study were medically reasonable and necessary. The case file indicated that the beneficiary complained of chest pain and had an elevated blood pressure. In this matter, there were clinical indications to warrant the ordering and rendering of tests performed. The case file included results of the procedures that were performed on the Beneficiary. There were medical indications that warrant the series of procedures that were performed on the Beneficiary on January 15, 2010.

ALJ decision at 12. The ALJ concluded:

The series of tests including 93923 ... 93924 ... 93965 ... 94725 ... 94375 ... 94200 ... 94350 ... 94370 ... 94240 ... 94750 ... and 94720 ... was medically reasonable and necessary under Section 1862(a)(1) and Section 1833(e) of the Social Security Act. Therefore, the Appellant has satisfied the policies and criteria necessary for Medicare to provide payment for the series of tests ... performed on the Beneficiary....

*Id.*

#### **Applicable Law, Regulation, and Medicare Policy:**

##### *Local Coverage Determinations*

Section 1862(a)(1)(A) of the Act explains that payment may be allowed only for 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. LCDs are contractor-wide determinations as to whether a service is reasonable and necessary under the provisions of Section 1862(a)(1)(A) of the Social Security Act (the Act). Section §1869(f)(2)(B) of the Act. According to the Medicare Program Integrity Manual (MPIM) (CMS Pub 100-08):

LCDs specify under what clinical circumstances a service is considered to be reasonable and necessary. They are administrative and educational tools to assist providers in submitting correct claims for payment. Contractors publish LCDs to provide guidance to the public and medical community within their jurisdictions. Contractors develop LCDs by

considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community.

MPIM, Chapter 3, § 13.1.3.

42 CFR 405.1062 provides that “(a) ALJs and the MAC are not bound by LCDs, LMRPs, or CMS guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. (b) if an ALJ or Mac declines to follow a policy in a particular case, the ALJ or MAC decision must explain the reasons why the policy was not followed...”

### Diagnostic Testing

Diagnostic tests are covered by Medicare under § 1861(s)(3) of the Act. “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.

42 C.F.R. § 410.32 sets forth the conditions for coverage of diagnostic tests under Medicare Part B. Specifically, § 410.32(a) provides, 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, “[t]ests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.” *Id.* 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 Act “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.*

Palmetto GBA issued several LCDs applicable to this case that were in effect in January 2010.

LCD L28230– *Abdominal and Retroperitoneal Ultrasound* sets forth coverage criteria for CPT code 76700. L28230 states, “An abdominal ultrasound may be reasonable and necessary to image structures or assess the conditions listed below, assuming throughout that clinically significant decisions will be based on the results.”

#### General Abdominal Ultrasound:

1. Suspected abdominal organ congenital abnormalities,
2. Multi-organ pre/post transplantation evaluation,
3. Abdominal, flank and/or back pain,
4. Pain that may be referred from the abdominal or retroperitoneal regions,
5. Palpable abnormalities such as possible abdominal mass or organomegaly,

6. Abnormal laboratory values suggestive of abdominal or retroperitoneal pathology,
7. Follow-up of known or suspected abnormalities in the abdomen or retroperitoneum,
8. Search for metastatic disease or occult primary sites,
9. Abdominal trauma,
10. Infectious or inflammatory conditions including but not limited to peritonitis, infectious or inflammatory colitis, and appendicitis.

LCD L28230.

LCD L28283 – *Noninvasive Cerebrovascular Studies*, provides the following coverage indications for CPT code 93880:

1. Cervical bruits.
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.
6. Blunt neck trauma.
7. Follow-up after a carotid endarterectomy.
8. Re-evaluation of existing carotid stenosis.
9. Evaluation of pulsatile neck mass.
10. Preoperative evaluation of patients scheduled for major cardiovascular surgical procedures.
11. Evaluation of nonhemispheric or unexplained neurologic symptoms.
12. Retinal arterial emboli.
13. Evaluation of suspected dissection.

LCD L28283.

LCD L28284 – *Noninvasive Peripheral Arterial Studies*, governs local coverage requirements for CPT codes 93923 and 93924. L28284 states:

Noninvasive peripheral arterial examinations performed to establish the level and/or degree of arterial occlusive disease are reasonable and necessary if significant signs and/or symptoms of possible limb ischemia are present and the patient is a candidate for invasive

therapeutic procedures.

Indications for peripheral arterial evaluations include:

1. Claudication of less than one block or such severity that interferes significantly with the patient's occupation or lifestyle
2. Rest pains (typically including the forefoot), usually associated with diminished or absent pulses, which become increasingly severe with elevation and diminishes with placement of the leg in a dependent position Diagnosis 729.5, Pain in limb, should only be billed when the patient's symptoms meet this criteria.
3. Tissue loss defined as gangrene or pre-gangrenous changes of the extremity or ischemic ulceration of the extremity occurring with diminished or absent pulses
4. Aneurysmal disease
5. Evidence of thromboembolic events
6. Blunt or penetrating trauma (including complications of diagnostic and/or therapeutic procedures)
7. Lower extremities surgical procedure where vascular disease is clinically suspected
8. For the patient with chronic renal failure and for whom an A/V fistula is planned
9. For radial artery evaluation in a patient scheduled for CABG

L28284. The LCD states further, "A routine history and physical examination, which includes Ankle/Brachial Indices (ABIs), can readily document the presence or absence of ischemic disease in a majority of cases. It is not reasonable and necessary to proceed beyond the physical examination for minor signs and symptoms unless related signs and/or symptoms are present which are severe enough to require possible invasive intervention." *Id.* Signs and symptoms that do not indicate testing is reasonable and necessary include:

"Leg pain, nonspecific" and "Pain in Limb" as a single diagnosis is too general to warrant further investigation unless they can be related to other signs and symptoms.

...

Absence of relatively minor pulses (i.e., dorsalis pedis or posterior tibial) in the absence of symptoms. The absence of pulses is not an indication to proceed beyond the physical examination unless it is related to other signs and/or symptoms.

Additionally, "Since the signs and symptoms of arterial occlusive disease and venous disease are so divergent, the performance of simultaneous arterial and venous studies during the same encounter should be rare. Therefore, documentation clearly supporting reasonableness and necessity of both procedures performed during the same encounter must be available for post-payment audit." *Id.*

LCD L28285 – *Noninvasive Peripheral Venous Studies*, which sets forth coverage requirements for CPT code 93965, states, “venous examinations ... are reasonable and necessary only if the patient can be a candidate for anticoagulation, thrombolysis or invasive therapeutic procedures for the following indications: deep vein thrombosis, chronic venous insufficiency, and evaluation of pre- and post-procedural venous conditions.”

LCD L28295 – *Pulmonary Function Testing* provides coverage guidelines for CPT codes 94200, 94240, 94350, 94370, 94375, 94720, 94725 and 94750. L28295 states:

Pulmonary Function Tests (PFTs) are a broad range of diagnostic procedures that measure two components of the respiratory system’s functional status: 1) the mechanical ability to move air in and out of the lungs, and 2) the effectiveness of providing oxygen to the body and removing carbon dioxide.

...

General limitations for any of the pulmonary function tests include:

- All diagnostic tests payable by Medicare must be ordered by a treating physician and used in patient care. Community standards always apply.
- The various modalities to assess pulmonary function must be used in a purposeful and logical sequence.
- Tests performed as components rather than as a single test will be denied. ...
- Medicare does not cover screening tests. Medicare coverage excludes routine (screening) tests for asymptomatic patients with or without high risk of lung disease (e.g., prolonged smoking history). It also excludes studies as part of a routine exam, and studies as part of an epidemiological survey.

Medical necessity is an overriding requirement for Medicare coverage of diagnostic testing. When a diagnosis or evaluation can be made clinically or when test results are not necessary to manage the patient’s disease, then Pulmonary Function Testing is not reasonable and necessary. In addition, on routine visits for other medical conditions, when a patient claims to be stable or does not report clinically meaningful changes in pulmonary status, and physical exam and interview confirm this, repeat testing is unlikely to be necessary. Palmetto GBA has found that in many patients routine use of PFTs at each office visit is not a necessary and reasonable clinical practice and as such, cannot be reimbursed.

Providers should pay particular attention to guidelines for the usage of the following CPT codes relative to Medicare’s standards of reasonable and necessary care: 94070, 94200, 94350, 94370, 94640, 94725, and 94750.

L28295 distinguishes five categories of pulmonary function testing:

### **1. Spirometry. ...**

Spirometry is most useful for assessing obstructive lung diseases such as asthma and chronic obstructive pulmonary disease (COPD).

CPT codes for Spirometry include 94010, 94011, 94012, 94060, 94070, 94150, 94200, 94370 and 94375. Routine and/or repetitive billing for unnecessary batteries of tests is not clinically reasonable.

...

Limitations to performing spirometry are:

- Routine or repetitive batteries of tests are not clinically reasonable.
- In many scenarios, simple spirometry is a mainstay of pulmonary function testing and is usually sufficient to differentiate between obstructive and restrictive disorders and evaluate their severity. Extensive testing may often not be necessary for adequate clinical assessment.

...

## **2. Lung volume**

...

Lung volume tests are most useful for assessing restrictive lung diseases such as those caused by scarring inside the lungs or by abnormalities in the ribcage or muscles of the chest wall.

CPT codes for lung volume determination are 94013, 94240, 94250, 94260, 94350, and 94360. CPT code 94750 may be added when clinically relevant (see Section 4).

Indications for a lung volume test are as follows, when consistent with community standards of reasonable clinical practice:

- Evaluation of the type and degree of pulmonary dysfunction,
- Evaluation of dyspnea, cough, and other symptoms,
- Early detection of lung dysfunction,
- Follow-up and response to therapy,
- Preoperative evaluation,
- Track pulmonary disease progression,
- Assess the effectiveness of therapy for pulmonary conditions,
- Pre and post-op evaluations for Lung Volume Reduction Surgery (LVRS).

Limitations to performing a lung volume test are:

- Functional Residual Capacity (FRC) may be artificially high if the measurement is taken at a higher lung volume secondary to pain or anxiety,
- Subject cooperation is necessary,
- A complete evaluation may require the use of inhaled gases,
- Repetitive testing of total lung volume is not usually clinically necessary.

### **3. Diffusion Capacity**

Diffusion capacity tests are most useful for the assessment of how well the lung tissues transfer oxygen from the air inside the lungs, across thin membranes, into the blood.

CPT codes for diffusion capacity include 94720 and 94725.

Indications for diffusion capacity (DLCO) are as follows, when consistent with community standards of reasonable clinical practice:

- Evaluate and follow up parenchymal lung diseases associated with dusts or drug reactions or Sarcoidosis,
- Evaluate and follow up emphysema and cystic fibrosis,
- Differentiate between chronic bronchitis, emphysema, and asthma in patient with obstructive patterns,
- Evaluate the pulmonary involvement in systemic diseases (e.g., rheumatoid arthritis, systemic lupus),
- Help in the evaluation of some types of cardiovascular disease (e.g., primary pulmonary hypertension, pulmonary edema, acute or recurrent thromboembolism),
- Predict arterial desaturation during exercise in chronic obstructive pulmonary disease,
- Evaluate and quantify the disability associated with interstitial lung disease,
- Evaluate the effects of chemotherapy agents or other drugs known to induce pulmonary dysfunction,
- Evaluate hemorrhagic disorders.

Limitations to performing a diffusion capacity test are:

- Mental confusion or muscular incoordination preventing the subject from adequately performing the maneuver,
- Single breath DLCO requires breath holding at maximal inhalation. Some patients may be limited by syncopal symptoms triggered by an associated Valsalva or Muller maneuver which may slow the heart rate.

### **4. Lung Compliance**

Lung compliance studies are performed only when all other PFTs give equivocal results or results which must be confirmed by additional lung compliance testing. Lung compliance measures the elastic recoil/stiffness of the lungs. It is more invasive than other PFTs, because the patient is required to swallow an esophageal balloon.

The CPT code for lung compliance testing is 94750.

### **5. Pulmonary Studies during Exercise Testing**

L28295.

Waiver of Liability Determinations Under § 1862(a)(1)(A) of the Act

Section 1879 of the Social Security Act provides financial liability protections to beneficiaries and providers by allowing payment for certain items and services for which Medicare payment would otherwise be denied. The limitation on liability provisions of Section 1879 apply to claims that are denied under Section 1862(a)(1) of the Social Security Act as not reasonable and necessary to diagnose or treat an illness or injury.

**Discussion:**

In each of the four appeals, the MAC's redetermination letters upheld the overpayments because routine services are not covered. Exh 2 at 1-11. The QIC denied the services generally because the patient's diagnosis was already known and so it was unclear why the tests were being furnished. The QIC also found none of the documented symptoms or physical findings indicated the tests were reasonable and necessary according to LCD criteria. In its position papers, the QIC also cited discrepancies between the physician examination and progress notes and the physician orders. The ALJ found, on the contrary, that the tests were reasonable and necessary pursuant to § 1862(a)(1)(A) of the Act, in particular because the patient's complaints of chest pain and an elevated blood pressure (for example), constituted "clinical indications to warrant the ordering and rendering of tests performed." ALJ decision at 12.

In finding the services were covered, the ALJ did not consider 42 CFR § 410.32(a), which requires that diagnostic testing be ordered and used 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." In these cases, there is no indication the Appellant saw the patients at any time before or after the day of service, nor is there any documentation that the Appellant relied on or used the results to manage the beneficiaries' conditions. All of the beneficiaries presented with generalized complaints of pain (e.g., headaches, neck pain, chest pain, back pain, abdominal pain, bilateral knee pain). However, it is never clear what specifically the Appellant is trying to diagnose or treat, why he orders a particular test, why he orders so many tests (including so many similar tests), or how he might use the results. Furthermore, the physician progress notes are unclear as to what constitutes physician findings, what the physician is trying to diagnose, and what the physician is trying to treat. For example, in ALJ appeal 1-840363739, "type II diabetes" is listed under the patient's medical history and also appears to be part of what the Appellant is trying to assess.<sup>3</sup> Exh 3 at 52. Additionally, the physician order forms do not specify which tests are to be performed. See e.g., Exh 3 at 60, 64. There is no order for the peripheral venous study billed with CPT code 93965. *Id* (see test results at 57). Tests

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<sup>3</sup> In all cases, the field labeled "DIAGNOSIS" is scratched out on the Appellant's progress notes and replaced with the handwritten label "Assess."

not ordered by the treating physician to treat a specific medical problem do not meet the requirements of covered diagnostic tests. 42 CFR § 410.32(a)

Additionally, the ALJ did not consider pertinent coverage requirements outlined in LCDs L28230– *Abdominal and Retroperitoneal Ultrasound*, LCD L28283 – *Noninvasive Cerebrovascular Studies*, L28284 – *Noninvasive Peripheral Arterial Studies*, L28285 – *Noninvasive Peripheral Venous Studies*, and L28295 – *Pulmonary Function Testing*. While the ALJ cited some of the applicable LCDs in his decision, he did not apply indications and criteria to the documentation before determining that the services were covered. For example, L28284 states that “signs and symptoms of arterial occlusive disease and venous disease are so divergent” that only in rare instances will the two be performed together and documentation must clearly support the need for both. In all four cases, the Appellant billed for peripheral arterial studies (93923 and 92924) as well as peripheral venous studies (93965). Similarly, L28295 states that a lung compliance test is only covered “when all other [pulmonary function tests] give equivocal results or results which must be confirmed by additional lung compliance testing.” In all four cases, the Appellant performed a battery of eight pulmonary function tests with no indication as to why the lung compliance study (94750) was necessary.

Medical documentation in the record consists generally of a one- or two-page progress note form, a two-page comprehensive physical examination form, an order for pulmonary function tests, an order for “Bilateral Lower Extremity Arterial Study”<sup>4</sup> and some test results.<sup>5</sup> In all cases, the Appellant billed for peripheral arterial studies 93923 and 93924. *E.g.*, Exh 3 at 16. However, test results do not exist for 92922 and 93923. No results exist for 93924. *Id.* at 58-59. As noted above, test orders are nonspecific and inconsistent with test results. Also as noted above, symptoms, diagnoses and findings in “progress” and examination notes are often inconsistent with those listed in order forms. The scant physician notes document only generalized patient findings and lack clarity as to what needs to be assessed, what the physician assessed in his clinical evaluation, and what is part of the patient’s medical history. The lack of specificity is compounded by discrepancies between the physician evaluations and the order forms. None of the cases document any treatment plans or follow up visits. At best, documentation demonstrates the tests were furnished for screening purposes. However, routine tests performed without relationship to treatment or diagnosis for a specific illness, symptom, complaint or injury are noncovered. MBPM, Chapter 16, § 90.

The ALJ erred as a matter of law in failing to consider 42 CFR § 410.32(a). Pursuant to 42 C.F.R. § 405.1063(a), “all laws and regulations pertaining to the Medicare and Medicaid programs ... are binding on ALJs and the MAC.” The ALJ also erred as a matter of law in failing to consider applicable LCDs. While ALJs and the Medicare

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<sup>4</sup> The order for the lower extremity arterial study is on a form labeled “PVL Physician Order Form.” We assume the PVL stands for “peripheral vascular lab.” As noted above, it is unclear which tests the Appellant or his staff furnished and which tests he arranged to have furnished by a third party.

<sup>5</sup> Medical records also include clinical laboratory test results. However, any claims for these tests are not part of this appeal record.

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. 42 C.F.R. § 405.1062. Additionally, the ALJ's decision that services are reasonable and necessary and meet Medicare coverage guidelines is not supported by the preponderance of evidence.

Circumstances and facts specific to each case are discussed below.

### Appeal 1-840363739

The Appellant saw beneficiary P.T. on January 15, 2010. The Appellant's progress note from that day indicates the Beneficiary presented with chief complaints of "bilateral knee pain, leg pain, upper shoulder pain, back pain, headaches, dizziness, S.O.B.<sup>6</sup>, chest pain on effort." Exh 3 at 52. The history of her present illness was listed as osteoporosis, type II diabetes and degenerative arthritis. *Id.* The Appellant intended to assess the beneficiary for C.O.P.D. and A.S.H.D.,<sup>7</sup> type II diabetes, generalized degenerative osteoarthritis (?) and osteoporosis, diabetic neuropathy and peripheral vascular disease. *Id.* In addition to the January 15, 2010 progress note, medical documentation in the record includes a form labeled "Comprehensive Physical Exam," a form labeled "VASCULAR HISTORY" with only "Patient Demographic" information filled in, a "Segmental Pressure Summary" report, a "Lower Extremity Venous Output" report for CPT code 93965, a "Post Exercise PVT (Lower)" report for CPT codes 93922 and 93923, a "PVL<sup>8</sup> Physician Order Form," pulmonary function test results, a "PULMONARY FUNCTION TEST ORDER FORM," clinical laboratory blood test results, and other unidentified test results. *Id.* at 53-70. The "PVL Physician Order Form" listed the "Clinical Problem[s]" to include diabetes with peripheral circulatory disorders, atherosclerosis of the extremities, atherosclerosis of the extremities with intermittent claudication, peripheral pulses, chest pain, varicose veins of lower extremities with inflammation, pain in leg and swelling of limb. *Id.* at 60. The form has "Bilateral Lower Extremity Arterial Study (multiple levels w/ segmental measurements)" checked as the test(s) ordered. *Id.* The "PULMONARY FUNCTION TEST ORDER FORM" states the diagnoses to include acute and chronic respiratory failure, apnea, chronic cough, emphysema, pulmonary congestion and shortness of breath. *Id.* at 64. The form has check boxes for tests with CPT codes 94060, 94240, 94720, 94350, 94200, 94370, 94750 and 94725. None of the individual tests are checked but the header "Pulmonary Function Profile" for the entire battery of tests is circled. *Id.* Although listed diagnoses on this form include, *inter alia*, chronic cough, acute and chronic respiratory failure and apnea, neither the progress note nor the examination form document these findings. (Conversely, the physical examination form notes the symptoms to include "basal rales

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<sup>6</sup> Shortness of breath.

<sup>7</sup> Arteriosclerotic heart disease.

<sup>8</sup> Peripheral vascular lab (presumably).

and rhonchi with wheezing,” but “wheezing” is not a checked diagnosis on the “PULMONARY FUNCTION TEST ORDER FORM.” Both forms are dated January 15, 2010. *Compare* Exh 3 at 54 *with* Exh 3 at 64. Subsequently, the Appellant billed Medicare for tests with CPT codes 93000, 93923, 93924, 93965, 94200, 94240, 94350, 94370, 94375, 94720, 94725 and 94750.<sup>9</sup> Exh 3 at 16-17.

LCD L28284 sets forth coverage requirements for noninvasive peripheral arterial studies billed with CPT codes 93923 and 93924. The submitted medical documentation does not indicate that the beneficiary’s medical condition met any of the indications for peripheral arterial evaluations noted in the LCD.<sup>10</sup> For instance, the patient presented with “leg pain” but it is undocumented as to whether the pain was associated with diminished or absent pulses which become increasingly severe with elevation and diminishes with placement of the leg in a dependent position, as per the LCD. An example of symptoms that do not indicate testing is reasonable and necessary is “‘leg pain, nonspecific’ and ‘pain in limb’ as a single diagnosis since these are both too general to warrant further investigation unless they can be related to other signs and symptoms.” LCD L28284. Further, the order for “Bilateral Lower Extremity Arterial Study” does not specify which test(s) is ordered. The administrative record includes test results for 93922 and 93923 but is missing results for 93924. Exh 3 at 56-59. The Appellant billed Medicare for 93923 and 93924.

Additionally, there is no order for the peripheral venous study billed with CPT code 93965. Pursuant to L28284, it is rarely necessary to perform both peripheral arterial and peripheral venous studies, since symptoms are so divergent. When performed together, medical documentation must clearly demonstrate why both are necessary. *Id.*

L28295 sets forth coverage criteria for pulmonary function tests, which the Appellant billed with CPT codes 94200, 94240, 94350, 94370, 94375, 94720, 94725 and 94750. L28295 addresses five categories of pulmonary function tests, four of which the Appellant furnished. First, *spirometry* testing is represented in this case by CPT codes 94200, 94370 and 94375. “Spirometry is most useful for assessing obstructive lung diseases such as asthma and chronic obstructive pulmonary disease (COPD).” LCD L28295. It is unclear from the Appellant’s progress note whether COPD is a finding, a diagnosis, part of the patient’s medical history, or a condition to be assessed. To the extent the beneficiary’s COPD was already known, the spirometry tests were unnecessary to diagnose the patient’s condition and the testing did not meet the medical necessity requirements of the LCD. “When a diagnosis or evaluation can be made clinically or when test results are not necessary to manage the patient’s disease, then Pulmonary Function Testing is not reasonable and necessary.” L28295. Furthermore, the record does not document any clinical treatment plan for COPD or otherwise indicate how the test would be used to treat the beneficiary.

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<sup>9</sup> The QIC approved coverage of 93000 (electrocardiogram). Exh. 3 at 9.

<sup>10</sup> See page 8, above.

Second, *lung volume* tests “are most useful for assessing restrictive lung disease such as those caused by scarring inside the lungs or by abnormalities in the ribcage or muscles of the chest wall.” *Id.* Medicare covers lung volume tests, in this case billed with codes 94240, 94350 and 94750, “when clinically relevant.” *Id.* The medical notes do not indicate why the lung volume tests were ordered and there are no symptoms or physical findings to suggest the Appellant was attempting to assess a restrictive lung disease. Additionally, the documentation fails to indicate how the lung function test results would be used to treat the patient. “Supportive documentation evidencing the condition and treatment is expected to be documented in the medical record and be available upon request.” *Id.*

Third, *diffusion capacity* tests are useful in assessing the efficiency of lung tissue transferring oxygen from the air inside the lungs, across the membrane, into the blood. *Id.* The Appellant billed diffusion capacity tests with codes 94720 and 94725. There is no indication of why these tests were administered or how they were going to be used to treat the beneficiary.

Fourth, *lung compliance* studies, billed here with CPT code 94750, are performed “only when all other PFTs give equivocal results or results which must be confirmed by additional lung compliance testing.” *Id.* L28295 states further that lung compliance testing “is more invasive than other PFTs, because the patient is required to swallow an esophageal balloon.” There is no indication that 94750 was required because other pulmonary function tests results were inconclusive or required additional confirmation. All pulmonary function tests were completed on the same date of service. There is no indication why the test was ordered.

The administrative record does not document any follow-up treatment or indication of how any test results were used in the treatment and care of this beneficiary.

#### Appeal 1-840308131

The Appellant saw beneficiary M.G. on January 12, 2010. The Appellant’s progress note reflects that the Beneficiary presented with chief complaints of “abdominal pain, [lower back pain], bilateral knee pain and difficult mobilization, leg pain, headaches.” Exh 1 at 4. Her medical history included bipolar schizophrenia and Type II diabetes. *Id.* Findings and/or conditions to assess included obesity, difficult mobilization and swelling of both knees, edema secondary to congestive heart failure, bipolar schizophrenia, back spine tenderness and mobility, C.O.P.D., A.S.H.D. and type II diabetes. *Id.*

In addition to the January 12, 2010 progress note, medical documentation in the record includes a form labeled “Comprehensive Physical Exam,” a form labeled “VASCULAR HISTORY” with only “Patient Demographic” information and certain symptoms checked, a “Segmental Pressure Summary” report, a “Lower Extremity Venous Output” report for CPT code 93965, a “Post Exercise PVT (Lower)” report for CPT codes 93922 and 93923, a “PVL Physician Order Form,” pulmonary function test results, a “PULMONARY

FUNCTION TEST ORDER FORM,” a CERTIFICATE OF MEDICAL NECESSITY” form for diagnostic ultrasound, clinical laboratory blood test results, and other unidentified test results. *Id.* at 4-23. The “PVL Physician Order Form,” listed the “Clinical Problem[s]” to include diabetes with peripheral circulatory disorders, atherosclerosis of the extremities, peripheral vascular disease, obesity, pain in limb and swelling of limb. *Id.* at 12. The form does not list specific tests, but has “Bilateral Lower Extremity Arterial Study (multiple levels w/ segmental measurements)” checked as the test(s) ordered. *Id.* The “PULMONARY FUNCTION TEST ORDER FORM” states the diagnoses to include chronic cough, heart failure, shortness of breath and smoker’s cough. *Id.* at 64. The form has check boxes for tests with CPT codes 94060, 94240, 94720, 94350, 94200, 94370, 94750 and 94725. None of the individual tests are checked but the header “Pulmonary Function Profile” for the entire battery of tests is circled. *Id.* Although listed diagnoses on this form include chronic cough, heart failure, shortness of breath and smoker’s cough, only the congestive heart failure is documented in the progress note and the physical examination form. Likewise, pulmonary function test results indicate the patient had no cough. *Id.* at 13. Subsequently, the Appellant billed Medicare for tests with CPT codes 93000, 93923, 93924, 93965, 94200, 94240, 94350, 94370, 94375, 94720, 94725, 94750 and 99204.<sup>11</sup>

LCD L28284 sets forth coverage requirements for noninvasive peripheral arterial studies billed with CPT codes 93923 and 93924. The submitted medical documentation does not indicate that the beneficiary’s medical condition met any of the indications for peripheral arterial evaluations noted in the LCD.<sup>12</sup> For instance, the patient presented with “leg pain” but it is undocumented as to whether the pain was associated with diminished or absent pulses which become increasingly severe with elevation and diminishes with placement of the leg in a dependent position, as per the LCD. An example of symptoms that do not indicate testing is reasonable and necessary is “‘leg pain, nonspecific’ and ‘pain in limb’ as a single diagnosis since these are both too general to warrant further investigation unless they can be related to other signs and symptoms.” LCD L28284. Further, the order for “Bilateral Lower Extremity Arterial Study” does not specify which test(s) is ordered. The administrative record includes test results for 93922 and 93923 but not for 93924. Exh 3 at 56-59. The Appellant billed Medicare for 93923 and 93924.

Additionally, there is no order for the peripheral venous study billed with CPT code 93965. Pursuant to L28284, it is rarely necessary to perform both peripheral arterial and peripheral venous studies, since symptoms are so divergent. When performed together, medical documentation must clearly demonstrate why both are necessary. *Id.*

L28295 sets forth coverage criteria for pulmonary function tests, which the Appellant billed with CPT codes 94200, 94240, 94350, 94370, 94375, 94720, 94725 and 94750. L28295 addresses five categories of pulmonary function tests, four of which the

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<sup>11</sup> The QIC approved coverage of 93000 (electrocardiogram) and 99204 (office visit). Exh. 4 at 11.

<sup>12</sup> See page 8, above.

Appellant furnished. First, *spirometry* testing is represented in this case by CPT codes 94200, 94370 and 94375. “Spirometry is most useful for assessing obstructive lung diseases such as asthma and chronic obstructive pulmonary disease (COPD).” LCD L28295. On the date of service, the beneficiary was using an Advair inhaler. Exh 1 at 4. Advair is used in the treatment of chronic obstructive pulmonary disease (COPD).<sup>13</sup> Pursuant to LCD L28295, “when a diagnosis or evaluation can be made clinically or when test results are not necessary to manage the patient’s disease, then Pulmonary Function Testing is not reasonable and necessary.” Since the beneficiary’s COPD was already known, the spirometry tests were unnecessary to diagnose the patient’s condition and the testing did not meet the medical necessity requirements of the LCD.

Second, *lung volume* tests “are most useful for assessing restrictive lung disease such as those caused by scarring inside the lungs or by abnormalities in the ribcage or muscles of the chest wall.” *Id.* Medicare covers lung volume tests, in this case billed with codes 94240, 94350 and 94750, “when clinically relevant.” *Id.* The medical notes do not indicate why the lung volume tests were ordered and there are no symptoms or physical findings to suggest the Appellant was attempting to assess a restrictive lung disease. Additionally, the documentation fails to indicate how the lung function test results would be used to treat the patient. “Supportive documentation evidencing the condition and treatment is expected to be documented in the medical record and be available upon request.” *Id.*

Third, *diffusion capacity* tests are useful in assessing the efficiency of lung tissue transferring oxygen from the air inside the lungs, across the membrane, into the blood. *Id.* The Appellant billed diffusion capacity tests with codes 94720 and 94725. There is no indication of why these tests were administered or how they were going to be used to treat the beneficiary.

Fourth, *lung compliance* studies, billed here with CPT code 94750, are performed “only when all other PFTs give equivocal results or results which must be confirmed by additional lung compliance testing.” *Id.* L28295 states further that lung compliance testing “is more invasive than other PFTs, because the patient is required to swallow an esophageal balloon.” There is no indication that 94750 was required because other pulmonary function tests results were inconclusive or required additional confirmation. All pulmonary function tests were completed on the same date of service. There is no indication why the test was ordered.

The administrative record does not document any follow-up treatment or indication of how any test results were used in the treatment and care of this beneficiary.

*Appeal 1-840319452*

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<sup>13</sup> See <http://www.advair.com/> for additional information about Advair.

The Appellant saw beneficiary T.H. on January 15, 2010. The Appellant's progress note reflects that the Beneficiary presented with chief complaints of "generalized body pain, including [lower back pain], neck pain, chest pain, S. O. B., leg pain/ swelling of L.L. at ankle." Exh 3 at 36. The progress note indicates that the beneficiary survived a stab wound to the abdomen in 2000 and required a bowel resection with colostomy. The beneficiary's medical history also included severe hypertension, I.V. drug abuse, and pulmonectomy. *Id.* Findings and/or conditions to assess included history of cocaine and I.V. drug abuse, abdominal scar after bowel resection, multiple and frequent tremors (?), severe hypertension, C.O.P.D. and A.S.H.D. *Id.*

In addition to the January 12, 2010 progress note, medical documentation in the record includes a form labeled "Comprehensive Physical Exam," a form labeled "VASCULAR HISTORY" with only "Patient Demographic" information completed, a "Segmental Pressure Summary" report, a "Lower Extremity Venous Output" report for CPT code 93965, a "Post Exercise PVT (Lower)" report for CPT codes 93922 and 93923, a "PVL Physician Order Form," pulmonary function test results, a "PULMONARY FUNCTION TEST ORDER FORM," test results for abdominal ultrasound and bilateral carotid arteries duplex scan signed electronically by "N. Dzebolo, M.D." and listing the referring physician as "Dr. Knebel," a PHYSICIAN ULTRASOUND ORDER FORM, clinical laboratory blood test results, and other unidentified test results. *Id.* at 36-58. The "PVL Physician Order Form," listed the "Clinical Problem[s]" to include atherosclerosis of the extremities, atherosclerosis of the extremities with intermittent claudication, pain in limb, swelling of limb and mass of limb. *Id.* at 44. The form does not list specific tests, but has "Bilateral Lower Extremity Arterial Study (multiple levels w/ segmental measurements)" checked as the test(s) ordered. *Id.* The "PULMONARY FUNCTION TEST ORDER FORM" states the diagnoses to include lung disease (not otherwise specified), wheezing, gun shot wound, and pulmonectomy. *Id.* at 48. The form has check boxes for tests with CPT codes 94060, 94240, 94720, 94350, 94200, 94370, 94750 and 94725. None of the individual tests are checked but the header "Pulmonary Function Profile" for the entire battery of tests is circled. *Id.* Findings on the physical examination form include "basal rales and rhonchi consistent with [congestive heart failure]." *Id.* at 38. However, the "PULMONARY FUNCTION TEST ORDER FORM" does not list heart failure as a diagnosis. *Compare* Exh 3 at 38 *with* Exh 3 at 48.

Subsequently, the Appellant billed Medicare for tests with CPT codes 76700, 93000, 93880, 93923, 93924, 93965, 93978, 94200, 94240, 94350, 94370, 94375, 94720, 94725, 94750 and 99204.<sup>14</sup>

LCD L28230 indicates that a retroperitoneal ultrasound with real time image documentation, complete "may be reasonable and necessary to image the following [abdominal aorta, inferior vena cava, kidneys, ureter, bladder, renal transplants, adenopathy, prostate, adrenal gland and connective tissue tumors] *assuming throughout that clinically significant decisions will be based on the results.*" Emphasis

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<sup>14</sup> The QIC approved coverage of 93000 (electrocardiogram) and 99204 (office visit). Exh. 3 at 15.

added. The Appellant ordered an abdominal ultrasound, which it billed with CPT code 76700. The record lacks any treatment plan or indication of how this study and its results would be used in assessing or treating the beneficiary. The beneficiary did not complain of abdominal pain. It is unclear why the test was ordered or how it would be used in treating the beneficiary.

LCD L28284 sets forth coverage requirements for noninvasive peripheral arterial studies billed with CPT codes 93923 and 93924. The submitted medical documentation does not indicate that the beneficiary's medical condition met any of the indications for peripheral arterial evaluations noted in the LCD.<sup>15</sup> For instance, the patient presented with "leg pain" but it is undocumented as to whether the pain was associated with diminished or absent pulses which become increasingly severe with elevation and diminishes with placement of the leg in a dependent position, as per the LCD. An example of symptoms that do not indicate testing is reasonable and necessary is "'leg pain, nonspecific' and 'pain in limb' as a single diagnosis since these are both too general to warrant further investigation unless they can be related to other signs and symptoms." LCD L28284. Further, the order for "Bilateral Lower Extremity Arterial Study" does not specify which test(s) is ordered. The administrative record includes test results for 93922 and 93923 but not for 93924. Exh 3 at 42-43. The Appellant billed Medicare for 93923 and 93924.

Additionally, there is no order for the peripheral venous study billed with CPT code 93965. Pursuant to L28284, it is rarely necessary to perform both peripheral arterial and peripheral venous studies, since symptoms are so divergent. When performed together, medical documentation must clearly demonstrate why both are necessary. *Id.*

The beneficiary presented to the Appellant with scarring from a bowel resection completed in 2000. The January 15, 2010 progress note does not provide any abnormal indications supporting the need for the duplex scan of extracranial arteries, complete bilateral study billed with CPT code 93880. Pursuant to LCD L28283 "Studies will be denied if they are determined to be screening studies, were duplicative of other vascular studies or were not needed to manage decisions."

L28295 sets forth coverage criteria for pulmonary function tests, which the Appellant billed with CPT codes 94200, 94240, 94350, 94370, 94375, 94720, 94725 and 94750. L28295 addresses five categories of pulmonary function tests, four of which the Appellant furnished. First, *spirometry* testing is represented in this case by CPT codes 94200, 94370 and 94375. "Spirometry is most useful for assessing obstructive lung diseases such as asthma and chronic obstructive pulmonary disease (COPD)." LCD L28295. It is unclear from the Appellant's progress note whether COPD is a finding, a diagnosis, part of the patient's medical history, or a condition to be assessed. To the extent the beneficiary's COPD was already known, the spirometry tests were unnecessary to diagnose the patient's condition and the testing did not meet the

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<sup>15</sup> See page 8, above.

medical necessity requirements of the LCD. “When a diagnosis or evaluation can be made clinically or when test results are not necessary to manage the patient’s disease, then Pulmonary Function Testing is not reasonable and necessary.” L28295.

Furthermore, the record does not document any clinical treatment plan for COPD or otherwise indicate how the test would be used to treat the beneficiary. Exh 1 at 38.

Second, *lung volume* tests “are most useful for assessing restrictive lung disease such as those caused by scarring inside the lungs or by abnormalities in the ribcage or muscles of the chest wall.” *Id.* Medicare covers lung volume tests, in this case billed with codes 94240, 94350 and 94750, “when clinically relevant.” *Id.* The medical notes do not indicate why the lung volume tests were ordered and there are no symptoms or physical findings to suggest the Appellant was attempting to assess a restrictive lung disease. Additionally, the documentation fails to indicate how the lung function test results would be used to treat the patient. “Supportive documentation evidencing the condition and treatment is expected to be documented in the medical record and be available upon request.” *Id.*

Third, *diffusion capacity* tests are useful in assessing the efficiency of lung tissue transferring oxygen from the air inside the lungs, across the membrane, into the blood. *Id.* The Appellant billed diffusion capacity tests with codes 94720 and 94725. There is no indication of why these tests were administered or how they were going to be used to treat the beneficiary.

Fourth, *lung compliance* studies, billed here with CPT code 94750, are performed “only when all other PFTs give equivocal results or results which must be confirmed by additional lung compliance testing.” *Id.* L28295 states further that lung compliance testing “is more invasive than other PFTs, because the patient is required to swallow an esophageal balloon.” There is no indication that 94750 was required because other pulmonary function tests results were inconclusive or required additional confirmation. All pulmonary function tests were completed on the same date of service. There is no indication why the test was ordered.

The administrative record does not document how any test results were used in the treatment and care of this beneficiary.

#### Appeal 1-840363222

The Appellant saw beneficiary J.H. on January 19, 2010. The Appellant’s progress note reflects that the beneficiary presented with “inability to walk or move his lower limbs, upper limbs very weak muscle tone, generalized body pain.” Exh 3 at 36. His medical history included stroke affecting the left side in 2007 and blood clots in the left leg. *Id.* Findings and/or diagnoses include hypertension, gout, degenerative arthritis, lumbar disc degenerative disease, skin discoloration of left leg, A.S.H.D. and C.O.P.D. *Id.*

In addition to the January 19, 2010 progress note, medical documentation in the record includes a form labeled “Comprehensive Physical Exam,” a form labeled “VASCULAR HISTORY” with only “Patient Demographic” information entered, a “Segmental Pressure

Summary” report, a “Lower Extremity Venous Output” report for CPT code 93965, a “Lower Extremity Arterial PVR” report for CPT codes 93922 and 93923, a “PVL Physician Order Form,” pulmonary function test results, a “PULMONARY FUNCTION TEST ORDER FORM,” test results for echocardiography, aortic ultrasound and abdominal ultrasound signed electronically by “N. Dzebolo, M.D.” and listing the referring physician as “Dr. Knebel,” a PHYSICIAN ULTRASOUND ORDER FORM signed by the Appellant, clinical laboratory blood test results, and other unidentified test results. *Id.* at 36-57.

The “PVL Physician Order Form,” listed the “Clinical Problem[s]” to include atherosclerosis of the extremities, atherosclerosis of the extremities with intermittent claudication, peripheral vascular disease, stroke, pain in limb and swelling of limb. *Id.* at 42. The form does not list specific tests, but has “Bilateral Lower Extremity Arterial Study (multiple levels w/ segmental measurements)” checked as the test(s) ordered. *Id.* The “PULMONARY FUNCTION TEST ORDER FORM” states the diagnoses to include acute and chronic respiratory failure, chronic cough, heart failure and shortness of breath. *Id.* at 64. The form has check boxes for tests with CPT codes 94060, 94240, 94720, 94350, 94200, 94370, 94750 and 94725. None of the individual tests are checked but the header “Pulmonary Function Profile” for the entire battery of tests is circled. *Id.* None of the diagnoses listed on this form are documented in the progress note or the physical examination form. Subsequently, the Appellant billed Medicare for tests with CPT codes 76700, 93000, 93306, 93923, 93924, 93965, 94200, 94240, 94350, 94370, 94375, 94720, 94725, 94750 and 99204.<sup>16</sup>

LCD L28230 indicates that a retroperitoneal ultrasound with real time image documentation, complete “may be reasonable and necessary to image the following [abdominal aorta, inferior vena cava, kidneys, ureter, bladder, renal transplants, adenopathy, prostate, adrenal gland and connective tissue tumors] *assuming throughout that clinically significant decisions will be based on the results.*” Emphasis added. The Appellant ordered an abdominal ultrasound, which it billed with CPT code 76700. The record lacks any treatment plan or indication of how this study and its results would be used in assessing or treating the beneficiary. The beneficiary did not complain of abdominal pain. It is unclear why the test was ordered or how it would be used in treating the beneficiary.

LCD L28284 sets forth coverage requirements for noninvasive peripheral arterial studies billed with CPT codes 93923 and 93924. The submitted medical documentation does not indicate that the beneficiary’s medical condition met any of the indications for peripheral arterial evaluations noted in the LCD.<sup>17</sup> For instance, the patient was unable to use his lower legs but did not complain of leg pain. There are no symptoms that would indicate the need for peripheral arterial studies in accordance with the LCD.

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<sup>16</sup> The QIC approved coverage of 93000 (electrocardiogram), 93306 (echocardiogram) and 99204 (office visit). Exh. 4 at 11.

<sup>17</sup> See page 8, above.

Further, the order for “Bilateral Lower Extremity Arterial Study” does not specify which test(s) is ordered. The administrative record includes test results for 93922 and 93923 but not for 93924. Exh 3 at 41. The Appellant billed Medicare for 93923 and 93924. Additionally, there is no order for the peripheral venous study billed with CPT code 93965. Pursuant to L28284, it is rarely necessary to perform both peripheral arterial and peripheral venous studies, since symptoms are so divergent. When performed together, medical documentation must clearly demonstrate why both are necessary. *Id.*

L28295 sets forth coverage criteria for pulmonary function tests, which the Appellant billed with CPT codes 94200, 94240, 94350, 94370, 94375, 94720, 94725 and 94750. L28295 addresses five categories of pulmonary function tests, four of which the Appellant furnished. First, *spirometry* testing is represented in this case by CPT codes 94200, 94370 and 94375. “Spirometry is most useful for assessing obstructive lung diseases such as asthma and chronic obstructive pulmonary disease (COPD).” LCD L28295. The beneficiary did not present with indications indicative of C.O.P.D. The limited information on the physical examination form merely states “dullness of breathing sounds in both lungs.” Exh 1 at 38. There is no indication of why these tests were administered or how they were going to be used to treat the beneficiary.

Second, *lung volume* tests “are most useful for assessing restrictive lung disease such as those caused by scarring inside the lungs or by abnormalities in the ribcage or muscles of the chest wall.” *Id.* Medicare covers lung volume tests, in this case billed with codes 94240, 94350 and 94750, “when clinically relevant.” LCD L28295. The medical notes do not indicate why the lung volume tests were ordered and there are no symptoms or physical findings to suggest the Appellant was attempting to assess a restrictive lung disease. Additionally, the documentation fails to indicate how the lung function test results would be used to treat the patient. “Supportive documentation evidencing the condition and treatment is expected to be documented in the medical record and be available upon request.” *Id.*

Third, *diffusion capacity* tests are useful in assessing the efficiency of lung tissue transferring oxygen from the air inside the lungs, across the membrane, into the blood. *Id.* The Appellant billed diffusion capacity tests with codes 94720 and 94725. There is no indication of why these tests were administered or how they were going to be used to treat the beneficiary.

Fourth, *lung compliance* studies, billed here with CPT code 94750, are performed “only when all other PFTs give equivocal results or results which must be confirmed by additional lung compliance testing.” *Id.* L28295 states further that lung compliance testing “is more invasive than other PFTs, because the patient is required to swallow an esophageal balloon.” There is no indication that 94750 was required because other pulmonary function tests results were inconclusive or required additional confirmation. All pulmonary function tests were completed on the same date of service. There is no indication why the test was ordered. The administrative record does not document any

follow-up treatment or indication of how any test results were used in the treatment and care of this beneficiary.