

Comment and Response Document

LCD Database ID Number

DL31626

LCD Title

Independent Diagnostic Testing Facility

Contractor's Determination Number

PHYS-078

Comment:

Appendix A of the current policy recognizes the ISCD's credential of CDT (Certified Densitometry Technologist) as an appropriate credential for personnel performing CPT codes 77080 (DXA) and 77082. ISCD has a successor certification program Certified Bone Densitometry Technologist (CBDT) and request the appendix be updated.

ISCD requests an amendment to Appendix A to recognize the ISCD credential "Certified Clinical Densitometrist" (CCD) as an appropriate alternative to those listed for supervising physicians for CPT code 77080 (dual energy absorptiometry, "DXA) and CPT code 77082 (Vertebral Fracture Assessment, VFA").

Currently, the LCD only recognizes radiologists and internists as being qualified to serve as supervising physicians for DXA and VFA. As such, the policy excludes a necessary, substantial, and highly skilled portion of the provider community from interpreting DXA and VFA. For example, under this policy, family practitioners, orthopedists and gynecologists are excluded. WPS has advised ISCD that the CCD certification has not been recognized because the program is not accredited by NCCA. In the past, accreditation by NCCA or NOCA has not been dispositive and should not be so in this case. The introduction to Appendix A lends guidance on this issue and provides in relevant part:

"National credentialing bodies must be a member of the National Organization for Competency Assurance (NOCA) or certified by the Commission for Certifying Agencies (NCCA) which is the accreditation body of NOCA. In the absence of a National Credentialing body, the Carrier has the discretion to approve educational requirements or other certifications. For example, we are allowing technicians who are certified by Cardiovascular Credentialing International (CCI) for cardiac monitoring services sine there is no agency for those services that is recognized by NOCA or NCCA."

The ISCD program is in the same position as the Cardiovascular Credentialing program cited in the paragraph above, as currently there is no program to certify clinicians in the field of DXA and VFA that is accredited by NOCA or NCCA. However, the policy clearly permits the recognition of a non-accredited program under these circumstances—where no accredited program exists. The ISCD certification program for physicians, even though not accredited, meets rigorous standards and is the only program of its kind in the country certifying clinicians in the interpretation of DXA and VFA. We urge WPS to use the authority granted under the LCD to craft a policy that provides patients with the highest level of quality care by including the ISCD certification of CCD. Recognizing the CCD certification ensures that competency to perform bone density tests is based on physician training, education and experience rather than clinical specialty

Improving and ensuring quality in the assessment of skeletal health is at the heart of our organization. The Society educates clinicians and technologists, increases patient awareness and access to bone densitometry, and supports clinical and scientific advances in the field. CMS recognized the ISCD as a leading resource in the December 2006 Revisions to the Bone Mass Measurement Act. (Fed. Reg. Vol.71, No.62, p.49060 (Aug.22, 2006).

ISCD's clinician certification (CCD) is designed to achieve the highest level of quality in the interpretation of bone density scans. A standardized testing process covers the principles and concepts of bone density testing including the basic science of bone densitometry, device operating principles, x-ray science, radiation safety, quality assurance, clinical utility of bone densitometry, use of bone densitometry for diagnosis of osteoporosis, assessment of fracture risk and monitoring with bone densitometry. Clinicians who successfully pass the certification exam are designated Certified Clinical Densitometrists (CCD). This is a five year (5) certification. Recertification is dependent upon fulfilling specified educational requirements to ensure that practitioners are up to date on the latest developments in the field.

The current policy's limitation by specialty undermines the intended goal of providing patients with the highest quality of care by excluding physicians who have demonstrated competency through certification in favor of physicians who may have no experience in the field of bone densitometry. We urge WPS to add ISCD certified clinicians to the list of acceptable supervising physicians for DXA and VFA.

Response:

We have updated Appendix A to include Certified Bone Densitometry Technologist (CBDT) to CPT codes 77080-77082.

The physician supervision requirements listed in the appendix are based on specialty and not on certifications unless the certifications are outlined in a specific LCD regarding that procedure code. For example, we have an LCD that specifies the physician certifications that are required in order to perform sleep studies and have added those certifications to this appendix to assure consistency. The supervising physician is listed on the IDTF's enrollment form. An IDTF wishing to add a physician to their file that is not of the specialty listed in the appendix may send in additional information outlining their qualifications such as additional training or education to the enrollment department. The information will be reviewed by the medical staff.

The technologists are listed by certifications and therefore, CCI had been added.

Comment:

Why doesn't the appendix list physicians that are board certified in vascular medicine by the American Board of Vascular Medicine with RVPI certification for codes 93925-93971-9978?

Response: The physician supervision requirements listed in the appendix are based on specialty and not on certifications unless the certifications are outlined in a specific LCD regarding that procedure code. For example, we have an LCD that specifies the physician certifications that are required in order to perform sleep studies and have added those certifications to this appendix to assure consistency. The supervising physician is listed on the IDTF's enrollment form. An IDTF wishing to add a physician to their file that is not of the specialty listed in the appendix may send in additional information outlining their qualifications such as additional training or education to the enrollment department. The information will be reviewed by the medical staff.

Comments: We received numerous requests to allow non-radiologists, such as internal medicine, and family practice physicians should be allowed to supervise CT with contrast procedures. Below are excerpts from the letters:

Comment: The goal of the IDTF policy should be to hold out expertise to the public that select diagnostic tests can be performed safely by trained personnel who have expertise in performing the exams being offered and that the exams are being interpreted by physicians who also have expertise in interpreting the exams being offered. The current policy does not guarantee this to patients. The present policy does not insure that advanced imaging exams are being interpreted by physicians who have completed fellowships in those imaging modalities being performed. It would be an interesting study to look at the number of exams that are being performed needlessly due to ambiguous interpretations being rendered by radiologists who are not willing to make a definitive diagnosis due to their uncertainty with the information contained in the images of an advanced imaging exam. With the technology and advance of teleradiology, world class expertise is only a click of a mouse away. However, in the state of Illinois, this expertise is not available to patients who require contrast exams due to the personal/direct supervision requirements that are currently in effect and which can only be fulfilled by a radiologist. As a result, in rural areas, patients are being supervised by general radiologists who have not completed MSK fellowships and it is those same radiologists who are interpreting the exams being supervised. As a result of this policy, the competition that used to exist between hospitals and free standing IDTF's has greatly diminished and as a result hospitals have a monopoly for these studies and at a higher cost to the Medicare program and Medicare beneficiaries due to the difference in reimbursement between IDTF's and hospitals. This does not make any sense in an era where cost containment and rationing scarce resources in the rule instead of the exception. The new health care law touts the use of technology to lower health care costs while the current IDTF policy takes medicine back 20 years as it creates an economic barrier for fellowship trained physicians to provide their expertise in areas of need due to the personal/direct supervision requirements of the current IDTF policy. While it is the responsibility of Medicare to ensure the safety of Medicare beneficiaries in facilities that Medicare holds out to the public as having expertise to perform select diagnostic tests which the program pays for, the very goal of ensuring patient safety is thwarted by the current IDTF policy. I have talked to the radiologists that interpret the non contrast exams offered Medicare beneficiaries in facilities I operate. The last time most radiologists used a stethoscope was when they were in residency or medical school. They have indicated to me that this statement is true for the vast majority of their colleagues. They were also quick to point out that not a single hospital in the United States has a radiologist on the "Code Blue Team" for providing response to life threatening situations for good reason; namely, there are other medical personnel who are better trained to ensure an appropriate response to life threatening situations than a radiologist. Ask any radiologist the last time they ran a code or administered drugs in a code situation. Most are not even ACLS certified. This is not out of radiologists being lazy or uncaring, it is simply that other medical personnel are trained to respond to these situations and have a greater knowledge of what to do than radiologists. This should not be misconstrued to mean that radiologists should not be the one's interpreting advanced imaging studies. I am merely pointing out the the board certified internist across the parking lot is much better trained to respond to a contrast reaction than the radiologist standing over the patient. The very thing that the IDTF policy should be providing patients, ensuring their safety, is not happening due to the current IDTF policy which places patients in harm's way under the care of radiologists that have no experience handling code situations or even being required to be ACLS certified. Clearly this present IDTF policy is endangering Medicare patients who have contrast administered under the sole personal/direct supervision of a radiologist in an IDTF.

In order to correct the deficiency of the present policy, I am recommending that the qualifications of the physicians who provide personal/direct supervision of contrast injections in an IDTF be changed to ensure patient safety. Board certified internists, cardiologists, and anesthesiologists should be allowed to supervise contrast injections in IDTF's. In addition, any physician who is a member of a hospital's "Code Blue Team" should be permitted to supervise contrast injections if they have current ACLS certification. I would recommend that the current physicians listed as being qualified to supervise exams be qualified to interpret advanced imaging exams performed in IDTF's. This would allow an IDTF to contract with physicians who are qualified to respond to a contrast reaction to provide personal/direct supervision while contracting with a fellowship trained radiologist to interpret the advanced imaging exam. This will allow expertise to be available in rural areas where fellowship trained radiologists are unavailable due to geography. While most rural areas have board certified internists available, radiologists are in short supply and MSK fellowship trained radiologists in even shorter supply. This will increase competition between hospitals and IDTF's and should lower costs to the Medicare program and Medicare beneficiaries. I would like to think that these changes will provide high quality care at the lowest cost possible. The present policy inhibits this goal and lessens the safety of patients receiving services in IDTF's and encourages general radiologists to continue to provide interpretations of advanced imaging studies as they currently have no competition from outside sources for Medicare patients who require contrast studies. This may, in fact, explain some of the overuse of contrast in advanced imaging studies. If contrast is recommended, the patient's exam cannot be performed in an IDTF that does not have a radiologist physically present to supervise the contrast injection.

Comment:

Please consider changing the requirement of having "a radiologist available" for contrast injections for MRI's to having "a physician available. Most radiologists are not current on medications, reaction response, etc. A physician who deals with patients and their health problems, allergic reactions, medications etc. on a daily basis would be a better choice.

Comment:

As a non-radiologist physician (I am a board-certified emergency physician) I will never meet the outlined requirements to provide on-site supervision for patients receiving contrast at IDTF's as outlined in LCD L26687. It seems to me that the LCD for this needs to be revised to be more consistent with radiology practice in our digital age.

Much of what radiologists do is performed remotely, that is, at a distance (usually many miles away) from the patient. Patients in hospitals have contrast exams at all hours without a radiologist on-site. Any problems are managed by in-house physicians, such as emergency physicians or intensivists. I would like to see the same standard applied to IDTF's, where the supervision of personnel, imaging quality, and interpretation of exams can be done remotely by radiologists, while on-site supervision of patients for potential reactions to contrast can be done by non-radiologists. This would provide the best and safest care for patients by providing the most appropriately trained physicians serving in each respective supervisory capacity.

Furthermore, it would seem that the current LCD is inconsistent with regard to contrast and non-contrast exams. Radiologists are doing most of their work miles away from IDTF's since they are not required to provide direct supervision for non-contrast exams, even though it would seem logical that they require the same level of proficiency "in the performance and interpretation" as would the contrast exams which require them to be at the patient's bedside. The only differences are starting an IV for the contrast and managing a patient with a reaction to the contrast, both clinical skills that can easily be performed by non-radiologists.

Response:

We agree with the comment that multiple specialties are equipped to manage a contrast reaction. However, the administration of the contrast material is included in the procedure and requires personal physician supervision for the entire radiological procedure. The Code of Federal Regulations states in 42CFR 410.33: "The supervising physician must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF. The proficiency may be documented by certification in specific medical specialties or subspecialties or by criteria established by the carrier for the service area in which the IDTF is located. In the case of a procedure requiring the direct or personal supervision of a physician as set forth in Sec. 410.32(b)(3)(ii) or (b)(3)(iii), the IDTF's supervising physician must personally furnish this level of supervision whether the procedure is performed in the IDTF or, in the case of mobile services, at the remote location."

The law does not speak to the "supervision of the administration of contrast media", but rather, is a distinction drawn as to the degree of difficulty in the performance and the interpretation of the procedure. This degree of difficulty of the test is assigned to the levels of supervision and the warranted payment of the professional component of the CPT code. The supervision levels for all diagnostic tests (general, direct, personal supervision) are set nationally by CMS. Each code has one supervision level. We do not have the authority to split a procedure codes into multiple or "dual supervision" levels. The administration of the contrast can not be separated out from the supervision of the procedure /CPT code. CT with contrast is one procedure code. A radiologist is required to supervise MRI and CT procedures in an IDTF.

We disagree with the comment that "The present policy does not insure that advanced imaging exams are being interpreted by physicians who have completed fellowships in those imaging modalities being performed." Our Appendix states the Supervising physician must be board eligible or board certified.

Comment:

We wanted to be sure to point out that an IDTF would not necessarily know if a test ordered is to be used "by the doctor in the management of the beneficiary's specific medical condition" but we understand your position and purpose.

Concerning "Payment will be denied to the billing provider (IDTF) if the ordering provider does not respond to the documentation request or provides documentation which does not support the test" we ask that this request also be cc'd to the IDTF since they would be responsible for submitting that documentation and would like to see the original request as well.

Response:

Under the Documentation section of the LCD it states in part- Documentation may be requested from the ordering/treating provider or from the billing provider of the diagnostic test. Additional records **may** be requested from the ordering provider that is directly relevant to the medical necessity of the test.

Payment will be denied to the billing provider (IDTF) if the ordering provider does not respond to the documentation request or provides documentation which does not support the test.

Generally, the initial request for records would be sent to the billing provider for documentation of medical necessity. The regulations state that a contractor shall not solicit documentation from a third party unless the contractor first or simultaneously solicits the same information from the billing provider or supplier. Some examples of third parties are a physician's office

(e.g., if claim is for lab, x-ray, or Part A service requiring medical documentation), or a hospital (e.g., if claim is for physician's inpatient services), Beneficiaries are not third parties.

The Federal Register § 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests states:

(a) Ordering diagnostic tests. All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem.

Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

The following information was added to our Documentation requirements: Although all procedures performed by the IDTF must be specifically ordered in writing by the practitioner treating the beneficiary as noted above, the mere fact that the test(s) were properly ordered does not reflect or imply Medicare coverage for these services. Medical necessity must be apparent and statutory exclusions, national and local coverage determinations (LCDs) apply.

Comment:

Section B: Ordering diagnostic tests; subsection Orders:

Provider expressed concerns with option c: - An electronic mail by the treating physician/practitioner or his/her office to the testing facility. We have concerns over the integrity of e-mail, patient names and confidential information should not be transmitted via a non-secure or encrypted process. Instead we would offer that this option should be changed to "a secure web based ordering system by the treating physician/practitioner or his/her office to the testing facility". This would offer an added layer of encryption for the protection of confidential patient information

Response:

The intent of this section was to relay that orders can be sent electronically. Entities billing Medicare are subject to the regulations outlined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This includes the HIPPA [Privacy Rule](#) and the HIPPA [Security Rule](#). The Privacy Rule, or Standards for Privacy of Individually Identifiable Health Information, establishes national standards for the protection of certain health information. The Security Standards for the Protection of Electronic Protected Health Information (the Security Rule) establish a national set of security standards for protecting certain health information that is held or transferred in electronic form. The Security Rule operationalizes the protections contained in the Privacy Rule by addressing the technical and non-technical safeguards that organizations called "covered entities" must put in place to secure individuals' "electronic protected health information" (e-PHI). Covered entities must implement technical security measures that guard against unauthorized access to d-PHI that is being transmitted over an electronic network. It is assumed providers would adhere to all of the security requirements of HIPAA and haven not included them in this LCD.

Comment:

Section D: Non-Physician personnel

In the instance, when documentation of training and proficiency must be verified by the supervising physician and provided to the carrier we would like clarification on timing of when this must be submitted to the carrier. For example, if the requirement clearly states that in "...addition to the initial submission, the IDTF must annually provide written verification by the

supervising physician to the carrier." This would alleviate all guess work and allow IDTFs to integrate processes and comply with requirements.

Response:

The requirements regarding when to notify Medicare of changes to its enrollment are located in the IOM 100-08 Chapter 10. Our billing and coding article associated with this LCD includes some Medicare Manual excerpts:

“2. Provides complete and accurate information on its enrollment application. Changes in ownership, changes of location, changes in general supervision, and adverse legal actions must be reported to the Medicare fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 days”

We included some of the information in the regulations “excerpts”; however, we recommend the provider review the Medicare manuals for further information on the IDTF rules. The regulations for IDTF enrollment can be found in the Internet Only Manual (IOM) 100-08 Chapter 10.

Comment:

Section D: Non-Physician personnel and Attachment A

The draft policy and Attachment A address non-physician personnel used by the IDTF to perform tests. Attachment A addresses the appropriate accreditation for services provided - in the example of cardiac monitoring services. Provider would like to request that paramedics be included as appropriate staff if they meet the clinical competency requirements outlined in the draft policy. This would be an expansion of the CCI-CCT, RN, LPN as Paramedics have appropriate training and proficiency in performing these services (93224-93226 and 93268, 93270-93271) as evidenced training and certification by the State of IL.

Response:

We have added Paramedics to the technician section of the following CPT codes (93324-93326, 93268, 93270, and 93271).

Comment:

Allergy patch tests, photo patch tests and photosensitivity tests are performed by dermatologists.

Response

Dermatology has been added to supervising physician for CPT codes 95044, 95052, 95056.

Comment

We recognize CMS has identified that cardiac cath - and other angiographic procedures - do not qualify, by definition and principle, as "diagnostic tests" that fall under the diagnostic tests performed in IDTF's policy, but rather are considered diagnostic procedures. However, we feel it would be appropriate and help to clarify coverage if WPS would import language that will clarify that diagnostic cardiac cath performed in a cath lab located within an IDTF is covered by Medicare as they currently are (reference to J5 LCD).

Response

Our cardiac catheterization LCD (CV-006) addresses the place of service and specialties that are allowed to perform cardiac catheterizations. We did not include specialty 47-IDTF in the list of specialties that can bill this procedure. Since the former contractor in J5 had allowed cardiac cath

codes in their IDTF LCD we have been allowing providers that have been performing them in this setting to continue until the new IDTF LCD is in effect.

WPS did not include the cardiac cath codes in our IDTF LCD. Providers are enrolled as heart clinics or centers. Free standing cardiac cath entities are usually set up as clinics since they may be performing evaluation and management services, interventions, therapeutic procedures or other types of treatment. Evaluation and management services, therapeutic procedures and interventions are not payable services when they are performed in an IDTF. By definition, an IDTF is only allowed to perform diagnostic testing. It is for these reasons that WPS did not include the cardiac catheterizations procedures in the IDTF LCD.

In January 2011 new CPT codes were given to the cardiac cauterizations procedures. Our provider enrollment department has been informing providers that have requested updates to their enrollment file that the cardiac cath codes are not in our new IDTF LCD and providers will need to update their enrollment files.