section, Medicare may cover a bone mass measurement for a beneficiary if at least 23 months have passed since the month the last bone mass measurement was performed.

(2) *Exception.* If medically necessary, Medicare may cover a bone mass measurement for a beneficiary more frequently than allowed under paragraph (c)(1) of this section. Examples of situations where more frequent bone mass measurement procedures may be medically necessary include, but are not limited to the following medical circumstances:

(i) Monitoring beneficiaries on long-term glucocorticoid (steroid) therapy of more than 3 months.

(ii) Allowing for a confirmatory baseline measurement to permit monitoring of beneficiaries in the future if the requirements of paragraph (b)(3) of this section are met.

(d) *Beneficiaries who may be covered.* The following categories of beneficiaries may receive Medicare coverage for a medically necessary bone mass measurement:

(1) A woman who has been determined by the physician (or a qualified nonphysician practitioner) treating her to be estrogen-deficient and at clinical risk for osteoporosis, based on her medical history and other findings.

(2) An individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture.

(3) An individual receiving (or expecting to receive) glucocorticoid (steroid) therapy equivalent to an average of 5.0 mg of prednisone, or greater, per day for more than 3 months.

(4) An individual with primary hyperparathyroidism.

(5) An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy.

(e) *Denial as not reasonable and necessary.* If CMS determines that a bone mass measurement does not meet the conditions for coverage in paragraphs (b) or (d) of this section, or the standards on frequency of coverage in paragraph (c) of this section, it is excluded from Medicare coverage as not ''reasonable'' and ''necessary'' under section 1862(a)(1)(A) of the Act and § 411.15(k) of this chapter.

(f) *Use of the National Coverage Determination Process.* For the purposes of paragraphs (b)(2) and (b)(3) of this section, CMS may determine through the National Coverage Determination process that additional bone mass measurement systems are reasonable and necessary under section 1862(a)(1) of the Act for monitoring and confirming baseline bone mass measurements.

[71 FR 69783, Dec. 1, 2006]

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

(a) *Ordering diagnostic tests.* Except as otherwise provided in this section, 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).

(1) *Mammography exception.* A physician who meets the qualification requirements for an interpreting physician under section 354 of the Public Health Service Act as provided in § 410.34(a)(7) may order a diagnostic mammogram based on the findings of a screening mammogram even though the physician does not treat the beneficiary.

(2) *Application to nonphysician practitioners.* Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.

(3) *Public Health Emergency exceptions.* During the Public Health Emergency

for COVID–19, as defined in § 400.200 of this chapter, the order of a physician or other applicable practitioner is not required for one otherwise covered diagnostic laboratory test for COVID–19 and for one otherwise covered diagnostic laboratory test each for influenza virus or similar respiratory condition needed to obtain a final COVID–19 diagnosis when performed in conjunction with COVID–19 diagnostic laboratory test in order to rule-out influenza virus or related diagnosis. Subsequent otherwise covered COVID–19 and related tests described in the previous sentence are reasonable and necessary when ordered by a physician or nonphysician practitioner in accordance with this paragraph (a), or when ordered by a pharmacist or other healthcare professional who is authorized under applicable state law to order diagnostic laboratory tests. FDA-authorized COVID–19 serology tests are included as covered tests subject to the same order requirements during the Public Health Emergency for COVID–19, as defined in § 400.20 of this chapter, as they are reasonable and necessary under section 1862(a)(1)(A) of the Act for beneficiaries with known current or known prior COVID–19 infection or suspected current or suspected prior COVID–19 infection.

(4) *Application to audiologists.* Except as otherwise provided in this paragraph, audiologists may personally furnish diagnostic audiology tests for a patient once per patient per 12-month period without an order from the physician or nonphysician practitioner treating the patient. Such diagnostic audiology tests can be for non-acute hearing conditions, but may not include audiology services that are related to disequilibrium, or hearing aids, or examinations for the purpose of prescribing, fitting, or changing hearing aids that are outlined at § 411.15(d). Audiology services furnished without an order from the treating physician or practitioner are billed using a modifier CMS designates for this purpose.

(b) *Diagnostic x-ray and other diagnostic tests*— (1) *Basic rule.* Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act or, to the extent that they are authorized to do so under their scope of practice and applicable State law, by a nurse practitioner, clinical nurse specialist, physician assistant, certified registered nurse anesthetist, or a certified nurse-midwife. Services furnished without the required level of supervision are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

(2) *Exceptions.* The following diagnostic tests payable under the physician fee schedule are excluded from the basic rule set forth in paragraph (b)(1) of this section:

(i) Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.

(ii) Diagnostic tests personally furnished by a qualified audiologist as defined in section 1861(ll)(3) of the Act.

(iii) Diagnostic psychological and neuropsychological testing services when—

(A) Personally furnished by a clinical psychologist or an independently practicing psychologist as defined in program instructions; or

(B) Furnished under the general supervision of a physician or clinical psychologist; or under the general supervision of a nurse practitioner, clinical nurse specialist, physician assistant, certified registered nurse anesthetist or certified nurse-midwife, to the extent they are authorized to perform the tests under their scope of practice and applicable State laws.

(iv) Diagnostic tests (as established through program instructions) personally performed by a physical therapist who is certified by the American Board of Physical Therapy Specialties as a qualified electrophysiologic clinical specialist and permitted to provide the service under State law.

(v) Diagnostic tests performed by a nurse practitioner or clinical nurse specialist authorized to perform the tests under applicable State laws.

(vi) Pathology and laboratory procedures listed in the 80000 series of the

Current Procedural Terminology published by the American Medical Association.

(vii) Diagnostic tests performed by a certified nurse-midwife authorized to perform the tests under applicable State laws.

(viii) During the COVID–19 Public Health Emergency as defined in § 400.200 of this chapter, diagnostic tests performed by a physician assistant authorized to perform the tests under applicable State law.

(ix) Diagnostic tests performed by a physician assistant authorized to perform the tests under their scope of practice and applicable State laws.

(3) *Levels of supervision.* Except where otherwise indicated, all diagnostic x-ray and other diagnostic tests subject to this provision and payable under the physician fee schedule must be furnished under at least a general level of supervision as defined in paragraph (b)(3)(i) of this section. In addition, some of these tests also require either direct or personal supervision as defined in paragraph (b)(3)(ii) or (iii) of this section, respectively. When direct or personal supervision is required, supervision at the specified level is required throughout the performance of the test.

(i) *General supervision* means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

(ii) *Direct supervision* in the office setting means the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician (or other supervising practitioner) must be present in the room when the procedure is performed. Until the later of the end of the calendar year in which the PHE as defined in § 400.200 of this chapter ends or, December 31, 2021, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

(iii) *Personal supervision* means a physician must be in attendance in the room during the performance of the procedure.

(4) *Supervision requirement for RRA or RPA.* Diagnostic tests that are performed by a registered radiologist assistant (RRA) who is certified and registered by the American Registry of Radiologic Technologists or a radiology practitioner assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants, and that would otherwise require a personal level of supervision as specified in paragraph (b)(3) of this section, may be furnished under a direct level of physician supervision to the extent permitted by state law and state scope of practice regulations.

(c) *Portable x-ray services.* Portable x-ray services furnished in a place of residence used as the patient's home are covered if the following conditions are met:

(1) These services are furnished under the general supervision of a physician, as defined in paragraph (b)(3)(i) of this section.

(2) These services are ordered by a physician as provided in paragraph (a) or by a nonphysician practitioner as provided in paragraph (a)(2) of this section.

(3) The supplier of these services meets the requirements set forth in part 486, subpart C of this chapter, concerning conditions for coverage for portable x-ray services.

(4) The procedures are limited to—

(i) Skeletal films involving the extremities, pelvis, vertebral column, or skull;

(ii) Chest or abdominal films that do not involve the use of contrast media; and

(iii) Diagnostic mammograms if the approved portable x-ray supplier, as defined in subpart C of part 486 of this chapter, meets the certification requirements of section 354 of the Public Health Service Act, as implemented by 21 CFR part 900, subpart B.

(d) *Diagnostic laboratory tests*—(1) *Who may furnish services.* Medicare Part B

pays for covered diagnostic laboratory tests that are furnished by any of the following:

(i) A participating hospital or participating RPCH.

(ii) A nonparticipating hospital that meets the requirements for emergency outpatient services specified in subpart G of part 424 of this chapter and the laboratory requirements specified in part 493 of this chapter.

(iii) The office of the patient's attending or consulting physician if that physician is a doctor of medicine, osteopathy, podiatric medicine, dental surgery, or dental medicine.

(iv) An RHC.

(v) A laboratory, if it meets the applicable requirements for laboratories of part 493 of this chapter, including the laboratory of a nonparticipating hospital that does not meet the requirements for emergency outpatient services in subpart G of part 424 of this chapter.

(vi) An FQHC.

(vii) An SNF to its resident under §411.15(p) of this chapter, either directly (in accordance with §483.75(k)(1)(i) of this chapter) or under an arrangement (as defined in §409.3 of this chapter) with another entity described in this paragraph.

(2) *Documentation and recordkeeping requirements—*

(i) *Ordering the service.* Except for tests described in paragraph (a)(3) of this section, the physician (or qualified nonphysician practitioner, as defined in paragraph (a)(2) of this section), who orders the service must maintain documentation of medical necessity in the beneficiary's medical record.

(ii) *Submitting the claim.* Except for tests described in paragraph (a)(3) of this section, the entity submitting the claim must maintain the following documentation:

(A) The documentation that it receives from the ordering physician or nonphysician practitioner.

(B) The documentation that the information that it submitted with the claim accurately reflects the information it received from the ordering physician or nonphysician practitioner.

(iii) *Requesting additional information.* The entity submitting the claim may request additional diagnostic and other medical information to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

(3) *Claims review.*

(i) *Documentation requirements.* Except for tests described in paragraph (a)(3) introductory text, upon request by CMS, the entity submitting the claim must provide the following information:

(A) Documentation of the order for the service billed (including information sufficient to enable CMS to identify and contact the ordering physician or nonphysician practitioner).

(B) Documentation showing accurate processing of the order and submission of the claim.

(C) Diagnostic or other medical information supplied to the laboratory by the ordering physician or nonphysician practitioner, including any ICD–9–CM code or narrative description supplied.

(ii) *Services that are not reasonable and necessary.* If the documentation provided under paragraph (d)(3)(i) of this section does not demonstrate that the service is reasonable and necessary, CMS takes the following actions:

(A) Provides the ordering physician or nonphysician practitioner information sufficient to identify the claim being reviewed.

(B) Requests from the ordering physician or nonphysician practitioner those parts of a beneficiary's medical record that are relevant to the specific claim(s) being reviewed.

(C) If the ordering physician or nonphysician practitioner does not supply the documentation requested, informs the entity submitting the claim(s) that the documentation has not been supplied and denies the claim.

(iii) *Medical necessity.* The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific

test(s), taking into consideration current rules and regulations on patient confidentiality.

(4) *Automatic denial and manual review.* (i) *General rule.* Except as provided in paragraph (d)(4)(ii) of this section, CMS does not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation that is submitted with the claim (for example, justifications prepared by providers, primary and secondary diagnoses, and copies of medical records).

(ii) *Exceptions.* CMS may automatically deny a claim without manual review if a national coverage decision or LMRP specifies the circumstances under which the service is denied, or the service is specifically excluded from Medicare coverage by law.

(e) *Diagnostic laboratory tests furnished in hospitals and CAHs.* The provisions of paragraphs (a) and (d)(2) through (d)(4) of this section, inclusive, of this section apply to all diagnostic laboratory test furnished by hospitals and CAHs to outpatients.

[62 FR 59098, Oct. 31, 1997, as amended at 63 FR 26308, May 12, 1998; 63 FR 53307, Oct. 5, 1998; 63 FR 58906, Nov. 2, 1998; 64 FR 59440, Nov. 2, 1999; 66 FR 58809, Nov. 23, 2001; 69 FR 66421, Nov. 15, 2004; 72 FR 66398, Nov. 27, 2007; 75 FR 73615, Nov. 29, 2010; 77 FR 69361, Nov. 16, 2012; 83 FR 60073, Nov. 23, 2018; 85 FR 19286, Apr. 6, 2020; 85 FR 27620, May 8, 2020; 85 FR 54871, Sept. 2, 2020; 85 FR 85026, Dec. 28, 2020; 87 FR 70223, Nov. 18, 2022]

§ 410.33 Independent diagnostic testing facility.

(a) *General rule.* (1) Effective for diagnostic procedures performed on or after March 15, 1999, carriers will pay for diagnostic procedures under the physician fee schedule only when performed by a physician, a group practice of physicians, an approved supplier of portable x-ray services, a nurse practitioner, or a clinical nurse specialist when he or she performs a test he or she is authorized by the State to perform, or an independent diagnostic testing facility (IDTF). An IDTF may be a fixed location, a mobile entity, or an individual nonphysician practitioner. It is independent of a physician's office or hospital; however, these rules apply when an IDTF furnishes diagnostic procedures in a physician's office.

(2) *Exceptions.* The following diagnostic tests that are payable under the physician fee schedule and furnished by a nonhospital testing entity are not required to be furnished in accordance with the criteria set forth in paragraphs (b) through (e) and (g) and (h) of this section.

(i) Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.

(ii) Diagnostic tests personally furnished by a qualified audiologist as defined in section 1861(ll)(3) of the Act.

(iii) Diagnostic psychological testing services personally furnished by a clinical psychologist or a qualified independent psychologist as defined in program instructions.

(iv) Diagnostic tests (as established through program instructions) personally performed by a physical therapist who is certified by the American Board of Physical Therapy Specialties as a qualified electrophysiologic clinical specialist and permitted to provide the service under State law.

(b) *Supervising physician.* (1) Each supervising physician must be limited to providing general supervision to no more than three IDTF sites. This applies to both fixed sites and mobile units where three concurrent operations are capable of performing tests.

(2) 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 § 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 IDTF must maintain documentation of sufficient physician resources during all hours of operations to assure that the required physician supervision is furnished. In the case of procedures requiring direct