§ 410.31 Bone mass measurement: Conditions for coverage and frequency standards.

(a) Definition. As used in this section unless specified otherwise, the following definition applies:

Bone mass measurement means a radiologic, radioisotopic, or other procedure that meets the following conditions:

(1) Is performed for the purpose of identifying bone mass, detecting bone loss, or determining bone quality.

(2) Is performed with either a bone densitometer (other than single-photon or dual-photon absorptiometry) or with a bone sonometer system that has been
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cleared for marketing for this use by
the FDA under 21 CFR part 807, or ap-
proved for marketing by the FDA for
this use under 21 CFR part 814.

(3) Includes a physician’s interpreta-
tion of the results of the procedure.

(b) Conditions for coverage. (1) Medi-
care covers a medically necessary bone
mass measurement if the following
conditions are met:

(i) Following an evaluation of the
beneficiary’s need for the measure-
ment, including a determination as to
the medically appropriate procedure to
be used for the beneficiary, it is or-
dered by the physician or a qualified
nonphysician practitioner (as these
terms are defined in §410.32(a)) treating
the beneficiary.

(ii) It is performed under the appro-
riate level of supervision of a physi-
cian (as set forth in §410.32(b)).

(iii) It is reasonable and necessary for
diagnosing and treating the Condition
of a beneficiary who meets the condi-
tions described in paragraph (d) of this
section.

(2) Medicare covers a medically nec-
essary bone mass measurement for an
individual defined under paragraph
(d)(5) of this section if the conditions
under paragraph (b)(1) of this section
are met and the monitoring is per-
formed by the use of a dual energy x-
ray absorptiometry system (axial skel-
ton).

(3) Medicare covers a medically nec-
essary confirmatory baseline bone
mass measurement for an individual
defined under paragraph (d) of this sec-
tion, if the conditions under paragraph
(b)(1) of this section are met and the
confirmatory baseline bone mass meas-
urement is performed by a dual energy x-
ray absorptiometry system (axial skel-
ton) and the initial measurement
was not performed by a dual energy x-
ray absorptiometry system (axial skel-
ton).

(c) Standards on frequency of cov-
erage—(1) General rule. Except as al-
lowed under paragraph (c)(2) of this
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 measure-
ment was performed.

(2) Exception. If medically necessary,
Medicare may cover a bone mass meas-
urement for a beneficiary more fre-
quently than allowed under paragraph
(c)(1) of this section. Examples of situ-
ations where more frequent bone mass
measurement procedures may be medi-
cally necessary include, but are not
limited to the following medical cir-
cumstances:

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

(ii) Allowing for a confirmatory base-
line measurement to permit moni-
toring 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 bene-
ficiaries may receive Medicare cov-
erage for a medically necessary bone
mass measurement:

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

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

(3) An individual receiving (or ex-
pecting to receive) glucocorticoid (ster-
oid) 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 ther-
apy.

(e) Denial as not reasonable and nec-
essary. 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 stand-
ards on frequency of coverage in para-
graph (c) of this section, it is excluded
from Medicare coverage as not “rea-
sonable” and “necessary” under sec-
tion 1862(a)(1)(A) of the Act and
§411.15(k) of this chapter.

(f) Use of the National Coverage Deter-
mination Process. For the purposes of
paragraphs (b)(2) and (b)(3) of this sec-
tion, 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.

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

(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).

(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.

(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. 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 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 a clinical psychologist.

(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.


(vii) Diagnostic tests performed by a certified nurse-midwife authorized to perform the tests under 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 physician 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 paragraphs (b)(3)(ii)