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Pulse-Echo Ultrasound Bone Density Measurement

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None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Bone density measurement using pulse-echo ultrasound **is considered experimental, investigational and/or unproven.**

NOTE 1: This policy does not address other bone mineral density (BMD) technologies, including ultrasound densitometry, dual x-ray absorptiometry (DXA), or peripheral measurements of BMD to screen for the risk of or the diagnosis of osteoporosis.

Policy Guidelines

None.

Description

Bone mineral density (BMD) studies can be used to identify individuals with osteoporosis and to monitor response to osteoporosis treatment, with the goal of reducing the risk of fracture. One

technology that is available is the pulse-echo ultrasound which is portable and used to screen and diagnose osteoporosis.

Background

Osteoporosis

Osteoporosis is determined using the World Health Organization (WHO) diagnostic thresholds for osteoporosis based on BMD compared with a calculated T-score.

Risk factors for fracture include low bone mass, low bone strength, a personal history of fracture as an adult, or a history of fracture in a first-degree relative. Osteoporosis, defined as low bone mass leading to an increased risk of fragility fractures, is an extremely common disease in the elderly population due to age-related bone loss in both sexes and menopause-related bone loss in women. The WHO has diagnostic thresholds for osteoporosis based on BMD measurements compared with a T-score, which is the standard deviation difference between an individual's BMD and that of a young-adult reference population. Conditions that can cause or contribute to osteoporosis include lifestyle factors such as low intake of calcium, high intake of alcohol or cigarette smoking, and thinness. Other risk factors for osteoporosis include certain endocrine, hematologic, gastrointestinal tract and genetic disorders, hypogonadal states, and medications.

BMD can be measured either centrally (i.e., hip or spine) or peripherally (i.e., wrist, finger, heel) sites. While BMD measurements are predictive of fragility fractures at all sites, central measurements of the hip and spine are the most predictive. Fractures of the hip and spine (i.e., vertebral fractures) are also considered to be the most clinically relevant. BMD is typically expressed as a T-score.

The utility of screening BMD measurements can be established by demonstrating that screening identifies a population at increased risk of fracture and that, by treating those at-risk individuals, the rate of fractures is reduced thereby lowering fracture-related morbidity and mortality. These potential benefits of screening should outweigh the risks of screening (radiation exposure) or false positives (initiation of unnecessary treatment).

Pulse-Echo Ultrasound for Bone Density Measurement

Bindex® (Bone Index Finland OY) is a pulse-echo ultrasound tool for the screening and diagnosis of osteoporosis. (1) The device measures cortical bone thickness at the upper shaft of the tibia and calculates a density index from this measure alongside other clinical risk factors or patient characteristics.

The portable, pocket-size handheld Bindex® device is a transducer that can be connected to any computer or Windows tablet, through a USB (universal serial bus) cable. (1) A custom ruler is used to measure to a point one-third of the length of the proximal tibia from the knee joint, where the Bindex® ultrasound measurement will be taken. Ultrasound gel is applied to the measurement site and the hardware is calibrated using the Bindex® software. To take a measurement, the transducer is moved over the measurement site for a few minutes. Cortical

thickness is estimated by multiplying the speed of sound by the time lag between ultrasound echoes from the front and back surfaces of the cortical bone layer. The transducer collects the sound waves reflected from the bone and transmits the signal to the connected computer, which immediately displays the results using the Bindex® software. The Bindex® measurement typically takes under 15 minutes to do.

Bindex® software uses the cortical thickness measurement plus age, weight and height of the person being measured, to calculate the density index. (1) These values are displayed alongside pre-determined density index thresholds that estimate the probability of osteoporosis. Results are displayed using a 'traffic light' color bar; green shows a low probability of osteoporosis and a low need for further investigation, yellow shows that more investigations are needed, and red shows a high risk of osteoporosis and a need for treatment without dual-energy X ray absorptiometry (DXA). Results are saved in the Bindex® database on the computer and can be exported in a portable document format (PDF).

Regulatory Status

The Bindex® device and software (Bone Index Finland, Ltd., Kuopio, Finland) has been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process on January 9, 2017, as the Bindex® BI-2 device which is identical to the predicate device. (2, 3) The FDA-approved label states, “Bindex measures apparent cortical bone thickness at the proximal tibia and can be used in conjunction with other clinical risk factors or patient characteristics as an aid to the physician in the diagnosis of osteoporosis and other medical conditions leading to reduced bone strength and in the determination of fracture risk.” (3) The Bindex® BI-2 system consists of a handheld ultrasound transducer and software. Bindex® is designed to help guide further investigations and treatment in people who may have osteoporosis and may be used in the primary, secondary or home care setting (for example, on a home visit). Bindex® would be used by a trained healthcare professional. FDA product code: MUA.

Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function - including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions the alternative will be supportive care or surveillance. The

quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Pulse-Echo (PE) Ultrasound for Bone Density Measurement

Ultrasound transmission measurement through the os calcis is an emerging technique and a promising clinical tool for early assessment of osteoporosis. (4) In a Finnish study from Jurvelin et al. (2010), the investigators reported on the frequency measurements of 2.25- and 5.0-megahertz (MHz) to exact the dual frequency ultrasound (DRUS) used in axial pulse-echo (PE) ultrasound in order to minimize the effects on soft tissues overlying the bone and have the correct PE parameters. (5) The result was confirmation that DRUS used in PE ultrasound technique did detect the changes in bone density, despite variable composition of soft tissue. The safety frequency levels to soft tissue were determined by an earlier study from Reikkinen et al. in 2008, from Finland. (6) The prior study from Reikkinen et al. in 2006 studied the range of frequency from 0.3 to 6.7 MHz to determine what frequencies could be utilized. (7) Despite the Reikkinen et al. 2006 assessment having been done on human trabecular bone samples (n=25), the comparative study was necessary to determine the MHz frequencies for several techniques. A comparison was done using acoustic/ultrasound, dual energy x-ray absorptiometry (DXA) and mechanical techniques. The numerical corrections for PE ultrasound frequencies were determined to reduce any uncertainties to the overlying soft tissues and to arrive at the correct bone mineral density (BMD) measurements.

The primary evidence used for this medical policy were 3 studies of 2218 women: Karjalainen et al. (2016) (8), Schousboe et al. (2017) (9), and Karjalainen et al. (2018) (10), which are compared and summarized in Table 1. NICE reviewed 2 of the studies and included in their assessment of 2017. (1, 8, 9)

Table 1. Summary of Study Trials (1, 8-10)

Study	N of Pts	Study Design	Method	Outcome	Strength and Limitations
Karjalainen et al. (2016) (8) Based in Finland	572	Study design unclear if prospective or retrospective. Age range from 20 to 91 years.	PE compared with DXA. FRAX questionnaire used to compare to the Bindex® software risk calculation score.	The FRAX followed by Bindex® approach showed 85% sensitivity and 79% specificity for treatment decisions based on the Finnish	The study did not take into account the use of DXA for baseline measurements to monitor treatment efficacy. The same population was used to develop

				standard criteria. The false negative rate of the FRAX followed by Bindex® approach was 14.6%. Using the FRAX followed by Bindex® approach, 84% (of the total number of women) avoided DXA tests with the Bindex® approach. Reproducibility between Bindex® operators was good.	and validate the DI index thresholds, so the results do not validate the performance of Bindex®.
Schousboe et al. (2017) (9) Based in USA and Finland	555	Post-menopausal women (43% with hip osteoporosis, 57% without hip osteoporosis) Age range from 50 to 89 years.	PE compared with DXA.	Using single- or multi-site DI measures (taken from the proximal and distal tibia and radius) were shown to have good sensitivity and specificity (80.0%-82.0%). Avoiding DXA could have been done in 73% of pts.	Recruitment by mail has an effect on the participation of frail individuals with hip osteoporosis who could not travel to the clinic. The manufacturer states that measurements should be taken from the upper shaft of the tibia, but measurements were taken from other bones in this

					study. Authors suggest more prospective studies.
Karjalainen et al. (2018) (10) Based in Finland	1091	Study design unclear if prospective or retrospective. Post-menopausal women (888 had 1 or more risk factors, 100 deemed healthy). Age range from 50 to 89 years.	PE compared with DXA.	Using multi-site DI measures (taken from tibia and radius, with 988 women having measurements of the hip) were shown to have good sensitivity and specificity (93.7%-81.6%). Applications of thresholds for DI showed 32% of subjects would require additional DXA. For single-site for sensitivity and specificity was 84.7%-82.0%).	The study was not a RCT, nor was it clear as to the study design. Additionally, there were no details regarding recruitment or what was included from physical findings to be considered healthy or no-risk/low-risk for osteoporosis.

N: number; pts: patients; PE: pulse-echo ultrasound; DXA: dual-energy X-ray absorptiometry; DI: density index; FRAX: fracture risk assessment tool; RCT: randomized controlled trial.

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence (NICE)

In May of 2017, the United Kindom's NICE released a medical technology briefing for the use of Bindex® as a method to investigate suspected osteoporosis. (1) While NICE did not have a specific recommendation, they did provide a summary of the main points of evidence and key uncertainties:

1. "The main points from the evidence summarized in this briefing are from 2 diagnostic accuracy studies (1 United States and 1 Finland), including a total of 1,127 women in primary care. The studies show reasonable agreement for osteoporosis risk when determined in women with intermediate risk using FRAX and Bindex compared with FRAX and DXA." (This technology review did not include the third study of 1091 women published in January 2018 by Karjalainen et al. [10]).
2. "Key uncertainties around the evidence are that there are no prospective studies showing the effect of Bindex on the need for DXA scans, and limited data on the correlation between

tibial bone thickness and femoral bone mineral density. Also, the Bindex density index threshold values are only validated in women of white European family origin, which may limit the generalizability of the results."

American College of Obstetricians and Gynecologists (ACOG)

In 2021, the ACOG updated its guidelines on osteoporosis, screening, and diagnosis in women. (11) The guidelines recommend screening for osteoporosis in postmenopausal patients age 65 years and older with BMD testing to prevent osteoporotic fractures. Hip (femoral neck) and lumbar spine measurements provide the most accurate and precise measurements of BMD. The use of a risk assessment tool such as the United States Fracture Risk Assessment Tool (FRAX) can help determine the need for pharmacologic therapy if T-scores indicate low bone density.

In addition, ACOG recommends screening for osteoporosis with BMD testing to prevent osteoporotic fractures in postmenopausal patients younger than 65 years who are at increased risk of osteoporosis.

Most major osteoporosis screening guidelines do not provide guidance on the role or timing of retesting in patients with normal bone density and low fracture risk. ACOG, however, suggests repeat osteoporosis screening in postmenopausal patients with initial BMD test results near treatment thresholds or with significant changes in risk factors; for most patients, repeat BMD testing should be performed no sooner than 2 years after initial screening.

This Clinical Practice Guideline includes updated recommendations on the role of exercise, calcium, and vitamin D in osteoporosis prevention; osteoporosis screening and diagnosis; rescreening intervals; and interventions to prevent falls. Recommendations are classified by strength and evidence quality. Ungraded Good Practice Points are included to provide guidance when a formal recommendation could not be made because of inadequate or nonexistent evidence.

However, the ACOG guidelines do not address the use of PE ultrasound to determine osteoporosis risk or for screening.

Bone Health and Osteoporosis Foundation (BHOF)

In 2022, the Bone Health and Osteoporosis Foundation (BHOF), formerly known as the National Osteoporosis Foundation, updated its practice guidelines. (12) The BHOF guidelines state that bone density measurements are not indicated unless test results will influence treatment and management decisions.

Indications for BMD testing recommended by the BHOF include:

- Women age 65 and older and men age 70 and older, regardless of clinical risk factors;
- Postmenopausal women aged 50 to 64, regardless of clinical risk factors;
- Men aged 50 to 69 years with risk factors for osteoporosis;
- Adults age 50 years and older who have a fracture;

- Adults with a condition or taking a medication associated with low bone mass or bone loss.

The BHOF stated that repeat bone densitometry should be done in patients exhibiting signs of vertebral fracture, such as height loss or back pain.

The BHOF stated that measurements for monitoring patients should be performed in accordance with medical necessity, expected response, and in consideration of local regulatory requirements. The BHOF recommended that a follow-up BMD assessment be performed after 1 year of initial therapy or a change in therapy, with longer intervals once an effective treatment is established. The BHOF recommends repeat BMD assessments every 2 years in adults ages 65 years and older but recognized that testing more frequently may be warranted in certain clinical situations and should be guided by the clinical status of each patient.

However, the NOF practice guidelines do not address the use of PE ultrasound to determine osteoporosis risk or for screening.

American College of Physicians (ACP)

The 2008 guidelines from the ACP recommended that clinicians periodically perform individualized assessment of risk factors for osteoporosis in men older than 50 years (grade: strong recommendation; moderate-quality evidence). (13) Factors that increase the risk for osteoporosis in men included age (>70 years), low body mass index, weight loss, physical inactivity, corticosteroid use, androgen deprivation therapy, and previous fragility fracture. ACP recommended that clinicians obtain DXA for men who are at increased risk for osteoporosis and are candidates for drug therapy (grade: strong recommendation; moderate-quality evidence). The guidelines indicated that bone density measurement with DXA is the accepted reference standard for diagnosing osteoporosis in men; because treatment trials have not measured the effectiveness of therapy for osteoporosis diagnosed by ultrasound densitometry rather than DXA, the role of ultrasound in diagnosis remains uncertain. This evidence review found no studies that evaluated the optimal intervals for repeated screening by using BMD measurement with DXA in men.

A supplement to the 2008 recommendations was published in 2017. The supplement included a study of women and men comparing benefits and risks of short- and long-term pharmacologic treatments for low bone density. Additional evidence on new medications and biologic agents replaced the 2008 guideline. (14)

However, the ACP guidelines, including the 2017 update, do not address the use of PE ultrasound to determine osteoporosis risk or for screening.

American College of Radiology (ACR)

Practice guidelines from the ACR, last amended in 2022, state that BMD measurement is indicated whenever a clinical decision is likely to be directly influenced by the result of the test. (15) Indications for DXA included but were not limited to the following patient populations:

- All women age 65 years and older and men age 70 years and older (asymptomatic screening);
- Women younger than age 65 years who have additional risk for osteoporosis, based on medical history and other findings. Additional risk factors for osteoporosis include:
  - Estrogen deficiency,
  - A history of maternal hip fracture that occurred after the age of 50 years,
  - Low body mass (less than 127 lb. [pounds] or 57.6 kg [kilograms]),
  - History of amenorrhea (more than 1 year before age 42 years);
- Women younger than age 65 years or men younger than age 70 years who have additional risk factors, including:
  - use of cigarettes,
  - Current Loss of height, thoracic kyphosis;
- Individuals of any age with bone mass osteopenia, or fragility fractures on imaging studies such as radiographs, CT [computed tomography], or MRI [magnetic resonance imaging];
- Individuals age 50 years and older who develop a wrist, hip, spine, or proximal humerus fracture with minimal or no trauma, excluding pathologic fractures;
- Individuals of any age who develop 1 or more insufficiency fractures;
- Individuals being considered for pharmacologic therapy for osteoporosis;
- Individuals being assessed for the effectiveness of osteoporosis drug therapy.

However, the ACR practice guidelines do not address the use of PE ultrasound to determine osteoporosis risk or for screening.

<u>International Society for Clinical Densitometry (ISCD)</u>
The 2019 update of the ISCD guidelines recommended bone density testing in the following patients (16):
- "Women age 65 and older;
- For post-menopausal women younger than age 65 a bone density test is indicated if they have a risk factor for low bone mass fracture such as:
  - Low body weight,
  - Prior fracture,
  - High risk medication use,
  - Disease or condition associated with bone loss;
- Women during the menopausal transition with clinical risk factors for fracture, such as low bone weight, prior fracture or high-risk medication use;
- Men aged 70 and older;
- Men under < 70 years … if they have a risk factors for low bone mass such as:
  - Low body weight,
  - Prior fracture,
  - High risk medication use,
  - Disease or condition associated with bone loss;
- Adults with a fragility fracture;

- Adults with a disease or condition associated with low bone mass or bone loss….;
- Anyone being considered for pharmacologic therapy;
- Anyone being treated, to monitor treatment effect;
- Anyone not receiving therapy in whom evidence of bone loss would lead to treatment."

Women discontinuing estrogen should be considered for bone density testing according to the indications listed above.

However, the ISCD guidelines do not address the use of PE ultrasound to determine osteoporosis risk or for screening.

American Association of Clinical Endocrinologists (AACE) et al.

In 2020, the AACE and American College of Endocrinology (ACE) issued updated joint guidelines on the diagnosis and treatment of postmenopausal osteoporosis. (17) The guidelines listed the potential uses for BMD measurements in postmenopausal women as:

- "Screening for osteoporosis;
- Establishing the severity of osteoporosis or bone loss…;
- Determining fracture risk…;
- Identifying candidates for pharmacologic intervention;
- Assessing changes in bone density over time…;
- Enhancing acceptance of, and perhaps adherence with, treatment;
- Assessing skeletal consequences of diseases, conditions, or medications known to cause bone loss"

However, the AACE et al., joint guidelines do not address the use of PE ultrasound to determine osteoporosis risk or for screening.

North American Menopause Society

The North American Menopause Society updated their position statement in 2021, which indicated that osteoporosis, especially prevalent in older postmenopausal women, increases the risk of fractures that can be associated with significant morbidity and mortality. (18) The statement concluded that osteoporosis is a common disorder in postmenopausal women. Management of skeletal health in postmenopausal women involves assessing risk factors for fracture, reducing modifiable risk factors through dietary and lifestyle changes, and the use of pharmacologic therapy for patients at significant risk of osteoporosis or fracture. For women with osteoporosis, lifelong management is necessary. Treatment decisions occur continuously over the lifespan of a postmenopausal woman. Decisions must be individualized and should include the patient in the process of shared decision-making.

However, the North American Menopause Society, updated 2021, position statement does not address the use of PE ultrasound to determine osteoporosis risk or for screening.

U.S. Preventive Services Task Force (USPSTF)

The USPSTF updated its recommendations on screening for osteoporosis with bone density measurements in June 2018 (update in process as of January 5, 2022) (19) These recommendations are consistent with the 2011 recommendations on screening for osteoporosis. The USPSTF recommended screening for osteoporosis in women aged 65 years or older and in younger women who are at increased risk. For men, the USPSTF recommendations stated that there was inadequate evidence on the benefits and harms of treating screen-detected osteoporosis to reduce the risk of osteoporotic fractures. The Task Force did not recommend specific screening tests but said that the most commonly used tests are DXA of the hip and lumbar spine. Additionally, they did not address the use of PE ultrasound to determine osteoporosis risk through screening.

Medicare National Coverage

The Centers for Medicare and Medicaid (CMS) allows for a screening bone mass measurement (BMM) once every 2 years (at least 23 months have passed since the month the last covered BMM was performed). (20) When medically necessary, Medicare may allow for more frequent BMMs. Examples include, but are not limited to, monitoring beneficiaries on long-term glucocorticoid (steroid) therapy of more than 3 months and confirming baseline BMMs to permit monitoring of beneficiaries in the future.

Conditions for coverage of BMM can be found in chapter 15, section 80.5 of Pub. 100-02, Medicare Benefit Policy Manual. Medicare covers BMM under the following conditions:

1. "Is ordered by the physician or qualified non-physician practitioner who is treating the beneficiary following an evaluation of the need for a BMM and determination of the appropriate BMM to be used….
2. Is performed under the appropriate level of physician supervision as defined in 42 CFR 410.32(b).
3. Is reasonable and necessary for diagnosing and treating the condition of a beneficiary who meets the conditions described in §80.5.6.
4. In the case of an individual being monitored to assess the response to or efficacy of an FDA [U.S. Food and Drug Administration]-approved osteoporosis drug therapy, is performed with a dual-energy x-ray absorptiometry system (axial skeleton).
5. In the case of any individual who meets the conditions of 80.5.6 and who has a confirmatory BMM, is performed by a dual-energy x-ray absorptiometry system (axial skeleton) if the initial BMM was not performed by a dual-energy x-ray absorptiometry system (axial skeleton). A confirmatory baseline BMM is not covered if the initial BMM was performed by a dual-energy x-ray absorptiometry system (axial skeleton)."

However, CMS conditions for coverage does not address the use of PE ultrasound to determine osteoporosis risk or for screening.

American Association of Clinical Endocrinologists (AACE):

The AACE and American College of Endocrinology (ACE) Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis (21) list these indications for bone mineral density testing:

T-score is less than −1.0 AND one or more of the following is present:

- Women aged ≥70 years or men aged ≥80 years;
- Historical height loss >4 cm (>1.5 inches);
- Self-reported but undocumented prior vertebral fracture;
- Glucocorticoid therapy equivalent to ≥5 mg of prednisone or equivalent per day for ≥3 months.

Summary of Evidence

For individuals who are eligible for screening of bone mineral density (BMD) based on risk factor assessment who receive pulse-echo ultrasound analysis of peripheral sites, the evidence includes observational studies only. Relevant outcomes are disease-specific survival, morbid events, functional outcomes, health status measures, quality of life, and resource utilization. This technology is not commonly used for BMD measurements outside of the investigational setting; few studies have shown that they can select patients who benefit from treatment for osteoporosis. There is little to no evidence on the usefulness of repeat measurement of BMD using these techniques. There is a lack of support or endorsement from nationally recognized or United States governmental position statements or practice guidelines. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in August 2022 did not identify any ongoing or unpublished trials that would influence this policy.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	76977, 0508T
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
11/15/2024	Reviewed. No changes.
06/01/2023	Document updated with literature review. Coverage unchanged. Reference 12 added; others removed.
04/15/2022	Document updated with literature review. Coverage unchanged. Reference 21 added; others updated.
06/15/2021	Reviewed. No changes.
09/01/2020	Document updated with literature review. Coverage unchanged. Reference 15 added; others updated.
04/15/2019	Reviewed. No changes.
07/01/2018	New medical document. Bone density measurement using pulse-echo ultrasound is considered experimental, investigational and/or unproven.