Medical Coverage Policy | Bone Turnover Markers for the Diagnosis and Management of Osteoporosis and Diseases Associated with High Bone Turnover



EFFECTIVE DATE: 11|01|2019 **POLICY LAST UPDATED:** 02|01|2023

OVERVIEW

Bone turnover markers are biochemical markers of either bone formation or bone resorption. Commercially available tests are available to assess some of these markers in urine and/or serum by high-performance liquid chromatography or immunoassay. Assessment of bone turnover markers is proposed to supplement bone mineral density measurement in the diagnosis of osteoporosis and to aid in treatment decisions. Bone turnover markers could also potentially be used to evaluate treatment effectiveness before changes in bone mineral density can be observed.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans Measurement of bone turnover markers are covered.

Commercial Products

Measurement of bone turnover markers are considered not medically necessary for the following indications:

- to determine fracture risk in individuals with osteoporosis or with age-related risk factors for osteoporosis
- to determine response to therapy in individuals who are being treated for osteoporosis
- in the management of individuals with conditions associated with high rates of bone turnover, including but not limited to Paget disease, primary hyperparathyroidism, and renal osteodystrophy.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable not medically necessary benefits/coverage.

BACKGROUND

Bone Turnover

After cessation of growth, bone is in a constant state of remodeling (or turnover), with initial absorption of bone by osteoclasts followed by deposition of new bone matrix by osteoblasts. This constant bone turnover is critical to the overall health of the bone, by repairing microfractures and remodeling the bony architecture in response to stress. Normally, the action of osteoclasts and osteoblasts is balanced, but bone loss occurs if the 2 processes become uncoupled. Bone turnover markers can be categorized as bone formation markers or bone resorption markers and can be identified in serum and/or urine. There is interest in the use of bone turnover markers to evaluate age-related osteoporosis, a condition characterized by slow, prolonged bone loss, resulting in an increased risk of fractures at the hip, spine, or wrist. Measurement of bone turnover markers may aid in the diagnosis (by determining fracture risk) and therapeutic monitoring (by determining response to treatment) of osteoporosis. Bone turnover markers may also be used for the management of other diseases associated with high bone turnover (eg, primary hyperparathyroidism, Paget disease, renal osteodystrophy).

For individuals with osteoporosis or risk factors for age-related osteoporosis who receive a measurement of bone turnover markers to determine fracture risk, the evidence includes observational studies on the association between markers and osteoporosis and fracture risk, and systematic reviews of those studies. Relevant outcomes are test validity and morbid events. Few studies have directly addressed whether any bone turnover markers beyond bone mineral density (BMD) measurements are independent predictors of fracture risk. One meta-analysis investigated the independent role of bone turnover markers in fracture risk prediction and found a statistically significant but modest association between bone turnover markers (specifically, procollagen type 1 N-terminal propeptide and cross-linked C-telopeptide) and future fracture risk after adjusting for BMD and clinical risk factors. Other studies have suggested that bone turnover marker levels may be independently associated with osteoporosis and fracture risk in some groups, but there is insufficient evidence reporting on an association with any specific marker. Questions remain whether bone turnover markers are sufficiently sensitive to determine reliably individual treatment responses. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are being treated for osteoporosis who receive a measurement of bone turnover markers to determine response to therapy, the evidence includes an observational study, randomized controlled trials (RCTs), and a systematic review these RCTs. Relevant outcomes are test validity and morbid events. There is limited evidence on the impact of bone turnover markers on the management of osteoporosis. Individual RCTs and a systematic review of these RCTs have not found that feedback on bone turnover marker improves treatment adherence rates. No studies were identified that evaluated whether the use of bone turnover markers leads to management changes that are expected to improve outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. For individuals with conditions associated with high rates of bone turnover other than age-related osteoporosis (eg, primary hyperparathyroidism, Paget disease, renal osteodystrophy) who receive a measurement of bone turnover markers, the evidence includes observational studies on the association between markers and disease activity and a systematic review of those studies. Relevant outcomes are test validity and morbid events. The largest amount of evidence has been published on Paget disease; a systematic review found correlations between several bone turnover markers and disease activity prior to and/or after bisphosphonate treatment. There is a lack of evidence on how the measurement of bone turnover markers can change patient management or improve health outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans

The following CPT code(s) are medically necessary;83937 Osteocalcin (bone g1a protein)82523 Collagen cross links, any method

Commercial Products

The following code(s) are not medically necessary when filed with an ICD-10 Diagnosis Code* listed below; 82523 Collagen cross links, any method

83937 Osteocalcin (bone g1a protein)

*Not medically necessary ICD-10 Diagnosis Codes:

M81.0-M81.8 Z13.820 Z82.62

RELATED POLICIES

None

PUBLISHED

Provider Update, April 2023 Provider Update, April 2022 Provider Update, March 2021 Provider Update, April 2020 Provider Update, August 2018

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