NCD - Collagen Crosslinks, any Method (190.19)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Tracking Information

Publication Number

100-3

Manual Section Number

190.19

Manual Section Title

Collagen Crosslinks, any Method

Version Number

1

Effective Date of this Version

11/25/2002

Implementation Date

01/01/2003

Description Information

Benefit Category

Diagnostic Laboratory Tests

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Item/Service Description

Collagen crosslinks, part of the matrix of bone upon which bone mineral is deposited, are biochemical markers the excretion of which provide a quantitative measurement of bone resorption. Elevated levels of urinary collagen crosslinks indicate elevated bone resorption. Elevated bone resorption contributes to age-related and postmenopausal loss of bone leading to osteoporosis and increased risk of fracture. The collagen crosslinks assay can be performed by immunoassay or by high performance liquid chromatography (HPLC). Collagen crosslink immunoassays measure the pyridinoline crosslinks and associated telopeptides in urine.

Bone is constantly undergoing a metabolic process called turnover or remodeling. This includes a degradation process, bone resorption, mediated by the action of osteoclasts, and a building process, bone formation, mediated by the action of osteoblasts. Remodeling is required for the maintenance and overall health of bone and is tightly coupled; that is, resorption and formation must be in balance. In abnormal states of bone remodeling, when resorption exceeds formation, it results in a net loss of bone. The measurement of specific, bone-derived resorption products provides analytical data about the rate of bone resorption.

Osteoporosis is a condition characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased susceptibility to fractures of the hip, spine, and wrist. The term primary osteoporosis is applied where the causal factor in the disease is menopause or aging. The term secondary osteoporosis is applied where the causal factor is something other than menopause or aging, such as long-term administration of glucocorticosteroids, endocrine-related disorders (other than loss of estrogen due to menopause), and certain bone diseases such as cancer of the bone.

With respect to quantifying bone resorption, collagen crosslink tests can provide adjunct diagnostic information in concert with bone mass measurements. Bone mass measurements and biochemical markers may have complementary roles to play in assessing effectiveness of osteoporosis treatment. Proper management of osteoporosis patients, who are on long-term therapeutic regimens, may include laboratory testing of biochemical markers of bone turnover, such as collagen crosslinks, that provide a profile of bone turnover responses within weeks of therapy. Changes in collagen crosslinks are determined following commencement of antiresorptive therapy. These can be measured over a shorter time interval, such as three months, when compared to bone mass density. If bone resorption is not elevated, repeat testing is not medically necessary.

Indications and Limitations of Coverage

Indications

Generally speaking, collagen crosslink testing is useful mostly in "fast losers" of bone. The age when these bone markers can help direct therapy is often pre-Medicare. By the time a fast loser of bone reaches age 65, she will most likely have been stabilized by appropriate therapy or have lost so much bone mass that further testing is useless. Coverage for bone marker assays may be established, however, for younger Medicare beneficiaries and for those men and women who might become fast losers because of some other therapy such as glucocorticoids. Safeguards should be incorporated to prevent excessive use of tests in patients for whom they have no clinical relevance.

Collagen crosslinks testing is used to:

1. Identify individuals with elevated bone resorption, who have osteoporosis in whom response to treatment is being monitored;
2. Predict response (as assessed by bone mass measurements) to FDA approved antiresorptive therapy in postmenopausal women; and
3. Assess response to treatment of patients with osteoporosis, Paget's disease of the bone, or risk for osteoporosis where treatment may include FDA approved antiresorptive agents, anti-estrogens or selective estrogen receptor moderators.

Limitations

Because of significant specimen to specimen collagen crosslink physiologic variability (15-20%), current recommendations for appropriate utilization include: one or two base-line assays from specified urine collections on separate days; followed by a repeat assay about three months after starting anti-resorptive therapy; followed by a repeat assay in 12 months after the three-month assay; and thereafter not more than annually, unless there is a change in therapy in which circumstance an additional test may be indicated three months after the initiation of new therapy.

Some collagen crosslink assays may not be appropriate for use in some disorders, according to FDA labeling restrictions.

Note: Scroll down for links to the quarterly Covered Code Lists (including narrative).

Cross Reference

Also see the Medicare Claims Processing Manual, Chapter 120, Clinical Laboratory Services Based on Negotiated Rulemaking.

Transmittal Information

Transmittal Number

17

Coverage Transmittal Link

https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R17NCD.pdf

Revision History

07/2002 - Implemented NCD. Effective date 11/25/02. Implementation date 1/01/03. (TN AB-02-110) (CR 2130)

07/2004 - Published NCD in the NCD Manual without change to narrative contained in PM AB-02-110. Coding guidance now published in Medicare Lab NCD Manual. Effective and Implementation dates NA. (TN 17) (CR 2130)

Other

Covered Code Lists (including narrative)

July 2022 (PDF) (ICD-10)
April 2022 (PDF) (ICD-10)
January 2022 (PDF) (ICD-10)
October 2021 (PDF) (ICD-10)
July 2021 (PDF) (ICD-10)
April 2021 (PDF) (ICD-10)
January 2021 (PDF) (ICD-10)
October 2020 (PDF) (ICD-10)
July 2020 (PDF) (ICD-10)
April 2020 (PDF) (ICD-10)
January 2020 (PDF) (ICD-10)
October 2019 (PDF) (ICD-10)
July 2019 (PDF) (ICD-10)
April 2019 (PDF) (ICD-10)
January 2019 (PDF) (ICD-10)
October 2018 (PDF) (ICD-10)
July 2018 (PDF) (ICD-10)
April 2018 (PDF) (ICD-10)
January 2018 (ICD-10)
October 2017 (ICD-10)
July 2017 (ICD-10)
April 2017 (ICD-10)
January 2017 (ICD-10)

October 2016 (ICD-10)
January 2016 (ICD-10)
October 2015 (ICD-10, ICD-9)
October 2014 (ICD-10, ICD-9)

Changes to Lab NCD Edit Software

April 2022
January 2022
October 2021
July 2021
October 2020
April 2020
January 2020
October 2019
July 2019
January 2019
October 2018
April 2018
January 2018
July 2017
April 2017
January 2017
January 2016
October 2014

Additional Information

Other Versions

Title	Version	Effective Between
Collagen Crosslinks, any Method	1	11/25/2002 - N/A