Biochemical Markers of Bone Remodeling

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Approved By:	Highmark Health Options – Market Leadership
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Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 4

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary biochemical markers of bone remodeling.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

Bone turnover markers – Are biochemical markers of either bone formation or bone resorption. Assessment of bone turnover markers is proposed to supplement bone mineral density (BMD) measurement in the diagnosis of osteoporosis and to aid in treatment decisions.

PROCEDURES

Prior authorization is required.

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

- To determine fracture risk in individuals with osteoporosis or with age-related risk factors for osteoporosis; or
- To determine response to therapy in individuals who are being treated for osteoporosis; or
- For the management of individuals with conditions associated with high rates of bone turnover, including but not limited to:

    - Diabetes and other endocrine disorders; or
    - Oncological indications, including the monitoring of metastatic disease; or
    - Paget disease; or
    - Primary hyperparathyroidism; or
    - Renal osteodystrophy; or
    - Rheumatologic conditions; or
    - Vitamin D deficiency.

According to CMS: NCD 19.19 (2004), 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:

- Identify individuals with elevated bone resorption, who have osteoporosis in whom response to treatment is being monitored.
- Predict response (as assessed by bone mass measurements) to FDA approved antiresorptive therapy in postmenopausal women.
- 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, antiestrogens or selective estrogen receptor moderators”

Limitations and Frequency: “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 3 months after starting anti-resorptive therapy; followed by a repeat assay in 12 months after the 3-month assay; and thereafter not more than annually, unless there is a change in therapy in which circumstance an additional test may be indicated 3 months after the initiation of new therapy.”

Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

Place of Service: Inpatient/Outpatient

Measurement of bone turnover markers is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT code	Description
82523	Collagen cross links, any method
83937	Osteocalcin (bone G1a protein)
84080	Phosphate, alkaline; isoenzymes

DIAGNOSIS CODES
Noncovered Diagnosis Codes for Procedure Code 84080

E55.9	K80.00	K80.01	K80.10	K80.11	K80.12	K80.13
K80.18	K80.19	K80.20	K80.21	K80.30	K80.31	K80.32
K80.33	K80.34	K80.35	K80.36	K80.37	K80.40	K80.41
K80.42	K80.43	K80.44	K80.45	K80.46	K80.47	K80.50
K80.51	K80.60	K80.61	K80.62	K80.63	K80.64	K80.65
K86.0	M88.0	M88.1	M88.811	M88.812	M88.819	M88.821
M88.822	M88.829	M88.831	M88.832	M88.839	M88.841	M88.842
M88.849	M88.851	M88.852	M88.859	M88.861	M88.862	M88.869
M88.871	M88.872	M88.879	Z00.00	Z00.01	Z01.812	

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

The Endocrine Society – 2019

2019 guidelines from the Endocrine Society (the Society) recommend that in postmenopausal women with a low bone mineral density (BMD) and at high risk of fractures who are being treated for osteoporosis, monitoring should be conducted by dual-energy X-ray absorptiometry at the spine and hip every 1 to 3 years. The Society considers measuring bone turnover markers (serum CTX for antiresorptive therapy or P1NP for bone anabolic therapy) as an alternative way of monitoring for poor response or nonadherence to therapy. The Society notes that there is uncertainty over what constitutes an optimal response to treatment, but some experts suggest that a meaningful change is approximately 40% when compared from before to 3 to 6 months after starting treatment.

U.S. Preventive Services Task Force Recommendations – 2018

The U.S. Preventive Services Task Force (2018) recommended screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in women 65 years and older. The Task Force recommended screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in postmenopausal women younger than 65 years who are at increased risk of osteoporosis, as determined by a formal clinical risk assessment tool. The recommendations on osteoporosis screening addressed dual-energy x-ray absorptiometry testing but did not mention bone turnover markers.

References

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POLICY UPDATE HISTORY

10/8/2021	Approved in Medical Policy Committee
07/27/2022	Annual review, approved in medical policy committee