Letter of Medical Necessity for Biochemical Markers of Bone Turnover

Patient Name: _____

Date of Birth: _____

Insurance: _____

Policy Number: _____

To whom it may concern,

This letter sets to outline the clinical necessity for specific blood tests and or pharmacological therapies to identify and diagnose metabolic bone disease.

My name is Dr Irinel Stanciu. I am board certified in Internal Medicine and Endocrinology and a specialist in Metabolism and Metabolic Bone Disease, including: osteoporosis, Paget's disease, renal bone disease, osteogenesis imperfect. A twenty-five year career. along with participation in ASBMR (American Society for Bone and Mineral Research), ISCD (International Society of Clinical Densitometry), Endocrine Society, American Association of Clinical Endocrinology have positioned me as a leading expert in diagnosing and treating metabolic bone disease.

Today, we use specific tests to assess bone remodeling, or bone turnover, and to treat the complex disorders of bone metabolism. Bone turnover markers (BTM) are biological markers that measure how quickly bone is turned over and replaced by new bone. On average, the entire skeleton is replaced every 10 years by remodeling. This process repairs micro-cracks that occur in the skeleton with daily mechanical loading. BTM are released into the blood and can be measured by radioimmunoassay or immunoassay.

These markers help us:

1. Determine the rate of bone turnover (high bone turnover is an independent risk factor for osteoporotic fracture) and predict the rate of bone loss.
2. Assess the response to osteoporosis treatments (both anti-resorptive as well as anabolic agents). The change in the BTM after the initiation of treatment occurs rapidly – within 3 months of starting therapy. Therefore, measuring BTM provides much earlier information on compliance and a bone effect than bone mineral density (BMD), which requires 1-2 years to see a measureable change. A change in the BTM also predicts improvements in BMD and predicts fracture risk reduction

Two large international groups – The International Osteoporosis Foundation and the International Federation of Clinical Chemistry and two large national groups – the National Bone Health Alliance and the American Association of Clinical Chemistry have endorsed, based on evidence, that the preferred BTM for bone formation is the propeptide type I collagen (PINP) and for bone resorption the collagen cross-link, C-telopeptide (CTX).

Biochemical markers of bone turnover are reimbursed by national policy of the Centers for Medicare and Medicaid (CMS) - NCD 190.19 (2003) for the following indications:

- Monitoring individuals with elevated bone resorption, who have osteoporosis in whom response to treatment
- Predict response (as assessed by bone mass measurements) to FDA approved anti-resorptive therapy in postmenopausal women.
- Assess response to treatment in patients with osteoporosis and Paget's disease of the bone. Additionally assess the risk for osteoporosis where treatment may include FDA approved anti-resorptive agents, anti-estrogens, or selective estrogen receptor modulators (SERMS)

Please note that CMS policy was implemented before the more sensitive marker of bone resorption (CTX) was developed and anabolic markers (PINP) were not yet in use until teriparatide was more recently FDA approved.

CMS recommends that testing should be based on the following 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."*

** This policy was last reviewed by CMS -10/3/2013 - Minor changes. Added NCD from 2003 190.19 for reference*

Biochemical markers of bone turnover provide valuable information to assist in the management of patients with osteoporosis. When used appropriately and interpreted correctly they are independent predictors of fracture risk, can determine the rates of bone loss, and define the response to therapy within a short period of time after initiation of therapy. Biochemical markers of bone turnover are also being assessed in scientific studies as a means to monitor the important topic of "bisphosphonate drug holidays"

These testing protocols are reimbursed by CMS and have been since 2006. The reimbursement is based on scientific data and was reviewed again and supported in 2013.

Coverage for approved indications is a medical necessity.

Thank you

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