



Osteomark NTx



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Products

- Osteomark NTx Urine ELISA
- Osteomark NTx Serum ELISA
- Osteomark NTx POC Device

CPT Code: 82523 Collagen cross-links, any method



Contact and Ordering

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Further information is available at [www.Osteomark.com](http://www.Osteomark.com)

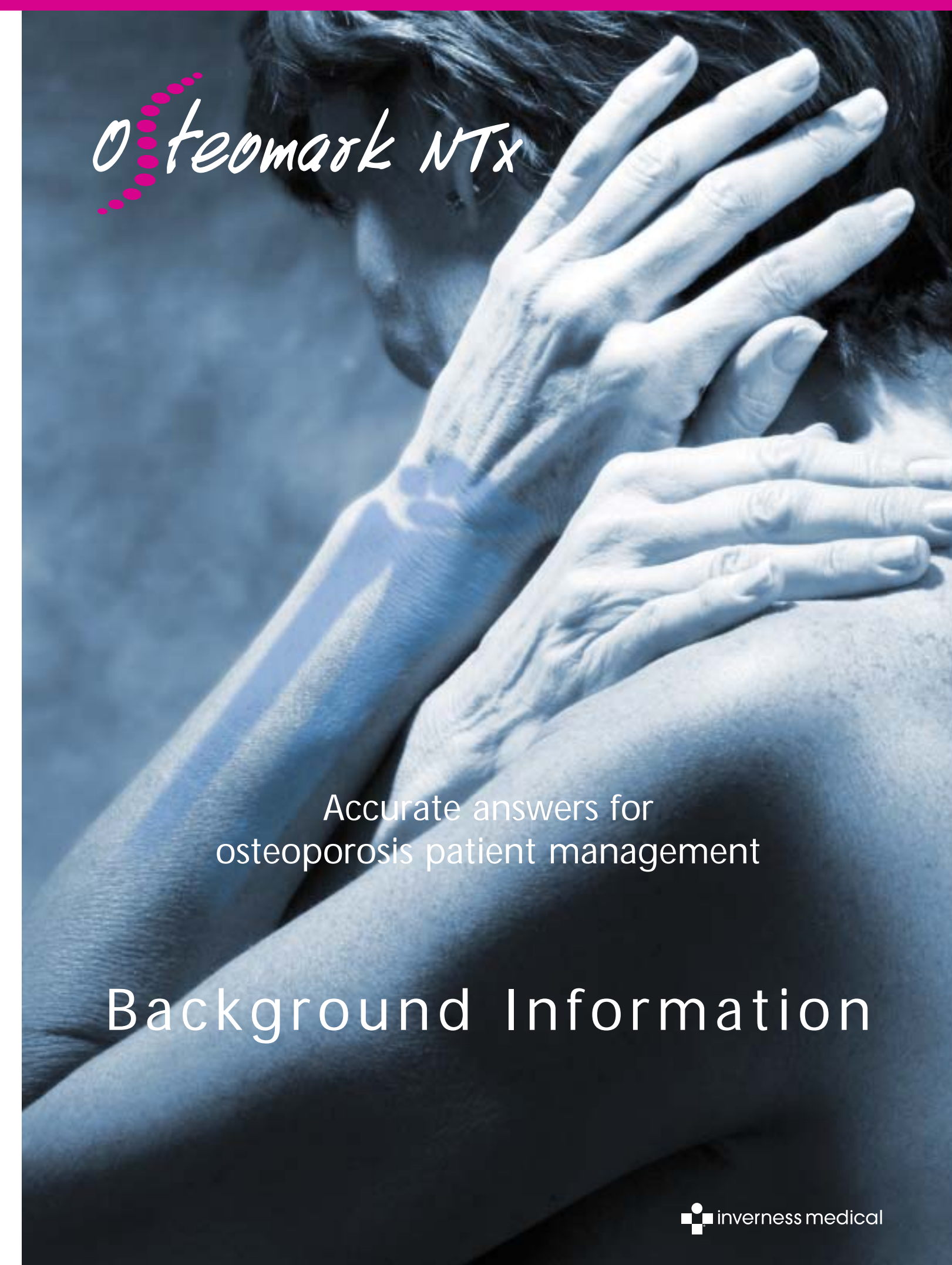
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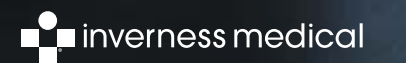


Osteomark NTx



Accurate answers for  
osteoporosis patient management

Background Information



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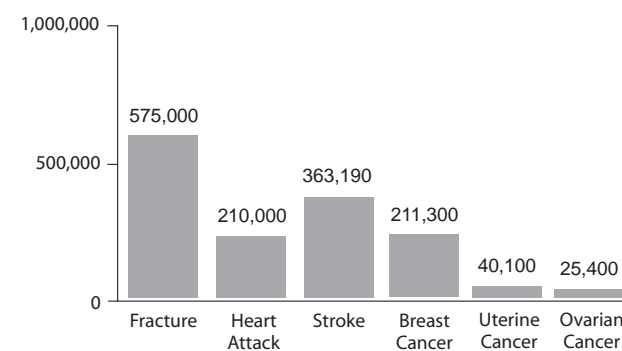


Accurate answers for osteoporosis management

## Osteoporosis

The commonest clinical disorder of bone metabolism is osteoporosis, which affects one in three women over 50 years, and 1 in 8 men. In the US alone, more than 10 million people over the age of 50 years currently have osteoporosis, and more than 33 million have low bone mass<sup>1,2</sup>. This is expected to rise significantly as the population ages. The association between osteoporosis and fractures makes osteoporosis a significant health concern, with the number of people who experience fractures higher than that of women who suffer breast, ovarian and uterine cancer (Figure 1)<sup>3</sup>. Osteoporosis related fractures result in huge costs to the healthcare system estimated at \$20Bn in the US and €25Bn in Europe per annum<sup>1,3</sup>. Despite this osteoporosis remains largely underdiagnosed and undertreated<sup>1</sup>.

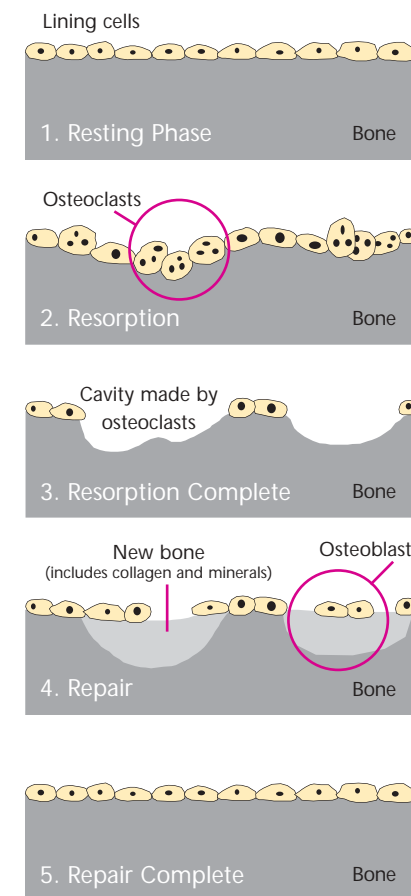
Figure 1. Annual Incidence of Selected Diseases in Women in the US<sup>3</sup>



## Bone Turnover and the Development of Osteoporosis

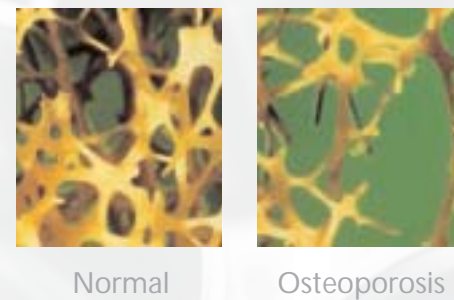
Bone is metabolically active throughout life. After skeletal growth is complete, remodelling of bone continues and results in an annual turnover of about 10% of the adult skeleton. The remodelling of bone requires the sequential and co-ordinated actions of the osteoclasts to remove bone, and the osteoblasts to replace it (Figure 2).

Figure 2. Normal Bone Remodelling Process



A change in the balance between bone resorption and bone formation ultimately results in a net loss or gain of bone tissue. High bone turnover, with increased bone resorption, can compromise bone strength. This then leads to thinning of the bone structure, resulting in abnormal bone micro-architecture, and reduced bone mineralization, leading to a greater propensity to fracture (Figure 3). An increased level of bone resorption is the primary cause of age-related bone loss often resulting in osteopenia, and is the major cause of osteoporosis<sup>1</sup>. Treatment of osteoporosis commonly involves drugs that inhibit bone resorption. These include bisphosphonates, estrogens, SERMS (selective estrogen receptor modulators) and calcitonin.

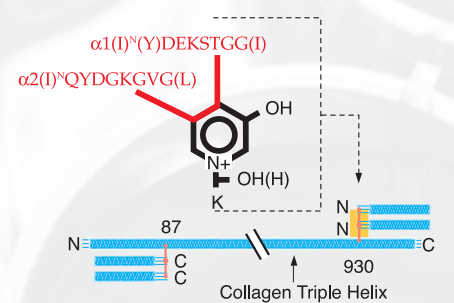
Figure 3. Microarchitectural Changes in Osteoporosis



## Bone Markers: NTx

Cross-linked N-telopeptide of type I collagen (NTx) is a specific indicator of bone resorption (Figure 4). It is generated from bone by osteoclasts as a degradation product of type I collagen, and it can be easily measured in urine and serum using the Osteomark NTx range of products.

Figure 4. Osteomark NTx Molecule.



The NTx molecule is specific to bone due to the unique amino acid sequence and orientation of the cross-linked alpha-2 (1) N-telopeptide<sup>4</sup>, and it is found both in serum and urine as a stable end product of bone degradation<sup>5,6,7</sup>. NTx can be measured easily in urine and serum by convenient immunoassay – Osteomark NTx.



## Clinical Utility of Osteomark NTx

Osteomark NTx is useful to:

- Help assess the need to initiate antiresorptive therapy by predicting skeletal response (Bone Mineral Density)
- Monitor patient response to therapy in just 3-6 months
- Identify treatment non-response
- Counsel patients about continuation of therapy and improve patient compliance

Bone turnover markers such as Osteomark NTx are not intended to replace BMD for the **diagnosis** of osteoporosis.

## NTx and BMD – Helping to assess your patients need for treatment

- NTx provides useful additional information, along with BMD, when assessing a patient for osteoporosis. A patient's current BMD is an important predictor of fracture risk, but gives no indication of the anticipated bone loss. Thus patients in the middle tertile of BMD may still be at risk of osteoporosis and fracture if they are losing bone rapidly. Studies have demonstrated that NTx may be useful in predicting rates of future bone loss, and provide independent information about fracture risk beyond BMD measurements alone<sup>8</sup>.
- The mean values of NTx are higher in patients with osteoporosis than in age- and sex-matched normal subjects. Studies have reported an inverse relationship between quartiles of urinary NTx and mean BMD<sup>9</sup>.
- Women with the highest NTx levels derive the greatest benefit from antiresorptive therapy<sup>10</sup>.

## Reference ranges for urine ELISA (nM BCE/mM Creatinine)

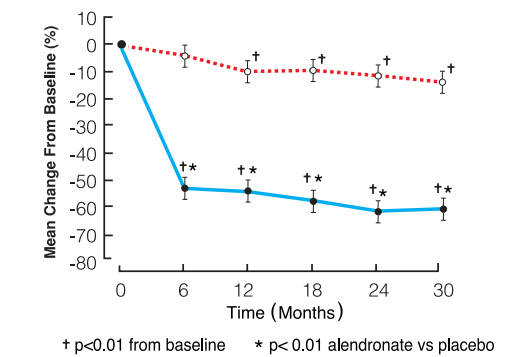
	Mean	Range
Pre-menopausal women	35	5-65
Men	27	3-51

## Reference ranges for serum ELISA (nM BCE)

	Mean	Range
Pre-menopausal women	12.6	6.2-19.0
Men	14.8	5.4-24.2



Figure 5. Mean change in NTx/Cr as % of baseline for patients taking Alendronate or Placebo



Typical response to daily Alendronate (+) or placebo (•) 120 women mean age 70 years (+/- 4.6) were recruited and randomised<sup>11</sup>. All subjects received appropriate calcium and vitamin D supplements (Oscal + D), to provide a total daily calcium intake of at least 1000mg.

## Fast Answers for Bone Therapy Monitoring

Osteoporosis treatments sometimes don't work – the main reasons for this are:

- Lack of efficacy
- Failure to follow the dosing instructions correctly
- Long term adherence and persistence with therapy is poor<sup>11,12</sup>

One of the problems facing clinicians and patients has been the 1-2 year wait to see the BMD response to therapy:

- Osteomark NTx can measure response to treatment in as little as 3-6 months after starting therapy (Figure 5)
- Percent change in bone resorption measured from baseline to 6 months following therapy is correlated to the percent change in BMD (Figure 6)<sup>13</sup>
- Patient monitoring has been shown to increase adherence by 57% compared with no monitoring, and subjects with a good marker response to raloxifene therapy were 92% more likely to adhere to therapy compared with usual care<sup>12</sup>

Figure 6. Correlation of mean change in NTx and total hip BMD in women receiving daily Alendronate or placebo for 30 months; all women received calcium and vitamin D supplementation

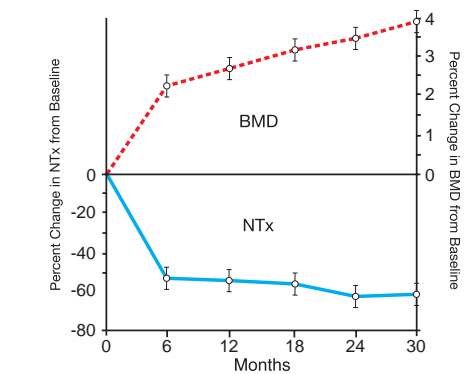


Table 1. Typical Response of NTx to Antiresorptive therapy after 6 months

Treatment	NTx Response Range
Alendronate (Fosamax <sup>®</sup> )	30-70% reduction <sup>11,14</sup>
Risedronate (Actonel <sup>®</sup> )	40-60% reduction <sup>15,16</sup>
Raloxifene (Evista <sup>®</sup> )	30% reduction <sup>17</sup>
HRT	30-50% reduction <sup>10,18,19</sup>