

# NEW PARADIGMS, Funding and Cautions – Appendix 7

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Osteoporosis poses a significant health burden and the rate of osteoporotic fracture is not declining in hospitals or community. The reasons include an ageing population, undetected osteoporosis cases (despite readily available DEXA services), and failure to both commence and maintain patients on anti-osteoporotic medications. A woman aged 75 with a T score at the spine or hip of -2.5, with previous minimal trauma fracture, has a 50% absolute risk of a further significant fracture in the next 10 years (30% in a male). Oral corticosteroids increase that risk. Mortality and morbidity costs of fracture are high. After hip fracture, there is 30% mortality at one year and chronic pain and disability in most cases, many requiring permanent hostel or nursing-home placement. Spinal fractures frequently lead to chronic back pain that is difficult to control. Other fractures such as Colle's, femoral shaft, pelvic, humeral neck and tibial plateau can lead to significant disability.

## **Medicare changes to screening and treatments**

As of April 1, Medicare will fund a bone density (DEXA) scan for all patients 70 years or older (male or female; MBS item 12323), without other restrictions.

Patients with a T score at one site of < -3.0, without a prior fracture, are eligible to commence alendronate (Fosamax) 70 mg weekly under new PBS criteria. Risedronate (Actonel) will be available for this indication shortly.

## **New Treatments**

Strontium ranelate (Protos) is a new class of agent, available from April 1, to treat post-menopausal women who have sustained a minimal trauma osteoporotic fracture. Two large studies in post-menopausal women demonstrated a reduced rate of all fractures (50% reduction at the spine and 30% elsewhere). The oral evening dose of 2g powder has a low rate of side-effects, usually nausea and diarrhoea and possibly a small increase in venous thrombo-embolism. This agent both stimulates bone formation and inhibits bone resorption.

Current evidence would support the use of either alendronate, risedronate, raloxifene (Evista) or strontium ranelate in the effective treatment of the osteoporotic patient. Any of these treatments will reduce the rate of osteoporotic fracture though raloxifene has not been demonstrated to reduce the rate of non-spine fractures. The doctor's role is to decide the most appropriate treatment for a particular patient and then encourage them to remain on treatment.

Newer potent bisphosphonates will be shortly available on the PBS either oral monthly or three monthly injectable ibandronate or yearly injectable zoledronate which are effective in reducing all osteoporotic fractures.

As with all pharmaceutical treatments without obvious symptomatic benefit, compliance requires a contract with the patient. Demonstrating that treatment is working, either by serial DEXA measurements or bone biochemical markers, will encourage compliance.

## **Exercise**

Encouraging resistive exercise programs will not only lead to modest increases in bone mass but will also prevent age-related bone loss, much of which is probably due to inactivity. It will also improve balance and sway and reduce the rate of falls.

Exercise needs to be prescribed as different musculoskeletal conditions are responsive to different programs of exercise. Resistive programs in a supervised group are most useful. Patients who have had prior vertebral fractures need careful supervision – programs that strengthen paraspinal musculature may help symptoms and prevent kyphosis.

### **Menopausal and Preventative Treatment**

Management of the perimenopausal or early postmenopausal female who is rapidly losing bone but may not yet be osteoporotic remains problematic. While her risk of fracture at age 55 with a T score of -1.5 may not be particularly high (absolute risk over 10 years of 10%), it clearly makes no sense to wait until she loses a substantial amount of bone to commence treatment. An anti-resorptive agent is required.

Unless HRT is needed to treat significant menopausal symptoms, there are better alternatives. One option is to commence alendronate 40 mg weekly (private script; approx \$150 for 30 tablets). Others include half a risedronate 70 mg tablet weekly, or raloxifene 60 mg daily (both more expensive).

### **Measuring Bone Loss**

A fasting metabolic bone study assesses if a patient is rapidly losing bone mass. The current bone resorption marker available in WA is the urinary NTX level, a sensitive and specific marker of bone breakdown.

A bone formation marker is occasionally useful, such as in the patient still losing bone mass on treatment due to poor bone formation or increased resorption. A specific marker is the serum P1NP level, which is the serum level of the propeptide of Type I collagen.

### **Treatment Precautions**

There is concern over the risk of osteonecrosis of the jaw (ONJ) in patients receiving bisphosphonates. Most of the risk is in oncology patients receiving high-dose bisphosphonates for preventing or treating metastatic bone disease. Using Australian survey data from oral and maxillofacial surgeons it was estimated that the risk of ONJ for an osteoporotic patient following an extraction was of the order of one in 1000. A recent German study estimated the incidence of ONJ in the nononcology setting at less than one in 100 000, which is also considerably lower than the Australian survey data. Reports are appearing that in a subgroup of osteoporotic patients receiving long-term treatment with bisphosphonates (i.e. >5 years), inert bone may result due to over-suppression of bone turnover, with poor bone formation and an increased rate of microfractures or pathological fractures. If suspected, bone turnover can be assessed with biochemical markers or a bone biopsy.

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**November 2007**