# NICE guidelines ration affordable osteoporosis drugs

December 11 2009

Los Angeles, London, New Delhi, Singapore and Washington DC (December 11, 2009) - Low cost osteoporosis drugs are strictly rationed for the under 75s, and UK physicians hampered by restrictive guidelines, according to findings which appear today in the journal *Therapeutic Advances in Musculoskeletal Disease*. A leading Cambridge University bone health expert has outlined flaws in NICE osteoporosis treatment guidance, which limits options for many postmenopausal women in the under-75 age bracket.

According to Cambridge University Professor of Bone Medicine, Juliet Compston, the current UK guidelines are unnecessarily complex. Physicians following the guidelines treat postmenopausal women aged over 75 with low trauma fractures (known as fragility fractures) with alendronate. This drug prevents further bone weakening by preventing the loss of bone that occurs with ageing.

However, physicians treating postmenopausal women under 75 with similar fractures have to demonstrate that the patient has bones scoring -2.5 or less on the 'T-score,' a measure of bone mass, to prescribe alendronate. There are alternatives for those who cannot take alendronate (etidronate, risedronate, or strontium ranelate or, for secondary prevention only, raloxifene) but a prescription for one of these often requires even more stringent criteria.

Alendronate, the first line of treatment, is available as a 'generic' drug and costs less than £20 per year to prescribe. With the second raft of

treatments costing £350 per year or less, physicians are faced with a difficult ethical dilemma in patients who are intolerant to alendronate as they know that these treatments are effective, yet they often cannot prescribe them until the patient has lost more bone. This is particularly unfortunate since intolerance to alendronate is common in frail elderly women, who are at very high risk of suffering further fractures.

There are no current NICE guidelines for treating men with fractures, or either men or women treated with glucocorticoids, which are a common cause of osteoporosis. Without NICE guidelines, cash-strapped primary care organisations may chose not to extend treatment to these individuals.

Osteoporosis leads to over 1000 deaths each month in the UK alone from hip fractures, and costs the National Health Service (NHS) and UK government £2.3 billion each year, according to figures from the National Osteoporosis Society charity. Factors such as drinking three or more units of alcohol per day, a family history of osteoporosis and long-term rheumatoid arthritis are among those that can increase fracture risk.

The National Osteoporosis Guideline Group (NOGG) has produced alternative guidelines, using different criteria to NICE. Recent national guidelines from other countries are more in keeping with NOGG, which takes independent clinical risk factors into account for fracture prediction and uses the WHO-supported FRAX® fracture risk algorithm. The NOGG approach to second-line therapy also eliminates the additional criteria for those unable to tolerate alendronate.

NICE is an independent organisation, which produces guidance in several areas including NHS drug prescriptions, which in general the NHS has to adhere to. Although NICE guidelines are often key to ensuring the best and most cost-effective treatments, the technology appraisals for osteoporosis have "fallen below the normally high

standards of NICE, resulting in outdated and inappropriately restrictive guidance," Compston argues, adding that when it comes to osteoporosis, "the fundamental principles of consistent use of the evidence base, transparency, and equity across disease states have not been observed."

Compston calls for a fresh NICE appraisal of osteoporosis treatments. A new appraisal may also benefit those beyond the UK - many other countries look to NICE guidelines as a template for their own national guidelines.

More information: NICE: its influence in treating osteoporosis in the UK and beyond by Juliet Compston Is published today in Therapeutic Advances in Musculoskeletal Disease, published by SAGE. DOI:10.1177/1759720X09354945

Source: SAGE Publications