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PRESS RELEASE

NICE issues final guidance on preventing fractures due to osteoporosis

The National Institute for Health and Clinical Excellence (NICE) has today (27 October) published final guidance on the use of drugs to prevent osteoporotic fractures in postmenopausal women. The two pieces of guidance cover the use of drugs in postmenopausal women with osteoporosis who have not yet had a fracture (known as primary prevention), and on the use of drugs for the prevention of further fractures in postmenopausal women who have already had a fracture (known as secondary prevention).

Osteoporosis is a skeletal disorder where the bone tissue deteriorates, leading to increased bone fragility and susceptibility to fracture. Osteoporosis is usually an age-related disease which can affect both sexes, but women are at greater risk because after the menopause bone loss accelerates.

This final guidance recommends access for postmenopausal women to a range of treatments for both primary prevention and secondary prevention. This includes options for women who are contraindicated to or intolerant of the recommended initial treatment, based on specified clinical criteria.

Professor Peter Littlejohns, NICE Clinical and Public Health Director and Executive Lead for the appraisal said: "These two new pieces of guidance will provide postmenopausal women with consistent access to the most cost-effective treatments to either prevent a first osteoporotic fracture or to help stop an osteoporotic fracture from happening again. This is the first time that national guidance has recommended drugs to help prevent a first fracture due to

osteoporosis, which is good news for those women at risk. The guidance on secondary prevention recommends wider access to alendronate – it now covers all postmenopausal women with confirmed osteoporosis, regardless of age. Alternative effective treatments are also recommended for women who cannot take alendronate.

“NICE guidance production has taken into consideration the comments received from health professionals, those at risk of osteoporosis-related fractures and their families and carers during consultations. We appreciate the feedback received and this has been helpful in informing this final guidance, which will benefit women at risk of osteoporotic fracture.”

The guidance on **primary prevention** recommends alendronate as a treatment option for primary prevention of osteoporotic fragility fractures in women aged 70 years or older who have an independent clinical risk factor for fracture or an indicator of low bone mineral density (BMD) and are confirmed to have osteoporosis (that is, a T-score of -2.5 SD or below). In women aged 75 years or older who have two or more independent risk factors for fracture or low BMD, a DXA scan may not be required if the responsible clinician considers it to be clinically inappropriate or unfeasible.

Alendronate is also recommended for primary prevention of osteoporotic fragility fractures in postmenopausal women younger than 70 years who have confirmed osteoporosis **and:**

- an independent clinical risk factor for fracture for those aged 65-69 years
- an independent clinical risk factor for fracture and at least one additional indicator of low BMD for those younger than 65 years.

For women who are contraindicated to or intolerant of alendronate, or cannot comply with the special instructions for its administration, risedronate and etidronate are recommended alternative options, based on a specified combination of age, T-score and number of independent clinical risk factors for fracture. Strontium ranelate is a recommended alternative treatment option for women who are contraindicated to, or intolerant of alendronate, risedronate and etidronate, or cannot comply with the special instructions for their administration, based on a specified combination of age, T-score and number of independent clinical risk factors.

Raloxifene is not recommended as a treatment option for primary prevention of osteoporotic fragility fractures.

For **secondary prevention** of osteoporotic fragility fractures, alendronate is recommended in all postmenopausal women who have confirmed osteoporosis. Women aged 75 years or older may not need a DXA scan if their doctor considers a DXA scan to be clinically inappropriate. For women who cannot take alendronate (reasons as outlined for primary prevention), risedronate and etidronate are recommended options based on a specified combination of age, T-score and number of independent clinical risk factors. For women who cannot take alendronate, risedronate and etidronate (reasons as outlined for primary prevention), strontium ranelate and raloxifene are recommended options based on a specified combination of age, T-score and number of independent clinical risk factors. Teriparatide is a recommended alternative option, based on a specified combination of age, T-score and number of independent clinical risk factors, for women who can't take any of the previous recommended options (reasons as outlined for primary prevention) or who've had an unsatisfactory response to alendronate, risedronate or etidronate.

Women who are currently receiving either primary or secondary prevention treatment with one of the drugs covered by this guidance, but for whom treatment would not have been recommended according to either piece of guidance, should have the option to continue treatment until they and their doctors consider it appropriate to stop.

Ends

Notes to Editors

About the guidance

1. The primary prevention guidance is available at: <http://www.nice.org.uk/TA160> and the secondary prevention guidance is available at: <http://www.nice.org.uk/TA161>.
2. For both pieces of guidance, independent clinical risk factors for fracture to be considered are: parental history of hip fracture, alcohol intake of 4 or more units per day, and rheumatoid arthritis.
3. For the purposes of the primary prevention guidance, indicators of low BMD are low body mass index (defined as less than 22 kg/m²) and medical conditions such as ankylosing spondylitis, Crohn's disease, conditions that result in prolonged immobility, and untreated premature menopause.
4. For the purposes of the primary prevention guidance, primary prevention refers to opportunistic identification, during visits to a healthcare professional for any reason, of postmenopausal women who are at risk of osteoporotic fragility fractures and who could benefit from drug treatment. It does not imply a dedicated screening programme.
5. For both pieces of guidance, intolerance of alendronate, risedronate or etidronate is defined as persistent upper gastrointestinal disturbance that is sufficiently severe to warrant discontinuation of treatment, and that occurs even though the instructions for administration have been followed correctly. For the purpose of the secondary prevention guidance, intolerance of strontium ranelate is defined as persistent nausea or diarrhoea, either of which warrants discontinuation of treatment. For the purpose of the secondary prevention guidance, an unsatisfactory response is defined as occurring when

a woman has another fragility fracture despite adhering fully to treatment for 1 year and there is evidence of a decline in BMD below her pre-treatment baseline.

6. Secondary prevention guidance TA161 replaces NICE technology appraisal guidance 87 issued in January 2005.

About NICE

7. The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.
8. NICE produces guidance in three areas of health:
 - **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
 - **health technologies** – guidance on the use of new and existing medicines, treatments and procedures within the NHS
 - **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.