

Understanding NICE guidance

Information for people who use NHS services

Alendronate, etidronate, risedronate, strontium ranelate and raloxifene for preventing bone fractures in postmenopausal women with osteoporosis who have not had a fracture

NICE 'technology appraisal guidance' advises on when and how drugs and other treatments should be used in the NHS.

This booklet is about when **alendronate, etidronate, risedronate, strontium ranelate** and **raloxifene** should be used in the NHS in England and Wales to prevent bone fractures in postmenopausal women (that is, women who have gone through the menopause). It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence). It is written for women with osteoporosis but it may also be useful for their families or carers or anyone with an interest in the condition.

The guidance covers women who have osteoporosis but who have not had a fracture because of it. Osteoporosis is usually diagnosed by a bone scan called a 'DXA scan', which measures bone density and shows how strong the bones are. The guidance does not cover preventing fractures in women who are on long-term steroids.

This booklet does not describe osteoporosis or the treatments in detail – a member of your healthcare team should discuss these with you. Some sources of further information and support are on the back page.



These may not be the only possible treatments for osteoporosis. Your healthcare team should talk to you about whether these are suitable for you and about other treatment options available.

What has NICE said?

Whether or not a postmenopausal woman with osteoporosis is offered one of these drugs to prevent bone fractures will depend on her age, her bone density and how many risk factors for fracture and indicators of fragile bones she has. The box on pages 4–5 gives further details. Your doctor will be able to explain this to you.

In principle, **alendronate** is recommended as a possible treatment for preventing bone fractures in postmenopausal women who have had osteoporosis diagnosed but have not had a fracture.

If a woman can't take alendronate, **risedronate** and **etidronate** are recommended under certain circumstances as possible alternative treatments to prevent fractures.

If a woman can't take alendronate or either risedronate or etidronate, then **strontium ranelate** is recommended under certain circumstances as a possible alternative treatment to prevent fractures.

Raloxifene is not recommended as a treatment for preventing fractures in postmenopausal women with osteoporosis who have not had a fracture.

The guidance says that women who are 75 or over may not need a bone scan to diagnose their osteoporosis.

Osteoporosis

Some of the materials that make up bone are lost as part of normal ageing. This can lead to osteoporosis, a condition in which bones become fragile and break easily. These fractures are most common in bones of the spine, wrists and hips. Women who have gone through the menopause are at increased risk of osteoporosis because their ovaries no longer produce oestrogen, which protects against bone loss.

Alendronate, etidronate, risedronate, strontium ranelate and raloxifene

Alendronate, etidronate, risedronate, strontium ranelate and **raloxifene** protect against bone fractures by slowing down the loss of materials that make up bone. This makes bones stronger. Strontium ranelate also helps to build new bone.

Alendronate, etidronate and risedronate belong to a group of drugs called bisphosphonates. Some people can't take bisphosphonates because they experience side effects, such as heartburn, or because they have trouble swallowing. Also, a woman might not be able to take certain bisphosphonates because it isn't possible for her to follow the special instructions for taking them – for example, having to remain upright for half an hour after taking the drug, and not eating for a while before and after taking it.

What does this mean for me?

When NICE recommends a treatment, the NHS must ensure it is available to those people it could help, normally within 3 months of the guidance being issued. So, if you are a postmenopausal woman who has been diagnosed with osteoporosis and you have not had a fracture, you should be able to have treatment with alendronate on the NHS if:

- it is recommended as a possible treatment for you in this guidance, and
- your doctor thinks that it is the right treatment for you.

If you are unable to take alendronate, you may be eligible for treatment with etidronate, risedronate or strontium ranelate (see the box on pages 4–5).

Please see www.nice.org.uk/aboutguidance if you appear to be eligible for treatment with one of these drugs but it is not available.

These drugs work best when the woman has adequate levels of calcium and vitamin D. So if you are prescribed one of these drugs, you will also be given supplements of vitamin D and calcium unless your doctor is sure that you don't need these supplements.

The evidence showed that raloxifene did not protect women against hip fractures, and therefore did not work as well as the other drugs in postmenopausal women who have osteoporosis but who have not had a fracture. This means that for the time being it should not be prescribed on the NHS to prevent fractures in these women.

If you are already taking alendronate, etidronate, risedronate, strontium ranelate or raloxifene, you should continue taking it. If the drug is not recommended for you in this guidance, you should be able to carry on taking it until you and your healthcare professionals decide that it is the right time to stop treatment.

More details about the treatments

Which drug you are offered will depend on a combination of your age, bone density, risk factors for fracture and indicators of fragile bones. The information below outlines these combinations and may help you to understand which drug your doctor may offer you.

Note that for women with osteoporosis, the bone scan gives a score for bone density which is a negative number. This means, for example, that a score of -3.5 is lower than a score of -3 .

Risk factors for fracture and indicators of fragile bones are explained at the end of the box.

Alendronate

Alendronate can be offered to postmenopausal women with osteoporosis who have not had a fracture and who are:

- 70 or over, with a risk factor for fracture *or* an indicator of fragile bones, **or**
- between 65 and 69, with a risk factor for fracture, **or**
- under 65, with a risk factor for fracture *and* an indicator of fragile bones.

Risedronate and etidronate

Risedronate or etidronate can be offered to women who can't take alendronate, and who are:

- 75 or over, with bone density of -3 or lower, **or**
- between 70 and 74, with bone density of -3.5 or lower, **or**
- between 70 and 74, with bone density of -3 or lower and one risk factor for fracture, **or**
- 70 or over, with bone density of -2.5 or lower and two risk factors, **or**
- between 65 and 69, with bone density of -3.5 or lower and one risk factor, **or**
- between 65 and 69, with bone density of -3 or lower and two risk factors.

Strontium ranelate

Strontium ranelate can be offered to women who can't take alendronate or either risedronate or etidronate, and who are:

- 75 or over, with bone density of -4 or lower, **or**
- 75 or over, with bone density of -3 or lower and two risk factors for fracture, **or**
- between 70 and 74, with bone density of -4.5 or lower, **or**
- between 70 and 74, with bone density of -4 or lower and one risk factor, **or**
- between 70 and 74, with bone density of -3.5 or lower and two risk factors, **or**
- between 65 and 69, with bone density of -4.5 or lower and one risk factor, **or**
- between 65 and 69, with bone density of -4 or lower and two risk factors.

Risk factors for fracture and indicators of fragile bones

When a woman has osteoporosis, a 'risk factor' is something that means she is more likely to fracture a bone than a woman with osteoporosis who doesn't have the same risk factor. An 'indicator' is a sign that a woman may have fragile bones.

Risk factors for fracture are:

- one or both of the woman's parents had a hip fracture
- drinking 4 or more units of alcohol a day
- rheumatoid arthritis.

Indicators of fragile bones are:

- body mass index (BMI) of less than 22 kg/m²
- ankylosing spondylitis
- Crohn's disease
- not being able to move about for long periods
- early menopause and the woman has not taken hormone replacement therapy.

More information

The organisation below can provide more information and support for people with osteoporosis. Please note that NICE is not responsible for the quality or accuracy of any information or advice provided by this organisation.

- National Osteoporosis Society, 0845 4500230, www.nos.org.uk

NHS Choices (www.nhs.uk) may be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider all the research on the disease or treatment, talk to people affected by it, and consider the costs involved. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This booklet and other versions of the guidance aimed at healthcare professionals are available at www.nice.org.uk/TA160

You can order printed copies of this booklet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1724).

Information on NICE's guidance on treatments for women with osteoporosis who have already had a fracture is available at www.nice.org.uk/TA161 (or contact NICE publications and quote reference N1726).

We encourage NHS and voluntary sector organisations to use text from this booklet in their own information about osteoporosis.