

Issue date: 2008

Audit support

Alendronate, etidronate, risedronate,
raloxifene and strontium ranelate for
the primary prevention of
osteoporotic fragility fractures in
postmenopausal women

NICE technology appraisal guidance 160



Audit support for alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women

Objective of the audit

The objective of this audit is to measure current practice in use of alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women against the recommendations in the technology appraisal. The audit criteria and data collection tool are intended to be used as part of a local audit project, by either using the whole tool or cutting and pasting the relevant parts into a local audit template.

Audit criteria and standards

This document provides audit criteria based on the technology appraisal guidance for use in clinical audit. Users can cut and paste these criteria into their own programmes. The standards given are typically 100% or 0%. If these are not achievable locally, a more appropriate standard should be set based on discussions with local clinicians. However, the standards remain the ultimate objective.

Data collection tool

A tool is provided that can be used or adapted for the data collection part of the clinical audit cycle by the trust, service or practice. Suggestions on where you might find relevant information are included, although this may be different in your organisation.

Patient groups and sample

Postmenopausal women being treated for the primary prevention of fragility fractures using those drugs detailed in the guidance. An appropriate sample should be selected in line with your local clinical audit strategy.

Data sources

The audit criteria may require data to be collected from a range of sources, including policy documents and patient records. Suggestions are indicated on the tools.

Re-audit

Re-auditing is a key part of the audit cycle. If the first data collection and analysis shows room for improvement, the audit should be re-run once changes to the service have had time to make an impact. Depending on the nature of the changes, this could take weeks or months. This process should be continued until the results of the audit meet the standards.

Links with other national priorities

It is suggested that the audit based on this technology appraisal is considered in conjunction with other national priorities such as:

- 'Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women', NICE technology appraisal 161.

Further guidance

Click here for [further guidance](#) and generic templates to support the reporting and monitoring of the audit of NICE guidance in your organisation.

Clinical criteria for alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women

Criterion 1	<p>Percentage of patients offered evidence-based written information about:</p> <ul style="list-style-type: none"> • their illness or condition • the treatment and care they should be offered, including being made aware of the ‘Understanding NICE guidance’ booklet [hyperlink to UNG] • the service providing their treatment and care.
Exceptions	None
Settings	Primary and secondary care
Standard	100%
Definitions	Patients should be offered written information to help them make informed decisions about their healthcare. This should cover the condition, treatments and the health service providing care. Information should be available in formats appropriate to the individual, taking into account language, age, and physical, sensory or learning disabilities.
Criterion 2	<p>Women prescribed alendronate for the primary prevention of osteoporotic fragility fractures must fit into one of the following three groups:</p> <ul style="list-style-type: none"> • women aged 70 years or older who are confirmed to have osteoporosis and have either: <ul style="list-style-type: none"> – an independent clinical risk factor for fracture <i>or</i> – an indicator of low bone mineral density (BMD) ▪ women aged 65–69 years with an independent clinical risk factor for fracture and confirmed osteoporosis ▪ postmenopausal women younger than 65 years who have: <ul style="list-style-type: none"> – an independent clinical risk factor for fracture <i>and</i> – an additional indicator of low BMD <i>and</i> – confirmed osteoporosis.
Exceptions	<p>A – Women who began treatment with alendronate before this guidance was issued but for whom treatment would now not be recommended.</p> <p>B – Women who are on long-term systemic corticosteroid treatment.</p> <p>C – Women aged 75 years or older with two or more independent clinical risk factors for fracture or indicators of low BMD who have not had dual-energy X-ray absorptiometry (DXA) scanning because their clinician considers it to be clinically inappropriate or unfeasible.</p>
Settings	Primary and secondary care
Standard	100%
Definitions	<p>Osteoporosis is defined as a T-score of –2.5 standard deviations (SD) or below on DXA scanning. T-score relates to the measurement of BMD using central (hip and/or spine) DXA scanning, and is expressed as the number of SD from peak BMD.</p> <p>Independent clinical risk factors for fracture are parental history of hip</p>

Clinical criteria for alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women

	fracture, alcohol intake of 4 or more units per day, and rheumatoid arthritis. Indicators of low BMD are low body mass index (defined as less than 22 kg/m ²), medical conditions such as ankylosing spondylitis and Crohn's disease, conditions that result in prolonged immobility, and untreated premature menopause. (Rheumatoid arthritis is also a medical condition indicative of low BMD.)																			
Criterion 3	<p>Women prescribed risedronate or etidronate for primary prevention of osteoporotic fragility fractures should:</p> <ul style="list-style-type: none"> • have a contraindication to or intolerance of alendronate or be unable to comply with the special instructions for its administration, <i>and</i> • have a combination of T-score, age and number of independent clinical risk factors for fracture as indicated in the following table. <p>T-scores (SD) at (or below) which risedronate or etidronate is recommended when alendronate cannot be taken</p> <table border="1"> <thead> <tr> <th rowspan="2">Age (years)</th> <th colspan="3">Number of independent clinical risk factors for fracture</th> </tr> <tr> <th>0</th> <th>1</th> <th>2</th> </tr> </thead> <tbody> <tr> <td>65–69</td> <td>–^a</td> <td>–3.5</td> <td>–3.0</td> </tr> <tr> <td>70–74</td> <td>–3.5</td> <td>–3.0</td> <td>–2.5</td> </tr> <tr> <td>75 or older</td> <td>–3.0</td> <td>–3.0</td> <td>–2.5</td> </tr> </tbody> </table> <p>^a Treatment with risedronate or etidronate is not recommended.</p>	Age (years)	Number of independent clinical risk factors for fracture			0	1	2	65–69	– ^a	–3.5	–3.0	70–74	–3.5	–3.0	–2.5	75 or older	–3.0	–3.0	–2.5
Age (years)	Number of independent clinical risk factors for fracture																			
	0	1	2																	
65–69	– ^a	–3.5	–3.0																	
70–74	–3.5	–3.0	–2.5																	
75 or older	–3.0	–3.0	–2.5																	
Exceptions	<p>A – Women who began treatment with risedronate or etidronate before this guidance was issued but for whom treatment would now not be recommended.</p> <p>B – Women who are on long-term systemic corticosteroid treatment.</p> <p>C – Women aged 75 years or older with two or more independent clinical risk factors for fracture or indicators of low BMD who have not had DXA scanning because their clinician considers it to be clinically inappropriate or unfeasible.</p>																			
Settings	Primary and secondary care																			
Standard	100%																			
Definitions	<p>Independent clinical risk factors for fracture are parental history of hip fracture, alcohol intake of 4 or more units per day, and rheumatoid arthritis.</p> <p>Intolerance of alendronate 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.</p>																			

Clinical criteria for alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women

Criterion 4	<p>Women prescribed strontium ranelate for primary prevention of osteoporotic fragility fractures should:</p> <ul style="list-style-type: none"> • have a contraindication to or intolerance of alendronate and either risedronate or etidronate, or be unable to comply with the special instructions for their administration, <i>and</i> • have a combination of T-score, age and number of independent clinical risk factors for fracture as indicated in the following table: <p>T-scores (SD) at (or below) which strontium ranelate is recommended when alendronate and either risedronate or etidronate cannot be taken</p> <table border="1" data-bbox="507 689 1390 936"> <thead> <tr> <th rowspan="2">Age (years)</th> <th colspan="3">Number of independent clinical risk factors for fracture</th> </tr> <tr> <th>0</th> <th>1</th> <th>2</th> </tr> </thead> <tbody> <tr> <td>65–69</td> <td>–^a</td> <td>–4.5</td> <td>–4.0</td> </tr> <tr> <td>70–74</td> <td>–4.5</td> <td>–4.0</td> <td>–3.5</td> </tr> <tr> <td>75 or older</td> <td>–4.0</td> <td>–4.0</td> <td>–3.0</td> </tr> </tbody> </table> <p>^a Treatment with strontium ranelate is not recommended.</p>	Age (years)	Number of independent clinical risk factors for fracture			0	1	2	65–69	– ^a	–4.5	–4.0	70–74	–4.5	–4.0	–3.5	75 or older	–4.0	–4.0	–3.0
Age (years)	Number of independent clinical risk factors for fracture																			
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65–69	– ^a	–4.5	–4.0																	
70–74	–4.5	–4.0	–3.5																	
75 or older	–4.0	–4.0	–3.0																	
Exceptions	<p>A – Women who began treatment with strontium ranelate before this guidance was issued but for whom treatment would now not be recommended.</p> <p>B – Women who are on long-term systemic corticosteroid treatment.</p>																			
Settings	<p>Primary and secondary care</p>																			
Standard	<p>100%</p>																			
Definitions	<p>Independent clinical risk factors for fracture are parental history of hip fracture, alcohol intake of 4 or more units per day, and rheumatoid arthritis.</p> <p>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.</p>																			
Criterion 5	<p>Postmenopausal women should not be prescribed raloxifene for the primary prevention of osteoporotic fragility fractures.</p>																			
Exceptions	<p>Women who were prescribed raloxifene treatment before this guidance was issued have the option to continue with this treatment until they and their clinicians consider it appropriate to stop.</p>																			
Settings	<p>Primary and secondary care</p>																			
Standard	<p>100%</p>																			
Definitions	<p>None</p>																			

Clinical criteria for alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women

Number of criterion replaced:	Local alternatives to above criteria (to be used where other data addressing the same issue are more readily available)
Exceptions	
Settings	
Standard	
Definitions	

Patient data collection tool for alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women

Complete one form for each patient. For definitions of the standards, please refer to the audit criteria and/or NICE technology appraisal.

Patient identifier:	Sex: M / F	Age:	Ethnicity:
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Crite- rion no.	Data item no.	Criterion	Yes	No	NA/ exceptions	NICE guideline ref.
Person-centred care						
1		Patient offered evidence-based written information about:				Person-centred care
	1.1	<ul style="list-style-type: none"> • their illness or condition 	<input type="checkbox"/>	<input type="checkbox"/>	
	1.2	<ul style="list-style-type: none"> • the treatment and care they should be offered 	<input type="checkbox"/>	<input type="checkbox"/>	
	1.3	<ul style="list-style-type: none"> – including being made aware of the 'Understanding NICE guidance' booklet [hyperlink to UNG] 	<input type="checkbox"/>	<input type="checkbox"/>	
	1.4	<ul style="list-style-type: none"> • the service providing their treatment and care. <p style="text-align: right; font-size: small;">(Data source: patient records)</p>	<input type="checkbox"/>	<input type="checkbox"/>	
Postmenopausal status						
	1.5	Woman considered to be postmenopausal?	<input type="checkbox"/>	<input type="checkbox"/>		1
Alendronate treatment						
2	2.1	Was the woman prescribed alendronate? (If 'No' go to 3)	<input type="checkbox"/>	<input type="checkbox"/>	A B C	1.1
	2.2	<ul style="list-style-type: none"> • Age 	_____ years			
	2.3	<ul style="list-style-type: none"> • T-score 	_____ SD			
	2.3	<ul style="list-style-type: none"> • Independent clinical risk factor for fracture: <ul style="list-style-type: none"> i) parental history of hip fracture ii) alcohol intake ≥4 units/day iii) rheumatoid arthritis 	<input type="checkbox"/>	<input type="checkbox"/>		
	2.4	<ul style="list-style-type: none"> • Indicator of low BMD: <ul style="list-style-type: none"> i) BMI <22 kg/m² ii) Medical conditions: <ul style="list-style-type: none"> a. ankylosing spondylitis b. Crohn's disease c. 'prolonged immobility' conditions d. untreated premature menopause e. other conditions <p style="text-align: right; font-size: small;">state:</p> <p style="text-align: right; font-size: small;">(Data source: patient records)</p>	<input type="checkbox"/>	<input type="checkbox"/>		
				<input type="checkbox"/>		

Patient data collection tool for alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women

Risedronate or etidronate treatment						
3	3.1	Was the woman prescribed: <ul style="list-style-type: none"> • risedronate • etidronate? (If 'No' to both, go to 4)	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	A B C	1.2
	3.2	Were they unable to be treated with alendronate because of: <ul style="list-style-type: none"> • contraindication • intolerance • being unable to comply with special administration instructions? 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
	3.3	<ul style="list-style-type: none"> • Age 	_____ years			
	3.3	<ul style="list-style-type: none"> • T-score 	_____ SD			
	3.4	<ul style="list-style-type: none"> • Independent clinical risk factor for fracture: <ul style="list-style-type: none"> i) parental history of hip fracture ii) alcohol intake \geq4 units/day iii) rheumatoid arthritis (Data source: patient records)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
Strontium ranelate treatment						
4	4.1	Was the woman prescribed strontium ranelate? (If 'No' go to 5)	<input type="checkbox"/>	<input type="checkbox"/>	A B	1.3
	4.2	Were they unable to be treated with alendronate because of: <ul style="list-style-type: none"> • contraindication • intolerance • being unable to comply with special administration instructions? 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
	4.3	Were they unable to be treated with risedronate or etidronate because of: <ul style="list-style-type: none"> • contraindication • intolerance • being unable to comply with special administration instructions? 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
	4.4	<ul style="list-style-type: none"> • Age 	_____ years			
	4.5	<ul style="list-style-type: none"> • T-score 	_____ SD			
	4.6	<ul style="list-style-type: none"> • Independent clinical risk factor for fracture: <ul style="list-style-type: none"> i) parental history of hip fracture ii) alcohol intake \geq4 units/day iii) rheumatoid arthritis (Data source: patient records)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		

Patient data collection tool for alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women

Raloxifene treatment						
5	5.1	Was the woman prescribed raloxifene? If 'Yes':	<input type="checkbox"/>	<input type="checkbox"/>		1.4
	5.2	Was this prescribed before publication of this guidance? If 'Yes':	<input type="checkbox"/>	<input type="checkbox"/>		
	5.3	Was the woman given the option to continue until they and their clinician consider it appropriate to stop? (Data source: patient records)	<input type="checkbox"/>	<input type="checkbox"/>		

Data collection completed