

## Bisphosphonates and Other Drugs Affecting Bone Metabolism – Osteoporosis

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### Summary – Primary Care

Medal rankings provide prescribers with a quick overview on cost-effective prescribing in areas where the formulary product choices have little therapeutic difference.

**Please routinely prescribe the agents offering greatest overall value to the health economy.**

Choice	Cost per 12 months' treatment	Recommended dose	Other considerations	Approval
<b>Alendronic Acid 70mg tabs</b>	<b>£4.92</b>	<b>Once Weekly</b>	C/I - abnormalities of the oesophagus and/or other factors which delay oesophageal emptying such as stricture or achalasia	
<b>Risedronate Sodium 35mg tabs</b>	<b>£6.96</b>	<b>Once Weekly</b> (also licensed for treatment of osteoporosis in men)		
<b>Ibandronic Acid 150mg tabs</b>	<b>£9.96</b>	<b>150mg Once Monthly</b>	C/I - abnormalities of the oesophagus and/or other factors which delay oesophageal emptying such as stricture or achalasia	
<b>Alendronic acid 10mg tabs</b>	<b>£16.56</b>	<b>10mg Once Daily</b> (also licensed for treatment of osteoporosis in men)	C/I - abnormalities of the oesophagus and/or other factors which delay oesophageal emptying such as stricture or achalasia	
<b>Risedronate Sodium 5mg tablets</b>	<b>£226.20</b>	<b>5mg Once Daily</b>		
<b>Fosavance®</b> 70 mg alendronic acid and 70 micrograms (2800 IU) colecalciferol (vitamin D3)	<b>£273.60</b>	<b>One tablet once weekly</b>		

<b>Actonel Combi®</b> Risedronate in combination with calcium and vitamin D	<b>£229.44</b>	<b>One tablet on the first day followed by 1 calcium and colecalciferol sachet daily for 6 days</b>		
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### Other options:

Raloxifene 60mg tablets (Evista®), £221.78 per year, is also documented as an option for secondary prevention of osteoporotic fragility fractures in postmenopausal women, as per [NICE TA161](#), where other therapies are contra-indicated, cannot be tolerated, or if there is a lack of response.

The CSM has advised that HRT should **not** be considered first-line therapy for long-term prevention of osteoporosis in women over 50 years of age. HRT is of most benefit for the prophylaxis of postmenopausal osteoporosis if started early in menopause and continued for up to 5 years, but bone loss resumes (possibly at an accelerated rate) on stopping HRT. It is recognised that newer treatments are now available since the 2008 NICE TA was published – [see secondary care section](#).

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## Rationale

The aim of this medal ranking is primarily to reduce costs associated with bisphosphonate prescribing in patients with osteoporosis. It is also recognised bisphosphonates are not appropriate for all patients and therefore a brief summary of other options is provided – [see secondary care section](#).

Bisphosphonates are adsorbed onto hydroxyapatite crystals in bone, slowing both their rate of growth and dissolution, and therefore reducing the rate of bone turnover. Bisphosphonates have an important role in the prophylaxis and treatment of osteoporosis and corticosteroid-induced osteoporosis; **alendronic acid** or **risedronate sodium** are considered the drugs of choice for these conditions.

Bisphosphonates should be prescribed in conjunction with adequate calcium and vitamin D, a separate document covers the prescribing of [calcium and vitamin D products](#) and [standalone vitamin D supplements](#).

When prescribing bisphosphonates consider:

- Bisphosphonate regimen - ALL bisphosphonates should be taken in line with the BNF counseling advice - *'Swallow tablets whole with full glass of water; on rising, take on an empty stomach at least 30 minutes before first food or drink of the day additionally with risedronate, if taking at any other time of the day, avoid food and drink for at least 2 hours before or after risedronate (particularly avoid calcium-containing products e.g. milk; also avoid iron and mineral supplements and antacids); stand or sit upright for at least 30 minutes; do not take tablets at bedtime or before rising.* It is recognised that some patients may find it easier to adhere to this advice if taking the medication on a weekly basis, yet others may prefer a monthly tablet or a

daily tablet. The dosing regimen should be discussed with the patient. Patients are advised to omit any calcium and D supplement dose on the morning they take the bisphosphonate.

Please see our information leaflet on:

[‘How to take your bisphosphonate tablets \(alendronic acid or risedronate\) for osteoporosis’](#)

- Contraindications/Cautions – Alendronic acid and ibandronic acid should not be given to patients with abnormalities of the oesophagus and/or other factors which delay oesophageal emptying such as stricture or achalasia. Risedronate should be used with caution in such patients
- Bisphosphonates: use and safety – [MHRA 2014](#)
- Atypical femoral fractures have been reported rarely with all bisphosphonate treatment, mainly in patients receiving long-term treatment for osteoporosis – [MHRA 2011](#)
- Bisphosphonates: osteonecrosis of the jaw - [MHRA 2009](#)
- Bisphosphonates: osteonecrosis of the external auditory canal - [MHRA 2015](#)
- Intolerance - Intolerance 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. Patients may be intolerant to one bisphosphonate but not another.

For patients where a bisphosphonate is not suitable, either due to contra-indication, multiple intolerance or adherence issues there are other options available via referral to secondary care. These options are detailed below in the [secondary care section](#) of this document.

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### Illustrative cost saving

If the silver and bronze medal items are replaced by the gold medal alendronic acid (assuming this choice is clinically suitable), in the last financial year the CCG cost saving would have been £2600.

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### Actions

Review prescribing in line with the medal ranking.

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### Other Options - via Secondary Care Only

These drugs are not listed in order of preference; the choice of product is made by secondary care specialists and is decided on an individual patient by patient basis. Patients with fractures are high risk patients and therefore preventative treatment is paramount. For patients that cannot take a bisphosphonate product, either due to contra-indication, intolerance or adherence issues, please refer [to pathway](#)

Name	Dose	Other information
Zoledronic acid 50 micrograms/mL (Aclasta®) Intravenous infusion	5 mg once a year via IV infusion	<b>Red</b> Treatment of postmenopausal osteoporosis and osteoporosis in men (including corticosteroid-induced osteoporosis), by intravenous infusion. See <a href="#">Y&amp;S Formulary</a>
Denosumab 60mg/ml (Prolia®)	60mg via injection every 6 months	<b>Amber Shared Care Guidance</b> Approved for the treatment of post-menopausal osteoporosis in women at increased risk of fractures in line with NICE TA204. <b>MHRA Drug Safety Alert :</b> <a href="#">Denosumab (Xgeva ▼) for giant cell tumour of bone: risk of clinically significant hypercalcaemia following discontinuation</a> <a href="#">Denosumab (Prolia, Xgeva ▼): reports of osteonecrosis of the external auditory canal</a> Denosumab: <a href="#">minimising the risk of osteonecrosis of the jaw; monitoring for hypocalcaemia—updated recommendations; intravenous bisphosphonates: osteonecrosis of the jaw—further measures to minimise risk</a> <a href="#">Denosumab : atypical femoral fracture</a>  <a href="#">See Y&amp;S Formulary</a>
Ibandronic acid 1mg/ml (Bonviva®) injection	3mg (1 pre-filled syringe) IV injection 3 monthly	<b>Red – hospital only</b> <a href="#">See Y&amp;S Formulary</a>
Teriparatide 250mcg/ml (Forsteo®) injection	By subcutaneous injection, 20 micrograms daily; max. duration of treatment 24 months (course not to be repeated)	<b>Red – hospital only.</b> For use in line with <a href="#">NICE TA161</a> <a href="#">See Y&amp;S Formulary</a>

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### References

- [NICE BNF Online 2018](#)
- [Drug Tariff Online April 2018](#)
- Do gastric adverse events influence the choice of bisphosphonate for the treatment of osteoporosis? Specialist Pharmacy Service <https://www.sps.nhs.uk/articles/do-gastric-adverse-events-influence-the-choice-of-bisphosphonate-for-the-treatment-of-osteoporosis-2/>

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