

ORAL BISPHOSPHONATES for treating osteoporosis

The Pan Mersey Area Prescribing Committee recommends the prescribing of ORAL BISPHOSPHONATES (alendronic acid, ibandronic acid and risedronate sodium) for treating osteoporosis in accordance with NICE TA464

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NICE [TA464](#) (last updated 08 July 2019) partially updates NICE [TA160](#) and NICE [TA161](#). It recommends the oral bisphosphonates; alendronic acid, ibandronic acid and risedronate sodium as options for treating osteoporosis in adults:

- > who are eligible for risk assessment as defined in NICE Clinical Guideline [CG146](#) on osteoporosis (recommendations 1.1 and 1.2) and the NICE Quality Standard [QS149](#) on osteoporosis, **and**
- > who have been assessed as being at higher risk of osteoporotic fragility fracture using the methods recommended in NICE CG146 (recommendations 1.3 to 1.12) and NICE QS149 on osteoporosis, **and**
- > when bisphosphonate treatment is appropriate, taking into account their risk of fracture, their risk of adverse effects from bisphosphonates, and their clinical circumstances and preferences.

The choice of treatment should be made on an individual basis after discussion between the responsible clinician and the patient, or their carers, about the advantages and disadvantages of the treatments available. If generic products are available, start treatment with the least expensive formulation, taking into account administration costs, the dose needed, and the cost per dose.^[1]

Where patients are unable to take oral bisphosphonates, refer to NICE [TA464](#) and [Pan Mersey APC Formulary](#) choices.

NICE [CG146](#) (last updated February 2017) recommends to consider assessment of fracture risk:

- > In all women aged 65 years and over and all men aged 75 years and over
- > In women aged under 65 years and men aged under 75 years in the presence of risk factors, for example:
 - previous fragility fracture
 - current use or frequent recent use of oral or systemic glucocorticoids
 - history of falls
 - family history of hip fracture
 - other causes of secondary osteoporosis
 - low body mass index (BMI) (less than 18.5 kg/m²)
 - smoking
 - alcohol intake of more than 14 units per week for men and women^[2]

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

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Do not routinely assess fracture risk in people aged under 50 years unless they have major risk factors (for example, current or frequent recent use of oral or systemic glucocorticoids, untreated premature menopause or previous fragility fracture), because they are unlikely to be at high risk.^[2]

NICE [QS149](#) (published April 2017) recommends that:

- > Adults who have had a fragility fracture or use systemic glucocorticoids or have a history of falls have an assessment of their fracture risk.
- > Adults at high risk of fragility fracture are offered drug treatment to reduce fracture risk.
- > Adults prescribed drug treatment to reduce fracture risk are asked about adverse effects and adherence to treatment at each medication review.
- > Adults having long-term bisphosphonate therapy have a review of the need for continuing treatment.^[3]

Duration of treatment

Concerns over rare adverse effects of long-term bisphosphonate therapy, particularly osteonecrosis of the jaw and atypical femoral fractures, have raised questions about the optimal duration of therapy. As bisphosphonates are retained in bone for varying periods of time, beneficial effects may persist for some time after cessation of treatment. This has led to the suggestion that some patients may benefit from a period off treatment, in which treatment is stopped after some years and the need for continued therapy is subsequently reassessed. This is known as a 'drug holiday'. Treatment review in patients taking bisphosphonates is therefore important. As pivotal clinical trials have mostly been limited to a duration of three years, recommendations for longer term use and for drug holidays are based on limited evidence from extension studies in postmenopausal women.^[4]

The National Osteoporosis Guideline Group (NOGG) 2017 [Clinical guideline for the prevention and treatment of osteoporosis](#) (last updated July 2018) advises that for postmenopausal women, treatment should be reassessed after 3 years of zoledronic acid therapy and 5 years of oral bisphosphonate treatment. Continuation of bisphosphonate treatment beyond 3-5 years can generally be recommended in the following situations:

- > Age ≥ 75 years.
- > Previous history of hip or vertebral fracture.
- > Occurrence of one or more low trauma fractures during treatment, after exclusion of poor adherence to treatment (for example, less than 80% of treatment has been taken) and after causes of secondary osteoporosis have been excluded.
- > Current treatment with oral glucocorticoids ≥ 7.5 mg prednisolone/day or equivalent.^[4]

If treatment is discontinued, fracture risk should be reassessed after a new fracture, regardless of when this occurs.

If no new fracture occurs, assessment of fracture risk should be performed again after 18 months to 3 years. There is no evidence to guide decisions beyond 10 years of treatment and management options in such patients should be considered on an individual basis. There is currently no evidence on which to base recommendations for men.^[4]

Safety

- > Please refer to the Summary of Product Characteristics (SPC) for each individual drug for full safety information.
- > Patients should be advised to report any thigh, hip, or groin pain during bisphosphonate treatment. Any patient who presents with such symptoms should be evaluated for an incomplete femur fracture.^[5]
- > All patients with cancer should have a dental check-up before bisphosphonate treatment. All other patients should have a dental examination only if they have poor dental status. During bisphosphonate treatment, patients should maintain good oral hygiene, receive routine dental check-ups, and report any oral symptoms such as dental mobility, pain, or swelling.^[6]

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References

1. National Institute for Health and Care Excellence. Bisphosphonates for treating osteoporosis. NICE Technology Appraisal 464; 08 July 2019. Accessed 15 October 2019 at: <https://www.nice.org.uk/guidance/ta464>
2. National Institute for Health and Care Excellence. Osteoporosis: assessing the risk of fragility fracture. NICE Clinical Guideline 146; February 2017. Accessed 04 July 2019 at: <https://www.nice.org.uk/guidance/cg146>
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4. National Osteoporosis Guideline Group. NOGG 2017: Clinical guideline for the prevention and treatment of osteoporosis; July 2018. Accessed 04 July 2019 at: <https://www.sheffield.ac.uk/NOGG/NOGG%20Guideline%202017.pdf>
5. Medicines and Healthcare products Regulatory Agency. Drug Safety Update, Bisphosphonates: atypical femoral fractures; 11 December 2014. Accessed 03 October 2019 at: <https://www.gov.uk/drug-safety-update/bisphosphonates-atypical-femoral-fractures>
6. Medicines and Healthcare products Regulatory Agency. Drug Safety Update, Bisphosphonates: osteonecrosis of the jaw; 11 December 2014. Accessed 03 October 2019 at: <https://www.gov.uk/drug-safety-update/bisphosphonates-osteonecrosis-of-the-jaw>