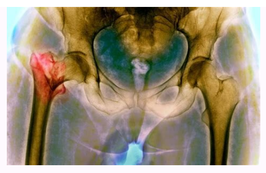
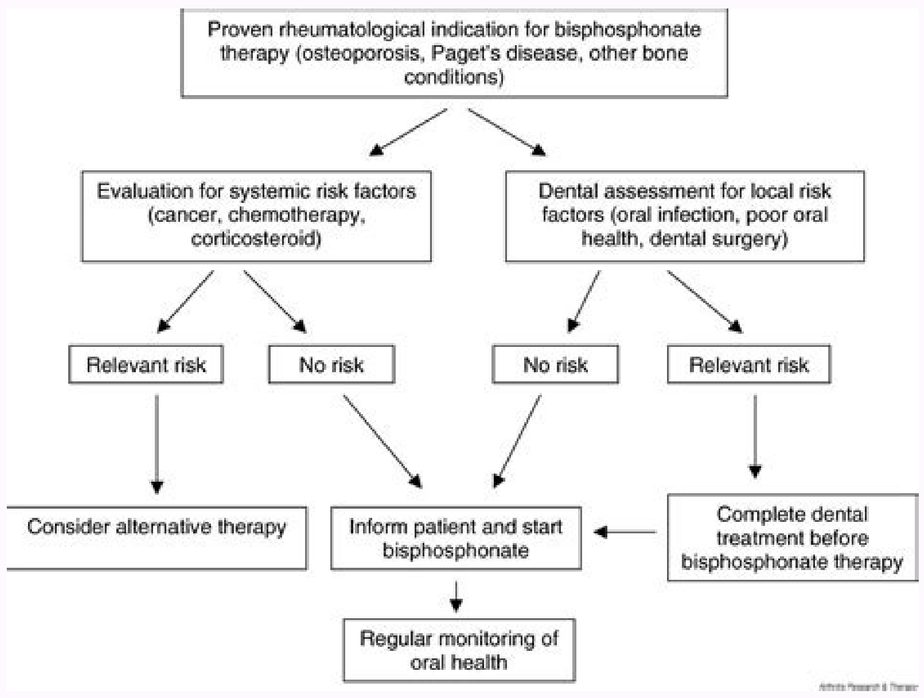
# Bisphosphonate treatment nice guidelines



NICE National Institute for Health and Care Excellence




## Table 5. Overview of FDA-Approved Medications for Osteoporosis

| Drug (Brand) | Dosing | Route | Adverse Effects |
|---|---|---|---|
| **Bisphosphonates** | | | |
| Alendronate (Fosamax) | Treatment: 10 mg once daily or 70 mg once weekly<br>Prevention: 5 mg once daily or 35 mg once weekly | Oral | Dyspepsia, abdominal pain, musculoskeletal pain |
| Ibandronate (Boniva) | Oral: 2.5 mg once daily or 150 mg once a month<br>IV: 3 mg every 3 months | Oral, IV | Dyspepsia, back pain, musculoskeletal pain, headache, abdominal pain |
| Risedronate (Actonel, Atelvia) | IR: 5 mg once daily or 35 mg once weekly or 150 mg once a month<br>DR: 35 mg once weekly | Oral | Rash, abdominal pain, dyspepsia, diarrhea, arthralgia |
| Zoledronic acid (Reclast) | 5 mg once a year | IV | Acute reaction (flulike symptoms, fever, myalgia) may occur within 3 days of infusion; hypotension, fatigue, eye inflammation, nausea, vomiting, abdominal pain |
| **Calcitonin** | | | |
| Calcitonin (Fortical) | 200 IU in 1 nostril daily alternating each day | Intranasal | Rhinitis, nasal irritation, dizziness, nasal dryness |
| Calcitonin (Miacalcin) | 100 IU every other day<br>200 IU in 1 nostril daily alternating each day | SC, IM<br>Intranasal | Injection site reactions, nausea, vomiting, abdominal cramping, flushing |
| **Selective Estrogen Receptor Modulator** | | | |
| Raloxifene (Evista) | 60 mg once daily | Oral | VTE, arthralgia, leg cramps, flu syndrome, peripheral edema, hot flashes |
| **Parathyroid Hormone Analogue** | | | |
| Teriparatide (Forteo) | 20 mcg once daily | SC | Transient hypercalcemia, nausea, rhinitis, arthralgia, pain |
| **Monoclonal Antibody** | | | |
| Denosumab (Prolia) | 60 mg every 6 months | SC | Dermatitis, rash, mild bone/muscle pain, UTIs |

*DR: delayed-release; IM: intramuscular; IR: immediate-release; SC: subcutaneous; UTI: urinary tract infection; VTE: venous thromboembolism.*
*Source: Reference 7.*

| Fracture risk | Assessment | Recommendation/comment |
|---|---|---|
| High (> 20% 10-year risk of fracture),<br>Previous fragility fracture and FN still<br>T-score ≤ −2.5 | NA | Drug holiday not justified,<br>Continue bisphosphonate therapy or switch to another proven drug such as teriparatide or denosumab |
| Moderate (1% - 20% 10-year risk of fracture),<br>FN now (T-score > −2.5), and no previous history of fragility fracture | • Assess clinical risk factors for fracture<br>• Assess FN BMD<br>• Request lateral spine X-ray scan to investigate for any subclinical vertebral fractures | • May be candidate for drug holiday<br>• If vertebral fractures are found, stratify patient as high risk and continue bisphosphonate therapy<br>• If there is no previous history of fragility fracture, a drug holiday can be considered if FN BMD T-score is > −2.5 and there are no other important clinical risk factors<br>Restart when indications for therapy are met |
| Low (<10% 10-year risk of fracture),<br>Did not meet current treatment criteria at the time of treatment initiation | • No important clinical risk factors for fracture | At low future fracture risk, should be withdrawn from therapy<br>• Monitor at extended intervals (3 - 5 years) |

BMD—bone mineral density; FN—femoral neck; NA–not applicable.

15 Nov The following information is taken from the NOS. Leading osteoporosis experts have warned GPs and healthcare professionals to exercise caution over recently issued guidance about the use of bisphosphonates. The new guidance, published by NICE during the summer, incorporates both fracture risk assessment tools and the availability of low-cost generic forms of bisphosphonates and concludes these drugs are cost-effective at very low fracture risk thresholds. The appraisal recommends treatment with oral bisphosphonates for people with a probability of major osteoporotic fracture (eg, hip, spine, wrist, or humerus) that exceeds 1%  over 10 years and treatment with intravenous bisphosphonates for those with a probability of more than 10%. At the time, NICE's Professor Carole Longson MBE said the guidance would "provide clarity for health professionals about when to start treatment with bisphosphonates and  provide people who have osteoporosis with access to the most cost-effective treatments to prevent them getting a fracture." But, in a letter published in leading health journal the Lancet, clinicians including Nicholas Harvey, Juliet Compston, John Kanis and Eugene McCloskey warned that "the strict application of cost-effectiveness thresholds for inexpensive drugs might lead to counterintuitive and potentially harmful guidance." "Unthinking assimilation of the NICE multiple technology appraisal risks a generation of older individuals taking a bisphosphonate regardless of the individual benefit-to-risk ratio and an increased burden of rare long-term side-effects across the population. Given recent debates about the role of pharmaceutical interventions in the prevention of several chronic noncommunicable diseases, this would be an unexpected and unwelcome consequence of national guidance," the letter concludes. The National Osteoporosis Society's Clinical Director Fizz Thompson said the letter highlighted an important issue. The National Osteoporosis Society works hard to ensure people affected by osteoporosis have access to a range of safe and effective treatments and that the benefits of those treatments outweigh the risks. It will be important that prescribing clinicians understand the concerns expressed in this letter and use existing expert guidance to help guide decision making so that these drugs are used appropriately. The National Osteoporosis Guideline Group (NOGG), established in 2007, is a multidisciplinary group that includes patient representation and professionals involved in the care of people with osteoporosis. NOGG provides a clinical guideline that reviews the assessment and diagnosis of osteoporosis, the therapeutic interventions available and the approaches for the prevention of fragility fractures, in postmenopausal women, and in men aged 50 years or older. In October 2021 NICE reaccredited the process used by the National Osteoporosis Guideline Group to produce this clinical guideline for the prevention and treatment of osteoporosis. The NOGG guideline is intended for all healthcare professionals involved in the prevention and treatment of osteoporosis and fragility fractures. This includes primary care practitioners, allied health professionals and relevant specialists in secondary care including rheumatologists, gerontologists, gynaecologists, endocrinologists, clinical biochemists and orthopaedic surgeons. The guideline includes recommendations for training in osteoporosis care. The guideline is supported by a series of Frequently Asked Questions (FAQs) Access FAQs 1.1 Oral bisphosphonates (alendronic acid, ibandronic acid and risedronate sodium) and intravenous bisphosphonates (ibandronic acid and zoledronic acid) are recommended, within their marketing authorisations, as options for treating osteoporosis in adults: who are eligible for risk assessment as defined in NICE's guideline on osteoporosis (recommendations 1.1 and 1.2) and NICE's quality standard on osteoporosis and who have been assessed as being at higher risk of osteoporotic fragility fracture using the methods recommended in NICE's guideline on osteoporosis (recommendations 1.3 to 1.12) and NICE's quality standard 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. 1.2 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. 1.3 These recommendations are not intended to affect treatment with alendronic acid, ibandronic acid, risedronate sodium and zoledronic acid that was started in the NHS before this guidance was published. Adults having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop. Why the committee made these recommendations Alendronic acid, ibandronic acid, risedronate sodium and zoledronic acid are bisphosphonates, licensed for treating osteoporosis. Currently clinicians offer bisphosphonates to people with osteoporosis who are eligible for risk assessment and who have a high fracture risk. To simplify the criteria for treatment and bring the guidance into line with NICE's guideline on osteoporosis, the evidence on bisphosphonates has been reviewed. A new network meta-analysis confirms that bisphosphonates are more effective at reducing the risk of fracture than placebo. Risk assessment tools are used in clinical practice (FRAX and QFracture), in line with NICE's guideline on osteoporosis. These tools measure risk differently and can give different levels of risk in the same person. Oral and intravenous bisphosphonates are recommended because new analyses show they are cost effective for people who have been assessed as being at higher risk of osteoporotic fragility fracture using the methods recommended in NICE's guideline on osteoporosis and NICE's quality standard on osteoporosis. The recent National Institute for Health and Care Excellence (NICE) updated multiple technology appraisal on bisphosphonate use in osteoporosis1National Institute for Health and Care ExcellenceBisphosphonates for treating osteoporosis. demonstrates how, for a common disorder, the strict application of cost-effectiveness thresholds for inexpensive drugs might lead to counterintuitive and potentially harmful guidance. The multiple technology appraisal incorporates the development of fracture risk calculators based on individualised clinical risk factors, such as FRAX and QFracture (recommended by NICE for the assessment of fracture risk in some sections of the population2National Institute for Health and Care ExcellenceOsteoporosis: fragility fracture risk. Short clinical guideline—evidence and recommendation.), and the availability of low-cost generic forms of oral and intravenous bisphosphonates. In the NICE analysis, the development of these bisphosphonates has led to cost-effectiveness at very low-risk thresholds. For individuals who qualify for osteoporosis assessment based on NICE Clinical Guideline CG146,2National Institute for Health and Care ExcellenceOsteoporosis: fragility fracture risk. Short clinical guideline—evidence and recommendation. the appraisal recommends treatment with oral bisphosphonates for people with a probability of major osteoporotic fracture (eg, hip, spine, wrist, or humerus) that exceeds 1% over 10 years and treatment with intravenous bisphosphonates for those with a probability of more than 10%. These health–economic-derived thresholds create a real danger of excessive bisphosphonate prescription in the general population, with treatment of substantial numbers of people who are at very low risk of fracture; for example, every person eligible for assessment under CG146, including women aged 65 years or older and men aged 75 years or older, would be recommended treatment if the multiple technology appraisal recommendations were interpreted as intervention thresholds.3Kanis JA McCloskey EV Johansson H Strom O Borgstrom F Oden A Case finding for the management of osteoporosis with FRAX—assessment and intervention thresholds for the UK.Crossref PubMed Scopus (472) Google Scholar Additionally, very rare, but serious, side-effects of bisphosphonate treatment (eg, atypical femur fracture and osteonecrosis of the jaw) could be observed far more commonly than at present.4Adler RA El-Hajj Fuleihan G Bauer DC et al.Managing osteoporosis in patients on long-term bisphosphonate treatment: report of a Task Force of the American Society for Bone and Mineral Research.Crossref PubMed Scopus (378) Google Scholar Furthermore, the benefit-to-risk ratio for individuals at low risk would be adversely affected in contrast to the positive benefit-to-risk ratio associated with intervention at more clinically appropriate treatment thresholds.4Adler RA El-Hajj Fuleihan G Bauer DC et al.Managing osteoporosis in patients on long-term bisphosphonate treatment: report of a Task Force of the American Society for Bone and Mineral Research.Crossref PubMed Scopus (378) Google Scholar,  Although the NICE document1National Institute for Health and Care ExcellenceBisphosphonates for treating osteoporosis. makes reference to the approach to assessment and intervention thresholds established by the UK National Osteoporosis Guideline Group (NOGG; recently NICE-accredited), this appears beyond the recommendations and incorrectly states that the NOGG thresholds have not been shown to be cost-effective. Indeed, the intervention thresholds of NOGG are higher at all ages than those deemed cost-effective in the current multiple technology appraisal.1National Institute for Health and Care ExcellenceBisphosphonates for treating osteoporosis.,  Although the derivation of treatment thresholds is necessarily arbitrary, NOGG developed its guideline on the basis of clinical appropriateness, setting the threshold at the age-specific probability of fracture equivalent to an individual having already sustained a fracture. Thus, economic thresholds were not used to set intervention thresholds but, more appropriately, to validate the use of clinically driven intervention thresholds. This approach, which avoids inappropriate over-treatment of older individuals and under-treatment of younger individuals, has been shown to be cost-effective3Kanis JA McCloskey EV Johansson H Strom O Borgstrom F Oden A Case finding for the management of osteoporosis with FRAX—assessment and intervention thresholds for the UK.Crossref PubMed Scopus (472) Google Scholar and has been adopted in many countries.6Kanis JA Harvey NC Cooper C Johansson H Oden A McCloskey EV A systematic review of intervention thresholds based on FRAX: a report prepared for the National Osteoporosis Guideline Group and the International Osteoporosis Foundation.Crossref PubMed Scopus (233) Google ScholarUnthinking assimilation of the NICE multiple technology appraisal risks a generation of older individuals taking a bisphosphonate regardless of the individual benefit-to-risk ratio and an increased burden of rare long-term side-effects across the population. Given recent debates about the role of pharmaceutical interventions in the prevention of several chronic non-communicable diseases, this would be an unexpected and unwelcome consequence of national guidance.NCH has received consultancy fees, lecture fees, honoraria, and grant funding from Alliance for Better Bone Health, Amgen, MSD, Eli Lilly, Servier, Shire, Consilient Healthcare, and Internis Pharma, and is a member of the (NOGG) Expert Advisory Group. EM has received consultancy fees, lecture fees, grant funding, and honoraria from ActiveSignal, Amgen, Consilient Healthcare, Gilead, GlaxoSmithKline, Internis, Lilly, Merck, Radius Pharmaceuticals, Roche, Synexus, UCB, and I3 Innovus, and is a member of the NOGG Expert Advisory Group. JAK reports grants from Amgen, Lilly, and Radius Health, and consulting fees from Meda; he is a member of NOGG and the architect of FRAX but has no financial interest. JC has received advisory and speaking fees from Gilead, speaking fees from Amgen, and is Chairman of NOGG. CC has received consultancy fees, lecture fees, honoraria, and grant funding from Amgen, GlaxoSmithKline, Alliance for Better Bone Health, MSD, Eli Lilly, Pfizer, Novartis, Servier, Medtronic, and Roche, and is a member of the NOGG Expert Advisory Group.Published: 18 November 2017DOI: 17)32850-7© 2017 Elsevier Ltd. All rights reserved.Access this article on ScienceDirect

Bisphosphonate treatment can stop some types of cancer from spreading into the bone for some people. Studies have also shown that bisphosphonates can help some people with breast cancer and myeloma to live longer. ... (NICE), July 2017. ... ESMO Clinical Practice Guidelines. R Coleman and others, 2014. Annals of Oncology, 2014. Volume 25 ... Aug 31, 2016 · The following is the treatment protocol I use (based on the Bennell study) for clients with compression fractures. Once your muscles have started adapting to the change in height caused by the spinal compression fracture and the compression fracture has had time to heal (usually 8 to 12 weeks after the episode of increased pain) you should ... Bisphosphonate treatment should be reviewed after 5 years of treatment with alendronic acid, risedronate sodium or ibandronic acid, and after 3 years of treatment with zoledronic acid. Based on fracture-risk assessment, continuation beyond this period can generally be recommended for patients who are over 75 years of age, have a history of ... Jul 18, 2018 · Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, ... 1.9.3 Discuss the benefits and risks of bisphosphonate treatment with women, particularly the risk of osteonecrosis of the jaw, ... The National Osteoporosis Guideline Group (NOGG), established in 2007, is a multidisciplinary group that includes patient representation and professionals involved in the care of people with osteoporosis. NOGG provides a clinical guideline that reviews the assessment and diagnosis of osteoporosis, the therapeutic interventions available and the approaches for the prevention of ... Apr 30, 2021 · If this side-effect occurs, it tends to happen within a few weeks of starting treatment and is more likely with higher doses. Some people even become confused, and irritable; they may develop delusion, and suicidal thoughts. These mental health effects can also occur when steroid treatment is being withdrawn. Nov 12, 2021 · NICE. Falls in older people: assessing risk and prevention. Clinical guideline [CG161]. Published in 2013. Available from: Banu J. Causes, consequences, and treatment of osteoporosis in men. Published in 2013. Available from: NICE. Osteoporosis: assessing the risk of fragility fracture. Clinical guideline [CG146]. Published in 2012. Aug 31, 2016 · The following is the treatment protocol I use

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That’s because all hormones can be marketed as “natural” or “plant-based,” and many pharmaceutical companies are capitalizing on women’s quest for ... 4.5 Drugs used in the treatment of obesity. 4.5.1 Anti-obesity drugs acting on the gastro-intestinal tract; 4.6 Drugs used in nausea and vertigo. 4.6.1 Drugs for the short-term treatment of nausea and vomiting. 4.6.1.1 Motion sickness; 4.6.2 Vertigo; 4.7 Analgesics. 4.7.1 General management of acute pain. 4.7.1.1 Non-opioid & compound analgesics 4.5 Drugs used in the treatment of obesity. 4.5.1 Anti-obesity drugs acting on the gastro-intestinal tract; 4.6 Drugs used in nausea and vertigo. 4.6.1 Drugs for the short-term treatment of nausea and vomiting. 4.6.1.1 Motion sickness; 4.6.2 Vertigo; 4.7 Analgesics. 4.7.1 General management of acute pain. 4.7.1.1 Non-opioid & compound analgesics On this page you will find our RED, AMBER, GREEN and DNP/GREY lists for adults (scroll down to see the list). Please check the paediatric RAG list for those drugs/indications which are specific to use in children only. RAG list entries may be subject to a lag period to allow for implementation by Trusts/CCGs. Please check with your individual Trust or CCG. If an indication is not stated then ... Nov 12, 2021 · NICE. Falls in older people: assessing risk and prevention. Clinical guideline [CG161]. Published in 2013. Available from: Banu J. Causes, consequences, and treatment of osteoporosis in men. Published in 2013. Available from: NICE. Osteoporosis: assessing the risk of fragility fracture. Clinical guideline [CG146]. Published in 2012. An audit of compliance with the British Society for Haematology (BSH) guidelines for the diagnosis and treatment of cobalamin and folate disorders August 2020 An audit of compliance with the British Society for Haematology (BSH) guidelines on the management of drug-induced immune and secondary autoimmune haemolytic anaemia Feb 23, 2009 · 1.3.12 For patients who are receiving treatment with trastuzumab for advanced breast cancer, discontinue treatment with trastuzumab at the time of disease progression outside the central nervous system. Do not discontinue trastuzumab if disease progression is within the central nervous system alone. (Recommendations on the use of trastuzumab are covered by … On this page you will find our RED, AMBER, GREEN and DNP/GREY lists for adults (scroll down to see the list). Please check the paediatric RAG list for those drugs/indications which are specific to use in children only. 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