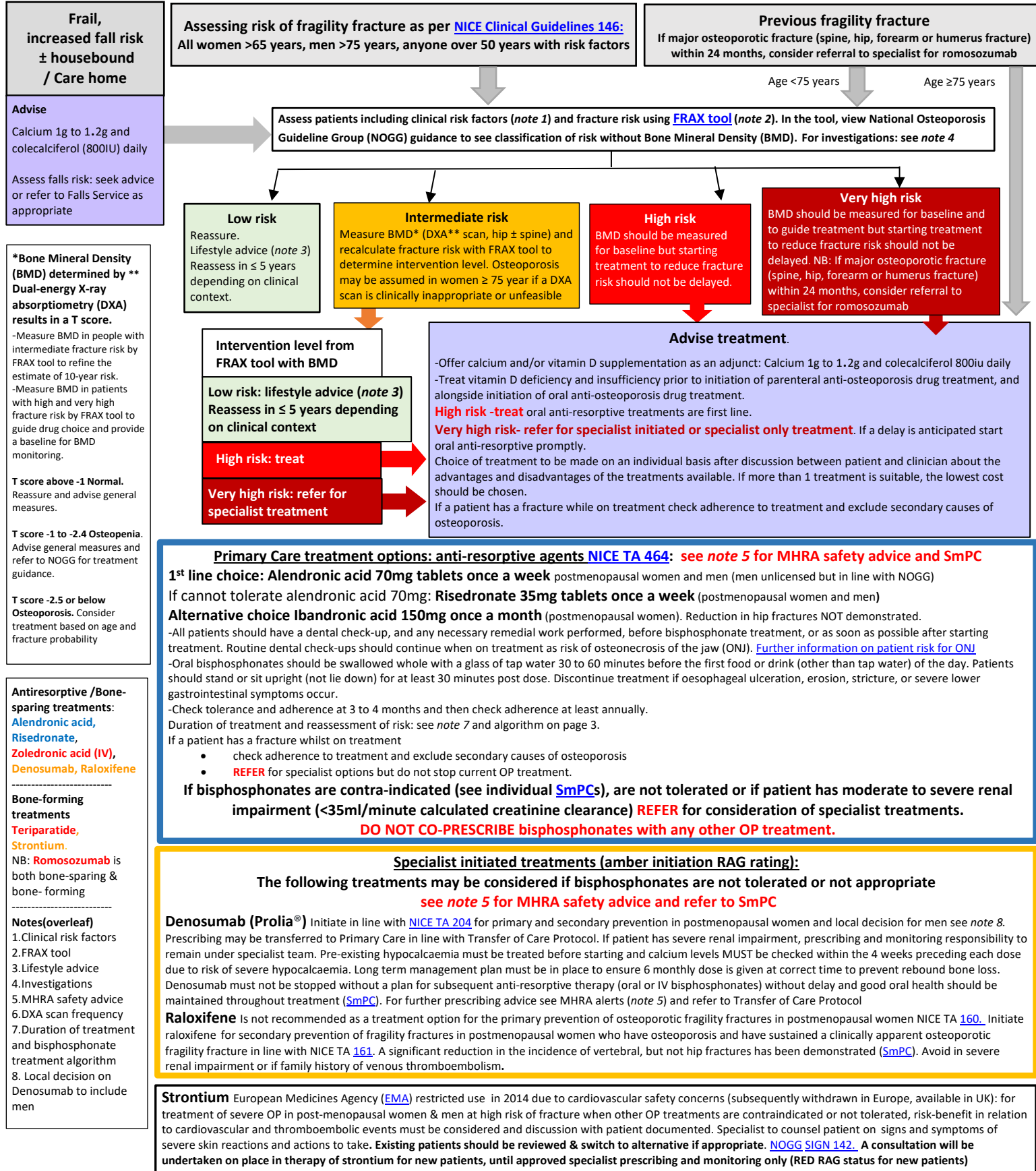


Prescribing guidelines for women and men over 50 years with or at risk of osteoporosis (OP)



Hospital-only treatments (red RAG rating): see note 5 for MHRA safety advice and refer to SmPC.

1st line bisphosphonate: IV Zoledronic acid [NICE TA 464](#) (postmenopausal women & men) see [MHRA 'Adverse effect on renal function'](#)

Alternative bisphosphonate: IV Ibandronic acid [NICE TA 464](#) (postmenopausal women). Reduction in hip fractures NOT demonstrated

Teriparatide: Initiate in line with [NICE TA 161](#) for secondary prevention of fragility fractures in postmenopausal women who have osteoporosis and have sustained a clinically apparent osteoporotic fragility fracture. For additional criteria detail see [TA 161](#) Lifetime treatment duration must not exceed 24 months. Once treatment stopped, start anti-resorptive treatment (oral or IV bisphosphonate or denosumab) without delay. Teriparatide is contraindicated in severe renal impairment and hypercalcaemia. Teriparatide for the secondary prevention of osteoporotic fragility fractures in men is recommended in line with NHSE Clinical Commissioning Policy Statement: [Teriparatide for Osteoporosis in Men \(adults\)](#)

Romosozumab: Initiate in line with [NICE TA 791](#). Postmenopausal women who are at high risk of fracture and only if they have had a major osteoporotic fracture (spine, hip, forearm or humerus fracture) within 24 months (so are at imminent risk of another fracture). Usual treatment length 12 months, lifetime treatment must not exceed this. Once treatment complete start antiresorptive treatment (oral or IV bisphosphonate or denosumab) without delay. Specialist to counsel patient and advise primary care to add note to patient record stating: **If patient has a heart attack or stroke whilst on romosozumab treatment to inform the specialist.**

***Bone Mineral Density (BMD) determined by ** Dual-energy X-ray absorptiometry (DXA) results in a T score.**

- Measure BMD in people with intermediate fracture risk by FRAX tool to refine the estimate of 10-year risk.
- Measure BMD in patients with high and very high fracture risk by FRAX tool to guide drug choice and provide a baseline for BMD monitoring.

T score above -1 Normal.
Reassure and advise general measures.

T score -1 to -2.4 Osteopenia.
Advise general measures and refer to NOGG for treatment guidance.

T score -2.5 or below Osteoporosis. Consider treatment based on age and fracture probability

Antiresorptive /Bone-sparing treatments:
[Alendronic acid](#),
[Risedronate](#),
[Zoledronic acid \(IV\)](#),
[Denosumab](#), [Raloxifene](#)

Bone-forming treatments
[Teriparatide](#),
[Strontium](#).

NB: [Romosozumab](#) is both bone-sparing & bone-forming

Notes(overleaf)

1. Clinical risk factors
2. FRAX tool
3. Lifestyle advice
4. Investigations
5. MHRA safety advice
6. DXA scan frequency
7. Duration of treatment and bisphosphonate treatment algorithm
8. Local decision on Denosumab to include men

Patient Information

Versus Arthritis <https://www.versusarthritis.org/about-arthritis/conditions/osteoporosis/>

Royal Osteoporosis Society <https://theros.org.uk/>

NHS.uk <https://www.nhs.uk/conditions/osteoporosis/>

Patient .co.uk <https://patient.info/bones-joints-muscles/osteoporosis-leaflet>

Abbreviations:

NICE TA: National Institute for Health and Care Excellence Technology Appraisal

NOGG: National Osteoporosis Guideline Group

SIGN: Scottish Intercollegiate Guidelines Network

SmPC: Summary of Product Characteristics

Note 1: Clinical Risk Factors (CRFs) / Indicators of Low Bone Mineral Density (BMD) to be considered when assessing the patient. [NICE CG146](#)

- Age
- Previous fragility fracture
- Parental history of hip fracture
- Alcohol intake of more than 14 units per week
- Oral corticosteroids current or frequent use
- Causes of secondary OP (FRAX tool includes rheumatoid conditions only)
- Low body mass index (defined as <math><18.5\text{kg/m}^2</math>)
- Conditions that result in prolonged immobility
- Smoking

Note 2: FRAX® tool

Algorithms can integrate the weight of CRFs for fracture risk with or without information on BMD. The FRAX® tool computes the 10-year probability of hip fracture or a major osteoporotic fracture (clinical spine, hip, forearm or humerus) for several European countries, including the UK. The tool has been externally validated in independent countries and widely used. The FRAX® tool is used and recommended by local specialists.

Limitations of using the FRAX® tool are:

- When the absolute fracture risk in patients of extreme ages is calculated.
- Neck of Femur BMD used to assess risk of fracture, not lumbar spine.

QFracture2012 tool. NICE have recommended the use of fracture risk assessment tools FRAX or QFracture2012 (<https://qfracture.org/>) in the assessment of patients

Note 3: Lifestyle advice [NOGG](#), [CKS](#)

- Recommend a balance diet especially with adequate calcium and vitamin D intake
- Recommend regular tailored weight bearing and muscle-strengthening exercise
- Maintain body weight
- Support and encourage smoking cessation and drink alcohol within recommended limits
- Assess falls risk and give advice if appropriate
- Reduce dose of glucocorticoid when possible

Note 4 Investigations for all patients

- FBC, ESR (If ESR raised, measure serum *paraproteins* and urine *Bence Jones protein*)
- Bone and liver function tests (Ca, P, Alk phos, albumin, ALT/ γ GT)
- Serum creatinine

Additional tests if indicated:

- Serum TSH.
- Serum 25 OH *VitD* and PTH
- Lateral thoracic and lumbar spine X rays
- Isotope bone scan
- Serum testosterone, LH and SHBG, PSA (men)
- BMD if monitoring required

Note 5 MHRA safety advice

[Bisphosphonates: atypical femoral fracture](#) (AFF) Dec 2014

[Bisphosphonates: osteonecrosis of the jaw](#) Dec 2014. See also [Further information on patient risk for ONJ](#)

[Bisphosphonates: atrial fibrillation](#) Dec 2014

[Bisphosphonates: very rare reports of osteonecrosis of the external auditory canal](#) Dec 2015

[IV Zoledronic acid: adverse effects on renal function](#) Dec 2014

[Denosumab: hypocalcaemia fatalities and risk during treatment](#) Dec 2014

[Denosumab: rare cases of atypical femoral fracture with long term use](#) Dec 2014

[Denosumab: minimising risk of osteonecrosis of the jaw and monitoring for hypocalcaemia](#) Dec 2014

[Denosumab: Reports of osteonecrosis of the external auditory canal](#) June 2017

[Denosumab: Increased risk of multiple vertebral fractures after stopping or delaying ongoing treatment](#) Aug 2020

[Strontium: cardiovascular risk. Restricted indication and monitoring requirements](#) Dec 2014

Note 6 Dual-energy X-ray absorptiometry (DXA) Scan frequency, measuring Bone Mineral Density

- Following initiation of bisphosphonate (oral or IV) or denosumab therapy consider a repeat DXA after 3 to 5 years therapy as part of ongoing review
- Ongoing bisphosphonate / denosumab therapy: consider repeating DXA every 2 to 3 years[^]
- Patients receiving glucocorticoids (long term): consider repeating DXA every 1 to 3 years[^]
- Presence of a recent fracture: Consider a repeat DXA after 1 to 3 years[^]
- Patients over 65 years who have had a recent fracture and who are prescribed short intermittent courses of steroids (i.e., not on a course for > 3 months): Consider repeating DXA after 1 to 3 years

[^]exact frequency will vary depending on clinical risk factors

Note 7: Duration of treatment

Bisphosphonates: see algorithm page 3

Denosumab: review patient in line with transfer of care protocol and refer back for ongoing management advice in line with protocol.

Drug holiday advice does not apply to denosumab as the suppressive effect on bone turnover appears to reduce within the first 6 months after stopping treatment.

Strontium: If still high risk in 3-to-5-year DXA discuss continuing treatment. Seek specialist advice for duration.

Teriparatide and romosozumab :- see 'hospital only' box on page 1

Note 8 Local decision on Denosumab to include men (HMMC Sept 2014, MOPB July 2016):

Denosumab (60mg) is recommended (Amber Initiation) as a treatment option for post-menopausal women with osteoporosis, and osteoporotic men (unless for treatment of bone loss associated with hormone ablation in men with prostate cancer as there was no submission for this indication in the NICE TA) in the following situations:

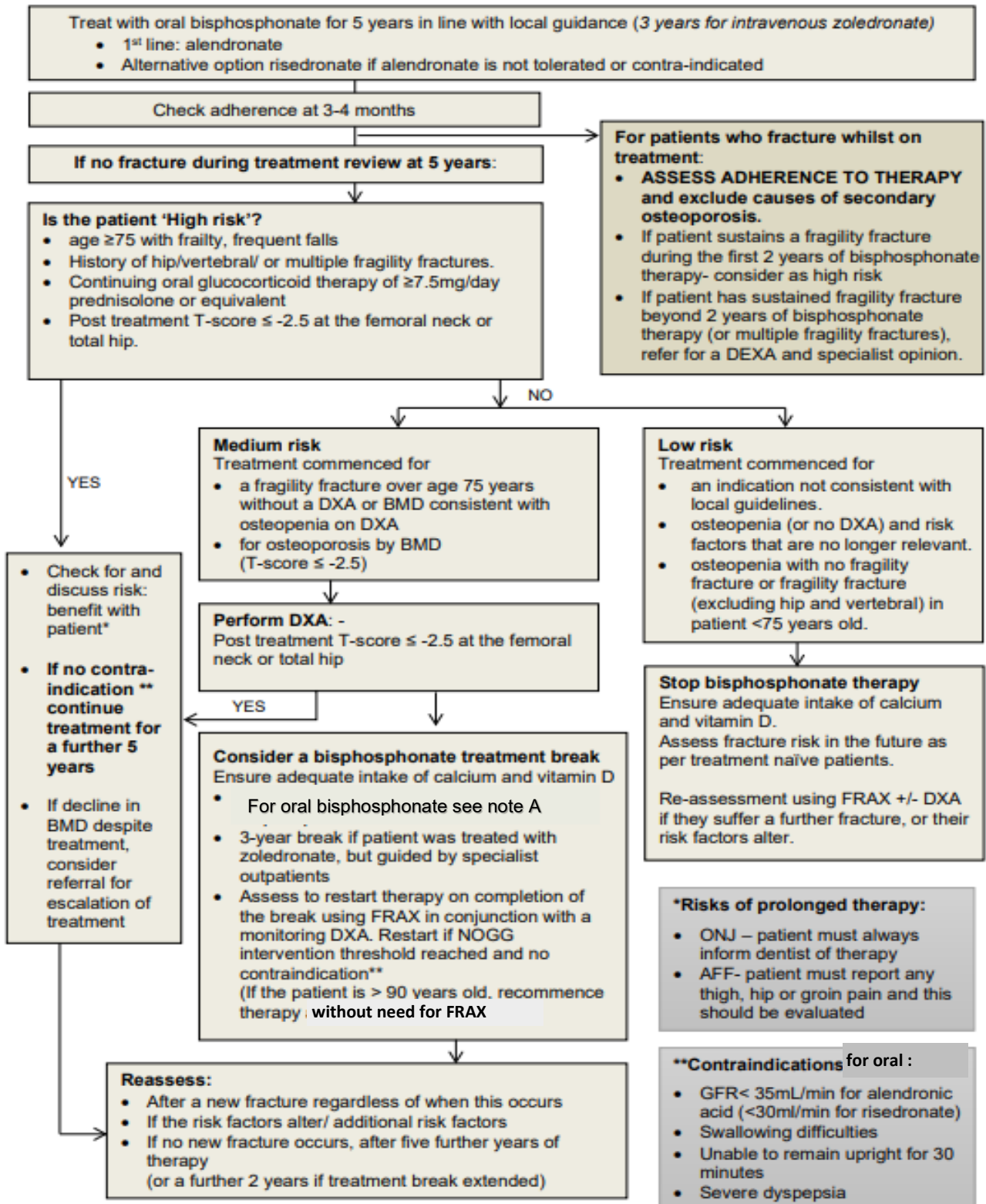
1st line in patients with severe renal impairment (eGFR <30ml/min) (as other treatments are contraindicated), **OR**

Where a patient is unable to comply with the administration instructions for oral/IV bisphosphonates **OR**

When oral/IV bisphosphonates are contraindicated or not tolerated (leading to discontinuation).

Primary Care Bisphosphonate Treatment Algorithm

see note 7 and 'hospital only' box page 1 for treatment duration for non bisphosphonates



Note A.

- 2-year treatment break if patient is on oral alendronic acid
- 18-month treatment break if patient is on risedronate or oral ibandronic acid

AFF- Atypical Femoral Fracture

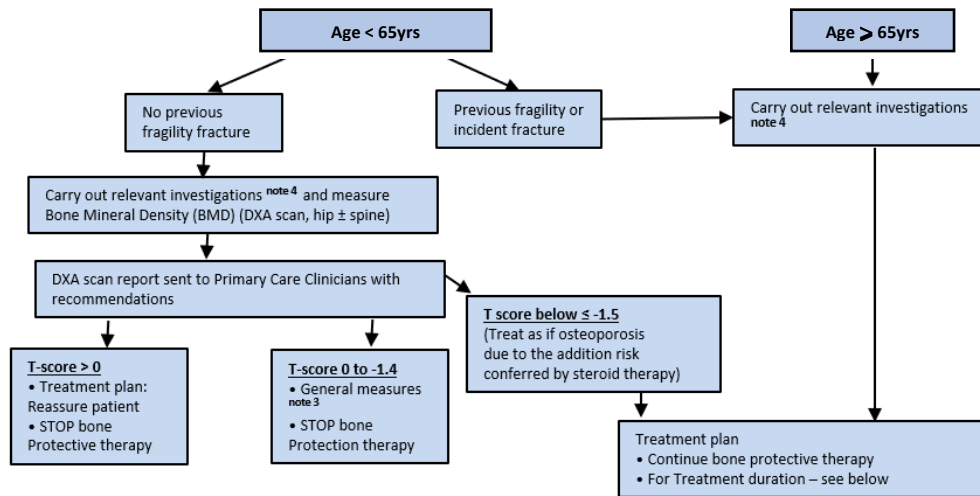
Prevention and Treatment of Glucocorticoid-induced Osteoporosis in Postmenopausal Women & Men (age ≥ 50 years). *Pre-menopausal women and men less than 50 years should be referred to a metabolic bone disease specialist*

Applicable Criteria: Post-menopausal Women & Men (age ≥ 50 years)

- Patients starting on long term oral corticosteroids (i.e. typically a steroid dose of prednisolone ≥ 7.5mg per day (or equivalent), and expected to be for ≥ 3 months) [SIGN 142]
- Patients already on long term glucocorticoid therapy (irrespective of dose prescribed as it depends on cumulative dose exposure) [SIGN]
- Patients who have received repeated short-term courses of steroids (e.g., for asthma) with a cumulative dose equivalent to 1.5g per year (High dose inhaled corticosteroids-Clinicians should be aware of the potential risk of developing osteoporosis and other side effects from the use of high-dose inhaled corticosteroids and should discuss the risk with patients. There are no set guidelines available and the need for bone protective therapy should be decided on a case by case basis (i.e., may be required if patient has multiple risk factors)

Initial Treatment plan : applicable to all patients who fit the above criteria

- Initiate bone protective therapy (see medical management options below) – duration is dependent on age, steroid dose, length of steroid exposure and associated clinical risk factors
- Prescribe calcium 1-1.2g + colecalciferol 20mg (800IU) daily unless confident that patient has an adequate calcium intake and is vitamin D replete.
- Request a DXA scan (if appropriate) (NB: treatment should always be started straight away regardless of whether a DXA scan has been requested or not, as it is known that rapid bone loss occurs within the first 3–6 months of steroid therapy)



The choice of treatment should be made on an individual basis after discussion between the patient and their clinician about the advantages and disadvantages of the treatments available. If more than 1 treatment is suitable, the lowest cost should be chosen (taking into account administration costs, dosage and cost per dose).

Primary Care treatment options: anti-resorptive agents: (NOGG) see note 5 for MHRA safety advice and SmPC
1st line choice: Alendronic acid 70mg tablets once a week
 If cannot tolerate alendronic acid 70mg: **Risedronate 35mg tablets once a week**
 All patients should have a dental check-up, and any necessary remedial work performed, before bisphosphonate treatment, or as soon as possible after starting treatment. Routine dental check-ups should continue when on treatment as risk of osteonecrosis of the jaw (ONJ). [Further information on patient risk for ONJ](#)
 -Oral bisphosphonates should be swallowed whole with a glass of tap water 30 to 60 minutes before the first food or drink (other than tap water) of the day. Patients should stand or sit upright (not lie down) for at least 30 minutes post dose. Discontinue treatment if oesophageal ulceration, erosion, stricture, or severe lower gastrointestinal symptoms occur.
 -Check tolerance and adherence at 3 to 4 months and then adherence at least annually.
If bisphosphonates are contra-indicated (see SmPC), are not tolerated or if patient has moderate to severe renal impairment (<35ml/minute calculated creatinine clearance) REFER to specialist.
DO NOT CO-PRESCRIBE bisphosphonates with any other OP treatment.
Clinicians should seek specialist opinion if patient sustains a fracture on therapy

Hospital only treatment option (NOGG)
IV Zoledronic acid see [MHRA 'Adverse effect on renal function'](#)

Treatment Duration review: Guidance for Primary Care Clinicians
For patients on long term steroids: Continue to prescribe bone protective therapy
 • Bisphosphonate oral therapy- review treatment +/- DXA after 5 years. Duration of treatment is dependent on presence of risk factors (see primary care bisphosphonate treatment algorithm)
For patients where steroid therapy has been discontinued:
 • Bisphosphonates - review patient and re-assess fragility fracture risk when steroid therapy is stopped (if no other risk factors). NOGG advises if glucocorticoid therapy is stopped, withdrawal of bone-protective therapy may be considered at the same time, provided on re-assessment of fracture risk using FRAX, the probabilities of both major osteoporotic fracture and of hip fracture lie below the intervention threshold.

References all accessed Dec 2022

NICE TAs

- [NICE TA 160](#) Raloxifene for the primary prevention of osteoporotic fragility fractures in postmenopausal women (Oct 2008 (amended Jan 2010 and Jan 2011))
- [NICE TA 161](#) Raloxifene and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women (Oct 2008 (amended Jan 2010 and Jan 2011))
- [NICE TA 204](#) Denosumab for the prevention of osteoporotic fractures in postmenopausal women (Oct 2010)
- [NICE TA 464](#) Bisphosphonates for treating osteoporosis, Aug 2017, updated Feb 18 (partially replaces TA160 & TA161)
- [NICE TA 791](#) Romosozumab for treating severe osteoporosis, May 2022

NICE clinical guidance and quality statements

- NICE CG 146 - Assessing the risk of fragility fractures in people with osteoporosis, Aug 2012 [CG146](#)
- NICE Quality Standard 149 Osteoporosis, April 2017 <https://www.nice.org.uk/guidance/qs149/resources/osteoporosis-pdf-75545487906757>
- NICE Clinical Knowledge Summary [Osteoporosis-prevention of fragility fractures](#)

Guidelines from other specialist bodies:

- SIGN :[142 osteoporosis](#)
- NOGG [Full clinical guideline](#)

[Electronic Medicines Compendium](#) (For SmPC)

- MHRA safety advice
- [Bisphosphonates: atypical femoral fracture](#) Dec 2014
- [Bisphosphonates: osteonecrosis of the jaw](#) Dec 2014
- See also [Further information on patient risk for ONJ](#)
- [Bisphosphonates: atrial fibrillation](#) Dec 2014
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- [Denosumab: Increased risk of multiple vertebral fractures after stopping or delaying ongoing treatment](#) Aug 2020
- [Strontium : cardiovascular risk. Restricted indication and monitoring requirements](#) Dec 2014

Oral bisphosphonate treatment algorithm has been included within the guidelines with kind permission from Derbyshire ICB.

Prevention and treatment of glucocorticoid-induced osteoporosis has been included based on the guidelines from Mid and South Essex ICS, with acknowledgement and thanks.

[Bisphosphonate length of treatment in osteoporosis.pdf \(derbyshiremedicinesmanagement.nhs.uk\)](#)

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Superseded version	