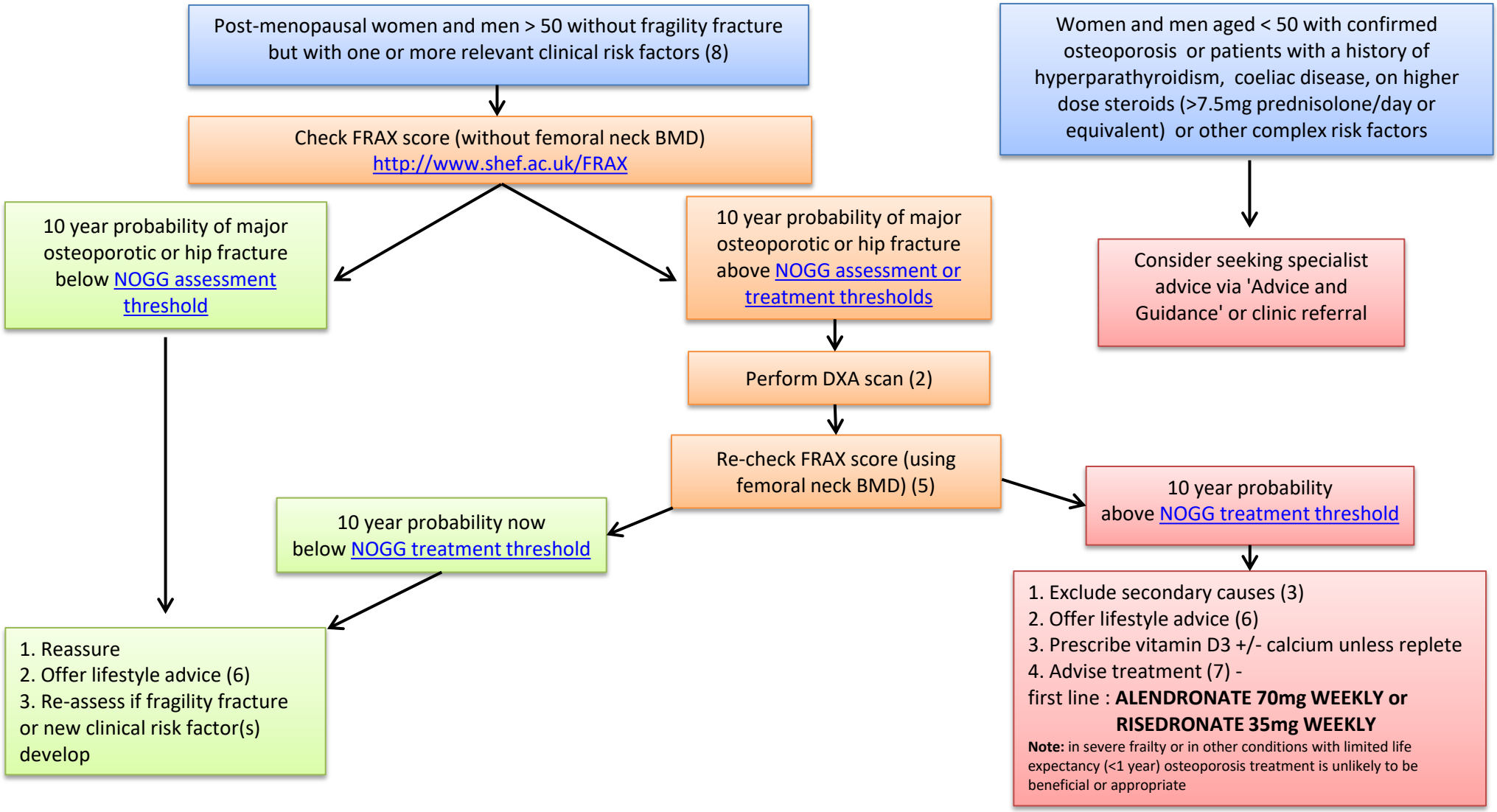
Primary Prevention

Excludes aromatase inhibitor-induced osteoporosis risk*



Authors: Dr Andy Monro Dr Gill Coombes
Approved by: GHNHSFT Drug and Therapeutics Committee
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Secondary Prevention

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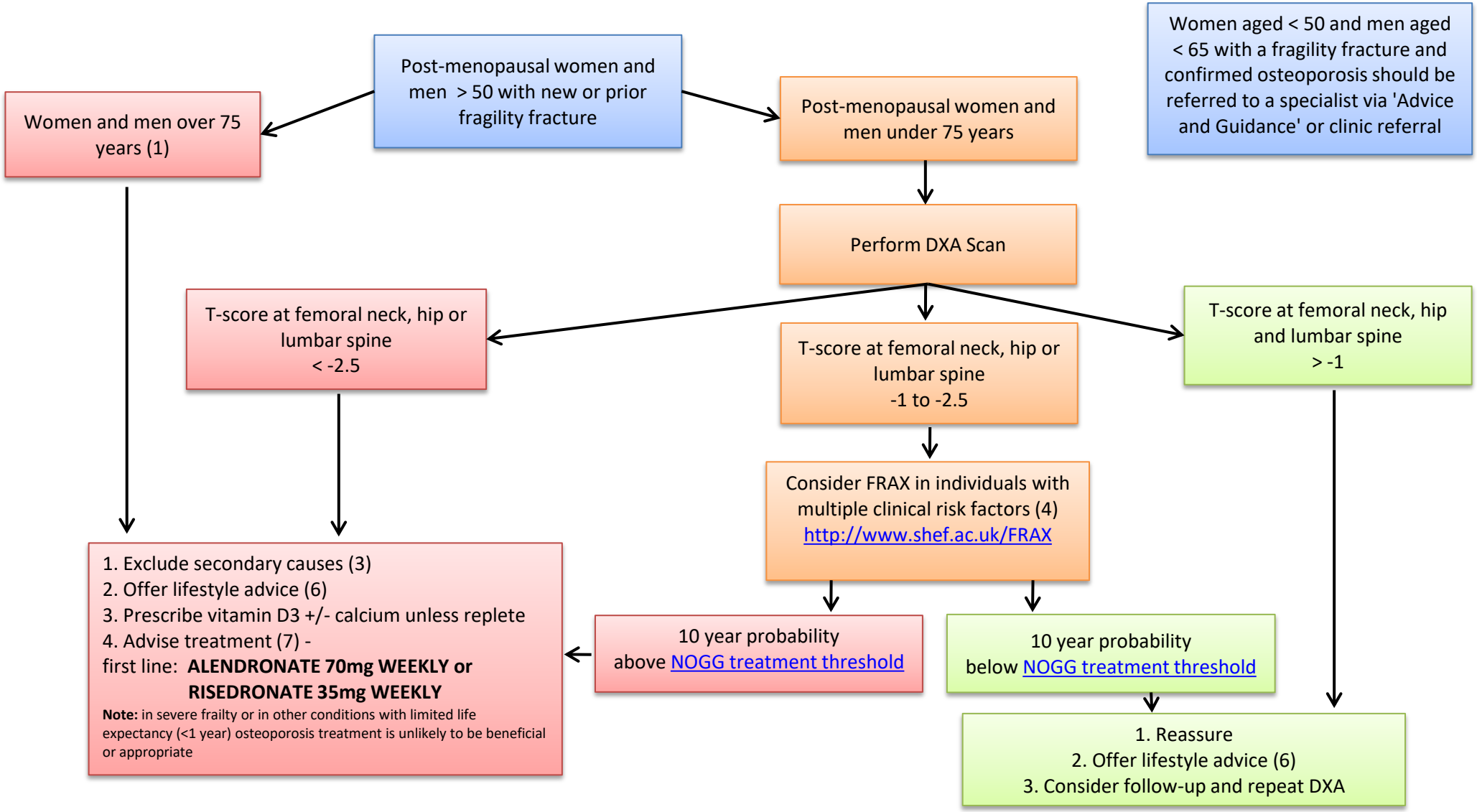

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MANAGEMENT GUIDELINES FOR THE PRIMARY AND SECONDARY PREVENTION OF OSTEOPOROSIS-RELATED FRACTURES IN POST-MENOPAUSAL WOMEN AND MEN AGED >50 YEARS

Gloucestershire Hospitals NHS
NHS Foundation Trust

* See published guidelines:

NOS consensus guidelines for prevention of fractures in women taking AI (2008)
https://nos.org.uk/media/98027/bone-health-guidelines-breast-cancer-treatments.pdf

1) DXA in over 75 year old men and women with a clinically apparent osteoporotic fragility fracture
NICE advises that if a women aged 75 years or older has not previously had her BMD measured, a DXA scan may not be required if the responsible clinician considers it to be clinically inappropriate or unfeasible.

2) DXA scans are less reliable in the very elderly (generally over 85s) and at this age usually not helpful in informing treatment decisions.

3) Other investigations
Men are more likely to have secondary osteoporosis: It is recommended that men <65yrs and women <50 years with confirmed osteoporosis are referred to a specialist for further investigation.

All Patients:
- FBC
- PV (If PV significantly raised or suspicion of myeloma, or vertebral fractures - check immunoglobulins/serum paraproteins and urine for Bence Jones protein)
- U&E's
- Bone profile inc phosphate
- Liver function tests
- TSH

Additional tests if indicated
- Vitamin D
- PTH (if hypercalcaemic or renal impairment)
- Testosterone, LH and SHBG (younger men, generally <75yrs)
- PSA
- TTG
- Lateral thoracic and lumbar spine X rays

4) FRAX
Individuals with additional clinical risk factors and a T-score in the osteopenic range may have a fracture risk greater than that associated with osteoporosis and a fragility fracture. Consideration of treatment, may be appropriate, especially in the presence of a vertebral body fracture. The FRAX score may help here to determine 10 year fracture probability and inform clinical decision making.
Caution in interpretation is advised when using the NOGG intervention threshold linked to FRAX as it may lead to over-treatment in younger individuals or under-treatment in certain other patient groups.

5) When using DXA within FRAX the femoral neck BMD value is recommended and the most accurate in predicting future fracture risk. If there is a significant difference between femoral neck and lumbar sites, or unable to image the femoral neck (e.g bilateral hip replacements) the total lumbar T-score can be used to make treatment decisions.

6) Lifestyle measures
Include advice on weight-bearing exercise with impact, adequate nutrition optimising calcium and vitamin D3 intake, avoidance of tobacco, sensible drinking of alcohol, safe sun exposure.

7) Treatment
- Advise periodic review of adherence to therapy.
- Consider referral or check concordance if patient sustains a fracture on therapy (although treatment does not abolish fracture risk – see section on treatment failure below for further information).
- Refer if significant renal impairment (Creatinine clearance <30ml/min).
- Calcium 1 – 1.2 gram + Vitamin D3 (Colecalciferol) 800-1000 units daily. If issues with tolerating combined preparation consider giving Vitamin D3 alone and counsel on adequate calcium rich diet. NB osteoporosis is an exception to the CCG 'Do not prescribe' list.
- Oral bisphosphonate: 1st Line ALENDRONATE 70mg WEEKLY or RISEDRONATE 35mg WEEKLY (fasting, with water, sitting or upright for >30 minutes).

If ORAL BISPHOSPHONATES not tolerated or contraindicated or difficulties with compliance:
- **INTRAVENOUS BISPHOSPHONATES (Ibandronate 3 monthly IV, Zoledronic acid 12 monthly IV)**. These are also licensed for use in men and steroid induced osteoporosis. Refer to specialist for initiation.
- **DENOSUMAB 60mg s/c 6 monthly**: NICE TA 204 has given a positive recommendation for denosumab if bisphosphonates are not tolerated or contraindicated in secondary prevention of osteoporotic fracture in post-menopausal women without any other restrictions. Denosumab is also licensed for use in men and treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture. Refer to specialist for initiation. **Prescribing restrictions apply in primary prevention** – seek specialist guidance.
- **TERIPARATIDE daily SC injection 24 month course:** should be considered if bisphosphonates or other agents are not tolerated, are contraindicated, or if patients have failed on treatment. Patients must be 65 years + with a T-score of -4.0 or –3.5 plus >2 fractures OR aged 55–64 years with a T-score of –4 plus >2 fractures. Refer to Specialist for initiation.
- **RALOXIFENE 60mg** daily (for postmenopausal women with vertebral osteoporosis if intolerant of bisphosphonates or other agents). Raloxifene is not licensed for men and is not advised if risk of VTE. Not recommended as a treatment option in primary prevention (NICE).
- **HRT** may be appropriate in menopausal women before age 50 who are also experiencing menopausal symptoms that require treatment. Not advised if risk of VTE.
- **STRONTIUM RANELATE 2grams** daily (at bed-time 2 hours after food) can be considered for the treatment of severe osteoporosis in postmenopausal women and adult men. Should only be prescribed on specialist recommendation and if other options have failed, are not tolerated, or are inappropriate. Not suitable for those at high risk of thrombo-embolism or cardiac disease.

Duration of treatment
Due to safety concerns relating to the risk of atypical femoral fracture, a break in therapy should be considered after 5 years with Alendronate, Risedronate or Ibandronate and after 3 years with Zoledronic acid. Those at high risk (age 75 yrs or older, vertebral fractures, hip fracture, BMD still in the osteoporotic range, fracture on treatment, on higher dose steroids i.e. >7.5mg/day prednisolone or equivalent) may benefit from longer-term treatment. Patients require full counselling on the relative risks of continuing or discontinuing therapy as well as the risks of fracture even if they continue on treatment. If a treatment break is considered appropriate, then the following durations are suggested:
- Alendronate: 2-3 years
- Ibandronate: 1-2 years
- Risedronate: 1-2 years
- Zoledronic acid: 3 years

There is no evidence base to guide decisions on bisphosphonate treatment beyond 10 years and management of such patients should be considered on an indivdual basis.

A shorter duration of oral bisphosphonate treatment may be appropriate in patients with multimorbidity, provided the principles in NICE NG56 are applied.

Current evidence suggests that Denosumab can be continued for at least 10 years. Denosumab should **not** be stopped abruptly as rebound bone loss may occur, resulting in a potentially increased risk of fracture. Patients should be reviewed before Denosumab is stopped and the need for alternative therapy considered.

Treatment Failure with Oral Bisphosphonates
Treatment failure should be considered if a patient develops a major osteoporotic fracture (i.e. hip or vertebral fracture) despite at least 12 months treatment with an oral bisphosphonate. Those who meet this criteria should be considered for a step-up in treatment to a more potent agent.

8) Clinical Risk factors For Fracture (NICE CG146)

Current use or frequent recent use of oral or systemic glucocorticoids	BMI < 18.5 kg/m2
History of falls	Smoking
Family history of hip fracture	Alcohol intake of more than 14 units/week for men and women
Other causes of secondary osteoporosis	

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