BLMK Primary Care guideline

Prevention and Treatment of Glucocorticoid-induced Osteoporosis in Post-menopausal Women & Men (age ≥ 50 years) in the Primary Care Setting

Points to note:

- **Pre-menopausal women, and men less than 50 years old** lie outside these guidelines as they will require an individual assessment– primary care clinicians should use 'advice and guidance' to seek advice / arrange a referral to a specialist**.**

- **Transgender (Transpeople)*: -**
  Assess fracture risk on an individual basis and consider seeking specialist advice
  (For further information see:- :Royal Osteoporosis Society factsheet Transgender people & osteoporosis)

- These guidelines should be used to aid management decisions, but do not replace the need for clinical judgement in the care of individual patients in clinical practice.

- To assist in decision making, NICE have published a Patient Decision Aid for the use of bisphosphonates in the treatment of osteoporosis - Available here

The following organisations contribute to and participate in the BLMK APC – Bedfordshire, Luton and Milton Keynes Integrated Care Board; Bedfordshire Hospitals NHS Foundation Trust; Cambridgeshire Community Services NHS Trust; Central and North West London NHS Foundation Trust; East London NHS Foundation Trust; Milton Keynes University Hospital NHS Foundation Trust

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Glucocorticoid-induced Osteoporosis Management Algorithm

Prevention and Treatment of Glucocorticoid-induced Osteoporosis in Post-menopausal Women & Men (age ≥ 50 years) in the Primary Care Setting

(Pre-menopausal women and men less than 50 years – seek advice from a metabolic bone disease specialist)

Suspected or at risk of Glucocorticoid-induced Osteoporosis

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

- **Patients starting on long term corticosteroids** (i.e. typically a steroid dose of prednisolone ≥ 5mg per day (or equivalent), and expected to be for ≥ 3 months)
- **Patients already on long term glucocorticoid therapy (**irrespective of dose prescribed as it depends on cumulative dose exposure)
- **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 for COPD - 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).

1) Initial Treatment plan :- applicable to all patients who fit the criteria stated above

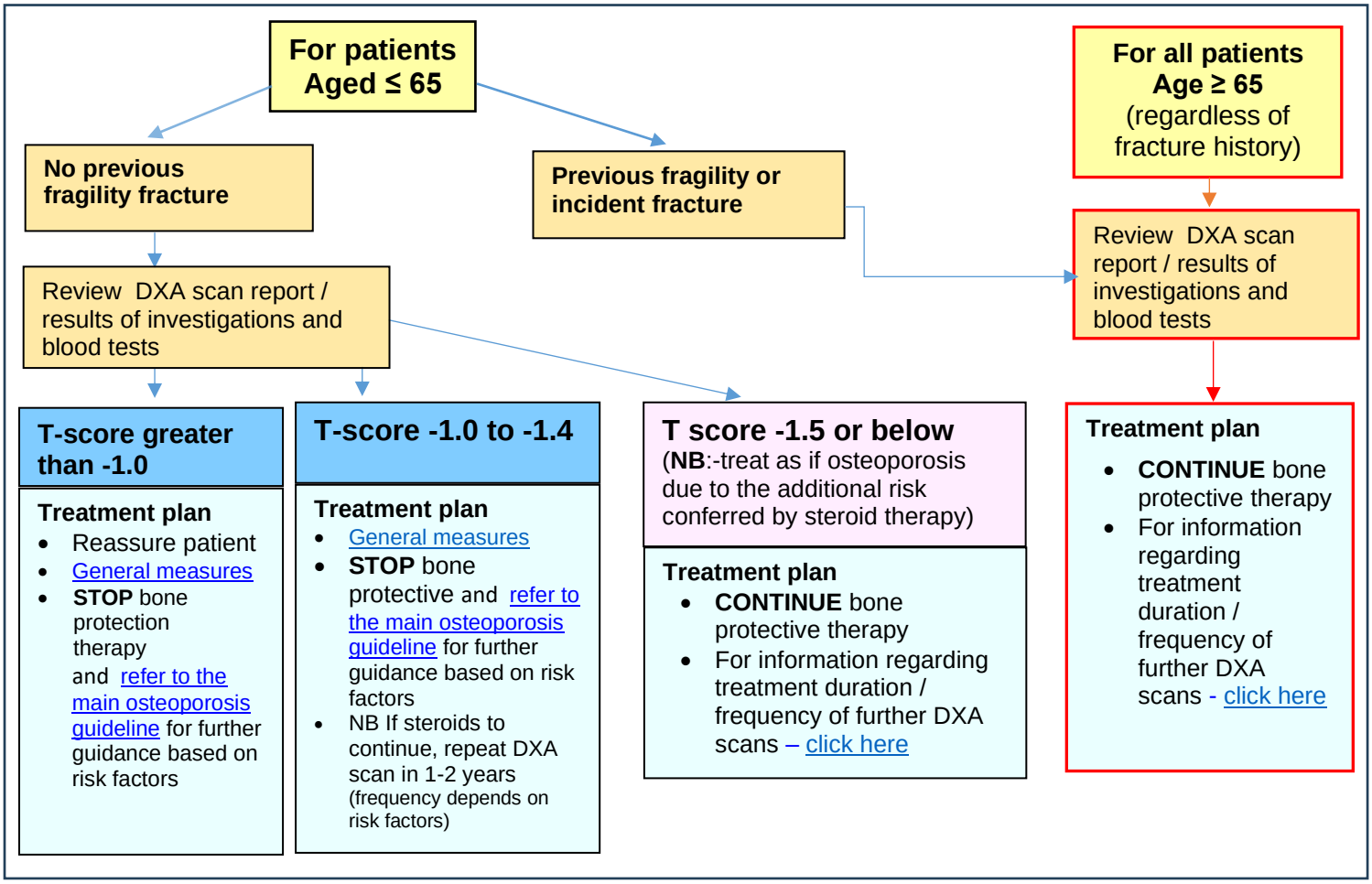
a) Initiate **bone protective therapy** (see drug choices)
b) Prescribe calcium 1-1.2g + colecalciferol 20mcg (800IU) daily unless confident that patient has an adequate calcium intake **and** is vitamin D replete.

Important note:-Treatment should always be started straight away as it is known that rapid bone loss occurs within the first 3 – 6 months of steroid therapy

c) Request a DXA scan and other relevant investigations / blood tests (the results when known will help determine duration of treatment required)

2) Duration of bone protective therapy:-

The decision of how long bone protective therapy should be continued for is dependent on several factors such as DXA results, other test results, age, dose of steroid, length of steroid exposure, and other clinical risk factors:- see flow chart below.



Management of Glucocorticoid induced Osteoporosis

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This guideline is specific for glucocorticoid induced osteoporosis – for detailed information on risk factors / use of FRAX® fragility score / bisphosphates / denosumab / general measures, see the main osteoporosis guideline

General points

- Discuss the advantages and disadvantages of the various treatment choices available.
- Choice of therapy should be tailored to the individual and patient choice must be factored in.
- Oral bisphosphonates are not licensed for glucocorticoid induced osteoporosis, however local specialists advice that once weekly oral bisphosphonates are routinely used **(off label use**)
- Consult electronic BNF or Summary of Product Characteristics (SmPC) for full prescribing details.
- Clinicians should be aware of the various MHRA drug safety advice (DSU) documents relating to bisphosphonates and denosumab regarding osteonecrosis of the jaw, osteonecrosis of external auditory canal, atypical fractures, hypercalcaemia; increased risk of multiple vertebral fractures after stopping or delaying ongoing treatment (with denosumab) - Click here to view individual MHRA DSU advice
- If considering a bisphosphonate or denosumab treatment options, ensure dental examinations / any required dental treatment is carried out as appropriate **before** starting treatment and give advice regarding dental hygiene etc. due to low risk of Osteonecrosis of the Jaw (ONJ) associated with bisphosphonates and denosumab therapy.
- Check compliance with bisphosphonate therapy after first month, after 3 months and then annual review
- Prescribe generic products when available.

Important note:-

- ❖ Clinicians should seek specialist opinion if patient sustains a fracture while on therapy.
- ❖ Refer patients at very high risk to specialist team for consideration of anabolic treatment.
- ❖ Discontinue oral bisphosphonates if patient is started on an IV bisphosphonate / denosumab / teriparatide / romosozumab / abaloparatide by secondary care clinician.
- ❖ Denosumab treatment should not be stopped or delayed without specialist review (due to increased risk of vertebral fractures)
- ❖ Secondary care clinician will advise GP on **which follow on bone therapy** treatment is required post use of an IV bisphosphonate / denosumab / teriparatide / romosozumab / abaloparatide.

Click here for drug treatment options

Click here for criteria for secondary care referral

Drug Treatment Choices

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NB: Refer to **general prescribing points** before starting treatment – click here

First line options:-

Bisphosphonates

- **Oral bisphosphonate**
  - Alendronic acid 70mg once weekly or Risedronate 35mg once weekly
    (ibandronic acid 150mg monthly tablets can be used as an alternative if compliance is an issue)

Note:-

- Oral bisphosphonates are not licensed for glucocorticoid induced osteoporosis, however local specialists advise that once weekly oral bisphosphonates are routinely used **(off label use**).

Note:

- **Bisphosphonates (PO and IV) are contraindicated in severe renal impairment -** refer to specialist for consideration of s/c denosumab
- **Patients who cannot take or who are intolerant of oral bisphosphonates** – refer to Specialist team for consideration of IV bisphosphonate or denosumab s/c.

Prescribing notes:-

- Emphasise administration advice specific to oral bisphosphonates (see eBNF). If patient not willing / able to follow the timing schedule, consider alternative treatment.
- If oesophageal irritation occurs, consider prescribing a proton pump inhibitor unless contra-indicated.
- Consider a switch to the alternative oral bisphosphonate if intolerance* occurs
- Alendronic acid is also available as an effervescent tablet or as a liquid for patients who have difficulties swallowing tablets.

*Intolerance is defined as persistent upper GI disturbance that is sufficiently severe to warrant discontinuation of treatment, and that occurs even though the instructions for administration have been followed correctly.

Second line options (require specialist referral)

- Denosumab 60mg s/c every 6 months (specialist initiation, then GP prescribing via shared care)
  or
- Zoledronic acid IV 5mg once a year or IV Ibandronic acid 3mg every 3 months (secondary care only)
  or
- Teriparatide (if high risk) (secondary care only)

Note:-

- **Oral bisphosphonates** should be **discontinued** if patient is started on an IV bisphosphonate, s/c denosumab, teriparatide, romosozumab or abaloparatide.
- **Denosumab** treatment should **not** be stopped or delayed without specialist review (due to risk of vertebral fractures).

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Treatment Duration of Bone Protective therapy: Guidance for GPs

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(Applicable for patients with a T score -1.5 or below; patients who have had a previous fragility fracture; all patients aged 65 years or over)

For patients on long term steroids / or who have received repeated short-term courses of steroids (e.g. for asthma) with a cumulative dose equivalent to 1.5g per year:-

- Reduce dose of glucocorticoid if / when possible
- Consider glucocorticoid sparing therapy if appropriate or consider alternative route of administration
- **Continue bone protective therapy:-**
    - review treatment +/- DXA scan **after** 3-5 years, noting that patients on steroids may require longer term bone protective treatment (often at least 10 years)
    - consider repeating DXA every 2-3 years* if treatment to continue beyond 3-5 years

NB: If patient receiving denosumab, seek specialist advice as denosumab should not be stopped without a specialist review (due to increased risk of vertebral fracture) (MHRA advice Aug 2020)

*exact frequency will vary depending on present steroid dose / duration of steroids / other risk factors

For patients where steroid therapy has been discontinued:-

- **Continue bone protective therapy:-**
    - repeat DXA after 2-3 yrs and re-assess fracture risk (using Frax®) to decide if continuation of bone protective therapy is still required or if discontinuation can be considered.
    - review other risk factors - refer to the main osteoporosis guideline

NB: If patient receiving denosumab, seek specialist advice as denosumab should not be stopped without a specialist review (due to increased risk of vertebral fracture) (MHRA advice Aug 2020)

Criteria for secondary care referral

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Specialist referral should be considered if treatment is required in the following scenarios:-

- If patient sustains a fracture while on current osteoporosis treatment
- If patient has been identified as being at very high risk of fracture and may benefit from anabolic treatment (as per NOGG recommendations)
- Patients with severe renal impairment
- Pre-menopausal women at risk of fracture / risk of developing osteoporosis
- Male osteoporosis if less than 50 years old
- Male osteoporosis if considering prescribing a drug unlicensed for treating osteoporosis in men
- For consideration of IV bisphosphonates / denosumab due to intolerance or poor response to treatment with oral bisphosphonates
- For patients already prescribed denosumab – GP should seek further specialist advice if there is a need to stop or delay treatment as per MHRA DSU advice

Treatment options that may be prescribed by secondary care are:- (no GP prescribing)

- **Anti-resorptive drugs**
    - IV zolendronic acid or IV Ibandronic acid
    - Denosumab s/c (initiation by specialist, continuation by GP via shared care)

- **Anabolic drugs:-**
    - Teriparatide (NICE TA 161)
    - Romosozumab (NICE TA 791) (for post-menopausal people at high risk of fracture)
    - Abaloparatide (NICE TA 991) (for post-menopausal people at very high risk of fracture)

Note:-

- **Oral bisphosphonates** should be discontinued if patient is started on IV bisphosphonate, denosumab, or teriparatide, romosozumab or abaloparatide.
- Anabolic treatment is for a defined time period - the specialists will advise if anti-resorptive therapy should be restarted once the anabolic treatment course has finished.

Supporting Notes

This guideline is specific for glucocorticoid induced osteoporosis – for detailed information on risk factors / use of FRAX® fragility score / bisphosphates / denosumab / general measures, refer to the main osteoporosis guideline

General Measures

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- Recommend good nutrition especially with adequate calcium and vitamin D
- Recommend regular weight bearing exercise
- Maintain body weight
- Avoid tobacco use and alcohol abuse
- Assess falls risk and give advice

Investigations / Blood tests

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- FBC, ESR
- Bone and liver function tests (calcium, phosphate, Alkphos, albumin, ALT/γGT)
- Serum creatinine
- Serum TSH
- Serum PTH
- Serum paraproteins and urine Bence Jones protein
- Anti TTG (coeliac antibody)

Additional test if indicated:

- Serum testosterone and PSA in men, LH and SHBG
- Serum Vitamin D
- Lateral thoracic and lumbar spine X rays, or VFA* (if available)

* **VFA -** Vertebral fracture assessment (Sheffield criteria) should be considered in:-

- women >65 or men >70
- history of: 4cm height loss or kyphosis
- recent or current corticosteroid therapy (prednisolone ≥5mg for >3 months)
- BMD T-score lower than or equal to -2.5
- vertebral fracture in patients over 45
- non-vertebral fracture in patients over 50

Vitamin D / Calcium plus Vitamin D

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- Assess for evidence of vitamin D deficiency and low dietary calcium intake, especially if**:-**
  - >65 years
  - low exposure to sunlight
  - dietary calcium intake <700mg / day
  - risk of falls

- Prescribe vitamin D supplementation **or** calcium plus vitamin D supplementation (if low dietary calcium intake). (To assess daily calcium intake using the online calcium intake calculator)

  If Vitamin D monotherapy required:-
  - Colecalciferol 800 IU once daily

    or
  - Calcifediol 266 microgram (Domnisol®) – one capsule monthly.
    Calcifediol can be considered an alternative in certain circumstances as per formulary status below:-
    - First line for those with impaired hepatic function (alanine transaminase (ALT) aspartate aminotransferase (AST) are twice the upper limit of normal), malabsorption, or obesity.
    - Second line option when adherence is poor or when patients are unable to become replete with first line options.

  If calcium plus vitamin D required:-
  - Calcium 1-1.2g / colecalciferol 800 IU once daily

  If frailty / care home residents:-
  - Calcium 1-1.2g / colecalciferol 800 IU once daily

  Do not prescribe calcium and vitamin D preparations to people with:
  - Any disease or condition that results in hypercalcaemia and/or hypercalciuria (for example some malignancies, such as myeloma).
  - Hyperparathyroidism.
  - Renal stone disease.
  - Hypervitaminosis D.
  - Severe chronic kidney disease (chronic kidney disease [CKD] stage 4 or 5).
  - An allergy to peanuts or soya — soya oil-free products are available.

  Prescribe calcium and vitamin D preparations with caution to people with:
  - Mild to moderate CKD (stages 2–3B) or mild hypercalciuria. Manufacturers recommend periodic checks of plasma calcium levels.
  - In patients with severe renal failure (creatinine clearance of less than 30 mL/minute) dosage adjustments may be necessary.
  - A history of renal stone disease.

- See eBNF for side effects and drug interaction information regarding calcium and vitamin D preparations.

Ref CKS

Safety Issues and MHRA Drug Safely Updates

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Calcium & Vitamin D

- Re-analysis of data from a large randomised controlled trial has found a modest increase in the risk of some cardiovascular events in post-menopausal women using calcium and vitamin D supplements to prevent osteoporotic fractures. The MHRA has considered the data, and **no change to prescribing practice is currently recommended. (Oct 2011)** Prescribers should consider the recent data in discussions with patients and weigh the potential benefits and risks of using calcium and vitamin D on an individual basis in line with current NICE guidance.

Bisphosphonates

- **MHRA/CHM advice: atypical femoral fractures (June 2011)**
  Atypical femoral fractures have been reported rarely with bisphosphonate treatment, mainly in patients receiving long-term treatment for osteoporosis.
  The need to continue bisphosphonate treatment for osteoporosis should be re-evaluated periodically based on an assessment of the benefits and risks of treatment for individual patients, particularly after 5 or more years of use.
  Patients should be advised to report any thigh, hip, or groin pain during treatment with a bisphosphonate.
  Discontinuation of bisphosphonate treatment in patients suspected to have an atypical femoral fracture should be considered after an assessment of the benefits and risks of continued
- **MHRA/CHM advice: Osteonecrosis of the jaw**
  The risk of osteonecrosis of the jaw is substantially greater for patients receiving intravenous bisphosphonates in the treatment of cancer than for patients receiving oral bisphosphonates for osteoporosis or Paget's disease.
  Risk factors for developing osteonecrosis of the jaw that should be considered are: potency of bisphosphonate (highest for zoledronate), route of administration, cumulative dose, duration and type of malignant disease, concomitant treatment, smoking, comorbid conditions, and history of dental disease.
  All patients should have a dental check-up (and any necessary remedial work should be performed) before bisphosphonate treatment, or as soon as possible after starting treatment.
  During bisphosphonate treatment patients should maintain good oral hygiene, receive routine dental check-ups, and report any oral symptoms.
  Guidance for dentists in primary care is included in Oral Health Management of Patients Prescribed Bisphosphonates: Dental Clinical Guidance, Scottish Dental Clinical Effectiveness Programme, April 2011 (available at www.sdcep.org.uk).

Denosumab (Prolia®)

There has been several MHRA Safety Updates issued:-

- **MHRA/CHM advice: atypical femoral fractures (February 2013)**
  Atypical femoral fractures have been reported rarely in patients receiving denosumab for the long-term treatment (2.5 or more years) of postmenopausal osteoporosis
  Patients should be advised to report any new or unusual thigh, hip, or groin pain during treatment with denosumab. Discontinuation of denosumab in patients suspected to have an atypical femoral fracture should be considered after an assessment of the benefits and risks of continued treatment.

- **MHRA advice: Minimising the risk of osteonecrosis of the jaw; monitoring for hypocalcaemia – updated recommendations (September 2014): Advice for healthcare professionals**
  (NB: The MHRA have issued advice regarding the use of denosumab 60mg (treatment of osteoporosis) and 120mg (cancer indication).
  The extract below relates to the **denosumab 60mg for Osteoporosis indication only.** (See MHRA website for full details):-

  Denosumab 60 mg (osteoporosis indication):-

  - **Osteonecrosis of the jaw**
    Check for ONJ risk factors before starting denosumab 60 mg. A dental examination and appropriate preventive dentistry are now recommended for patients with risk factors.

Tell all patients to maintain good oral hygiene, receive routine dental check-ups, and immediately report any oral symptoms such as dental mobility, pain, or swelling to a doctor and dentist.

- **Hypocalcaemia**
  Calcium levels should now be monitored as follows:
  Check calcium levels:
  - before each dose
  - within two weeks after the initial dose in patients with risk factors for hypocalcaemia (e.g. severe renal impairment, creatinine clearance <30 ml/min)
  - if suspected symptoms of hypocalcaemia occur.

  Tell all patients to report symptoms of hypocalcaemia to their doctor (e.g. muscle spasms, twitches, or cramps; numbness or tingling in the fingers, toes, or around the mouth).
  Click here for full details regarding ONJ and hypocalcaemia.

- **MHRA advice: reports of osteonecrosis of the external auditory canal (June 2017)**
  The MHRA issued an additional warning in relation to denosumab. The possibility of osteonecrosis of the external auditory canal should be considered in patients receiving denosumab who present with ear symptoms including chronic ear infections or in those with suspected cholesteatoma.
  https://www.gov.uk/drug-safety-update/denosumab-prolia-xgeva-reports-of-osteonecrosis-of-the-external-auditory-canal

- **MHRA DSU, Published August 2020: Increased risk of multiple vertebral fractures after stopping or delaying ongoing treatment**
  In august 2020, the MHRA published a DSU article reporting an increased risk of multiple vertebral fractures in patients within 18 months of stopping or delaying ongoing denosumab 60mg treatment for osteoporosis. Patient's individual benefits and risks should be evaluated before initiating therapy. **Treatment for existing patients should not be stopped without specialist review.**
  Click here for full information: Denosumab: Increased risk of multiple vertebral fractures after stopping or delaying ongoing treatment

References

The following main references sources were used when preparing these guidelines. Adaptations have been made based on input from local specialists.

- National Osteoporisis Guideline Group (NOGG) :- Clinical guideline for the prevention and treatment of osteoporosis (Updated December 2024)
- CKS :- Osteoporosis - prevention of fragility fractures (Last revised in April 2025)