THE
THE SOUTH YORKSHIRE & BASSETLAW

Clinical Guideline

For

Denosumab 60mg/ml Injection (Prolia ®)

Shared care guideline developed by:

Lee Wilson, Consultant Pharmacist, DBTH NHS FT
Mahmoud Al-Khoffash, Consultant Rheumatologist

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NHS Doncaster Clinical Commissioning Group

NHS Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

Prescribing Guideline for Denosumab 60mg/ml (Prolia ®)

Statement of Purpose

This shared care guideline (SCG) has been written to enable the continuation of care by primary care clinicians of patients initiated on Denosumab 60mg/ml (Prolia ®) by the Doncaster and Bassetlaw Hospitals NHS Foundation Trust where this is appropriate and in the patients' best interests. Primary care will only be requested to take over prescribing of Denosumab 60mg/ml (Prolia ®) within its licensed indication unless specifically detailed otherwise below.

Responsibilities of specialist clinician

- To discuss benefits and side effects of treatment with the patient/carer and obtain informed consent, in line with national guidance. This is particularly important for unlicensed products.
- To provide patient / carer with contact details for support and help if required; both in and out of hours
- To initiate Denosumab 60mg/ml (Prolia ®) in appropriate patients
- To undertake baseline investigations including DXA scan, bone chemistry, vitamin D levels, serum PTH and P1NP
- Ensure patient is calcium and vitamin D replete.
- Consider dental health and advise patient accordingly.
- To prescribe and administer the first dose.
- To contact patient's primary care prescriber to request prescribing and monitoring under shared care and send a link to or copy of the shared care guideline.
- To advise the primary care prescriber regarding continuation of treatment, including the duration of treatment and any investigations needed during duration of treatment mainly interval to repeating DXA scan .
- To discuss any concerns with the primary care prescriber regarding the patient's therapy
- The patient to normally remain under the specialists' care but if ongoing specialist co-ordination of the patient's care is not required the specialist must provide access to advice and intervention of that specialist in a more timely manner than via a new referral.

Responsibilities of the primary care clinician

- To refer appropriate patients to secondary care for assessment
- Confirm the agreement and acceptance of the shared care prescribing arrangement and that supply arrangements have been finalised (see appendix for template letter). or to contact the requesting specialists if concerns in joining in shared care arrangements,
- To report any serious adverse reaction to the appropriate bodies, eg. MHRA and the referring specialist
- To continue to prescribe for the patient as advised by the specialist
- Ensure monitoring as indicated in monitoring section below

- Ensure patient continues calcium and vitamin D as directed
- Treatment should be administered within 1 month of due date
- To inform the specialist if the patient discontinues treatment for any reason
- To seek the advice of the specialist if any concerns with the patient's therapy

Responsibilities of Patients or Carers

- To be fully involved in, and in agreement with, the decision to move to shared care
- To attend hospital and primary care clinic appointments and to bring monitoring information eg: booklet.
- Inform the primary care prescriber or specialist should the patient sustain a low trauma fracture.
- Report any suspected adverse effects to their specialist or primary care prescriber whilst taking Denosumab 60mg/ml (Prolia ®)
- To read the product information given to them

- Inform the specialist, primary care prescriber or community pharmacist dispensing their prescriptions of any other medication being taken – including over-the-counter medication.

Indication

Denosumab (60mg subcutaneous injection every 6 months) is licensed for the treatment of:

(a) osteoporosis in postmenopausal women and in men at increased risk of fractures due to osteoporosis

(b) bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures

(c) bone loss associated with long term systemic glucocorticoid therapy in patients at increased risk of fractures

NICE Guidance is available via: https://www.nice.org.uk/guidance/TA204

Selection of patients

Denosumab is suitable for patients who cannot be treated with alendronic acid or risedronate because of side effects, inability to comply with dosing instructions or malabsorption.

Denosumab may be particularly suitable for patients who have mild to moderate renal impairment (CKD3) where bisphosphonate treatment is contraindicated or showed lack of response to bisphosphonates .

NICE Guidance is available via: https://www.nice.org.uk/guidance/TA204

Exclusion From Shared Care

Patients with eGFR <30ml/min/1.73m^2 should be kept under secondary care for prescribing, administration and monitoring of this treatment.

Dosage

60mg denosumab is administered as subcutaneous injection once every 6 months into the thigh, abdomen or back of the arm (usually in conjunction with calcium and vitamin D supplementation, e.g. Calci D chewable tablets – one tablet daily)

Contra-indications

The details below are not a complete list and the BNF and the SPC remain authoritative

Treatment should not be administered if there is hypocalcaemia or hypersensitivity to the active substance or any of the product excipients.
Patients with rare hereditary problems of fructose intolerance should not use denosumab.

Side –effects

The details below are not a complete list and the BNF and the SPC remain authoritative

Common (≥ 1/100 to < 1/10)**:** urinary tract infection, upper respiratory tract infection, sciatica, cataracts, constipation, rash and pain in extremity, alopecia.

Uncommon (≥ 1/1000 to < 1/100): diverticulitis, lichenoid drug eruptions skin infections requiring hospitalisations were reported in postmenopausal women receiving denosumab.

Rare (≥ 1/10,000 to < 1/1,000): osteonecrosis of the jaw (ONJ), hypocalcaemia (< 1.88 mmol/l), atypical femoral fractures.

The needle cover of the pre-filled syringe contains dry natural rubber (a derivative of latex) which may cause allergic reactions.

Monitoring

(a) Check bone profile and vitamin D levels within 2 weeks prior to injection to ensure there is no hypocalcaemia or vitamin D deficiency. Correct any deficiency before administering Denosumab.

(b) Check bone profile 2-3 weeks after 1st injection to ensure there is no hypocalcaemia (done in secondary care) and after each injection.

In cases of hypocalcaemia, do not administer denosumab and seek advice from the specialist (see below).

Interactions

The details below are not a complete list and the current BNF and the SPC remain authoritative.

There are no clinical data on the co-administration of denosumab and hormone replacement therapy (HRT), however the potential for pharmacodynamics interactions would be considered low. Pharmacokinetics and pharmacodynamics were not altered by previous alendronate therapy.

Additional information

Re-Referral guidelines

The patient is to be re-referred at any time if there are concerns about side effects or inefficacy (e.g. new fractures). For all patients receiving pharmacological therapy for osteoporosis it is recommended that fracture risk is reviewed after 5 years treatment.

Ordering information

Order via the AAH ordering method. Simply log in at AAH.co.uk or call customer care on 0344 561 8899. Alternatively, Prolia® can be provided to patients through community pharmacy by writing an FP10. Please note, if obtaining denosumab via this route, it may take longer than 24 hours to obtain the medication ready for administration. Nb. Housebound or care home residential patients who require administration by community nursing services, the issuing must be via an FP10.

Contacts for Support, education and information

Rheumatology Nurse Advice Line:

Doncaster RI: 01302 644101 – option 4

Bassetlaw DGH: 01909 572398

Rheumatology consultant connect

Equality and Diversity

No relevant considerations

References

NICE Guidance is available via: https://www.nice.org.uk/guidance/TA204

Full list of side-effects is given in the Denosumab 60mg/ml (Prolia ®) summary of product characteristics (SPC), available from www.emc.medicines.org.uk

https://www.medicinescomplete.com/#/content/bnf/_442118148?hspl=denosumab

https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf

Template letter to primary care prescriber

Dear Prescriber

RE: _____ **DOB:**____/___/_____ **NHS:** _____

Address:_____**Postcode:** _____

Your patient is being started on treatment with Denosumab 60mg/ml (Prolia ®)

This treatment can be prescribed by primary care prescribers under the Traffic Light System under the "shared care" arrangements. This shared care guideline has been approved by the South Yorkshire and Bassetlaw Area Prescribing Groups.

We have chosen to use Denosumab 60mg/ml (Prolia ®) for the reasons outlined in the shared care protocol for this drug.

As part of shared care arrangements please can you monitor bone profile 2 weeks prior to administration and 3 months after administration to ensure there is no hypocalcaemia. Will you also please undertake to prescribe for your patient?

The prescriber will be responsible for ensuring monitoring of the patient on the medication being prescribed as per this guideline.

Do not hesitate to contact us if you have any concerns.

Yours sincerely

Clinician's Name

Clinician's Title

IMPORTANT REMINDER

The prescriber is responsible for monitoring the patient on the medication being prescribed

RE: _____ **DOB:**____/___/_____ **NHS:** _____

Address:_____**Postcode:** _____

Signed _____

Practice_____ Date_____