

Shared Care Protocol

For

Denosumab 60mg/mL injection (Prolia®)

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Denosumab 60mg/mL injection (Prolia®) for adult patients over the age of 18.

Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol ([section 2](#)) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see [section 11](#)) to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet including a [patient safety reminder card](#).
- Assess for contraindications and cautions (see [section 4](#)) and interactions (see [section 7](#)).
- Conduct required baseline investigations and initial monitoring (see [section 8](#)). This includes checking the patient is not hypocalcaemic (checking serum calcium).
- Identify those patients who are predisposed to hypocalcaemia (patients with severe renal impairment, creatinine clearance <30mL/min) and check their calcium levels within two weeks of the [initial dose](#).
- Ensure patient is calcium and vitamin D replete.
- Consider dental health and advise patient accordingly. *A dental examination with preventive dentistry and an individual benefit-risk assessment is recommended prior to treatment with denosumab in patients with concomitant risk factors. See [SPC](#) for full details.*
- Initiate treatment as outlined in [section 5](#).
- To assess tolerability of treatment in the individual.
- If treatment is tolerated, complete the standard form, and send to patient's GP practice detailing the diagnosis, current and ongoing dose, any relevant test results (including baseline serum calcium) and when the next injection and monitoring is required. Include contact information ([section 13](#)).
- Provide advice to primary care on the management of adverse effects if required.
- Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.

Primary care responsibilities

- To refer appropriate patients to secondary care for assessment
- Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being received by the practice where possible.
- If accepted, prescribe ongoing treatment as detailed in the specialists' request and as per [section 5](#), taking into any account potential drug interactions in [section 7](#).
- Ensure treatment is given in a timely manner (see below)

Treatment must be administered within 1 month window around the [6 month](#) due date. Practices are advised to use a robust recall system to ensure patients receive timely treatment.

The offset of action of denosumab is very quick and multiple vertebral fractures have been reported in patients who have stopped treatment. This is more likely to occur the longer the patient has been on treatment with denosumab.

- Conduct the required monitoring as outlined in [section 9](#). Communicate any abnormal results to the specialist if necessary.
- Do not administer treatment if evidence of hypocalcaemia. For further information, refer to [section 10](#).
- Check patient is taking calcium and vitamin D, as advised on initiation.
- Continue to advise about maintenance of dental health.

- To assess efficacy and tolerability of the treatment (secondary care colleagues can be contacted for advice if clarification needed).
- Manage adverse effects as detailed in [section 10](#) and discuss with specialist team when required. Check for new or unusual symptoms of hip, thigh or groin pain (if present, consider whether evaluation required to look for evidence of atypical femoral fractures). For information on what to do in worsening renal function see [section 10](#).
- To report any adverse reaction to the MHRA via the [yellow card scheme](#) and the referring consultant.
- 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.
- To conduct an annual face to face medication review (or via telephone if appropriate) or more frequent if required.
- After 5 years of treatment, **consider** referral to secondary care for a repeat fracture risk assessment, earlier review will be advised in some patients at high risk i.e. housebound patients. The timing of reassessment will be advised by the specialist. Treatment effect reverses rapidly so it is **not** appropriate to consider a 'drug holiday' with denosumab therapy as can be considered with bisphosphonate treatment.
- Refer the patient back to the specialist if the patient becomes or plans to become pregnant.
- In the event that the primary care clinician is not able to prescribe, or where the Shared Care Protocol (SCP) is agreed but the consultant is still prescribing certain items e.g. hospital only product; the primary care clinician will provide the consultant with full details of existing therapy promptly on request.
- For medication supplied from another provider, primary care clinicians are advised to clearly document these on the patient record as per local place protocol.

Patient and/or carer responsibilities

- Attend appointments for denosumab 60mg/mL (Prolia®) injection as prescribed and avoid abrupt withdrawal unless advised by the specialist.
- Take calcium and vitamin D preparations or follow calcium enriched diet as advised by clinician and inform clinician if these are stopped. Inform clinician if signs of hypocalcaemia, e.g. muscle spasms, twitches or cramps; numbness or tingling in the fingers, toes or around the mouth.
- Attend regularly for monitoring and review appointments with primary care clinician and specialist and keep contact details up to date with both prescribers. Failure to attend may potentially result in the medication being stopped.
- Present promptly to the primary care clinician or specialist should their clinical condition significantly worsen. Inform clinician or specialists if new hip, thigh or groin pain for longer than 3 weeks or any reported pain or swelling in the gums, loose teeth or difficulty chewing.
- Report adverse effects to their specialist or primary care prescriber whilst using denosumab. Seek immediate medical attention if they develop any symptoms as detailed in [section 11](#).
- To read the drug information given to them.
- Maintain good oral hygiene and attend regular dental check-ups.
- Inform the specialist, primary care clinician or community pharmacist dispensing their prescriptions of any other medication being taken including the use of any over the counter medications.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant and inform the specialist or primary care clinician immediately if they become pregnant or wish to become pregnant.

1. Background

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This SCP has been written to enable the continuation of care by primary care clinicians of patients initiated on denosumab 60mg/mL injection (Prolia®) by secondary care specialists across South Yorkshire as part of the Integrated Care Board. Primary care will be requested to take over the prescribing of denosumab within its licensed indication.

The secondary care specialist will administer the baseline injection; further treatment will be requested to be administered via the GP surgery.

This SCP does not cover denosumab 120mg (XGEVA®)

2. Indications

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Denosumab (60 mg Prolia®) is licensed for the treatment of osteoporosis in men and postmenopausal women at increased risk of fractures, and for the treatment of bone loss associated with hormone ablation in men with prostate cancer. It is also licensed for the treatment of bone loss associated with long term systemic glucocorticoid therapy in adult patients. Denosumab is a fully humanised monoclonal antibody to RANK ligand. It is a potent anti-resorptive agent and is effective in reducing the risk of vertebral and non-vertebral fractures, including hip fracture. Treatment is administered as a 6 monthly subcutaneous injection, usually in conjunction with calcium and vitamin D supplementation. Calcium absorption should be optimised prior to treatment. This is generally achieved by regular use of standard calcium and vitamin D supplements which should be continued regularly. Occasionally, patients with renal impairment or malabsorption may require pre-treatment with a vitamin D metabolite. All patients should have serum calcium levels monitored prior to each injection.

Bisphosphonates remains the first line treatment for osteoporosis in post-menopausal women in accordance with [NICE guidance](#). Approximately 25% of patients cannot be treated with bisphosphonates because of side effects, inability to comply with dosing instructions or malabsorption leading to inefficacy. Denosumab provides another option for those patients also unable to take bisphosphonates and has been recommended by [NICE](#) in this context.

Selection of patients

Denosumab is suitable for patients who cannot be treated with bisphosphonates. Bisphosphonates are excreted by the kidneys and should not be used in the presence of moderate to severe renal impairment. This is particularly important in the case of zoledronate, which is administered as an annual infusion, and is not recommended if the eGFR is below 35mL/min. Patients with moderate renal impairment requiring parenteral therapy may be considered for 3-monthly injections of ibandronate.

Denosumab may be particularly suitable for patients who have mild to moderate renal impairment (CKD3) where bisphosphonate treatment is contraindicated. However, these patients are at greater risk of developing hypocalcaemia following the injection, monitoring of serum calcium levels is recommended after the initial injection, this will be carried out in secondary care. No dosage adjustment is required in patients with renal impairment.

Denosumab is not suitable for use in patients with renal bone disease unless it has been established that this is associated with high bone turnover. Use in patients with CKD 4-5 should be avoided unless the patient has been evaluated / discussed with a specialist in secondary care or renal physician.

Prolia® should not be used in patients under 18 years due to the risk of [serious hypercalcaemia](#).

3. Locally agreed off-label use

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There are no known instances where denosumab will be initiated outside the licence. Please refer to secondary care specialist if there are any concerns.

4. Contraindications and cautions

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This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see [BNF](#) & [SPC](#) for comprehensive information.

Contraindications

- Hypocalcaemia or hypersensitivity to the active substance or to any of the product excipients.

Cautions

- Risk factors for osteonecrosis of the external auditory canal
- Risk factors for osteonecrosis of the jaw

5. Initiation and ongoing dose regime

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Denosumab is administered as a 60mg subcutaneous injection once every 6 months into the thigh, abdomen or back of arm. (See [information leaflet](#) for further information). Patients must be calcium and vitamin D replete, and in most cases, advice will be given to provide supplementation with calcium and vitamin D (daily dosage: calcium 1g -1.2g and colecalciferol 800 units). Some patients may not be able to tolerate calcium and vitamin D preparations, in such circumstances prescribers should ensure the patient is receiving sufficient dietary calcium (consider using a '[calcium calculator](#)') and advise the patient around vitamin D supplementation. Numerous low-cost preparations are available over the counter, if there is a need to prescribe vitamin D, please refer to local formulary.

Osteonecrosis of the jaw (ONJ) has been reported rarely in association with treatment for osteoporosis with denosumab or bisphosphonates. A dental examination with appropriate preventative dentistry is recommended prior to treatment with denosumab in patients with concomitant risk factors (refer to [SPC](#)). See [section 10](#) for ongoing surveillance regarding dental hygiene. Upon administering the first injection, patients should be provided with patient information including the **patient safety reminder card** which highlights the particular issue about the risk of ONJ. which highlights the particular issue about the risk of ONJ.

6. Pharmaceutical aspects

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Route of administration:	Subcutaneous
Formulation:	Injection
Administration details:	<p>60 mg denosumab is administered as a subcutaneous injection once every 6 months into the thigh, abdomen or back of arm. (See information leaflet for further information).</p> <p>It is important that treatment with denosumab is administered on time. Treatment should be administered within a one month window around each 6 monthly time point. Practices are advised to use a robust recall system to ensure patients receive timely treatment. In clinical studies examining the effects of discontinuation of denosumab, bone turnover markers temporarily increased to levels greater than baseline values which could be associated with an increase in fracture risk. Bone mineral density returned to approximately pre-treatment levels and remained above placebo within 18 months of the last dose. These data indicate that continued treatment with denosumab is required to maintain the effect of the medicinal product.</p>
Other important information:	<p><i>Storage Information</i></p> <ul style="list-style-type: none">• Denosumab must not be mixed with other medicinal products.• Store at 2°C to 8°C (in a refrigerator).• Denosumab may be exposed to room temperature (up to 25°C) for a maximum single period of up to 30 days in its original container. Once removed from the refrigerator it must be used within this 30 day period• Do not freeze• Keep in outer carton to protect from light <p><i>How to order</i></p> <p>Prolia® can be delivered directly to the GP practice within 24 hours for administration to the patient.</p> <p>To order, contact AAH Pharmaceuticals Product Code PRO2653L Telephone: 03445618899 (08:30 – 19:00 Mon – Fri) www.aah.co.uk Note : a 'personally administered' fee can be claimed if ordered via this route.</p>

	<p>Alternatively, Prolia® can be provided to patients through retail 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.</p> <p>Please note: Housebound or care home residential patients who require administration by community nursing services, the issuing of denosumab <u>must</u> be via an FP10. An account with AAH is also required to be opened whether it is ordered via the community pharmacy or GP surgery.</p> <p><i>Continuation of therapy</i></p> <p>When treatment with denosumab is stopped, it is important to substitute another bone-protective treatment 6 months after the last injection to avoid a potential increase in fracture risk.</p> <p><i>Support, education and information</i></p> <p>Royal Osteoporosis Society https://theros.org.uk/ 0808 800 0035</p> <p>There is also a one page protocol you may wish to use see Appendix One.</p>
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7. Significant medicine interactions

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The following list is not exhaustive. Please see [BNF](#) or [SPC](#) for comprehensive information and recommended management.

[Cinacalcet and Etelcalcetide](#) might increase the risk of hypocalcaemia when given with Denosumab. The manufacturer makes no recommendation on these interactions.

In an interaction study, denosumab did not affect the pharmacokinetics of midazolam, indicating that denosumab should not alter the pharmacokinetics of medicinal products metabolised by CYP3A4. There are no clinical data on the co-administration of denosumab and hormone replacement therapy (HRT), however the potential for pharmacodynamic interactions would be considered low. Pharmacokinetics and pharmacodynamics were not altered by previous alendronate therapy.

There are no clinical data on the co-administration of denosumab with other biologic agents.

8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

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Hypocalcaemia must be corrected by adequate intake of calcium and vitamin D before initiation of therapy. Monitoring of serum calcium levels is recommended 2–3 weeks prior to every injection. For patients predisposed to hypocalcaemia calcium levels should also be taken within two weeks of the initial injection. This will be carried out in secondary care. Patients should also be advised to report symptoms of hypocalcaemia, e.g. muscle spasms, twitches or cramps; numbness or tingling in the fingers, toes or around the mouth. If hypocalcaemia is suspected calcium levels and renal function should be taken. Also consider measurement of Parathyroid Hormone (PTH), magnesium and vitamin D. Denosumab should not be administered if serum calcium is below the reference range.

The secondary care specialist will make recommendations about the timing of repeat fracture risk assessment and will arrange clinic review with repeat fracture risk assessment at 24 months for more complicated patients. Secondary care colleagues are happy to discuss individual patient management whenever relevant. This guideline parallels the management using other anti-resorptive agents such as bisphosphonates in the specialist clinics.

9. Ongoing monitoring requirements to be undertaken by primary care

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See [section 10](#) for further guidance on management of adverse effects/responding to monitoring results.

Monitoring	Frequency
Calcium	All patients: 2 - 3 weeks prior to every injection For those predisposed to hypocalcaemia, calcium levels should also be taken within two weeks of the <u>initial</u> injection. This will be done in secondary care. Further information in section 10 .
Renal function	To be checked if hypocalcaemia is suspected, see section 10 .
PTH, Magnesium, Vitamin D	To be considered if hypocalcaemia is suspected, see section 10 .

10. Adverse effects and other management

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Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit

www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see [relevant summaries of product characteristics](#)

- Very common ($\geq 1/10$): Pain in extremity, musculoskeletal pain
- Common ($\geq 1/100$ to $< 1/10$): urinary tract infection, upper respiratory tract infection, sciatica, cataracts, constipation, rash, alopecia
- Uncommon ($\geq 1/1000$ to $< 1/100$): diverticulitis, lichenoid drug eruptions skin infections requiring hospitalisations were reported in postmenopausal women receiving denosumab.
- Rare ($\geq 1/10,000$ to $< 1/1,000$): osteonecrosis of the jaw (ONJ), hypocalcaemia (< 1.88 mmol/l), atypical femoral fractures.
- Unknown: Osteonecrosis of the external auditory canal

Please note: The needle cover of the pre-filled syringe contains a dry natural rubber (a derivative of latex) and does not present an allergy risk.

Osteonecrosis of the Jaw

Osteonecrosis of the jaw (ONJ) has been reported rarely in association with treatment for osteoporosis with denosumab or bisphosphonates. A dental examination with appropriate preventative dentistry is recommended prior to treatment with denosumab in patients with concomitant risk factors (refer to [SPC](#)). While on treatment, these patients should avoid invasive dental procedures if possible. Good oral hygiene and regular dental check-ups should be maintained during treatment with denosumab. Prompt referral is needed if a patient presents with oral symptoms during therapy (e.g. pain, swelling, dental mobility). In light of the [MHRA guidance](#) in July 2015, patients are also advised to have a [patient safety reminder card](#).

Hypocalcaemia

As highlighted by the [MHRA](#), hypocalcaemia is a known risk with denosumab use. It may occur within 24 hours of administration and is usually transient. The risk is greater in individuals with pre-existing hypocalcaemia and particularly in those with renal impairment. Monitor calcium levels and identify those patients who are predisposed to hypocalcaemia (patients with severe renal impairment, creatinine clearance < 30 mL/min) who should also have calcium levels checked within two weeks of the initial dose. These patients will be highlighted by secondary care on initiation.

Do not administer treatment if evidence of hypocalcaemia. If a patient presents with symptoms of hypocalcaemia between doses, measure calcium level and renal function. If hypocalcaemia is confirmed and the reason for this is not clear (such as the patient stopping their supplements), consider measurement of PTH, magnesium and vitamin D. It may be helpful to discuss the results with the specialist.

Atypical Femoral Fractures

Denosumab has been associated rarely with the occurrence of atypical femoral fractures. Patients presenting with new or unusual hip, thigh or groin pain should be evaluated for this possibility. Discontinuation of denosumab should be considered while the patient is being evaluated. Evolving atypical femoral fractures may not be apparent on radiographs and if the diagnosis is suspected and not seen on a radiograph, further evaluation with NM or MR imaging should be undertaken.

Renal function considerations

Denosumab should not be stopped purely because of worsening renal function. Denosumab does not rely on renal clearance. The risk of severe hypocalcaemia in patients who have already received the first two to three denosumab injections is low, even when kidney function worsens. This is because the 'hungry bone' syndrome is less likely when patients are well established on denosumab. Please discuss with secondary care specialists if concerned but be aware that usually there is no alternative treatment for patients with eGFR<35 mL/min.

11. Advice to patients and carers

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The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- Patients should be advised to report symptoms of hypocalcaemia e.g. muscle spasms, twitches or cramps; numbness or tingling in the fingers, toes or around the mouth.
- Patients should be advised to report any new or unusual hip, thigh or groin pain for longer than 3 weeks (to evaluate the possibility of atypical femoral fractures).
- Patients receiving denosumab may develop skin infections (predominantly cellulitis) requiring hospitalisation and if symptoms develop then they should contact a health care professional immediately.

The patient should be advised:

- While on treatment, patients should avoid invasive dental procedures if possible. Good oral hygiene and regular dental check-ups should be maintained during treatment with denosumab. Prompt referral is needed if a patient presents with oral symptoms during therapy (e.g. pain, swelling, dental mobility). The [patient safety reminder card](#) highlights the particular issue about the risk of ONJ.

Additional supporting information:

- [Patient safety reminder card](#)
- [Royal Osteoporosis Society Leaflet](#)
- [Amgen Patient Information Leaflet](#)

12. Pregnancy, paternal exposure and breast feeding

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It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

Pregnancy:

There are [no or limited amount of data](#) from the use of denosumab in pregnant women. Denosumab is not recommended for use in pregnant women and women of child-bearing potential not using contraception. Women should be advised not to become pregnant during and for at least 5 months after treatment with denosumab.

Breastfeeding:

It is unknown whether denosumab is excreted in human milk. A decision on whether to abstain from breast-feeding or to abstain from therapy with denosumab should be made, taking into account the benefit of breast-feeding to the newborn/infant and the benefit of denosumab therapy to the woman.

Paternal exposure:

No data are available on the effect on denosumab on human fertility.

Further information can be found in the [SPC section 4.6](#)

13. Specialist contact information

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Barnsley:

Advice and Guidance Service 01226 432387 or 01226 432421

barnsley.rheumatology@nhs.net

Doncaster:

Rheumatology Nurse Advice Line: 01302 644101 – option 4

dbth.rheumyscript@nhs.net

Rotherham:

01709 424131

rg-h-tr.bonehealthnursingstaff@nhs.net

Sheffield:

Metabolic Bone Centre, Northern General Hospital, Sheffield 0114 2715340

sth.metabolicbonecentrefax@nhs.net

14. Additional information

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Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's primary care clinician or their contact details

15. References

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NICE - Denosumab for the Primary and Secondary Prevention of Osteoporotic Fractures in Postmenopausal Women, Technology Appraisal, October 2010. Available at <https://www.nice.org.uk/Guidance/TA204>.

SPC Denosumab:

<https://www.medicines.org.uk/emc/product/568>

Patient Safety Reminder Card:

https://assets.publishing.service.gov.uk/media/55a66d9eed915d151b000003/AMGEN_PROLIA_patient_card.pdf

MHRA Denosumab Updates:

<https://www.gov.uk/drug-safety-update/denosumab-monitoring-recommended> (Dec 2014)

<https://www.gov.uk/drug-safety-update/denosumab-60-mg-prolia> (Dec 2014)

<https://www.gov.uk/drug-safety-update/denosumab-updated-recommendations> (Dec 2014)

<https://www.gov.uk/drug-safety-update/denosumab-xgeva-prolia-intravenous-bisphosphonates-osteonecrosis-of-the-jaw-further-measures-to-minimise-risk> (July 2015)

[Denosumab \(Prolia, Xgeva ▼\): reports of osteonecrosis of the external auditory canal - GOV.UK \(www.gov.uk\)](#) (June 2017)

[Denosumab 60mg \(Prolia\): increased risk of multiple vertebral fractures after stopping or delaying ongoing treatment - GOV.UK \(www.gov.uk\)](#) (August 2020)

<https://www.gov.uk/drug-safety-update/denosumab-60mg-prolia-should-not-be-used-in-patients-under-18-years-due-to-the-risk-of-serious-hypercalcaemia> (May 2022)

16. Other relevant national guidance

- Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from Futures Platform
- NHSE policy – Responsibility for prescribing between primary & secondary/tertiary care. Available from <https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/>
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care>
- NICE NG197: Shared decision making. Last updated June 2021. <https://www.nice.org.uk/guidance/ng197/>.

17. Local arrangements for referral

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Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

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 assessment is reviewed after 5 years' treatment. **Consider** referral to secondary care for a repeat fracture risk assessment, earlier review will be advised in some patients at high risk. The timing of reassessment will be advised by the specialist. Treatment effect reverses rapidly so it is **not** appropriate to consider a 'drug holiday' with denosumab therapy as can be considered with bisphosphonate treatment.

Appendix One: Protocol for Primary Care

DENOSUMAB 60MG S/C (brand 'Prolia®') –TREATMENT FOR OSTEOPOROSIS

PROTOCOL FOR PRIMARY CARE

Important notes

This medication is given every 6 months subcutaneously. It strengthens bone, and is effective in prevention of fragility fracture, especially of spine and hip.

- a. Keep in **fridge**, however once removed, has shelf life of 30 days.
- b. Its effect reverses rapidly, so aim to give on time (one month window).
- c. Avoid giving if hypocalcaemic or patient is acutely unwell, defer until calcium level corrected.
- d. Patients should be taking calcium and vitamin D supplements **OR** on Vitamin D only if taking good dietary calcium.
- e. **Adjusted calcium** level must be checked 2-3 weeks prior to each injection and must be above normal levels

SEQUENCE

1. SCP accepted by primary care clinician (communication from secondary care shows next injection due date, baseline serum calcium and any additional instructions).
2. Add to recall for monthly patient search
3. Blood test for serum calcium 2-3 weeks prior to every injection due date.
4. If adjusted calcium result confirmed as normal, prescriber to issue the repeat prescription OR buy direct from supplier after setting up account. Store on delivery in practice fridge or, if Community Nursing Services to give, request pharmacy delivery to patient home fridge (with latter, approx. 4 days before due date helps avoid waste). For housebound or care home residential patients who require administration by community nursing services, the issuing of denosumab must be via an FP10.

NB Supplier is: AAH Pharmaceuticals Product Code PRO2653L (08:30 – 19:00 Mon – Fri)

Online: www.aah.co.uk

5. Give injection within 4 weeks of due date, record with SNOMED Code for 'denosumab therapy - 700139004'
6. Reset recall date. Patient can be encouraged to start the process in 5 months by booking a blood test 2-3 weeks prior to due date or send letter to invite to book.