University Hospitals Birmingham NHS
NHS Foundation Trust

CONTROLLED DOCUMENT

SHARED CARE AGREEMENT

Denosumab (Prolia®▼)
For the treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures

CATEGORY:	Guidelines
CLASSIFICATION:	Clinical
PURPOSE	This shared care agreement outlines the responsibilities for managing the prescribing and administration of Denosumab (Prolia®) for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures and how they are to be shared between the secondary care specialist (University Hospital Birmingham NHS Foundation Trust [**UHB**]) and primary care physician (GP)/primary care prescriber.
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Controlled Document Sponsor:	Service Lead, Endocrinology
Controlled Document Lead:	• Sherwin Criseno- Lead CNS, Endocrinology • Prof. Neil Gittoes- Consultant, Endocrinology
Approved By:	
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Distribution: • **Essential Reading for:** • **Information for:**	All clinical staff dealing with postmenopausal women and men at risk of osteoporosis. All other clinical staff.

1 Introduction

This shared care agreement outlines the roles and responsibilities for managing the prescribing and administration of denosumab (Prolia®) for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures and how they are to be shared between University Hospital Birmingham NHS Foundation Trust and primary care physician (GP) / primary care prescriber.

This shared care guideline has been produced to support the seamless transfer of prescribing, administration and patient monitoring from secondary to primary care and provides an information resource to support clinicians providing care to the patient. It does not replace discussion about sharing care on an individual patient basis.

2 Status of Denosumab (Prolia ®)

- Prolia is licensed for treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture.
- Prolia is also licensed as treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures. In men with prostate cancer receiving hormone ablation, Prolia significantly reduces the risk of vertebral fractures.
- Prolia is approved by NICE (NICE TA 204).
- Prolia has been approved by the Birmingham, Sandwell, Solihull and environs Area Prescribing Committee (BSSE APC) to be prescribed and administered in primary care under the Effective Share Care Agreement (Denosumab ESCA, July 2015).

3 The NICE technology appraisal (TA 204) states:

- NICE has produced technology appraisal guidance 'Denosumab for the prevention of osteoporotic fractures in postmenopausal women' available from http://guidance.nice.org.uk/TA204.
- Denosumab is recommended as a treatment option for the secondary prevention of osteoporotic fragility fractures in postmenopausal women at increased risk of fractures who are unable to comply with the special instructions for administering alendronate and either risedronate or etidronate, or have an intolerance of, or a contraindication to those treatments.

- The recommended dose of denosumab is 60 mg administered as a single subcutaneous injection once every 6 months into the thigh, abdomen or back of arm (refer to Appendix A: Guidelines for Administration of Denosumab).

4 Related National Guidelines:

- Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women (Technology Appraisal Guidance 160). Available at: http://www.nice.org.uk/guidance/TA160.

- Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women (Technology appraisal Guidance 161). Available at: http://www.nice.org.uk/guidance/TA161.

- Guidelines for the diagnosis and management of osteoporosis in postmenopausal women and men from the age of 50 years in the UK (National Osteoporosis Guideline Group, 2014).

- Osteoporosis: Assessing the Risk of Fragility Fracture (NICE Clinical Guideline 146). Available at: http://www.guidance.nice.org.uk/cg146.

- Osteoporosis: Clinical Guideline For Prevention and Management (National Osteoporosis Guideline Group, 2016).

5 Responsibilities and Roles

A. UHB Consultant/Specialist (Secondary Care Specialist)

- To confirm the diagnosis of osteoporosis.

- To assess the suitability of the patient for denosumab injection.

- To discuss the benefits and side effects of treatment with the patient including the risk of osteonecrosis of the jaw, cellulitis and atypical femoral fracture.

- To assess the patient to ensure that he/she has a good oral hygiene and advice patient of the need for dental examination prior to initiating therapy and the importance of undergoing regular dental check-up. Urgent treatment should not be delayed, however, a dental check-up should be advised and carried out as soon as possible (MHRA, 2014)

- To advise the clinical nurse specialist (CNS) of patient requiring denosumab treatment as per the Trust guidelines.

- To prescribe and administer the first two doses of denosumab if CNS is not a qualified prescriber.

- Issue to the patient “My Bone Passport”, ensure it is updated and explain the purpose of the passport.

- To ensure that patient is supplemented with Calcium and/or Vitamin D if required.

- To advise patient to stop other osteoporosis treatment (e.g. alendronate, risedronate, ibandronate, strontium) except Calcium and/or Vitamin D supplements (if indicated).

- To send GP a summary of out-patient review or in-patient stay within 10 days, and instructions provided to the patient.

- To review patient as agreed and whenever required as requested by the primary care physician.

- To ensure that arrangements are in place for GPs to obtain advice and support where needed.

- To report any adverse events to the MHRA.

B. Clinical Nurse Specialist (CNS) – Endocrinology (Secondary Care)

- To ensure that patient understand the indication, mode of action, side effects of the medication, duration of treatment and method of administration prior to initiating the treatment and complete the required checklist (see Appendix E- *Anti-fracture Medication Pre-treatment Screening and Administration Checklist*).

- To give patient a reminder card (Appendix F: *ONJ Reminder Card*).

- To initiate denosumab for the licensed indication in accordance with the manufacturer's Summary of Product Characteristics (SPC) and instruction from the prescriber.

- To ensure that patient is calcium and vitamin D replete prior to administering denosumab injection.

- To ensure that patient has stopped other osteoporosis treatments (e.g. alendronate, risedronate, ibandronate, strontium) except Calcium and/or Vitamin D supplements (if indicated) prior to administering first

dose of denosumab.

- To prescribe and administer the first two doses of denosumab and monitor patient's response and reaction to treatment. Pre-treatment screening checklist should be completed prior to administering each denosumab injection (see Appendix E- *Anti-fracture Medication Pre-treatment Screening and Administration Checklist*)

- To review patient in the Nurse-Led clinic prior to administering the second dose of denosumab injection.

- To discuss the Shared Care Agreement with the patient and ensure that she/he understands the treatment plan and follow-up arrangement.

- To request patient's GP, in writing, to enter into a shared care agreement after the patient had her/his second dose of denosumab treatment. CNS to send a copy of the following Shared Care Agreement (SCA):

    a. For patients within the Birmingham, Sandwell, Solihull and environs area (BSSE), copy of the BSSE Area Prescribing Committee Effective Shared Care Agreement on Denosumab (July 2015) should be sent to their respective GPs (Available at: http://www.birminghamandsurroundsformulary.nhs.uk/docs/esca/BSSE%20APC%20ESCA%20Denosumab.pdf?uid=105877703&uid2=20171191701085)

    b. For patients outside BSSE area, copy of this SCA should be sent to patient's GP.

- Following GP's confirmation of agreement with shared care, to handover the prescribing and administration of denosumab to the GP after the patient received her/his second dose of denosumab. This will be done within 7- 14 days after the administration of the second dose.

- When handing over the prescribing and administration of denosumab, CNS to ensure that the patient's GP is provided with a copy of the SPC, SCA/ESCA, treatment summary and educational materials relevant to the use of denosumab if needed.

- If considered appropriate, to give patient a copy of the Shared Care Agreement to give to their community pharmacist.

- To ensure that patient is registered to the PROLONG Programme and given a 'My Bone Passport' at the start of treatment.

- To give patient contact details of key worker at UHB for any queries or concerns.

- Give patient a copy of the ‘Patient Information Leaflet on Prolia Shared Care’.

C. Primary Care Physician

- To reply to the request from UHB specialist for shared care as soon as possible taking into account the extent of the care they are asked to be involved in e.g. prescribing of Denosumab, administering the Denosumab injection, storage of Denosumab, monitoring of treatment and/or patient's condition. This should ideally be done within 10 working days of receiving the request for shared care.

- To report to and receive advice from the UHB specialist on any aspect of patient care that is of concern.

- To prescribe and administer denosumab injection at six monthly intervals for 5 years (or as specified by UHB specialist).

- To ensure practice system is set-up to recall patient at six month interval. This should include checking patient’s serum Calcium and Vitamin D levels prior to the administration of denosumab.

- To ensure that patient is calcium and Vitamin D replete prior to administering denosumab.

- To ensure that other osteoporosis treatments (e.g. alendronate, risedronate, ibandronate, strontium) are stopped and removed from the patient’s repeat prescription.

- To ensure that a system is set up to order denosumab. Order from primary care can be placed directly with **Movianto** (see Section 6 for contact details).

- To ensure practice arrangements are made to ensure that denosumab is stored in a vaccine refrigerator - temperatures monitored daily. If a practice refrigerator is not available, the practice should consider drawing up a protocol with a local pharmacy(ies) for denosumab prescriptions so that the patient is not required to make multiple journeys.

- To report any adverse events to the specialist and the MHRA http://yellowcard.mhra.gov.uk/). Denosumab is a black triangle product.

- To refer the patient back to UHB specialist if the patient's condition deteriorates and/or if patient experience any adverse reactions. Particular attention should be paid to symptoms of hypocalcaemia, skin infections (especially cellulitis), osteonecrosis of the jaw and adverse reactions listed as 'common' in the Denosumab SPC.

- To refer the patient back to UHB specialist at the end of Year 5 of treatment for review.

- To arrange DXA bone scan at the end of Year 5 of treatment (prior to patient's outpatient appointment at UHB) and send copy of the report to the UHB specialist.

D. Patient's role (or that of carer)

- Patient to immediately report any adverse events to the doctor or clinical nurse specialist. The following signs and symptoms should be reported promptly: swollen and red area of skin, most commonly in the lower leg that feels hot and tender (cellulitis); symptoms of fever, muscle aches, dizziness; any dental problems, and symptoms of hypocalcaemia (e.g., muscle spasms; twitches or cramps; numbness or tingling in the fingers, toes, or around the mouth).

- Patient to see her/his dentist before commencing denosumab treatment, particularly if experiencing any dental problem.

- Patient to inform the secondary care specialist or her/his GP if she/he has any problems with her/his mouth or teeth before and during treatment and seek consultation and treatment from her/his dentist as soon as possible (e.g., loose teeth, pain, swelling, non-healing sores or discharge).

- Patient to maintain good oral hygiene, undertake to have regular dental checkups.

- Patient to take calcium and/or vitamin D supplements (if necessary) while on treatment with denosumab as prescribed by the secondary care specialist or GP.

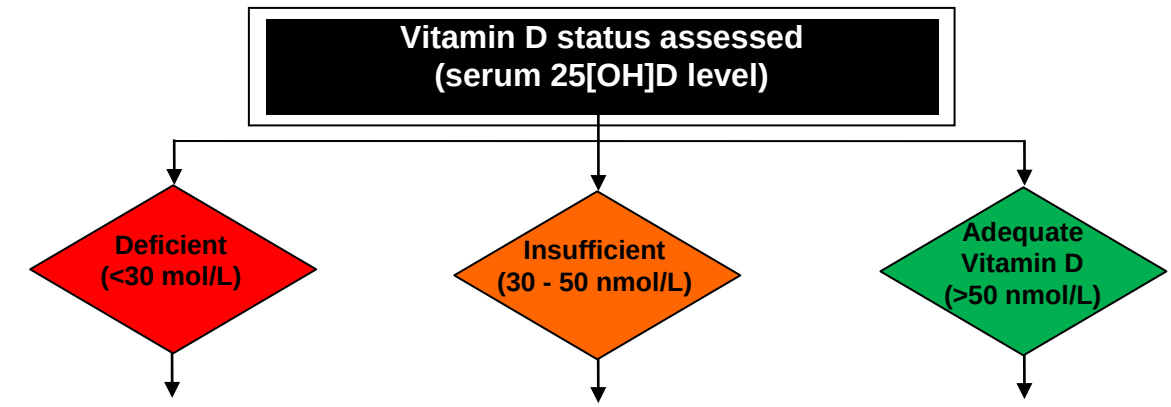
- Patient to respond in timely manner to primary care recall for appointment for blood test and administration of denosumab to ensure it is received at a six monthly interval.

- Patient to keep a record of treatment ensuring her/his 'MY BONE PASSPORT' is updated at 6 monthly visit for denosumab injection.

- Patient to consult the GP or secondary care specialist should their condition significantly worsen or they experience any adverse reactions.

6 Vitamin D Supplementation

- Below is the recommended regimes for correction of Vitamin D deficiency with colecalciferol in patients commencing or receiving active bone metabolism drug



- Commence patient on pharmacological strength vitamin D.
  a. **<u>Loading dose:</u> Colecalciferol 40000 - 50000IU weekly for 6 - 7 weeks followed by**
  b. **<u>Maintenance dose:</u> Colecalciferol 800IU – 2000IU daily.**
- Check serum vitamin D level after the loading regime.
- Advise patient on appropriate sun exposure and dietary source of Vitamin D.

- Commence patient on pharmacological strength vitamin D.
  a. **Loading dose: Colecalciferol 3200IU daily for 6 weeks, followed by**
  b. **Maintenance dose: Colecalciferol 800IU – 2000IU daily.**
- Check serum vitamin D level after the loading regime.
- Advise patient on appropriate sun exposure and dietary source of Vitamin D.

- Adequate Vitamin D level.
- If patient is already on vitamin D supplementation, continue as normal.
- Patients who are not on daily supplementation do not require any treatment.
- Advise patient on appropriate sun exposure and dietary source of Vitamin D.

6.A Fixed Loading Dose Regime Loading regimen should provide a total of approximately 300,000 IU. Below are the recommended loading dose regimes.		
Example Preparation	**Dose**	**Duration of Treatment**
Fultium-D3 capsules (colecalciferol)	3200 IU one daily	10-12 weeks (224,000-268,800IU in total)
Fultium-D3 capsules (colecalciferol)	20,000 IU two weekly	7 weeks (280,000 IU in total)
InVita-D3 oral solution (colecalciferol)	50,000 IU one weekly	6 weeks (300,000 IU in total)
Ergocalciferol (intramuscular injection) ***only to be used in patients with malabsorption problem.**	300000 IU single dose	May be repeated every 3-6 months if needed.

6.B Maintenance Dose Regime Typical maintenance dose is 800IU – 2000IU tailored to individual needs and condition.	
Example Preparation	**Dose**
Fultium-D3 capsules (colecalciferol)	800 IU (1-2 capsules daily)
Densunin tablets (colecalciferol)	800 IU (1-2 tablets daily)
InVita-D3 capsules (colecalciferol)	800 IU (1-2 capsules daily)
Stexerol-D3 caplets (colecalciferol)	1000 IU (1-2 caplets daily)

7 Useful Contact Numbers

Prof. Neil Gittoes **Clinical Lead, Bone Service** **(Consultant Endocrinologist)**	**Contact via switchboard**
Specialist Registrar **Endocrinology**	**Contact via switchboard**
Sherwin Criseno **Lead Clinical Nurse Specialist** **Endocrinology**	**0121-371-6950** **Sherwin.criseno@uhb.nsh.uk**
Movianto Orders can be placed between 8.30am – 5.30pm, Monday to Friday. To ensure next day delivery, please place orders by 4.30pm If the pharmacy/GP surgery does not currently have a direct account with Movianto, this can usually be set up within a few hours	**Movianto Customer Service Team** Movianto UK, Progress Park Bedford, MK42 9XE Tel orders: 01234 248631 Fax orders: 01234 248705 **E-mail: orders.uk@movianto.com**

8 References

- Keele University: EFFECTIVE SHARED CARE AGREEMENT Denosumab (Prolia®▼) For the treatment of osteoporosis in postmenopausal women at increased risk of fractures http://www.esca-keele.co.uk/denosumab/agreement.php?ReferenceCode=F7D60E5A

- MHRA (2014) 'Denosumab: updated recommendations', Medicines and Healthcare Products Regulatory Agency. [Online]. Available at: https://www.gov.uk/drug-safety-update/denosumab-updated-recommendations (Accessed: 03 March 2016).

- NICE (2010) Technology Appraisal Guidance 204: Denosumab for the prevention of osteoporotic fractures in postmenopausal women.

- NOGG (2014) 'Guideline for the Diagnosis and Management of Osteoporosis in Postmenopausal Women and Men from the Age of 50 years in the UK', National Osteoporosis Guideline Group. [Online]. Available at: https://www.shef.ac.uk/NOGG/NOGG_Pocket_Guide_for_Healthcare_Professionals.pdf (Accessed: 03 October 2015).

- NOGG (2016) 'Osteoporosis: Clinical Guideline For Prevention and Treatment', National Osteoporosis Guideline Group. [Online]. Available at: https://www.shef.ac.uk/NOGG/NOGG_Executive_Summary.pdf (Accessed: 03 March 2016).

APPENDIX A: Patient Pathway

Patient Pathway

Patient Requiring Denosumab (Prolia ®) 6-monthly Injection

Patient requiring Denosumab (Prolia ®) Injection for the treatment of Osteoporosis

Refer patient to the Endocrine Nurse

- Discuss the treatment with the patient if not covered during the consultation (including duration of treatment, side effects, method of administration and follow-up arrangement).
- Give patient relevant information and contact details.
- Ensure that baseline Calcium and Vitamin D levels are checked.

6-monthly Injection (Year 1)

- First 2 doses to be arranged and administered at QE Hospital Birmingham by the Endocrine Clinical Specialist Nursing Team.

Refer to GP for Shared Care

- Endocrine Nurse to ask GP to enter into a Shared Cared Agreement after patient completed the first two doses of Denosumab injection.

Shared Care Agreed

- GP to continue prescribing and administering 6-monthly Denosumab up to Year 3-5.
- Endocrine Nurse to arrange Follow-up Hospital appointment (NJ7Q) at the end of Year 5.

Shared Care NOT Agreed

- Continue treatment at the hospital or community pharmacy as per protocol.
- 6-monthly follow-up in the Nurse-Led Clinic (BV9Q).
- Endocrine CNS to arrange Consultant review at the end of Year 3 and Year 5.

Consider Review by UHB Specialist (Year 3)

- If necessary (according to patient's response to treatment), patient can be referred to UHB specialist for review, otherwise continue treatment up to Year 5.

Continue Treatment

- GP to continue prescribing and administering 6-monthly Denosumab up to Year 5.
- GP to arrange DXA scan at the end of Year 5 and send result to Prof. Gittoes

Discontinue/Change Treatment

- Follow-up in Consultant bone clinic as required.

Hospital Consultant Review- UHB (Year 5)

- Review treatment.
- Consider Bone DXA Scan if not done by patient's GP.
- Arrange necessary follow-up (NJ7Q or BV9Q).

Consultants:
Prof. Neil Gittoes
Dr. John Ayuk
Dr. Tarek Hiwot
Dr. Zaki Hassan-Smith

Sherwin Criseno
Lead CNS-Endocrine (Metabolic Bone)

Sylvia Dent
Endocrine Nursing Team Administrator

0121-371-6950

APPENDIX B

REQUEST FOR SHARED CARE

DATE:

RE:

GP and address

Dear Dr.:

Your patient has been commenced on the following treatment for osteoporosis:

Anti Resorptive Agent	Denosumab (Prolia ®)
Dose and Frequency	60 mg six monthly subcutaneously injection
Date Treatment Started	

It is a RANK ligand inhibitor that is given every 6 months as a subcutaneous injection for 3 years in the first instance and may be continued for a total of 5 years depending on patient's response to treatment.

Denosumab has been approved by Birmingham, Sandwell, Solihull and environs Area Prescribing Committee (BSSE APC) and MTRAC (Midlands Therapeutic Review and Advisory Committee) as suitable to be prescribed and administered in primary care following initiation and stabilisation of treatment in secondary care through a shared care agreement. I would like to ask if you would be willing to enter into a Shared Care Agreement for the prescribing and administration of this medication in primary care setting.

I have enclosed a copy of the Shared Care Guidelines. Please kindly complete, sign and send a copy of the **'Confirmation of Shared Care Agreement'** to us as soon as possible. I have also enclosed a copy of the information leaflet on denosumab.

Please do not hesitate to contact us if you require any further information.

Yours sincerely,

Sherwin Criseno
Lead CNS, Endocrinology/Metabolic Bone Service
Sherwin.criseno@uhb.nhs.uk

APPENDIX C

CONFIRMATION OF SHARED CARE AGREEMENT

Denosumab (Prolia®▼)
For the treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures

RE: Patient's Details

Prof. Neil Gittoes
c/o Sherwin Criseno- Lead CNS Endocrinology
Endocrine Nurses Office
Third Floor, Heritage Building
QE Hospital Birmingham
Edgbaston
Birmingham
B15 2TH

Dear Prof. Gittoes:

This is to confirm that:

□ **I will**
□ **I will not**

be taking over the prescribing and administration of **Denosumab (Prolia ®)** for _____ (patient) through a shared a care agreement.

I understand that the treatment will be initiated in the hospital and that a treatment summary will be sent to me after the patient received her/his second dose.

Sincerely,

GP's Name and Signature
Date:

Please tick as required

□ **I would like a visit from the Medical Representative to go through the proper administration of denosumab with me/my practice nurse.**
□ **I would like a copy of the Training DVD on denosumab.**

APPENDIX E

Treatment Summary

Denosumab (Prolia®▼)
Shared Care Agreement

GP
ADDRESS

RE:

Dear Dr.:

Thank you for agreeing to take over the prescribing and administration of Denosumab for this patient through a shared care agreement. Below is the summary of her treatment.

Treatment Details	
Diagnosis	Osteoporosis
Anti Resorptive Agent	Denosumab (Prolia ®)
Dose and Frequency	60 mg six monthly subcutaneous injection
Duration of Treatment	3-5 Years
Supplementation	Details of Calcium and/or Vit D supplement (if required)
Next Clinic Appointment at UHB	

Dose History		
Dose	**Date**	**Site of Injection/Comments**
Dose 1		**Abdomen**
		Abdomen
		Abdomen
		Abdomen
Next Dose (Dose)	**Due by:**	

Please note that Denosumab has a quick 'on and off' effect and therefore must be given without delay on a 6-monthly basis. Patient's serum calcium and Vitamin D levels must be checked 6-8 weeks before each injection and ensure that patient is calcium and Vitamin D replete before administering next injection.

Additional useful information can be found below:

- Summary of Product Characteristics (SPC): http://www.medicines.org.uk/emc/medicine/23127/SPC/prolia/
- DVD (if requested will be sent by post by AMGEN)
- Information on how to administer Denosumab and how to set up a system for recalling patient can be found on: http://www.prolia.co.uk

Should you have any queries regarding this treatment, please find below some useful contact details.

Sherwin Criseno **Lead Clinical Nurse Specialist** **Endocrinology/Metabolic Bone**	**0121-371-6950** **Sherwin.criseno@uhb.nsh.uk**
Sylvia Dent **Secretary** **Endocrine Nursing Team**	**0121-371-6950** **Sylvia.dent@uhb.nhs.uk**

Yours sincerely,

Sherwin Criseno
Lead Clinical Nurse Specialist- Endocrinology
(Tel. No.: 0121-371-6950)

APPENDIX F: Pre-treatment Screening and Administration Checklists

Anti-Fracture Medication Pre-treatment Screening Checklist	Affix Patient's Label

Anti-resorptive Agent	☐ **Zoledronic Acid (Dose: _____) IV infusion** ☐ **Denosumab 60 mg subcutaneous injection** ☐ **Other: _____**
Treatment Cycle	

Checklist	**Date**	**Remarks**
1. Clinic Review (specify: NJ6Q, NJ7Q, AV7Q, BV9Q, BG6Q, AV5Q)		
2. Blood Test Done (GP / QEHB / Other:_____)		
3. Blood results eGFR		
Serum Calcium		
Serum Vitamin D		
4. Confirmed suitable for treatment		
5. Checklist for Initiating Anti-Fracture Medication completed (for new patient only)		
6. Medication: Pre-authorised/Rx prepared		
Meds ready		

Additional notes and special instruction/s:

For Admin Use Only	
TCI done	
Letter Sent	
Booked On Calendar	
Database Updated	

Date and Time of Appointment	

Please return this form to the Endocrine CNS Secretary		
Serum Calcium Check (2 weeks post injection) (for Denosumab patient only if applicable)	☐GP ☐QEHB Date:	Reviewed by

Administration Checklist

Affix Patient's Label

Date and Time of Day Case Admission		
Pre-administration Checklist		
Pre-treatment screening completed by prescriber.	Yes	**No-** Check and confirm with. Dr./Prescriber.
Is the patient pregnant?	No/NA	**Yes-** do not give medication.
Baseline observations within normal parameters and the patient appears well.	Yes	**No-** Discuss with Dr./Prescriber.
Patient appears well hydrated and most recent U&E results within normal parameters (Zol only).	Yes	**No-** Do not give medication. Discuss with Dr./Prescriber.
Creatinine clearance result greater than or equal to 35ml/hr (Zol only).	Yes	**No-** Do not give medication. Discuss with Dr./Prescriber.
Vitamin D level within normal limits (checked within the last 12 weeks).	Yes	**No-** Do not give medication. Discuss with Dr./Prescriber.
Most recent calcium result within normal limits (checked within the last 12 weeks).	Yes	**No-** Do not give medication. Discuss with Dr./Prescriber.
Patient has no dental problem/concerns.	No concern/problem	Discuss with Dr./Prescriber if patient has concern.
Patient has no complaint of groin/lateral thigh pain.	No concern/problem	Discuss with Dr./Presriber if patient has concern.
Allergies		
Observations: Pre-treatment (time:_____) Post-treatment (time: _____)	**BP: HR: RR: Temp:** **BP: HR: RR: Temp:**	

Time	**Administration Checklist**	**Signature**
	Admitted patient in Endocrine Day Case Unit for _____ dose of _____.	
	Explained the procedure and possible side effects.	
	Advice given regarding appropriate management of potential side effects of treatment.	
	Observations (PR, RR, BP and Temp.) taken and recorded as above.	
	No contraindication for the administration of this medication (including allergies) noted.	
	Verbal consent given by patient.	
	(When applicable) Cannulated patient with G.____ cannula on _____ x ___ attempt. Flushed with 10 mls. 0.9% NaCl. Cannula patent.	
	☐ **Zoledronic Acid _____ mg IV infusion over _____ mins commenced.** ☐ **Denosumab 60mg given as subcutaneous injection (site:_____).** **(Batch/Lot Number: _____ / Expiry Date: _____).**	
	Offered patient a drink.	
	Encouraged patient to drink plenty of fluids (for patient receiving Zoledronic infusion only).	
	Treatment completed.	
	MRSA Screening done (Nose & Throat Swabs).	
	(When applicable) Cannula removed. Sterile dressing applied on venenpucture site.	
	Post-administration observations taken and recorded as above.	
	For patient on denosumab injection, register with PROLONG/update Bone Passport.	
	Advised patient to maintain good oral hygiene and to see dentist regularly (at least yearly).	
	Next clinic appointment confirmed (Date: _____ Time: _____).	
	Discharged patient with advice.	

APPENDIX G: Prolia ONJ Reminder Card

This reminder card contains important safety information that you need to be aware of before and during treatment with denosumab (Prolia).

Your doctor has recommended that you receive denosumab (Prolia), which is used to treat osteoporosis and bone loss. These diseases involve thinning and weakening of the bones so they may break more easily.

A side effect called osteonecrosis of the jaw (ONJ) (bone damage in the jaw) has been reported rarely (may affect up to 1 in 1,000 people) in patients receiving Prolia for osteoporosis. ONJ can also occur after stopping treatment.

It is important to try to prevent ONJ developing as it may be a painful condition that can be difficult to treat. In order to reduce the risk of developing ONJ, there are some precautions you should take.

Before starting treatment:

Tell your doctor/nurse (health care professional) if you have any problems with your mouth or teeth.

Your doctor may ask you to undergo a dental examination if you:

- were previously treated with a bisphosphonate
- are taking medicines called corticosteroids (such as prednisolone or dexamethasone)
- are a smoker
- have cancer
- have not had a dental check up for a long time
- have problems with your mouth or teeth

While being treated:

- You should maintain good oral hygiene and receive routine dental check-ups. If you wear dentures you should make sure these fit properly.
- If you are under dental treatment or will undergo dental surgery (e.g. tooth extractions), inform your doctor and tell your dentist that you are being treated with Prolia.
- Contact your doctor and dentist immediately if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, or non-healing of sores or discharge, as these could be signs of osteonecrosis of the jaw

Please read the package leaflet that comes with your medicine for further information.

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet, You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of Prolia

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AMGEN®