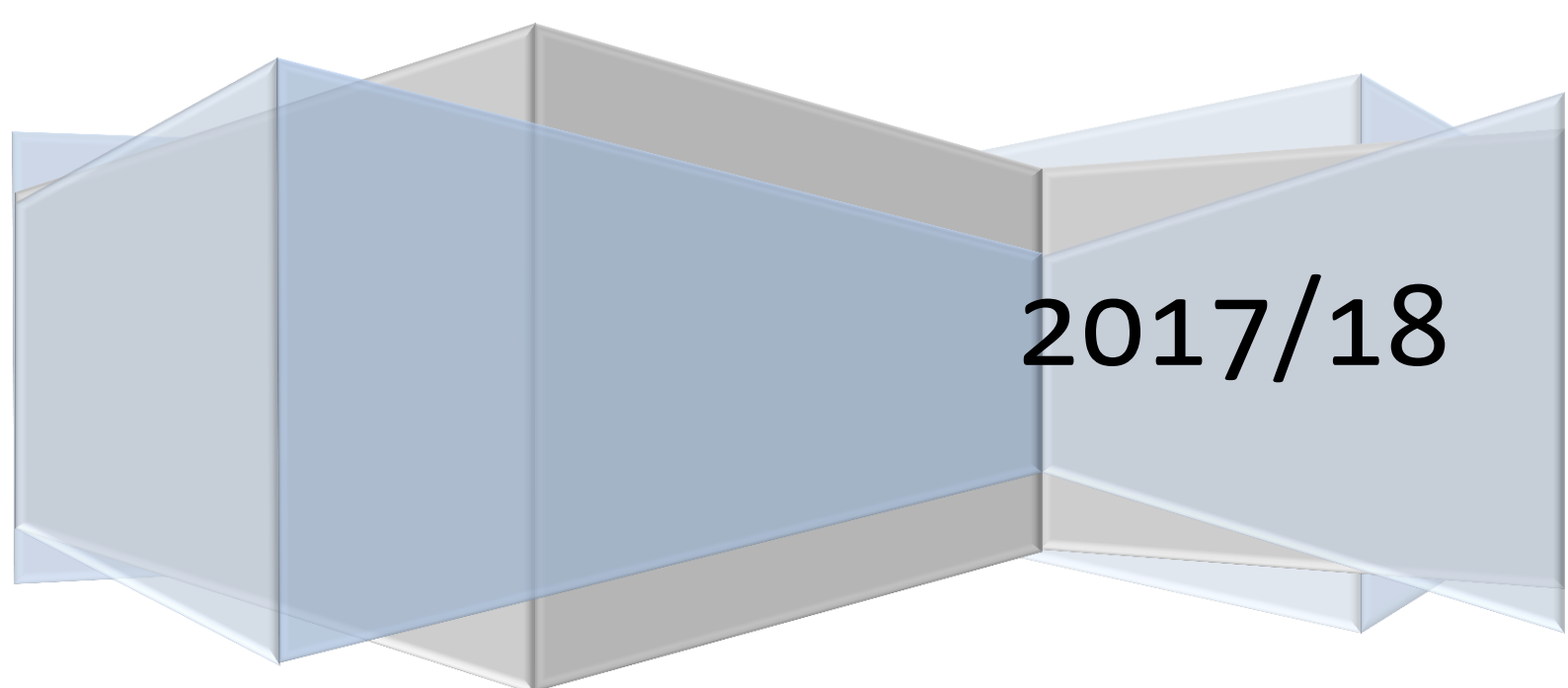


Saddleworth Medical Practice

Standard Operating Procedure

Drug Management - Denosumab

Dr Ian Watson



2017/18

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Introduction

Denosumab is a monoclonal antibody that binds to the RANK ligand protein produced by osteoblasts that then normally activates and develops osteoclasts. It inhibits this action and as such decreases bone resorption that is accelerated in osteoporosis.

Scope

Secondary care initiate Denosumab therapy. After twelve months of therapy stable patients are handed over to primary care.

Denosumab drug management provided to patient handed over to the Practice includes:

- Blood test monitoring (renal function and bone profile) six monthly
- Administering and monitoring Denosumab therapy six monthly
- refer for DEXA scans three yearly

Responsibilities

Task	Responsibility
Sister Joanne Grocott	Lead Nurse
Elizabeth Hampson	Data Quality Administrator
Victoria Howard	Contract Administrator
Lesley Styles	Denosumab Administrator
Dr Ian Watson	Lead GP



Process

Admin

Data Recording & Recall

Clinicians will:

- pass all new notifications of Denosumab being given in primary care to Denosumab Administrator.
- update the patients diary entries after administering Denosumab therapy
- refer patients when they require a DEXA scan

Data Quality Administrator will:

- code details from the secondary care hand over – first Denosumab therapy & last DEXA scan
- set up diary entries – next Denosumab Therapy and next DEXA
- apply patient warning “Denosumab 6/12 - DEXA 3 yearly (see diary) “
- search diary entries each month for patients due Denosumab therapy and DEXA, pass detail of patients due to the Denosumab Administrator.

Denosumab Administrator will:

- ensure that bloods (renal function and bone profile) are checked two week before administration of the drug is due.
- arrange for the Denosumab prescription one week before administration of the therapy is due
- arrange for the prescription to be kept refrigerated at the practice.
- make an appointment for patient to be given Denosumab (ideally with a practice nurse but on occasion with a doctor).
- maintain a Denosumab register on an spreadsheet
Location: N:\Shared\Saddleworth_Medical_Practice\Registers
Name: Denosumab
- Request Data Quality Administrator codes and sets up diary entries for all new notifications of Denosumab being given in primary care

Patient will be:

- given the Practice Denosumab Administrators contact details
- encouraged to take an active role in their treatment
- notified that the company making the drug offer a free reminder for patients by email or post.

Contract Administrator will:

- assist leads in ensuring contractual requirements and reporting arrangements are met
- Set up and oversee administrative processes



Clinical

Administration and cautions

All patients with a persistent eGFR <30 will stay within the secondary care setting.
If there is a transient drop in eGFR to below 30 and not due to AKI or other serious cause, the drug may be given whilst checking eGFR 10-14 days later.
If eGFR remains below 30 then, the patient is to be referred back to Pennine MSK

Hypocalcaemia should be treated before administration.

Patients should not be given the drug if:

- they have cellulitis (a side effect is lower limb cellulitis)
- Are due orthopaedic surgery within 12 weeks after
- If they have had metalwork inserted 12 weeks prior to the injection
- If they have fractured a bone 6 weeks prior to the injection
- If they unwell or taking antibiotics
- If the patient during their treatment plan develops a latex allergy they should be referred back to Pennine MSK as the needle is latex covered.

The injection itself is a subcutaneous injection. Given into the abdomen. The needle is self-retracting.

Side effects

- Flu like symptoms
- Cellulitis
- Osteonecrosis of the jaw – 1:1000
- Osteonecrosis auditory canal – 29 cases worldwide
- Atypical fracture – if the patient develops any new thigh, hip or knee pain this may need investigating for an atypical fracture.

Clinical checklist at time of administration

- Ensure bloods have been checked and are normal
- Check if due any orthopedic surgery
- Check if recent fracture or metalwork insertion
- Check date next DEXA is due – if due ask to make an appointment with a GP
- Check compliance to all medication especially calcium and vitamin D
- Identify any side effects
- Provide lifestyle advice
- Assess risk of falls and refer falls team if necessary



Reporting arrangements

EQALS Scheme – Drug Management

Indicator Ref. No.	Reporting Frequency	Min Threshold	Reports required
DM2	Quarterly	100%	No. of patients receiving treatment in primary care

Training requirements

The practice lead is responsible for providing / facilitating staff training (clinical and non-clinical).

References

Pennine MSK Rheumatology Advice Line

0161 621 3575

Template

EQALS template

The CCG provided clinical system template will be used to record data.
To access the template in emis consultation select 'Run template' then search for EQALS PLUS.

Supporting documents/Links

EQALS guidance

CCG supplied EQALS Plus scheme for 2017 / 18 documents are saved on the shared drive in the EQALS PLUS folder.

Location - N:\Shared\Saddleworth_Medical_Practice\EQALS PLUS

- EQALS Plus Specification 2017 18 FINAL revised 23.06.2017
- EQALS Plus 2017 18 Guidance FINAL 23.06.2017
- EQALS - Read Coded Specification 2017-18 - v24-08-2017

NICE guidance

<https://www.nice.org.uk/guidance/qs149>

Prolia® Patient Support Program

<https://www.prolia.com/services/patient-support-program/>



Appendix

Appendix 1 – Read Codes

Read Code	Description
8BPW.	Denosumab therapy
58E.	DEXA – Dual Energy X-ray photon Absorption



Document Control

Document Details

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V1	12/09/17	Victoria Howard		Admin SOP
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V1.3	28/07/17	Victoria Howard	Dr I Watson	Admin & Clinical SOP combined

Version Notice

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N:\Shared\Saddleworth_Medical_Practice\Standard Operating Procedure.

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