

Adding Prolia[®] (denosumab) to EMIS PCS



Date of preparation October 2014
DMB-GBR-AMG-658-2014-P

How to order Prolia[®] (denosumab)

Prolia[®] can be delivered directly to your practice within 24 hours.

To order, contact Movianto UK – Product code 9001231.

Telephone: 01234 248631 (08:30 to 16:30 Mon-Fri)

Fax: 01234 248705

Email: orders.uk@movianto.com

Alternatively, Prolia[®] can be provided to patients through retail pharmacy by writing an FP10.

How to store Prolia[®]

Prolia[®] should be stored in a refrigerator (2°C - 8°C). Do not freeze. Keep the pre-filled syringe in the outer carton to protect from light.

Prolia[®] has a shelf life of 36 months and may be stored at room temperature (25°C) for up to 30 days in the original container. Once removed from the refrigerator it must be used within this 30 day period¹.

[For further information contact Amgen medical information](#)

Telephone: 01223 436441

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Prolia® (denosumab)

Prolia® is indicated for the treatment of osteoporosis in postmenopausal women at increased risk of fractures. Prolia® significantly reduces the risk of vertebral, non vertebral and hip fractures.

Administration of Prolia®

The recommended dose of Prolia® is 60 mg administered as a single subcutaneous injection once every 6 months into the thigh, abdomen or the upper arm. Administration should be performed by an individual who has been adequately trained in injection techniques. Hypocalcaemia is a contraindication and patients must be adequately supplemented with calcium and vitamin D. Clinical monitoring of calcium levels is recommended before each dose and, in patients predisposed to hypocalcaemia, within 2 weeks after the initial dose. Regular monitoring of calcium levels is especially important in patients with severe renal impairment or on dialysis. Measure calcium levels if suspected symptoms of hypocalcaemia occur.

Ensuring subsequent doses are administered

Prolia® is often initiated in secondary care with the responsibility for the administration of further doses subsequently transferred to primary care^{2,3}.

It is critical to enter Prolia® correctly onto your primary care clinical system for patients to be able to receive subsequent doses within the recommended time frame.

This guide has been designed to help you enter Prolia® correctly into EMIS PCS specifically following initiation of treatment in secondary care.

In addition, this guide will show you how to create a search to identify patients for whom Prolia® is due or overdue. This should be run on a monthly basis. Instructions are also included on creating a recall system for Prolia® patients.

Ensuring the right patients are identified and treated to impact your Osteoporosis QOF outcomes

2014/2015 – Osteoporosis: Secondary Prevention of Fragility Fractures

Indicator	Points	Achievement thresholds
Records		
<p>OST004. The contractor establishes and maintains a register of patients:</p> <ol style="list-style-type: none"> 1. Aged 50 or over and who have not attained the age of 75 with a record of a fragility fracture on or after 1 April 2012 and a diagnosis of osteoporosis confirmed on DXA scan, and 2. Aged 75 or over with a record of a fragility fracture on or after 1 April 2014 and a diagnosis of osteoporosis <p><i>NICE 2011 menu ID: NM29</i></p>	3	
Ongoing Management		
<p>OST002. The percentage of patients aged 50 or over and who have not attained the age of 75, with a record of fragility fracture on or after 1 April 2012, in whom osteoporosis is confirmed on DXA scan, who are currently treated with an appropriate bone-sparing agent.</p> <p><i>NICE 2011 menu ID: NM30</i></p>	3	30-60%
<p>OST005. The percentage of patients aged 75 or over with a record of a fragility fracture on or after 1 April 2014 and a diagnosis of osteoporosis, who are currently treated with an appropriate bone-sparing agent</p> <p><i>NICE 2011 menu ID: NM31</i></p>	3	30-60%

Disease register

Although the register indicator OST004 defines two separate registers, the disease register for the purposes of calculating the Adjusted Disease Practice Factor is defined as the sum of the number of patients on both registers.

In order to ensure the [QOF Osteoporosis indicators](#) are met it is imperative the below information is correctly Read coded from the hospital discharge letters.

If information is missing the hospital department should be contacted to establish the information.

- **DXA Scans**
- **T-Scores**
- **Fragility Fractures** – unless fragility fractures are entered the Disease Register incidence will be affected, this will in turn affect the value of each QOF point for the osteoporosis domain.
- **Medication** – If Prolia[®] is incorrectly entered this will affect indicators **OST002** and **OST005** as these patients will appear to be on no medication.

To ensure you record the correct Read codes for DXA Scans, T-Scores and fragility fractures it is recommended you use the built-in QOF osteoporosis templates within your clinical system.

How to record Prolia[®] correctly on EMIS PCS

The step-by-step instructions will guide you how to

Step 1 - **Record an initial issue** of Prolia[®] given in secondary care.

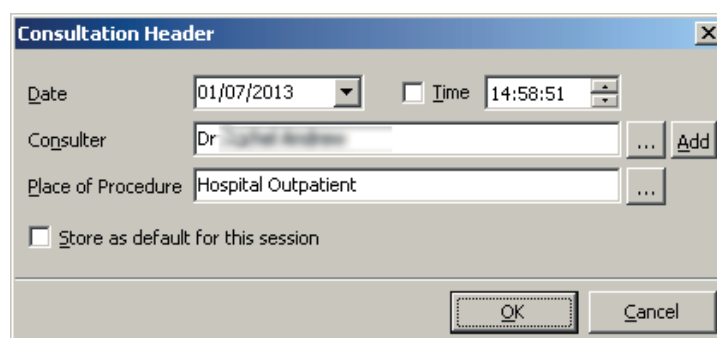
Step 2 - **Set up a recall** for each Prolia[®] patient to ensure subsequent doses are not missed.

Step 3 - **Set up a search** to proactively identify patients that may be overdue a repeat dose of Prolia[®] (this step is **only ever carried out once**, at initial system setup)

All 3 steps **must** be followed the first time the system is set up.

Step 1 – How to Record an initial issue of Prolia[®] given in secondary care

1. From the **Outpatient Letter** enter the “**Date**” and “**Consulter**” fields, ensuring the **date matches** the **date of the clinic appointment** when the patient was **administered Prolia[®]**



Consultation Header

Date: 01/07/2013 Time: 14:58:51

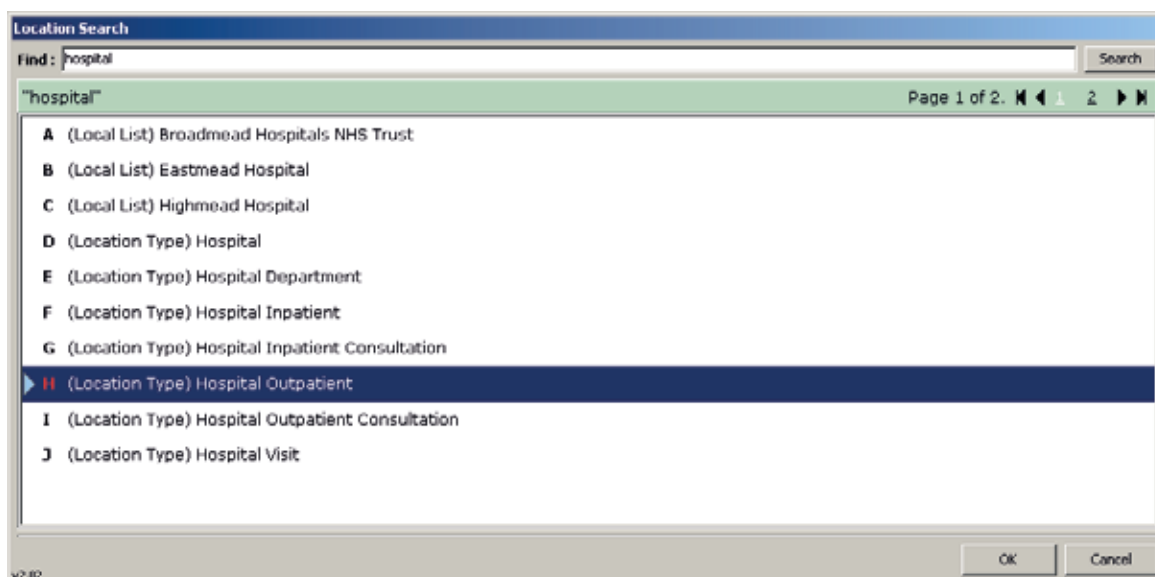
Consulter: Dr [Name] Add

Place of Procedure: Hospital Outpatient

Store as default for this session

OK Cancel

2. Use the drop down list under “**Place of Procedure**” to choose **Hospital Outpatient** or the specific hospital.



Location Search

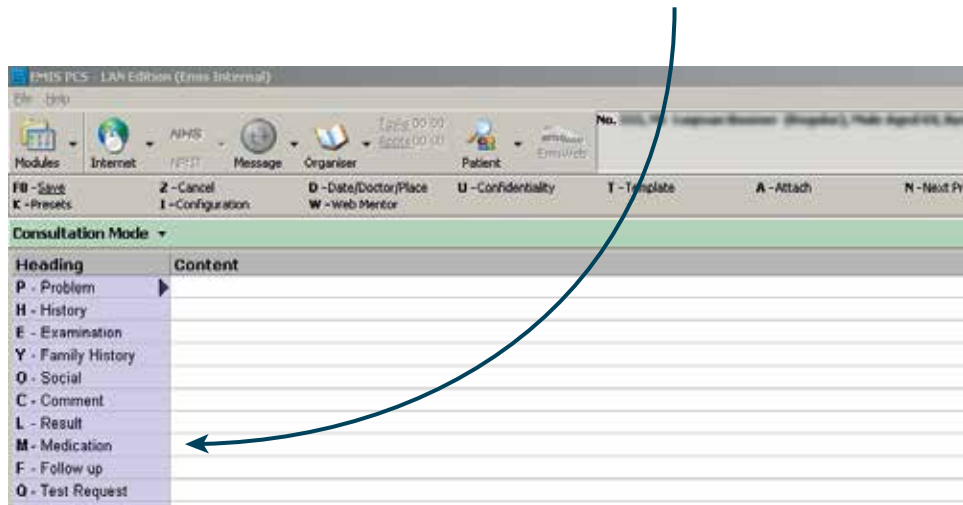
Find: hospital Search

"hospital" Page 1 of 2

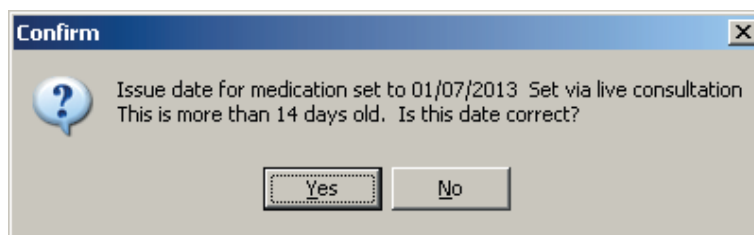
- A (Local List) Broadmead Hospitals NHS Trust
- B (Local List) Eastmead Hospital
- C (Local List) Highmead Hospital
- D (Location Type) Hospital
- E (Location Type) Hospital Department
- F (Location Type) Hospital Inpatient
- G (Location Type) Hospital Inpatient Consultation
- H (Location Type) Hospital Outpatient
- I (Location Type) Hospital Outpatient Consultation
- J (Location Type) Hospital Visit

OK Cancel

- From the **Consultation Screen**, double click on **Medication**.

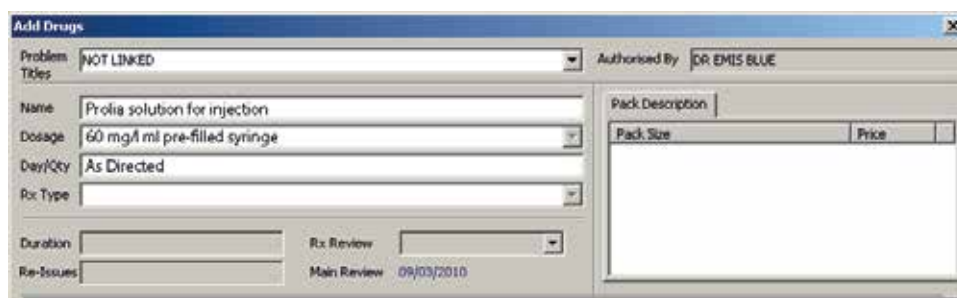


As you have backdated the consultation, to match the date that Prolia was administered in hospital, you may receive a warning message. Click Yes to continue.



The system will default to the patient's usual GP. Click **OK** to continue

- Find **“Prolia”** and **select it** off the picking list



- Complete the **“Dosage”** as **“As Directed”**, the **“Day/Qty”** as **“1”** and the **“Rx Type”** as **“Acute”**

6. Click "Issue"

The screenshot shows the 'Add Drugs' window with the following details:

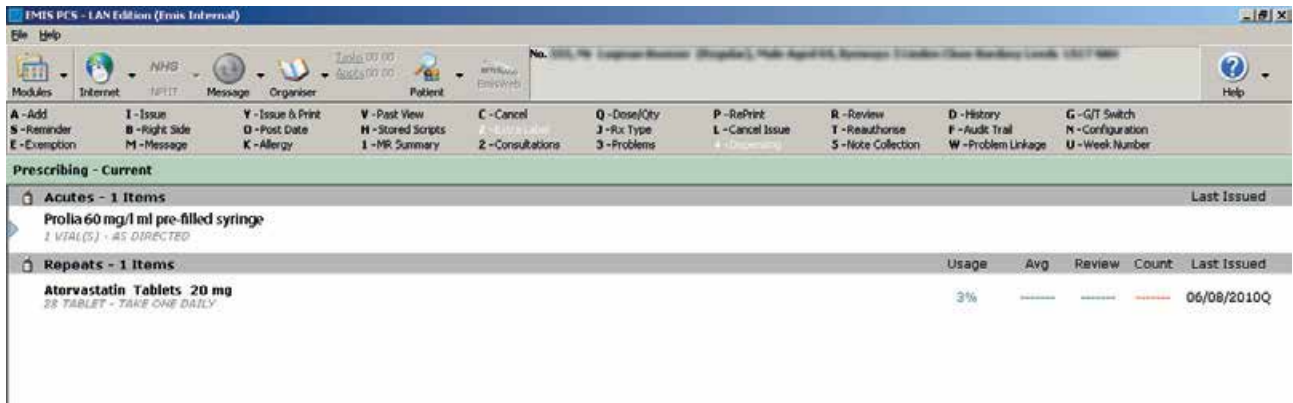
- Problem Title: NOT LINKED
- Authorized By: DR EMIS BLUE
- Name: Prolia solution for injection
- Dosage: 60 mg/ml pre-filled syringe
- Day/Qty: As Directed
- Rx Type: [Empty]
- Duration: [Empty]
- Rx Review: [Empty]
- Re-Issues: [Empty]
- Main Review: 18/01/2014
- Formulary: TESTING
- Options: Warnings & Status | Preparations | Drug Details
- STATUS:
 - CLINICAL TERM (READ CODE) : F07X.(TERM IDENTIFICATION : YOHAR)
 - SCHEDULE : NOT LINKED
 - LEGAL STATUS : PRESCRIPTION ONLY MEDICINE.
 - CSM WARNING STATUS : REPORT ALL ADVERSE REACTIONS TO THE CSM.
 - PRACTICE PRESCRIBABLE STATUS : NHS PRESCRIBABLE.
- INTERNAL DRUG INFORMATION:
 - NOT LINKED
- Buttons: Clear, G/T Switch, BNF Data, Next, Issue & Print, Issue, Cancel

7. Select "O) Outside" from the "Issue Medications" list

The screenshot shows the 'Issue Medications' dialog box with the following details:

- Issue Details tab
- Authorising User: Dr Emis Blue
- Issue Date: 01/07/2013
- Set as course Authoriser
- Script Destination Text: [Empty]
- Total NHS Cost: [Empty]
- Issue Method list:
 - N) None
 - P) Print
 - S) Store
 - H) Hand Written
 - X) Private
 - O) Outside (Selected)
 - Q) Issue Without Scripts
 - B) Repeat Dispensing
- Buttons: OK, Cancel

The issued medication will now appear in the medication screen with a flag “O” for Other.



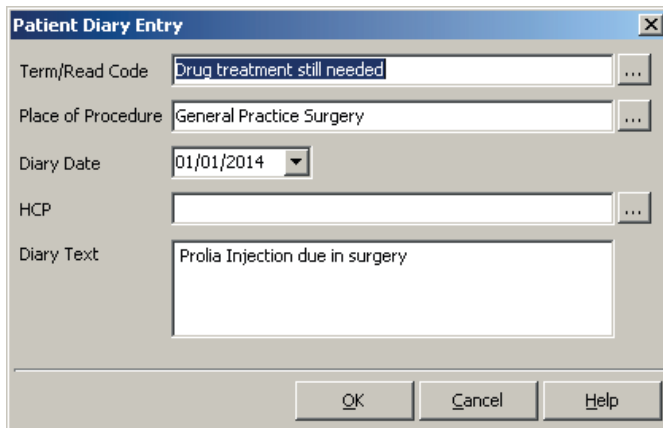
9. Press “**Esc**” to return to your Consultation Screen

NB: Do not exit consultation before completing Step 2

This will ensure the medication is now **correctly entered** within the patient record **and qualifies for QOF**.

Step 2 - Set up a recall for each Prolia® patient to ensure subsequent doses are not missed.

1. Double Click on “Follow Up” to add a diary entry to the patient record.



Patient Diary Entry

Term/Read Code: Drug treatment still needed

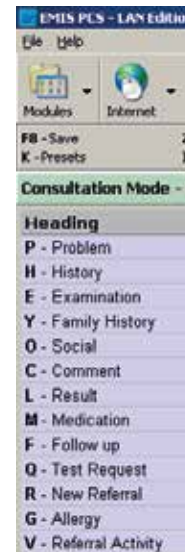
Place of Procedure: General Practice Surgery

Diary Date: 01/01/2014

HCP:

Diary Text: Prolia Injection due in surgery

OK Cancel Help



2. Enter the “**Term/Read Code**” Drug Treatment Still Needed 8BIX and work out the **exact date** the next 6 monthly Prolia® injection is due. Enter the **calculated date** in the “**Diary Date**” field.

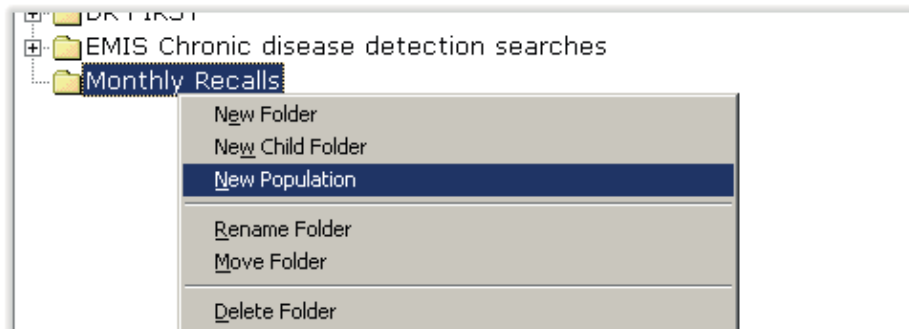
It is **crucial** that the **correct recall date** is entered above. If the system default of 6M is used, it will calculate the recall date from **today's date**, and not the date Prolia® was administered in hospital.

3. Click **OK** and then **save your consultation**.

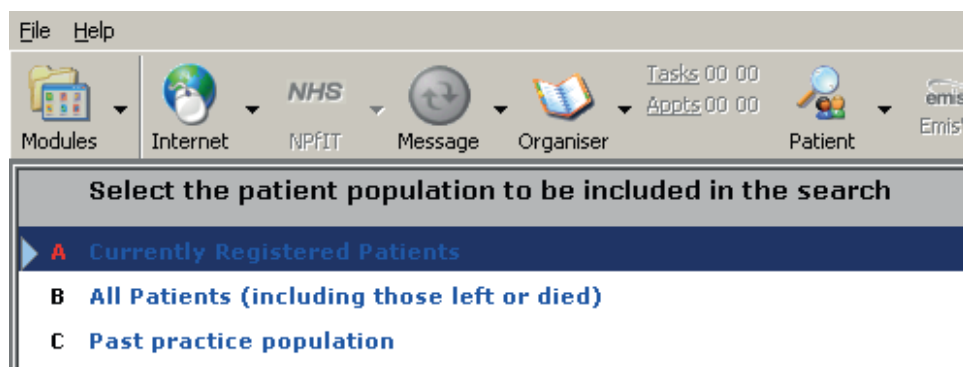
Step 3 - Set up a search to proactively identify patients that may be overdue a repeat dose of Prolia®

NB: The creation of the search needs to be done once. Once created the search can then be re-run at regular intervals

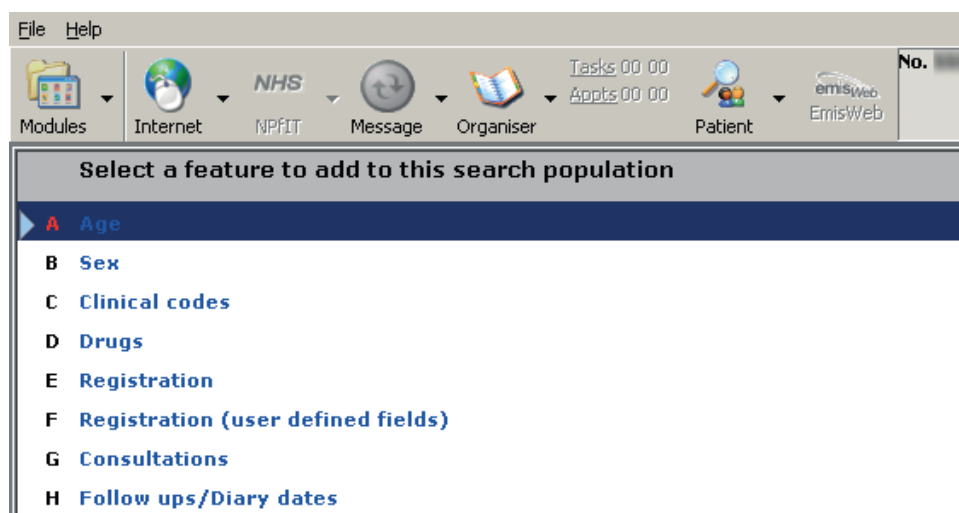
1. From “**Search and Reports**”, choose “**Search Population Manager**” and create a “**New Population**”



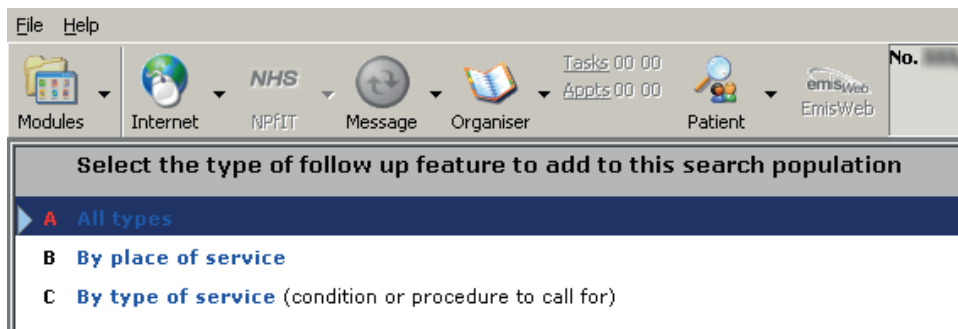
2. Select “**Currently Registered Patients**”



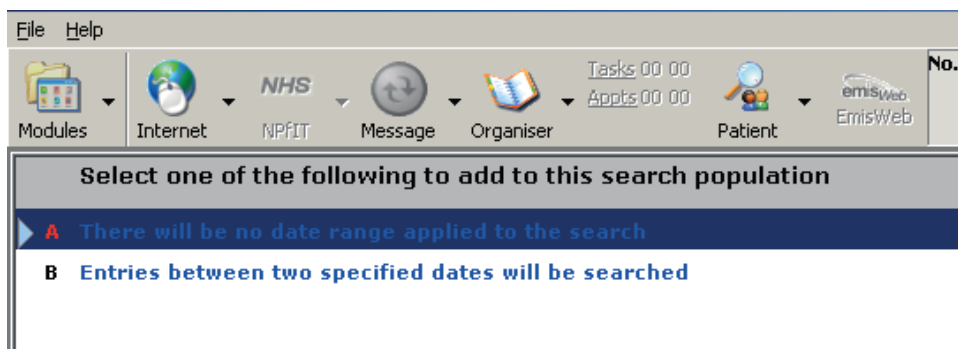
3. Choose “**Follow ups/Diary Dates**” as your feature



4. Select **“By type of service”** from the next list

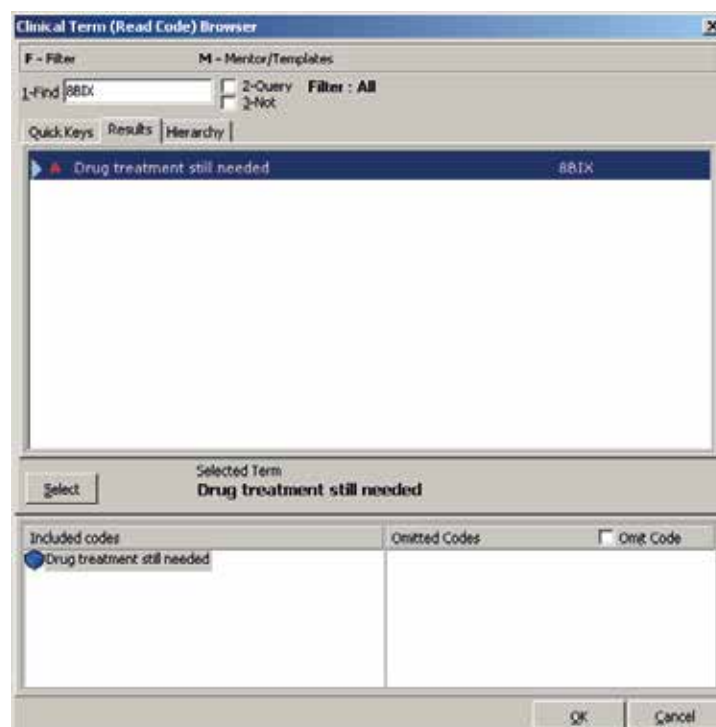


5. Select **“Entries between two specified dates will be searched”**

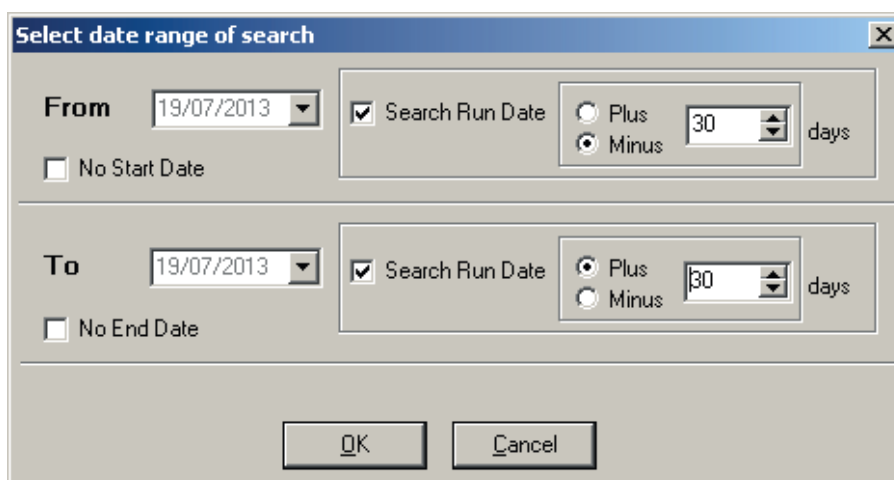


NB: The date box will appear **after** you have chosen the code to be included in the search.

6. Enter the **8BIX** Read code and click **Select**, then click **OK**



7. Set the “**From**” date as **today’s date**, tick the “**Search Run Date**” box, select the “**Minus**” button and set the **days** to **30**.



The screenshot shows a dialog box titled "Select date range of search". It has two sections for "From" and "To" dates. Both are set to "19/07/2013". Each section has a "Search Run Date" checkbox which is checked. For the "From" section, the "Minus" radio button is selected and the "days" field is set to "30". For the "To" section, the "Plus" radio button is selected and the "days" field is set to "30". There are also "No Start Date" and "No End Date" checkboxes, both of which are unchecked. At the bottom, there are "OK" and "Cancel" buttons.

8. Set the “**To**” date as **today’s date**, tick the “**Search Run Date**” box, select the “**Plus**” button and set the **days** to **30**.
9. Click **OK** and **name the search** and **run** it when prompted.

Running your search

On a regular monthly basis it is **important** to **run your search** to ensure patients are recalled for their Prolia[®] injection.

Adding future Prolia[®] patients to EMIS PCS

The next time new Prolia[®] patients are added to EMIS PCS only Steps 1 & 2 need to be followed

Step 1 - **Record an initial issue** of Prolia[®] given in secondary care

Step 2 - **Set up a recall** for each Prolia[®] patient to ensure subsequent doses are not missed

PROLIA® (denosumab)

Brief Prescribing Information

Please refer to the Summary of Product Characteristics (SmPC) before prescribing Prolia. **Pharmaceutical Form:** Pre-filled syringe with automatic needle guard containing 60 mg of denosumab in 1 ml solution for injection for single use only. Contains sorbitol (E420). **Indication:** Treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures. Treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures.

Dosage and Administration: 60 mg Prolia administered as a subcutaneous injection once every 6 months. Patients must be supplemented with calcium and vitamin D. No dosage adjustment required in patients with renal impairment. Not recommended in paediatric patients under 18 years of age. **Contraindications:** Hypocalcaemia or hypersensitivity to the active substance or to any of the product excipients. **Special Warnings and Precautions:**

Hypocalcaemia: Identify patients at risk for hypocalcaemia. Hypocalcaemia must be corrected by adequate intake of calcium and vitamin D before initiation of therapy. Clinical monitoring of calcium levels is recommended before each dose and, in patients predisposed to hypocalcaemia, within 2 weeks after the initial dose. Measure calcium levels if suspected symptoms of hypocalcaemia occur. **Renal Impairment:** Patients with severe renal impairment (creatinine clearance < 30 ml/min) or receiving dialysis are at greater risk of developing hypocalcaemia. Regular monitoring of calcium levels in these patients is especially important. **Skin infections:** Patients receiving Prolia may develop skin infections (predominantly cellulitis) requiring hospitalisation and if symptoms develop then they should contact a health care professional immediately. **Osteonecrosis of the jaw (ONJ):** ONJ has been reported rarely with Prolia 60 mg every 6 months. For information on known risk factors for ONJ, please refer to the SmPC. A dental examination is recommended prior to treatment with Prolia in patients with concomitant risk factors. Good oral hygiene practices and routine dental check-ups should be maintained during treatment with Prolia. While on treatment, patients should avoid invasive dental procedures if possible. **Atypical femoral fracture (AFF):** AFF has been reported in patients receiving Prolia. Discontinuation of Prolia therapy in patients suspected to have AFF should be considered pending evaluation of the patient based on an individual benefit risk assessment. **Dry natural rubber:** The needle cover of the pre-filled syringe contains dry natural rubber (a derivative of latex) which may cause allergic reactions. **Concomitant medication:** Patients with rare hereditary problems of fructose intolerance should not use Prolia. **Interactions:** Prolia did not affect the pharmacokinetics of midazolam, which is metabolized by cytochrome P450 3A4 [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 of Prolia were not altered by previous alendronate therapy. **Fertility, pregnancy and lactation:** There are no adequate data on the use of Prolia in pregnant women and it is not recommended for use in these patients. It is unknown whether denosumab is excreted in human milk. A risk/benefit decision should be made in patients who are breast feeding. Animal studies have indicated that the absence of RANKL during pregnancy may interfere with maturation of the mammary gland leading to impaired lactation post-partum. No data are available on the effect of Prolia on human fertility. **Undesirable Effects:** The following undesirable effects have been reported: 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, abdominal discomfort, rash, and eczema. Uncommon ($\geq 1/1000$ to $< 1/100$): Diverticulitis, cellulitis, and ear infection. Rare ($\geq 1/10,000$ to $< 1/1,000$): Osteonecrosis of the jaw, hypocalcaemia (including severe symptomatic hypocalcaemia) and atypical femoral fractures. In the postmarketing setting, musculoskeletal pain (including severe cases) rare cases of severe symptomatic hypocalcaemia, and rare events of hypersensitivity (including rash, urticaria, facial swelling, erythema and anaphylactic reactions) have been reported. Please consult the Summary of Product Characteristics for a full description of undesirable effects. **Pharmaceutical Precautions:** Prolia must not be mixed with other medicinal products. Store at 2°C to 8°C (in a refrigerator). Prolia 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 Prolia must be used within this 30 day period. Do not freeze. Keep in outer carton to protect from light. **Legal Category:** POM. **Presentation, Basic Costs and Marketing Authorisation Number:** Prolia 60 mg: Pack of 1 pre-filled syringe with automatic needle guard: £183.00; EU/1/10/618/003. **Marketing Authorisation Holder:** Amgen Europe B.V., Minervum 7061, NL-4817 ZK Breda, The Netherlands. Further information is available from Amgen Limited, 240 Cambridge Science Park, Milton Road, Cambridge, CB4 0WD. Prolia is a registered trademark of Amgen Inc. **Date of PI preparation:** August 2014 (Ref: DMB-GBR-AMG-314-2014-P)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Amgen Limited on +44 (0) 1223 436712

References

1. Prolia® (denosumab) Summary of Product Characteristics.
2. NICE TA204 <http://www.nice.org.uk/nicemedia/live/13251/51293/51293.pdf> - Issue date: October 2010 (last accessed September 2014)
3. SMC advice denosumab (Prolia) http://www.scottishmedicines.org.uk/files/advice/denosumab_Prolia_FINAL_November_2010_for_website.pdf (last accessed September 2014)

