Prescribing information
can be found on page 19

Adding Prolia® (denosumab) to INPS Vision

Date of preparation October 2014
DMB-GBR-AMG-661-2014-P

Amgen have fully funded the development, by Oberoi Consulting, of this user guide

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 period[1].

For further information contact Amgen medical information

Telephone: 01223 436441

Contents

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 INPS Vision specifically following initiation 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		
OST004. The contractor establishes and maintains a register of patients: 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 *NICE 2011 menu ID: NM29*	3	
Ongoing Management		
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. *NICE 2011 menu ID: NM30*	3	30-60%
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 *NICE 2011 menu ID: NM31*	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** - When entering the DXA scan result, make sure that you check the recommended recall schedule for the patient. This date could be between 2 and 5 years, depending on the individual patient's circumstances.
  Pages 7-8 show you how to create a system wide recall for DXA scans and Read code the scan correctly
- **T-Scores** - Page 7 shows you how to enter T-Scores correctly
- **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.

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Coding the DXA scan result for Osteoporotic patients

Depending on your workflow and practice processes you may code your DXA scan results before during or after you scan the paperwork or when you receive the result electronically.

If the OCR workflow doesn't pick up a Read code then an osteoporotic code if applicable can be entered

The codes below can be entered as part of your scan workflow or as a Read coded entry if the patient is osteoporotic.

Description	Code
Hip DXA scan result osteoporotic	58EG.
Lumbar DXA scan result osteoporotic	58EM.
Femoral neck DEXA scan result osteoporotic	58EV.

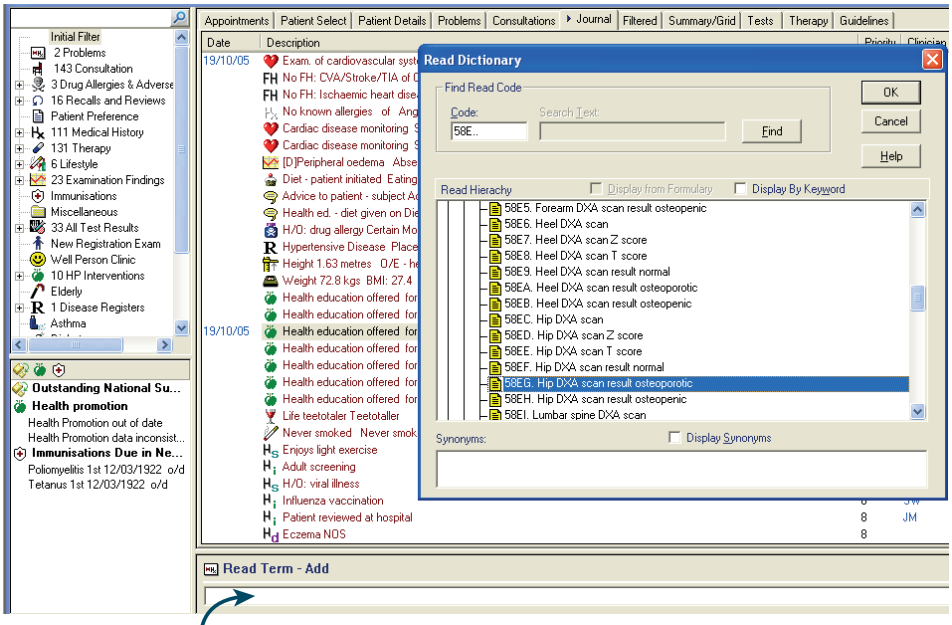
These Read codes will populate your QOF domain for Osteoporosis if a Fragility Fracture code has also been entered and the patient is aged between 50 and 74 years.

A T-Score value can only be entered through using Read codes that are aligned to numeric results. These codes are shown below:

Description	Code
Hip DXA scan T score	58EE.
Lumbar spine DXA scan T score	58EK.
Femoral neck DEXA scan T score	58ES.

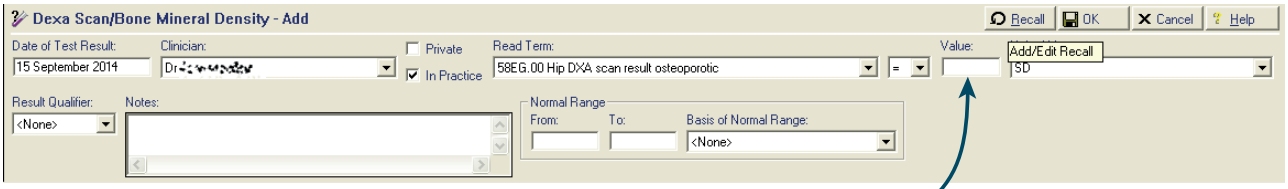
Identify the correct patient in the normal way

1. With a patient selected and an open consultation, select the **Journal tab**.



2. **Type a Keyword** in the **Read Term Add** box at the base of the screen - press the **Enter key**. If the Read Term box is not visible, **start typing** and it will appear automatically.

3. **Double click** in the **Read Term Add box** and **type** in the correct Read code for the DXA Scan.



You can add the T-Score in the value box if appropriate.

Click on **Recall** and follow the instructions on page 10 to create the DXA recall

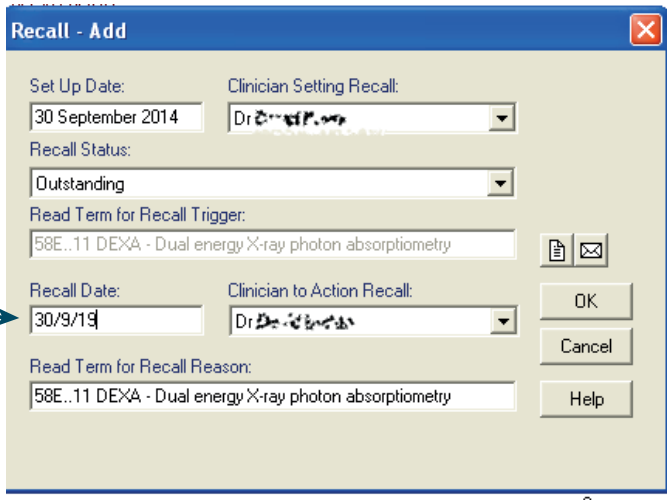
The table on page 9 shows a full list of Read codes that can be used to code all DXA results including normal and Osteopenia results.

Description	Code	QOF code	Numeric
Forearm DXA scan	58E0.		
Forearm DXA scan Z score	58E1.		Yes
Forearm DXA scan T score	58E2.		Yes
Forearm DXA scan result normal	58E3.		
Forearm DXA scan result osteoporotic	58E4.		
Forearm DXA scan result osteopenic	58E5.		
Heel DXA scan	58E6.		
Heel DXA scan Z score	58E7.		Yes
Heel DXA scan T score	58E8.		Yes
Heel DXA scan result normal	58E9.		
Heel DXA scan result osteoporotic	58EA.		
Heel DXA scan result osteopenic	58EB.		
Hip DXA scan	58EC.		
Hip DXA scan Z score	58ED.		Yes
Hip DXA scan T score	58EE.	Yes	Yes
Hip DXA scan result normal	58EF.		
Hip DXA scan result osteoporotic	58EG.	Yes	
Hip DXA scan result osteopenic	58EH.		
Lumbar spine DXA scan	58EI.		
Lumbar spine DXA scan Z score	58EJ.		Yes
Lumbar spine DXA scan T score	58EK.	Yes	Yes
Lumbar DXA scan result normal	58EL.		
Lumbar DXA scan result osteoporotic	58EM.	Yes	
Lumbar DXA scan result osteopenic	58EN.		
DEXA scan T score	58EP.		
Femoral neck DEXA scan	58EQ.		
Femoral neck DEXA scan Z score	58ER.		Yes
Femoral neck DEXA scan T score	58ES.	Yes	Yes
Femoral neck DEXA scan result normal	58ET.		
Femoral neck DEXA scan result osteoporotic	58EV.	Yes	
Femoral neck DEXA scan result osteopenic	58EW.		

Adding the recall for the DXA scan

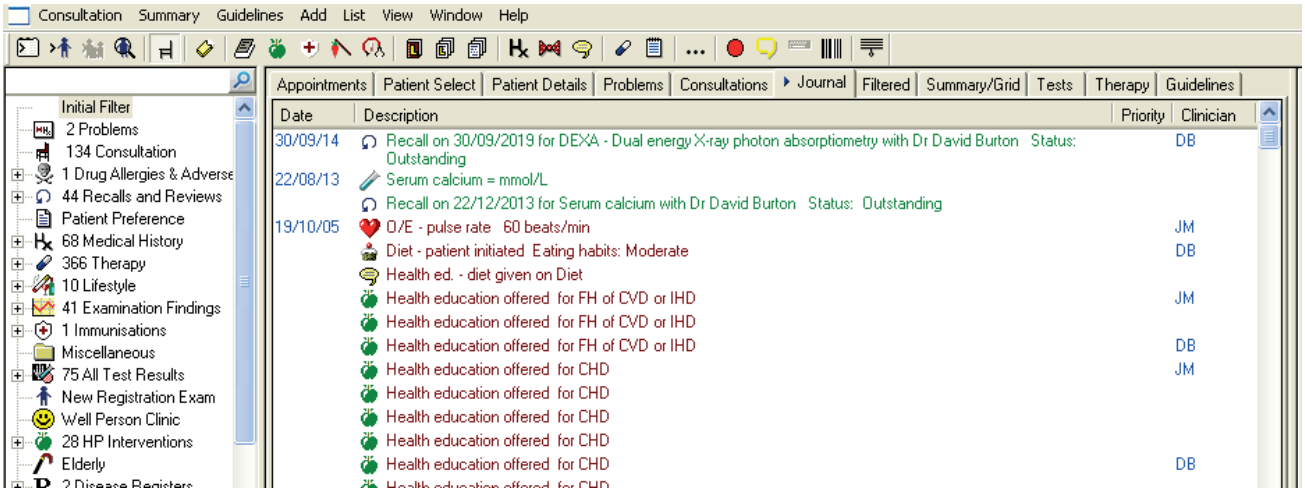
After the DXA scan has been entered, set up the recall.

1. Press "**Recall - Add**"
2. Enter "**Recall Date**"; which could be **2** or **5 years**, depending on your local guidance when the following screen appears :



3. Click **OK** to complete the recall

The entry is visible from the "**Recalls and Reviews**" section of the patient record, and will change colour from green to red **when overdue**. The notes entered are also visible from the "**Journal**".



How to record Prolia® correctly on INPS Vision

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 recall** for a pre-injection calcium blood test

Step 4 - **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)

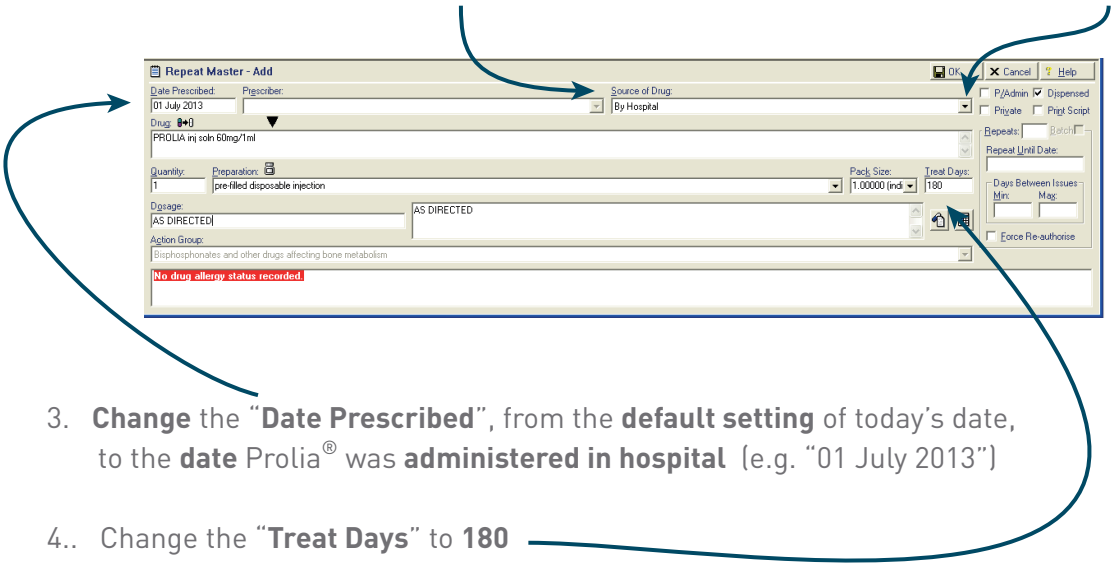
All 4 steps **must** be followed the first time the system is set up.

We have also included some guidance on adding Prolia® that is administered in practice following the initial administration in hospital by updating the original repeat master. This ensures future doses are linked to the initial therapy.

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

1. Add a New "**Repeat Master - Add**" for Prolia® as below

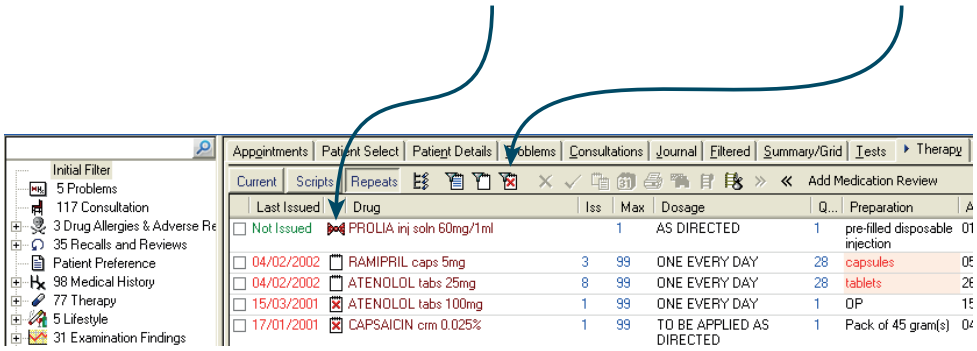
2. When choosing the "**Source of Drug**", use the drop down list and select "**By Hospital**"



3. **Change** the "**Date Prescribed**", from the **default setting** of today's date, to the **date** Prolia® was **administered in hospital** (e.g. "01 July 2013")

4.. Change the "**Treat Days**" to **180**

The exact date of the administration of Prolia® should be available from the **discharge summary** or **hospital letter**.
Prolia® is now recorded and will be given a "**bowtie icon**" and stored under **inactive repeats**



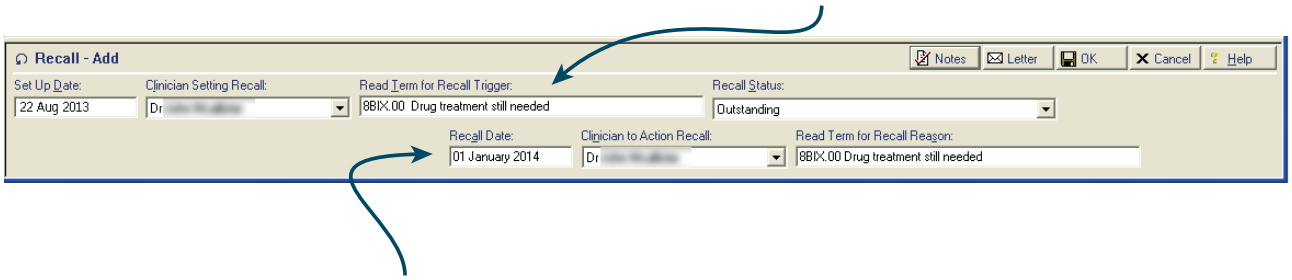
This will ensure the medication is now **correctly entered** within the patient record **and qualifies for QOF.**

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

Open the patient record (if not already open), for the patient where Step 1 has been carried out

1. From the **Toolbar** select **Add**. From the dropdown menu select **Recalls**

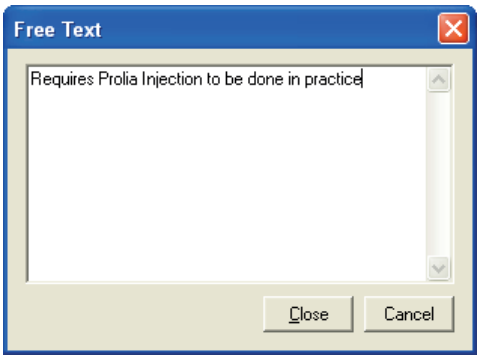
2. Complete the diary entry at the bottom of the screen shown below using the code "**8BIX Drug treatment still needed**" as the "**Read Term for Recall Trigger**".



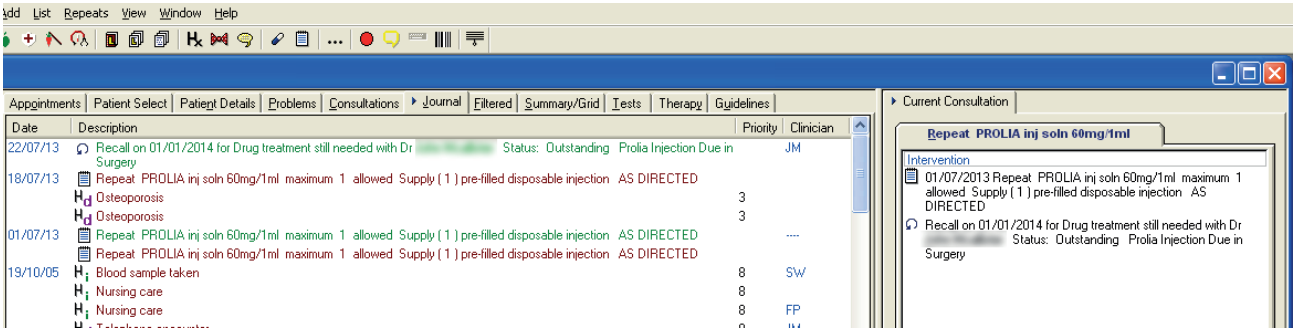
3. Calculate the "**Recall Date**"; which is **6 months** from the **date of administration** of Prolia®.

   It is **crucial** that the **correct recall date** is entered above.

4. Click on the **Notes** button and add additional information as below:



The entry is visible from the "**Recalls and Reviews**" section of the patient record, and will change colour from green to red **when overdue**. The notes entered are also visible from the "**Journal**".



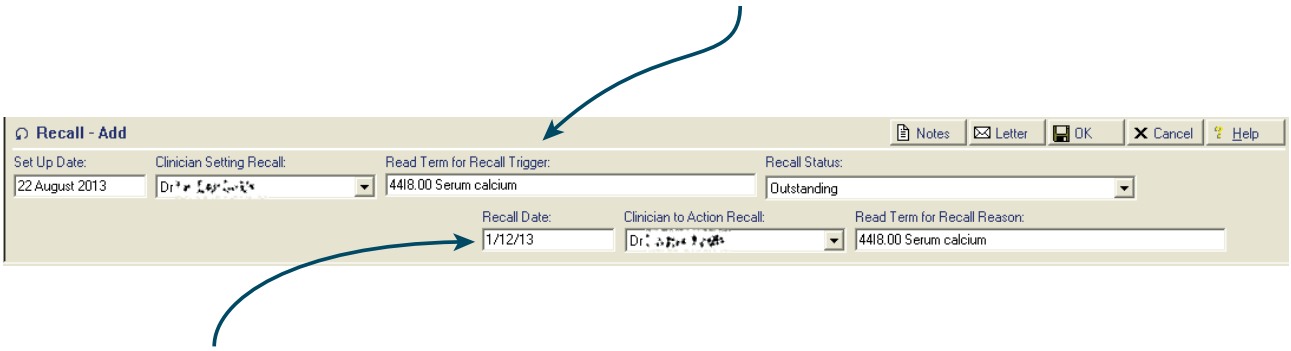
Step 3 - **Set up a recall for a "Pre-injection calcium blood test"**

Clinical monitoring of calcium levels is recommended before each dose and, in patients predisposed to hypocalcaemia within two weeks after the initial dose.

After the Prolia® recall for the next injection has been entered, set up the recall for the next pre-injection calcium blood test.

1. From the **Toolbar** select **Add**. From the dropdown menu select **Recalls**

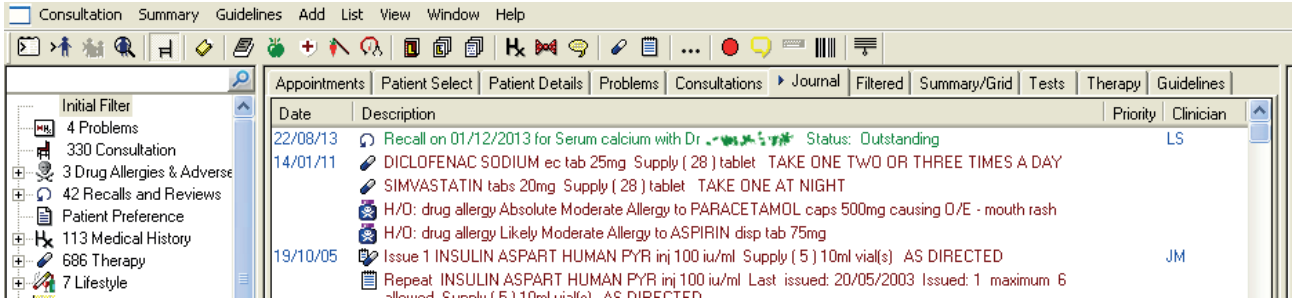
2. Complete the diary entry at the bottom of the screen shown below using the serum calcium code "**4418. Serum calcium**" as the "**Read Term for Recall Trigger**".



3. Enter "**Recall Date**"- which should be set 1 month before the injection is due to allow time for the patient to be contacted and the test results to be received.

4. Click **OK** to complete the recall

The entry is visible from the "**Recalls and Reviews**" section of the patient record, and will change colour from green to red **when overdue**. The notes entered are also visible from the "**Journal**".

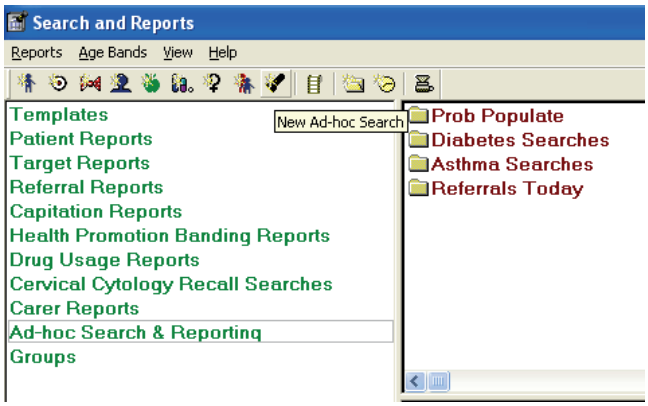


Step 4 - **Set up a search to proactively identify patients that may be overdue a repeat dose of Prolia®**

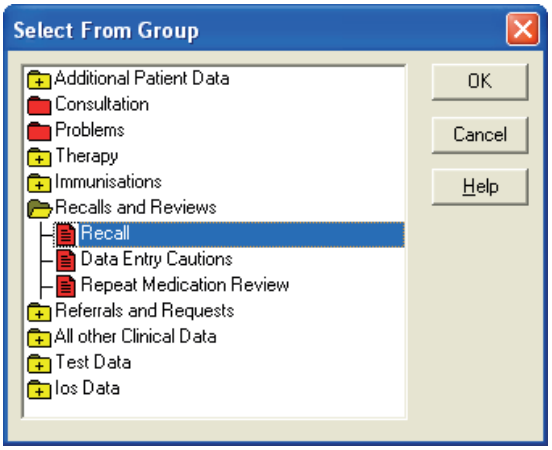
NB: The creation of the search **needs to be done once only**.

This will show all patients that are either due a subsequent dose of Prolia® or are overdue.

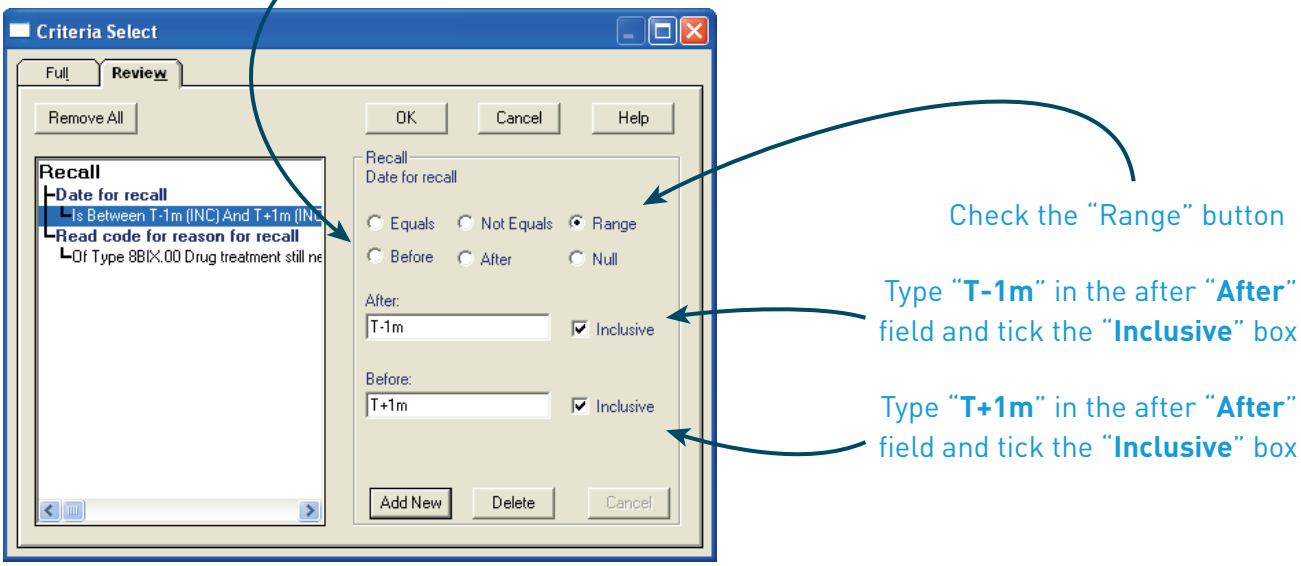
1. From "**Search and Reports**", set up an new "**Ad Hoc Search & Reporting**" to find patients with a Recall within your defined time scale.



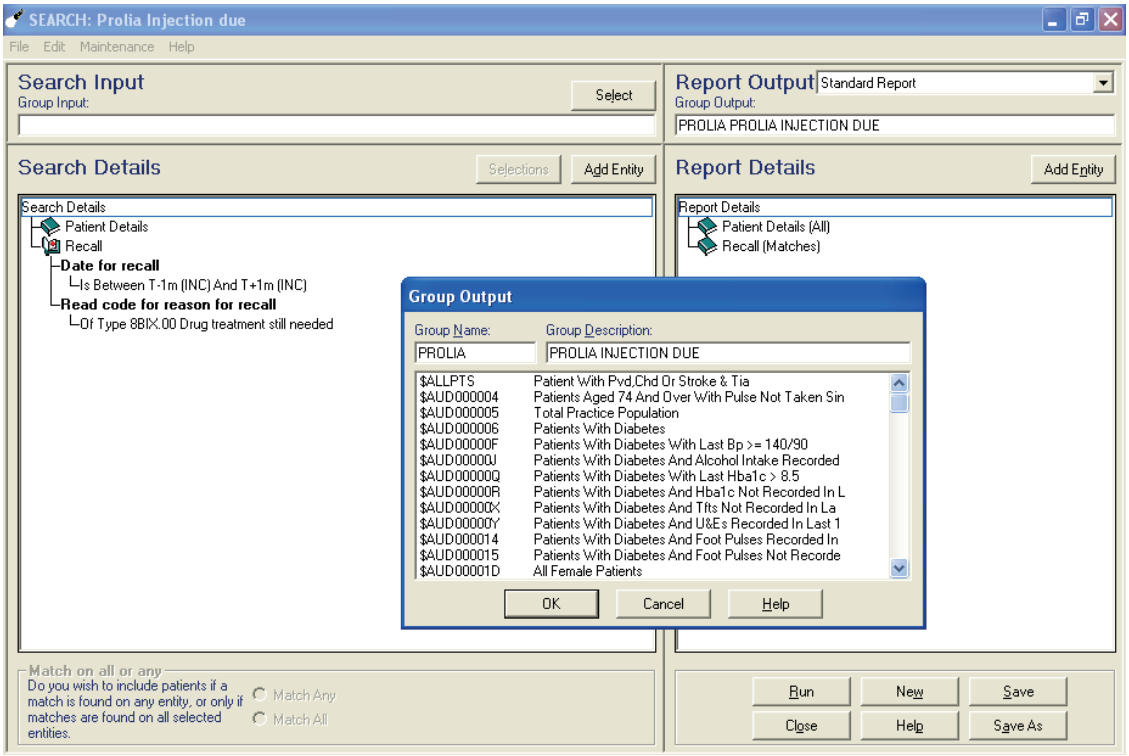
2. Select "**Recalls**" as a search entity.



3. Under "**Selection**", select "**Read Code for Reason**" and the code used when setting up the Recall code "**8BIX Drug Treatment Still Required**"



This will ensure the search picks up Prolia® patients who are overdue, and due an injection next month



4. **Double Click** into the "**Group Output**" field, and create a "**Group Name**" - "PROLIA" and "**Group Description**" - "PROLIA INJECTION DUE"

5. **Save** the search as normal.

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 INPS Vision

The next time new Prolia® patients, **from hospital**, are added to INPS Vision only Steps 1, 2 & 3 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

Step 3 - **Set up a recall** for a "Pre-injection calcium blood test"

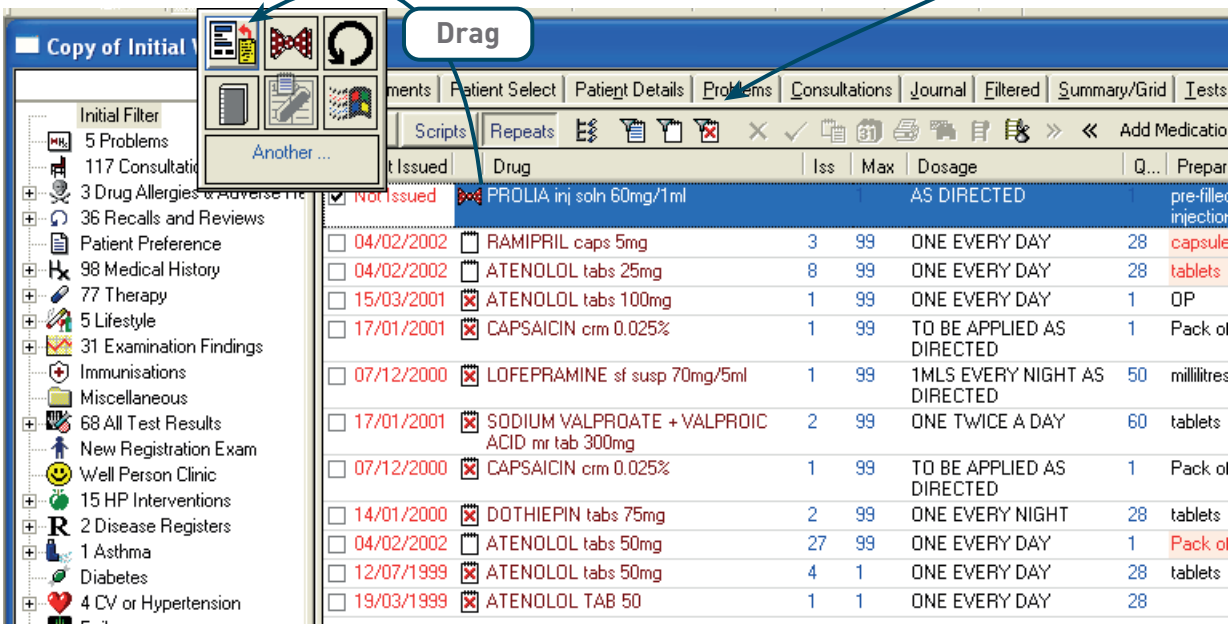
Updating the Repeat Master

This section includes guidance on adding Prolia® that is administered in practice following the initial administration in hospital by updating the original repeat master.

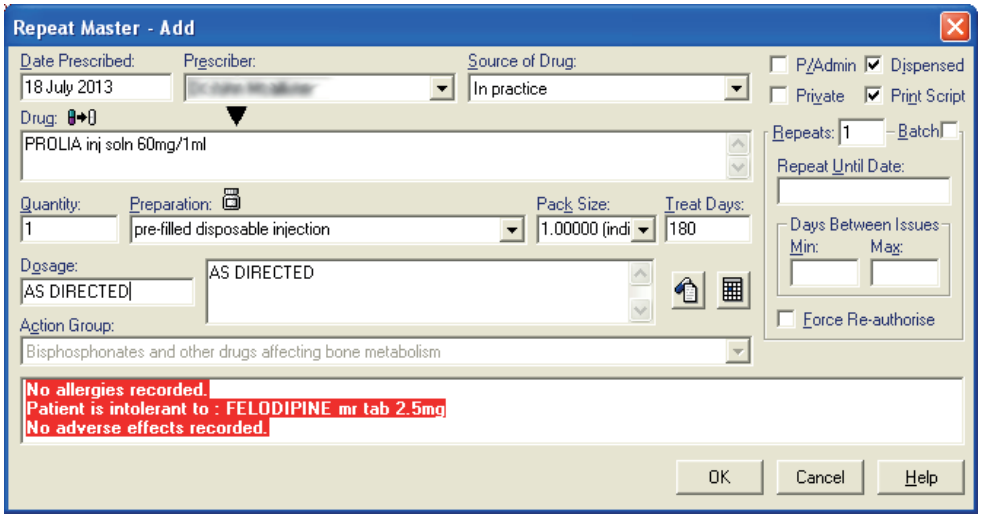
This ensures future doses are linked to the initial therapy.

1. Show all **inactive repeats**
2. Drag the line with Prolia® on to the floating toolbar top left icon

(NB: The floating toolbar will appear once you click and drag Prolia®)



Prolia® is now ready to be issued in the practice.



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 (≥ 1/10) pain in extremity, musculoskeletal pain. Common (≥ 1/100 to < 1/10) urinary tract infection, upper respiratory tract infection, sciatica, cataracts, constipation, abdominal discomfort, rash, and eczema. Uncommon (≥ 1/1000 to < 1/100): Diverticulitis, cellulitis, and ear infection. Rare (≥ 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)

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