

# Adding Prolia® (denosumab) to SystmOne



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## 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](mailto: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<sup>1</sup>.

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<sup>2,3</sup>.

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 SystmOne 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 overdue which is automatically run on a monthly basis. A “Task”, from SystmOne, is then sent to the assigned person so the patient can be proactively followed up.

## 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
<b>Records</b>		
<b>OST004.</b> 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 <i>NICE 2011 menu ID: NM29</i>	3	
<b>Ongoing Management</b>		
<b>OST002.</b> 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. <i>NICE 2011 menu ID: NM30</i>	3	30-60%
<b>OST005.</b> 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 <i>NICE 2011 menu ID: NM31</i>	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.

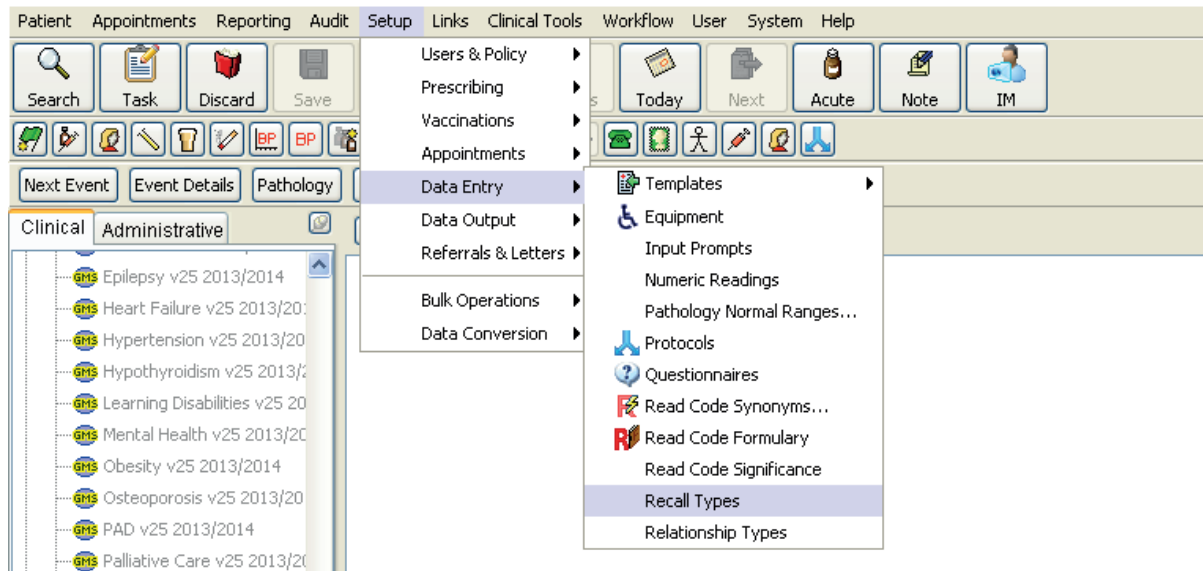
If information is missing the hospital department should be contacted to establish the information.

- **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 8 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.

# Creating a system wide “New Recall Type” for “DXA scan”

Create a system wide “**New Recall Type**” - This step is **only ever carried out once**.

1. Go to **Setup > Data Entry > Recall Types**.



2. Create a **New “Recall Type”**, called “**DXA scan recall**”
3. **Change** the “**default recall period**”, from the default setting of **12 months** to **5 years**

4. **Add** in the following linked **read codes** (optional) :

XaPE2 Femoral neck DEXA scan result osteoporotic  
XaITW Hip DXA scan result osteoporotic  
XaITb Lumbar DXA scan result osteoporotic  
XaPDy Femoral neck DEXA scan T score  
XaITU Hip DXA scan T score  
XaITZ Lumbar spine DXA scan T score

This will remove any DXA recalls due once any of the above codes are added to the patients record.

5. Click OK

A screenshot of the 'New Recall Type' dialog box. The 'Recall type name' field contains 'DXA scan recall'. The 'Category' dropdown is set to 'Miscellaneous'. Under 'Applicable genders', both 'Males' and 'Females' are checked. The 'Minimum applicable age' and 'Maximum applicable age' are both set to 'years'. The 'Default recall period' is set to '5' years. There is a checkbox for 'Repeats when seen'. Under 'Availability', there are four unchecked checkboxes: 'Cytology smear dialog (for waiting for results)', 'Cytology result dialogs (for scheduling next smear)', 'Vaccination dialog', and 'Contraception dialog'. At the bottom, there is a table for 'Linked Read codes' with columns 'Code' and 'Description'. The table contains the following entries: XaPE2 Femoral neck DEXA scan result osteoporotic, XaITW Hip DXA scan result osteoporotic, XaITb Lumbar DXA scan result osteoporotic, XaPDy Femoral neck DEXA scan T score, and XaITU Hip DXA scan T score. There are 'Ok' and 'Cancel' buttons at the bottom right. A blue arrow points from the text 'This will remove any DXA recalls due once any of the above codes are added to the patients record.' to the 'Linked Read codes' table. Another blue arrow points from the text '5. Click OK' to the 'Ok' button.

## 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 a 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
Lumbar DXA scan result osteoporotic	XaITb
Hip DXA scan result osteoporotic	XaITW
Femoral neck DEXA scan result osteoporotic	XaPE2

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.

Numeric results cannot be entered as part of the SystmOne scan workflow.

A T-Score value can only be entered through numeric results, not via the Read code browser, using the QOF Read codes as shown in the table below

Description	Code
Lumbar spine DXA scan T score	XaITZ
Hip DXA scan T score	XaITU
Femoral neck DEXA scan T score	XaPDy

The table overleaf, on page 9, shows a full list of CTV3 Read codes that can be used to code all DXA results including normal and Osteopenia results.



Description	Code	QOF code	Numeric
Lumbar DXA scan result normal	XaITa		
Lumbar DXA scan result osteoporotic	XaITb	Yes	
Lumbar DXA scan result osteopenic	XaITc		
Forearm DXA scan	XaITC		
Heel DXA scan	XaITD		
Hip DXA scan	XaITE		
Lumbar spine DXA scan	XaITF		
Forearm DXA scan Z score	XaITJ		Yes
Forearm DXA scan T score	XaITK		Yes
Forearm DXA scan result normal	XaITL		
Forearm DXA scan result osteoporotic	XaITM		
Forearm DXA scan result osteopenic	XaITN		
Heel DXA scan Z score	XaITO		Yes
Heel DXA scan T score	XaITP		Yes
Heel DXA scan result normal	XaITQ		
Heel DXA scan result osteoporotic	XaITR		
Heel DXA scan result osteopenic	XaITS		
Hip DXA scan Z score	XaITT		Yes
Hip DXA scan T score	XaITU	Yes	Yes
Hip DXA scan result normal	XaITV		
Hip DXA scan result osteoporotic	XaITW	Yes	
Hip DXA scan result osteopenic	XaITX		
Lumbar spine DXA scan Z score	XaITY		Yes
Lumbar spine DXA scan T score	XaITZ	Yes	Yes
Dual energy X-ray photon absorptiometry	X70pr		
Dual energy X-ray photon absorptiometry scan T score	XaP6z		
Femoral neck DEXA scan	XaPDm		
Femoral neck DEXA scan Z score	XaPDr		Yes
Femoral neck DEXA scan T score	XaPDy	Yes	Yes
Femoral neck DEXA scan result normal	XaPE1		
Femoral neck DEXA scan result osteoporotic	XaPE2	Yes	
Femoral neck DEXA scan result osteopenic	XaPE4		

## Creating a DXA recall within the patients record

Once the “DXA Scan” recall has been created, this can be used to create recalls for those patients where a DXA scan has been carried out.

1. On the **Clinical Tree**, right click “**recalls**” to create the recall.
2. Create the recall, changing the default time from 5 years to the timescale indicated on your local guidelines, if required.

The recall can be viewed at any time in the patient record.

If you are unsure how to create a recall follow the steps shown on page 14.

# How to record Prolia® correctly on SystemOne

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

Step 1 - **How to record an initial issue** of Prolia® given in secondary care

Step 2 - **Set up a system wide “New Recall Type”** for “Prolia® Injections Due”

Step 3 - **Set up a system wide “New Recall Type”** for “Pre-injection calcium blood test”

Step 4 - **Set up a recall** for each Prolia® patient to ensure subsequent doses are not missed & “Pre-injection calcium blood test” carried out

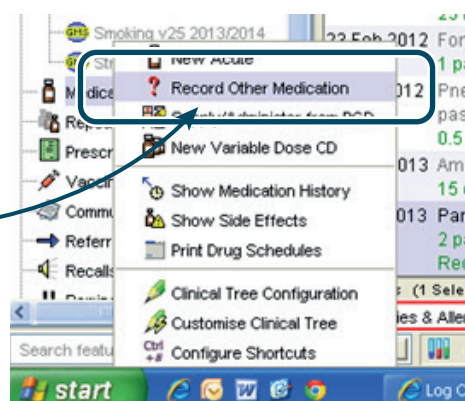
Step 5 - **Set up a search** to proactively identify patients that may be overdue a repeat dose of Prolia®

Step 6 - **Set up a monthly task** assigned to the relevant person in the practice for overdue patients

All 6 steps **must** be followed the first time the system is set up.

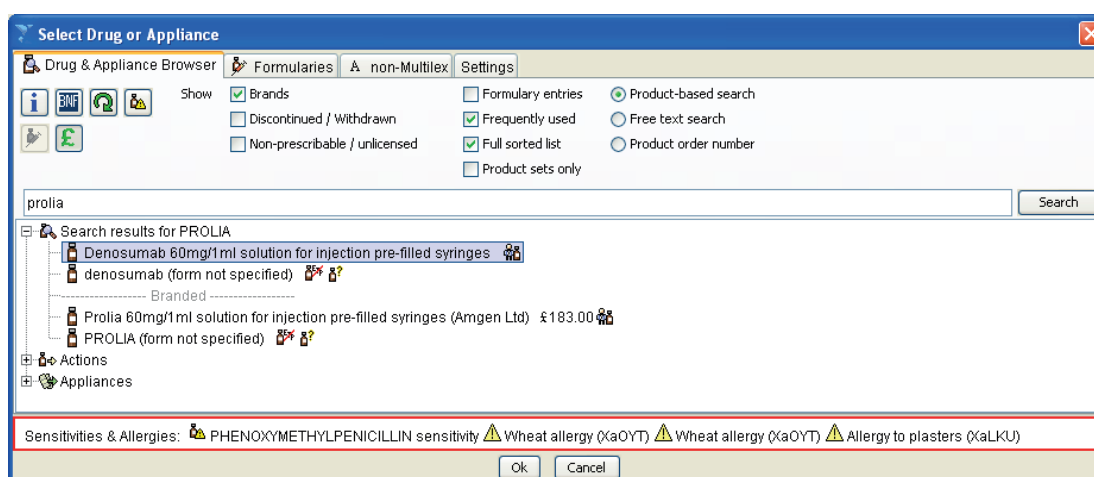
## Step 1 - How to record an in initial issue of Prolia® given in secondary care

1. Prolia® that has been issued in secondary care should be added as “**Other Medication**”. “**Record Other Medication**” is selected by right clicking on the medication section of the clinical tree.



Next, the “**Record Other Medication**” screen prompts the user to enter the **Drug**

2. Find Prolia® in the **dropdown list** of drugs



3. Change the **start date**, from the default setting of today's date, to the **date of the hospital letter** (e.g. "03 Apr 2013")

4. Make the **end date** the **end of the 6 month course**; in this case "03 Oct 2013".

**Record Other Medication**

Other Details... Exact date & time Tue 16 Jul 2013 11:40

Changing the consultation date will affect all other data entered. To avoid this, cancel and press the 'Next' button [Hide Warning](#)

Start date: 03 Apr 2013  
End date: 06 Oct 2013

Medication source: ☐ Other Medication ☐ Dental Medication ☒ Hospital Medication

Drug: Prolia 60mg/1ml solution for injection pre-filled syringes (Amgen Ltd)

Dose:   
Quantity:   
Script notes:   
Administrative notes: Prescribed by xx consultant at xx hospital

Ok Ok & Another Cancel

5. Change the "**Medication Source**" radio button from the default setting of "**Other Medication**" to "**Hospital Medication**"

6. Put in the "**Administrative notes**" **which consultant** prescribed Prolia® and at **which hospital** it was administered

Prolia® will now appear in the medication screen with a flag of a blue "**H**".

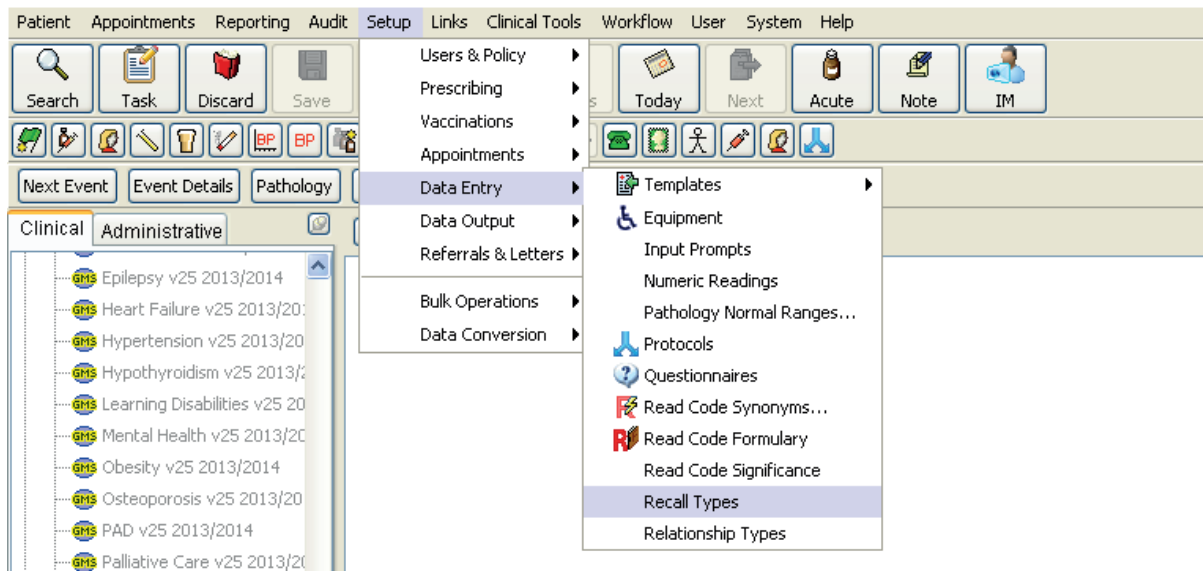
Start Date	Drug	Scheduled End	Days ...	Medication Type	Flags
25 Aug 2011	Diltiazem 60mg modified-release tablets 1 pack of 84 tablet(s) - x2 a day Hypertension (XEOUb)	20 Oct 2011	56	Private issue	\$
07 Sep 2011	Paracetamol 500mg tablets 2 packs of 32 tablet(s) - Take one or two tablets 4 times a day When Required (for Pain)	15 Sep 2011	8	Private issue	\$
24 Oct 2011	Paracetamol 500mg tablets 2 packs of 32 tablet(s) - Take one or two tablets 4 times a day When Required (for Pain)	01 Nov 2011	8	Private issue	\$
08 Dec 2011	Aciclovir 200mg tablets (A A H Pharmaceuticals Ltd) 25 tablets - take one as directed	09 Dec 2011	1	Private issue	\$
08 Dec 2011	Aciclovir 200mg tablets (A A H Pharmaceuticals Ltd) 20 tablets - one five times a day	12 Dec 2011	4	Private issue	\$
23 Feb 2012	Fortisip Range Starter Pack liquid (Nutricia Ltd) 1 pack - prn acbs	24 Feb 2012	1	Private issue	\$
24 Oct 2012	Pneumovax II vaccine solution for injection 0.5ml vials (sanofi pasteur MSD Ltd) 0.5 ml -	25 Oct 2012	1	NHS issue	
03 Apr 2013	Prolia 60mg/1ml solution for injection pre-filled syringes (Amgen Ltd) Administrative Notes: Prescribed by xx consultant at xx hospital	03 Oct 2013	186	Hospital	H
02 May 2013	Amoxicillin 500mg capsules 15 capsules - Take one capsule 3 times a day (antibiotic)	07 May 2013	5	Private issue	\$
23 May 2013	Sudocrem antiseptic healing cream (Forest Laboratories UK Ltd) 1 - 1 Administrative Notes: fvgdg			Other medication	?
03 Jun 2013	Paracetamol 500mg tablets 2 packs of 32 tablet(s) - Take one or two tablets 4 times a day When Required (for Pain)	11 Jun 2013	8	Private issue	\$

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

## Step 2 - Set up a system wide “New Recall Type” for “Prolia® Injections Due”

Create a system wide “**New Recall Type**” - This step is **only ever carried out once**.

1. Go to **Setup > Data Entry > Recall Types**.



2. Create a **New “Recall Type”**, called “**Prolia Injection Due**”
3. **Change** the “**default recall period**”, from the default setting of **12 months** to **6 months**
4. Tick “**Repeats when seen**” then press **Ok**

A screenshot of the 'New Recall Type' dialog box. The 'Recall type name' field contains 'Prolia Injection Due'. The 'Category' dropdown is set to 'Miscellaneous'. Under 'Applicable genders', both 'Males' and 'Females' are checked. The 'Minimum applicable age' and 'Maximum applicable age' fields are empty, with 'years' as the unit. The 'Default recall period' is set to '6' with a dropdown menu showing 'Months'. The 'Repeats when seen' checkbox is checked. Under 'Availability', there are four unchecked checkboxes: 'Cytology smear dialog (for waiting for results)', 'Cytology result dialogs (for scheduling next smear)', 'Vaccination dialog', and 'Contraception dialog'. At the bottom, there's a section for 'Linked Read codes' with a table with two columns: 'Code' and 'Description'. The 'Ok' and 'Cancel' buttons are at the bottom right. Two blue arrows point from the instructions to the 'Default recall period' and 'Repeats when seen' fields.

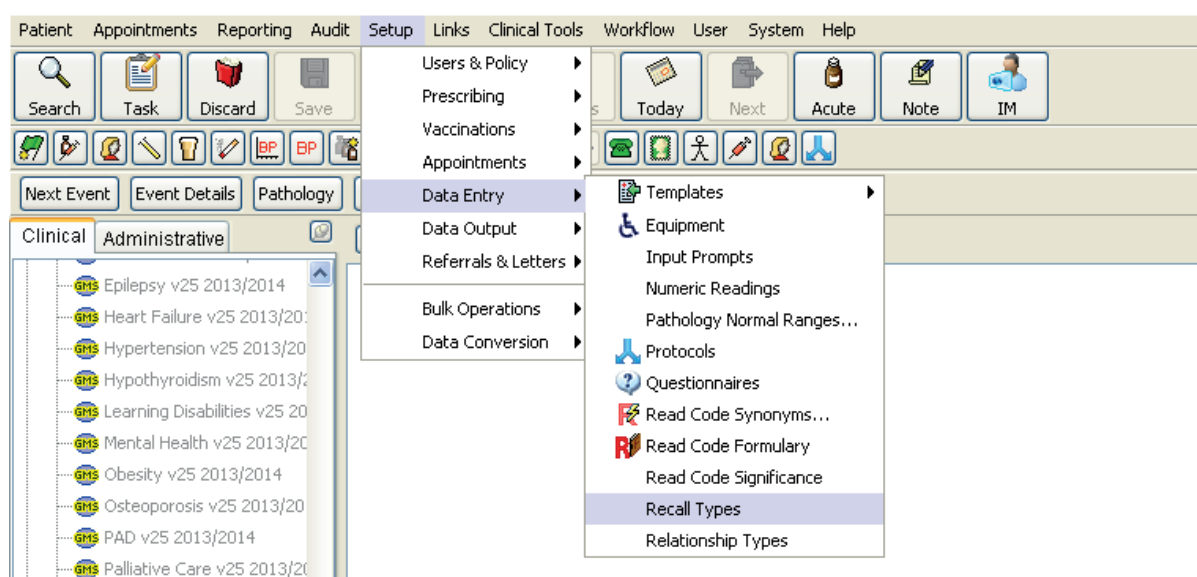
### Step 3 - Set up a system wide “New Recall Type” for “Pre-injection calcium blood test”

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

Follow the instructions below to set up a “**New Recall Type**” to ensure levels of calcium are monitored.

This step is **only ever carried out once**.

1. Go to **Setup > Data Entry > Recall Types**.



2. Create a **New “Recall Type”**, called “**Pre-injection calcium blood test**”

3. **Change the “default recall period”**, from the default setting of **12 months** to **5 months**

A screenshot of the 'New Recall Type' dialog box. The 'Recall type name' field contains 'Pre-injection calcium blood test'. The 'Category' is set to 'Miscellaneous'. Under 'Applicable genders', both 'Males' and 'Females' are checked. The 'Default recall period' is set to '5' with 'Months' as the unit. There are 'Ok' and 'Cancel' buttons at the bottom. A blue arrow from the text in step 3 points to the 'Default recall period' field.

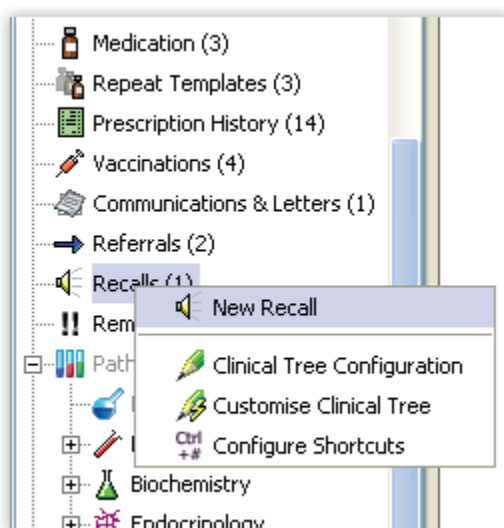
The recall date for the calcium blood test should be set 1 month before the next Prolia® injection is due, to allow time for the patient to be contacted and the test results received.

## Step 4 - Set up a recall for each Prolia® patient to ensure subsequent doses are not missed & “Pre-injection calcium blood test” carried out

Once the “Prolia Injection Due” recall has been created (Step 2), this can be used to **create recalls** for those patients where Prolia® has been added to SystmOne as a hospital administered medication (Step 1).

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

1. On the **Clinical Tree**, right click “**recalls**” to create the recall, as shown below.



2. **Create the recall** as shown below

A screenshot of the 'Create Recall' dialog box. At the top, there's a header bar with the title 'Create Recall' and a close button. Below the header, there's a section for 'Other Details...' with a dropdown menu set to 'Exact date & time', a date field showing 'Thu 06 Jun 2013', and a time field showing '14:31'. A warning message states: 'Changing the consultation date will affect all other data entered. To avoid this, cancel and press the 'Next' button'. Below this, the 'Category' is set to 'All categories' and the 'Type' is set to 'Prolia Injection Due 6 Months'. There's a 'Settings' button and a checked checkbox for 'Hide inappropriate types'. The 'Comments' field contains the text 'Requires Prolia injection to be done in practice'. The 'Recall on' date is set to 'Thu 03 Oct 2013' and the 'Initial status' is set to 'Pending'. At the bottom, there are three buttons: 'Ok', 'Ok & Another', and 'Cancel'.

Repeat Step 4 to create a **recall** for the “Pre-injection calcium blood test”.

The due recalls can be viewed at any time in the patient record, as below, and will be shown in **black**.

2 Weeks before Prolia® is due a reminder will appear on the home page of the patient's record and appear in **orange**, and on the due day, onwards, the recall reminder will change to **red**.

Created	Recall D...	Type	Comments	Status	Flags
03 Jun 2013	03 Jun 2013	Asthma		Pending	
06 Jun 2013	06 Oct 2013	Prolia Injection Due	Requires Prolia injection to be done in practice	Pending	

When the **subsequent dose** is administered the HCP must remember to **change the status** on the recall to “seen”.

Created	Recall D...	Type	Comments	Status	Flags
03 Jun 2013	03 Jun 2013	Asthma		Pending	
06 Jun 2013	06 Oct 2013	Prolia Injection Due	Requires Prolia injection to be done in practice	Pending	

SystmOne will now prompt the HCP to **automatically create another recall** for the next 6 monthly Prolia® injection along with the “Pre-injection calcium blood test”.

Created	Recall D...	Type	Comments	Status	Flags
03 Jun 2013	03 Jun 2013	Asthma		Pending	
06 Jun 2013	06 Oct 2013	Prolia Injection Due	Requires Prolia injection to be done in practice	Seen	

This process will continue for **all subsequent doses** of Prolia®, in the future.

## Step 5 - 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**.

1. **Set up** a new report called **Prolia® Injection Recall Due** from “**Clinical Reporting**”; to find patients with “**Prolia Injection Due**”.
2. **Tick recall date** and enter the “date” **one year ago**, from today's date. Then tick the **Relative** box.

The screenshot shows the 'Create Report' dialog box in a medical software interface. The 'Reporting' menu is highlighted in the top toolbar. The 'Create Report' window shows the report name 'Prolia Injection Recall Due', category 'Miscellaneous', and sub-category. The 'Report on recalls' section has 'Recall type' set to 'Prolia Injection Due', 'Recall date' set to 'After 17 Jul 2012' with the 'Relative' checkbox checked, and 'Recall status' set to 'Pending'. The 'Available' list contains various recall statuses, and the 'Selected' list shows 'Pending'.

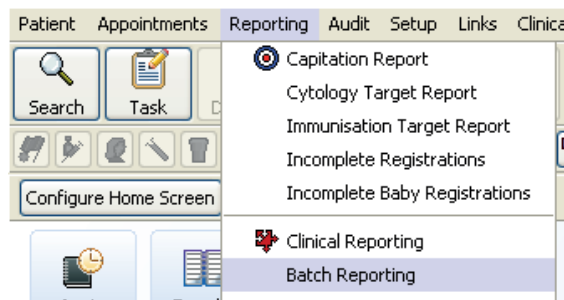
3. Select **Recall Status** as 'Pending'.



## Step 6 - Set up a monthly task assigned to the relevant person in the practice for overdue patients

This step is **only ever carried out once**.

1. Go to **Reporting > Batch Reporting** and click 'Create New Batch'



2. Enter the Batch name as "Prolia Injections overdue" and add in the "report created in Step 4".

A screenshot of the 'New Batch Report' dialog box. The 'Batch name' field contains 'Prolia Injections overdue'. Under the 'Details' section, there are 'Add...' and 'Remove' buttons, and a list box containing 'Prolia Injection Recall Due (Miscellaneous)'. Below this, the 'On this date' field is set to '16 Jul 2013'. The 'Then re-run every' checkbox is checked, with '1' in the frequency field and 'months' in the unit dropdown. In the 'Task details' section, the 'Send task to' radio buttons are set to 'Staff member', and a dropdown menu is open showing a list of staff members. At the bottom are 'Ok' and 'Cancel' buttons. Arrows from external text blocks point to the 'Send task' checkbox, the 'Then re-run every' section, and the staff member dropdown.

3. Click on 'Send task'

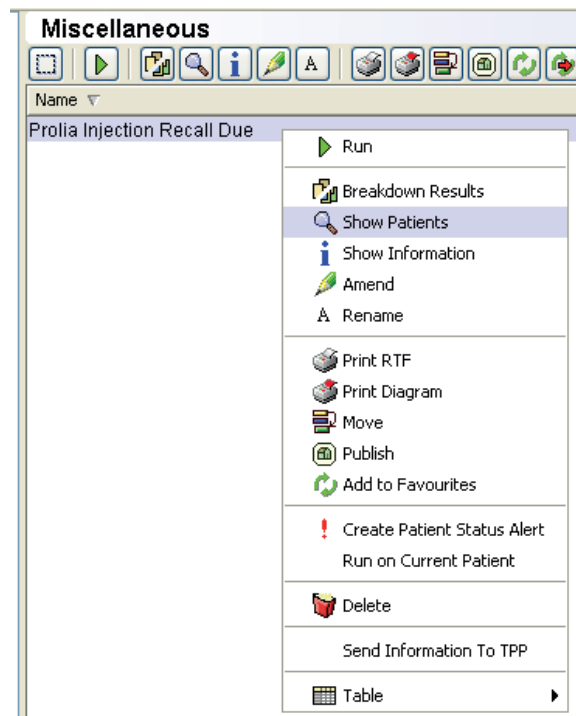
4. Click on the "Staff member" and select the member of staff, from the **dropdown list**, who is responsible for **administering Prolia®**

5. Set the date to run the first report and tick "Then re-run every" and select **1 month**.

The "Batch report" created will now **run every month automatically** and send a **task** to the member of staff selected to **administer Prolia®**.

The task will take the selected member of staff to the report.

Right click on the report and click show patients.



This will show all patients that are either **due a subsequent dose** of Prolia<sup>®</sup> or are **overdue**.

## Adding future Prolia<sup>®</sup> patients to SystmOne

The next time new Prolia<sup>®</sup> patients are added to SystmOne only Steps 1 & 3 need to be followed

**Step 1 - Record an initial issue** of Prolia<sup>®</sup> given in secondary care.

**Step 3 - Set up a recall** for each Prolia<sup>®</sup> patient to ensure subsequent doses are not missed and the pre-injection calcium blood test is carried out.

## 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](http://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](http://www.scottishmedicines.org.uk/files/advice/denosumab_Prolia_FINAL_November_2010_for_website.pdf) (last accessed September 2014)

