PDSA PRACTICE GUIDE

Prolia (denosumab) recall management

A worked PDSA cycle for recovering overdue denosumab (Prolia) recalls, building a reliable reminder system that keeps patients within the 6-month dosing window, and meeting CPD requirements as a whole practice team.

AUTHOR

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CPD HOURS

Up to 9 hours (EA + RP + MO)

MBS ITEMS

Item 10997 (nurse monitoring and support) where applicable

TIMELINE

Three monthly cycles

Why run a PDSA in your practice

CPD for the whole team

A completed PDSA generates up to 9 hours of CPD across EA, RP and MO categories, applicable to all GPs in the practice. Submitted as a practice-based or group activity, one GP can record the activity for the team.

GP retention

Structured team quality improvement activities contribute to a positive practice culture and are associated with GP and staff retention.

Quality of care

Reliable denosumab recall keeps patients within the 6-month dosing window and prevents rebound fractures from missed or delayed doses.

Revenue and clinical value

Consistent recall supports continuity of care, GP Chronic Condition Management Plan review where appropriate, and fewer missed appointments.

Delayed dosing and fracture risk

Denosumab (Prolia) is administered subcutaneously every 6 months for osteoporosis. Unlike bisphosphonates, which bind to bone and maintain effect after cessation, denosumab has no residual activity. When a dose is delayed or missed, bone turnover rebounds rapidly and bone mineral density (BMD) gains are quickly reversed.

The clinical risk is not theoretical. A UK population-based cohort study (Annals of Internal Medicine, 2020; doi:10.7326/M20-0882) of 2,594 patients aged 45 and over found:

- On-time dosing: 27.3 fractures per 1,000 patients over 6 months.
- Short delay (4 to 16 weeks after due date): 32.2 per 1,000.
- Prolonged delay (more than 16 weeks): 42.4 per 1,000.
- Vertebral fracture hazard ratio for prolonged delay: 3.91 (95% CI 1.62 to 9.45).

Permanent discontinuation of denosumab carries even greater risk. Without sequential bisphosphonate therapy, rebound vertebral fractures have been documented within 6 to 12 months of the last injection. The TGA has issued strengthened warnings on this risk.

For GP practices, the management task is procedural: ensure no patient on denosumab falls more than a few weeks outside the 6-month dosing window. This PDSA documents one practice's systematic approach to identifying and recovering a backlog of 66 overdue patients.

KEY FACTS

Delaying a Prolia dose increases fracture risk. Even a 4-week delay raises risk by approximately 18%. Beyond 16 weeks, vertebral fracture risk nearly quadruples. Stopping Prolia without sequential therapy causes rapid bone loss and rebound fractures. Every GP practice with Prolia patients needs a reliable recall and reminder system that is updated at the time of each administration.

Why a PDSA rather than a straight protocol roll-out

A protocol roll-out states what the team should do. A PDSA tests whether the change holds in this practice and produces data across cycles. For recall recovery the measure is simple and repeatable: how many denosumab patients are overdue, and whether that number falls and stays down.

CPD HOURS FROM THIS PDSA

Up to 9 hours when submitted as a practice-based or group activity: 3 EA (review of denosumab management, fracture risk evidence and the practice knowledge base), 3 RP (reviewing overdue Prolia recalls against the dosing schedule and setting recovery targets), 3 MO (tracking overdue recalls across three monthly cycles and confirming the trend holds). The RACGP classifies PDSA activities under Measuring Outcomes.

CPD hours from this PDSA

CATEGORY	FOCUS	HOURS
Educational Activities (EA)	Review of denosumab management, fracture risk evidence and the practice knowledge base	3
Reviewing Performance (RP)	Reviewing overdue Prolia recalls against the dosing schedule and setting recovery targets	3
Measuring Outcomes (MO)	Tracking overdue recalls across three monthly cycles and confirming the trend holds	3
Total		9

GPs must complete 50 hours of CPD annually under the Medical Board of Australia registration standard. This includes at least 12.5 hours of Educational Activities, a minimum of 25 hours combined Reviewing Performance and Measuring Outcomes with at least 5 hours each, and the remaining 15 hours allocated to either as suits scope of practice. The RACGP classifies PDSA activities under Measuring Outcomes. This PDSA may be submitted as a group or practice-based activity.

How this guide works

● Worked example from Dr Chris Mitchell's practice ○ Your practice: fill in your own details

Grey boxes with a red left border are worked examples drawn directly from Dr Chris Mitchell's practice. They describe what the practice did, what was measured and what was learned. Off-white boxes with a dashed red border are insert boxes for your own practice. Fill these in as you complete each stage. They become the basis for your CPD submission.

CM

Dr Chris Mitchell AM

Dr Chris Mitchell AM, FAICD is co-founder of Medius Global and a Rural General Practitioner and Rural Generalist with more than 35 years of experience in Northern NSW. He is a Fellow of the Australian Institute of Company Directors and a Past President of the Royal Australian College of General Practitioners. He was previously Head of Adoption, Benefits and Change at the National eHealth Transition Authority (NEHTA). He has served on numerous health sector boards, including the RACGP, NPS MedicineWise, Therapeutic Guidelines Ltd, The Rural Doctors Network and North Coast GP Training. Chris was awarded Member of the Order of Australia (AM) in 2013 for services to general practice and received a Rural Doctors Network Rural Medical Service Award in 2025.

Important notes

- Pharmaceutical Benefits Scheme (PBS) criteria and Medicare Benefits Schedule (MBS) item descriptors change periodically. Verify current PBS listings and MBS items against Commonwealth government sources before applying them in practice.
- Clinical content in this guide is intended as educational background only. It does not constitute clinical advice and should not substitute for clinical judgement applied to individual patients.
- Medius Global provides this guide as a professional development resource for GP practice teams. Medius Global is not a registered training organisation and does not provide accreditation services.

The PDSA cycle

The following worked example documents a practice-based PDSA conducted November 2022 to January 2023. The activity was initiated as a quality improvement measure following accreditation. It was subsequently peer-reviewed and approved by the RACGP. Individual clinician data has been de-identified; aggregate figures are used.

Idea

WORKED EXAMPLE: IDEA

Missed Prolia doses can rapidly lead to bone loss and fractures. The practice identified that Prolia reminders were not consistently being updated in the clinical system at the time of administration, and that some patients were not returning for their 6-month injection without follow-up contact.

Objective: reduce the number of patients with overdue Prolia reminders and establish a reliable recall system that prevents the backlog recurring. The PDSA also offered an opportunity to update the practice knowledge base on denosumab and improve database quality.

Plan

WORKED EXAMPLE: PLAN

Three objectives:

- Identify all patients with overdue Prolia reminders via database search.
- Contact overdue patients and manage appropriately (book appointment, inactivate, or document refusal).
- Establish a system to prevent recurrence: reminders updated at the time of administration; reminder card given to patient.

Data extraction and review planned over three monthly cycles to monitor trend reduction. Secondary objective: test and compare phone contact against automated recall (Automed) to determine the more effective approach for this practice.
Additional actions to test:

- Providing a Prolia script at the time of injection with the due date noted.
- Booking the next appointment at the time of administration.
- Adding Prolia to the patient care plan (to enable MBS item 10997).
- Adding osteoporosis to the patient active problems list.

Do: working through the overdue list

WORKED EXAMPLE: DO

Planning meeting: 1 November 2022. Activity led by the nursing team. Initial database search (2 November 2022): 66 patients identified with overdue Prolia reminders spanning the previous 12 months. Key finding from the initial search:

- 64 of 66 overdue reminders involved patients who had not attended, not a system failure.
- 2 patients had received Prolia from a GP without the reminder being updated.
- 2 patients had received Prolia from a nurse without the reminder being updated.

Doctors reviewed the overdue list and identified additional actions:

- Inactive patients to be suspended in the database.
- Diagnoses to be confirmed and added to active health problems.
- GP Chronic Condition Management Plans considered where appropriate, to enable MBS item 10997 billing.
- Clinical appropriateness of Prolia to be reviewed for patients with frequent missed doses.

Record your practice data below. Insert a row for each GP and record overdue reminders at each data extraction.

INSERT BOX: YOUR PRACTICE DATA, COMPLETE FOR EACH CYCLE

DOCTOR NAME	OVERDUE REMINDERS IDENTIFIED	CONTACT ATTEMPTED	OUTCOME

Study: data across three cycles

WORKED EXAMPLE: STUDY FINDINGS

Three data cycles over 3 months:

DATA CYCLE	DATE	OVERDUE REMINDERS	KEY ACTIONS TAKEN
Cycle 1	November 2022	66	Initial search; 10 made inactive; 2 deceased; 4 reminder errors corrected; GPs notified
Cycle 2	December 2022	34	8 made inactive; 12 booked for administration; 12 phone calls with messages left; 1 on specialist advice; 1 refusal
Cycle 3	January 2023	22	2 inactivated; 2 awaiting specialist advice; 8 appointments booked; 5 aware but not committed; 5 messages left

WORKED EXAMPLE: WHAT WE LEARNED

Phone contact was more effective than automated recall (Automed) for getting patients to book and attend. Providing a script with the Prolia due date noted, and a reminder card given at the time of injection, worked well in keeping patients informed. Booking the appointment 6 months in advance at the time of administration was not effective. Patients did not reliably attend a booking made that far ahead. Private fee arrangements had reduced some patients' willingness to return for chronic disease management visits. The reminder-at-time-of-administration protocol, consistently applied, is the core system change required to prevent recurrence. A follow-up search was planned at 6 months to track ongoing performance.

INSERT BOX: WHAT DID WE LEARN?

What worked well?

What did not work as expected?

Unexpected findings

Act: what to change and embed

WORKED EXAMPLE: ACT

Changes implemented:

- Prolia reminders are now updated in the clinical system at the time of each administration by the clinician who gives the injection.
- Reminder cards are given to patients at the time of the injection with the due date for the next dose.
- Osteoporosis is added to the active health problems list for all Prolia patients.
- GP Chronic Condition Management Plan and review initiated where appropriate to enable the use of MBS item 10997.
- Phone contact is the preferred recall method. Automated recall used as a supplement.
- The clinical appropriateness of ongoing Prolia use was reviewed for patients with a history of missed doses.
- 6-month follow-up search planned to confirm the trend holds.

INSERT BOX: WHAT CHANGES WILL YOU MAKE?

Changes to implement	
Responsible person	
Review date	

Setting up your practice

Recall and reminder systems

The core requirement is that Prolia reminders are updated in the clinical system at the time of each administration, rather than recalled from memory later.

- Nominate a single responsible clinician (nurse or GP) to update the reminder before leaving the room after each injection.
- Set the reminder interval to 6 months from the date of administration, not from the calendar date.
- Give the patient a written reminder card at the time of injection with the due date for the next dose.
- Run a monthly search on overdue Prolia reminders. Even a well-functioning system will have occasional lapses; catching them early prevents the backlog from growing.

On recall method:

- Phone contact is more reliable than automated recall for this patient group (typically older women who may not engage with digital or automated messages).
- Where automated recall is used, follow up by phone any patients who have not responded within 2 weeks.
- Do not rely on patients self-managing recall. The clinical evidence on rebound fractures makes this a practice responsibility, not a patient responsibility.

At the time of administration: checklist

CHECKLIST: AT EACH PROLIA INJECTION

- Update the Prolia reminder to 6 months from today in the clinical system.
- Give the patient a written reminder card with the next due date.
- Confirm the patient's contact details are current.
- Add osteoporosis to the active health problems list if not already there.
- Consider whether a GP Chronic Condition Management Plan is in place and whether a review is appropriate.
- Consider the use of MBS item 10997 if appropriate.
- If the patient has a dental procedure planned, discuss timing (see "Dental extractions: timing guidance").

Billing considerations

MBS Item 10997 is a Medicare benefit in Australia that allows a practice nurse or an Aboriginal and Torres Strait Islander health practitioner to provide ongoing monitoring and support to patients with chronic diseases. Nurse administration of Prolia may qualify for this rebate for patients whose care plan includes Prolia administration.

Note on private fees: This practice found that private fee arrangements had a measurable effect on patient follow-through. When patients present inconsistently, it is worth checking whether cost is a factor.

Submitting for CPD hours

Submit this PDSA via the RACGP CPD portal at portal.racgp.org.au/CPD. Select GP-led activity (individual or group) and PDSA as the activity type.

TIMING TIP

Submit as a group or practice-based activity via the RACGP portal for each of the participating GPs, consider the time committed to each cycle, but submit collated times, averaged across each GP to reduce the administrative burden.

Doctors involved in this activity

DOCTOR'S NAME	QI AND CPD NUMBER

Resources

RESOURCE	DETAIL
NPS MedicineWise: denosumab	nps.org.au/medicine-finder/prolia-solution-for-injection
TGA: denosumab warnings	tga.gov.au (search: denosumab discontinuation fracture risk)
Annals of Internal Medicine 2020: delayed dosing and fracture risk	doi:10.7326/M20-0882
Osteoporosis Australia	osteoporosis.org.au
RACGP: Osteoporosis guidelines	racgp.org.au/clinical-resources/clinical-guidelines

EDUCATIONAL BACKGROUND MATERIAL

Background and reference

This section forms part of the Educational Activities (EA) component of your CPD submission. Read it before or alongside the PDSA cycle to build the knowledge base for denosumab management.

Mechanism of action

Denosumab inhibits RANKL (receptor activator of nuclear factor kappa-B ligand), a protein involved in osteoclast formation. By blocking RANKL, denosumab inhibits osteoclast activity, reduces bone resorption, increases BMD and reduces fracture risk.

Unlike bisphosphonates (which bind to bone mineral and remain active for years after cessation), denosumab has no residual bone effect. Once treatment is stopped or delayed, osteoclast activity rebounds rapidly.

Indications and patient selection

Standard indication

- Postmenopausal women with osteoporosis at high fracture risk.
- Men with osteoporosis at high fracture risk, particularly those receiving androgen deprivation therapy for prostate cancer.

When to consider denosumab over oral bisphosphonates

- Patients who cannot tolerate or comply with oral bisphosphonate dosing requirements (upright posture for 30 minutes, specific food restrictions, dysphagia).
- Significant renal impairment (creatinine clearance less than 30 mL/min): oral bisphosphonates are relatively or absolutely contraindicated; denosumab does not require dose adjustment for renal function, though calcium monitoring is required.
- Very low BMD where rapid fracture risk reduction is the priority.
- Intolerance of or inadequate response to other therapies.

Contraindications

- Hypocalcaemia: must be corrected before starting denosumab.
- Vitamin D deficiency: replace before administration.
- Ensure calcium and vitamin D supplementation throughout treatment.

Administration

- Denosumab 60 mg subcutaneous injection, every 6 months.
- Supplied as a pre-filled syringe with an automatic needle guard. Administered subcutaneously (not intramuscularly).
- The interval of 6 months is not a guideline. It is a clinical requirement. See "Delayed dosing and fracture risk" for the data on delayed doses.

Monitoring

PARAMETER	WHO REQUIRES IT	TIMING
Serum calcium	All patients with CKD (CrCl below 30 mL/min) or conditions predisposing to hypocalcaemia (for example malabsorption)	Approximately 10 days after each injection
Serum calcium	Patients without hypocalcaemia risk factors	Not routinely required
BMD (DEXA)	All patients on denosumab	Not earlier than 2 years after commencement; interval thereafter based on clinical judgement
Infections / skin reactions	All patients	Advise patients to seek attention for signs of infection or skin reaction. Higher rate reported with denosumab than placebo in trials.

Discontinuation and transition therapy

Stopping denosumab, for any reason, requires a plan. Without sequential therapy, bone turnover rebounds rapidly and BMD gains are lost within months.

IF DENOSUMAB IS STOPPED OR DELAYED BEYOND 2 TO 3 MONTHS

- Administer alternative therapy (typically a bisphosphonate) to prevent rapid bone loss and increased vertebral fracture risk.
- If transitioning to alendronate: initiate 6 months after the last denosumab dose. Continue for at least 1 to 2 years.
- Zoledronic acid IV is an alternative when oral bisphosphonates are not tolerated.
- Risedronate has shown less effectiveness than alendronate or zoledronic acid in preventing post-denosumab bone loss.
- The optimal sequential strategy after long-term denosumab (more than 3 years) is still evolving. Refer to current osteoporosis guidelines or specialist input for complex cases.

Dental extractions: timing guidance

Denosumab is associated with medication-related osteonecrosis of the jaw (MRONJ), a risk that increases with duration of use and concurrent corticosteroid therapy. The risk is substantially lower than with high-dose IV bisphosphonates used in oncology, but it is not zero.

The clinical concern in general practice is the temptation to delay a Prolia injection to allow dental work to be done first. The fracture data above shows this is often the wrong trade-off. The evidence-based approach is:

- Dental extractions should be timed toward the end of the 6-month dosing cycle, ideally 2 to 3 weeks before the next Prolia is due.
- This allows adequate healing time before the injection without delaying the injection.
- Prolia should not usually be withheld to accommodate elective dental procedures.
- Where urgent dental work cannot be avoided mid-cycle, discuss with the patient and dentist, document the clinical reasoning and keep the delay to the absolute minimum.

TIMING	FRACTURE RATE PER 1,000 (6 MONTHS)	RELATIVE RISK
On time (within 4 weeks of due date)	27.3	Reference
Short delay (4 to 16 weeks late)	32.2	+18%
Prolonged delay (more than 16 weeks)	42.4	+55%

Source: population-based cohort study, Annals of Internal Medicine, 2020 (doi:10.7326/M20-0882). N=2,594, UK, mean age 76, 94% female.

Patient education

Key messages for patients on Prolia:

- The injection must be given every 6 months without delay. Missing or delaying a dose significantly increases fracture risk.
- Tell your dentist you are on Prolia before any dental procedure.
- Do not stop Prolia without discussing it with your doctor first. Stopping without a transition plan can cause bone fractures.
- Take calcium and vitamin D supplements as recommended. Do not stop these without advice.
- Contact the practice if you notice signs of skin infection, jaw pain or unusual bone or muscle pain.

Annual CPD requirements

CATEGORY	MINIMUM ANNUAL HOURS	NOTES
Educational Activities (EA)	12.5	Reading, online learning, structured education, knowledge base review
Reviewing Performance (RP)	5 minimum	Part of combined RP and MO minimum of 25 hours
Measuring Outcomes (MO)	5 minimum	RACGP classifies PDSA under MO

CATEGORY	MINIMUM ANNUAL HOURS	NOTES
Total annual requirement	50	Remaining RP and MO hours allocated as suits scope of practice