

PMOS item: Denosumab

PMOS Objective:

- Cost-effective prescribing: use of locally agreed best value product Zadenvi (denosumab) 60mg solution for injection in pre-filled syringe for existing and new patients.

Denosumab 60mg biosimilar factsheet

1. Summary

Prolia (denosumab) 60mg (Amgen) has lost patent exclusivity. Several denosumab 60mg biosimilars are now licensed in the UK.

Denosumab 60mg biosimilars, including Zadenvi, are approved for all reference product (Prolia) indications.

NICE Technology appraisal guidance (TA204): [Denosumab for the prevention of osteoporotic fractures in postmenopausal women](#) recommends denosumab as a treatment option for the primary and secondary prevention of osteoporotic fragility fractures only in [defined cohorts](#) of postmenopausal women at increased risk of fractures.

Where NICE have recommended the use of a biological reference product, the same advice will apply to the biosimilar medicine(s).

In primary care, Prolia is prescribed to circa 1,000 patients across Cornwall and the Isles of Scilly, at a cost of almost £336,000* per year.

The biosimilar Zadenvi (denosumab) 60mg product offer a significant cost saving over Prolia 60mg (Amgen).

Under the NHS Framework awards, Zadenvi (denosumab) 60mg solution for injection in pre-filled syringe has been allocated for use in secondary care in Cornwall and the Isles of Scilly.

*OpenPrescribing data [12 months to August 2025](#)

2. Background

Biologic medicines

Denosumab, a human monoclonal IgG2 antibody, is a biological medicine. These are large, complex molecules, which show a small degree of expected variation within their molecular structures. This occurs even between different batches of the same product due to the inherent variability of biological systems and manufacturing processes.

Biosimilar medicines

When an existing licensed biological medicine is approaching loss of exclusivity, biosimilar medicines may be developed to compete commercially. The existing biological medicine is known as the reference product (RP). A biosimilar medicine is a type of biological medicine that is highly similar in structure and function to the RP. The similarity is demonstrated by data confirming clinical efficacy, safety and immunogenicity equivalence.

Interchangeability

The [MHRA](#) highlights that:

- biosimilars are interchangeable with the RP
- biosimilars of the same RP are also interchangeable

Within the NHS, there is significant experience of intentional switching between products. Once the MHRA authorises a product as a biosimilar, the prescriber should consider it therapeutically equivalent to the RP in the authorised indications. This is supported by a systematic review of real-world data.

Switching patients from the RP to a biosimilar, if this is the best value biologic, has become standard clinical practice. 'Switching' describes a collaborative managed process to change the patient's prescribed treatment from their existing biologic medicine to a biosimilar.

Where [NICE](#) has recommended the RP, the same guidance applies to the biosimilar medicine.

NHS England supports a 'best value first' approach for biological medicines.

Further information may be found on the [SPS website](#).

Substitution and consent

Biosimilars should be prescribed by brand name in line with [MHRA advice](#) to prevent inadvertent switching.

Switching should be a managed process involving both prescribers and patients. Decisions about initiating treatment with a biosimilar, or switching should be shared, and both parties aware of the brand name of the product received. This is important

for traceability and reporting purposes if there are any suspected safety issues relating to the RP or biosimilar medicine.

Patient letter and text message templates are available from PrescQIPP; copies may also be found in the PMOS support pack.

Denosumab 60mg

- Prescribing and review

Denosumab 60mg (Prolia – October 2025) is a second line drug on the [Cornwall formulary](#).

Denosumab is licensed for osteoporosis in postmenopausal women, men, bone loss related to long term systemic steroids in adults, bone loss related to hormone ablation in men with prostate cancer at increased fracture risk.

The NICE Technology appraisal guidance (TA204): [Denosumab for the prevention of osteoporotic fractures in postmenopausal women](#) recommends denosumab as a treatment option for the primary and secondary prevention of osteoporotic fragility fractures only in [defined cohorts](#) of postmenopausal women at increased risk of fractures.

In Primary care, circa 1000 patients (broadly split 90% female, 10% male) were prescribed denosumab 60mg at a cost of almost £370,000. All practices in Cornwall and the Isles of Scilly prescribed denosumab; the number of patients per practice ranged between 2 and 70 people.

The Cornwall Referral Management System (RMS) clinical guideline [Rheumatology: Osteoporosis](#) gives further information regarding prescribing, monitoring and review. Current guidance is to refer for review at 5 years. Devon [Osteoporosis - South & West](#) guidance is also available for Derriford-facing practices.

[Patients should not stop denosumab without specialist review](#) because of the increased risk of multiple vertebral fractures.

Further information regarding denosumab treatment related drug safety updates, are available from the [Medicines and Healthcare products Regulatory Agency \(MHRA\)](#).

Prescribing of denosumab 60mg is further supported through the Cornwall Specialised medicines shared care service local enhanced service (LES).

3. Additional resources

- PMOS data collection Denosumab 26-27 PMOS
- PrescQIPP latest versions available from [PrescQIPP](#) (free log-in required)
 - Prolia to biosimilar denosumab 60mg injection SOP
 - Patient letter template
 - Patient message template

- Denosumab Biosimilar Patient Info SPS
- Zadenvi Patient Medication Information Leaflet

4. References

PrescQIPP [Hot Topics: Biosimilar Denosumab](#) (accessed 15 January 2026)

NHS Specialist Pharmacy Service (SPS) [The licence and supporting evidence for denosumab 60mg biosimilars](#) (accessed 25 November 2025)

ePACT2 data (7 months to end December 2025)