South West London
Postmenopausal Osteoporosis High Cost Drug Pathway

Version 1.2

Contents:

Approved by: SWL Integrated Medicines Optimisation Committee
Approval Date: 22/04/2026

Abbreviations:
TA, technology appraisal; PO, oral; IV, intravenous; SC, subcutaneous, HCD; High-Cost Drug

SWL Drug Pathway – Postmenopausal Osteoporosis Treatment Pathway

Version 1.2 (based on NICE CG146 guidelines, NICE TA464, NICE TA161 and NICE TA204: with local adaptation)

Osteoporosis after menopause
(in women, trans men and non-binary people)

Yes

High fracture risk – *(see Note 3)*

Yes

Very high fracture risk
(according to FRAX calculator - fraxplus.org and/or risk factors outlined by NOGG – see note 4)

Yes – *start oral bisphosphonate **and** refer to secondary care for anabolic treatment*

Oral Bisphosphonates (TA464) (note 1)**:**
- *1st line*: Alendronic acid tablets (70mg/week)
- *2nd line*: Risedronate sodium tablets (35mg/week)
- *3rd line*: Alendronic acid effervescent tablets (70mg/week)

Patient has tried at least two forms of oral bisphosphonate and/or 3rd option or HRT have been tried/not appropriate (note 1, 2)

No

Yes - *continue bisphosphonate where possible and refer*

Specialist secondary care setting only	
• Raloxifene PO (TA161) - lack of evidence for hip fracture prevention[1]	**£**
• Zoledronic acid IV (TA464) • Teriparatide SC biosimilar (TA161) (note 3) • Denosumab SC (TA204)	**££**
• Ibandronic acid IV (TA464) - lack of evidence for hip fracture prevention[1] • Romosozumab SC (TA791) – only if patient has had major osteoporotic fracture (spine, hip, forearm or humerus fracture) within the last 24 months and severe osteoporosis ***[HCD; Blueteq form required]***	**£££**

If these treatments are unsuitable/contraindicated, consider treatment options for patients with high fracture risk

Specialist secondary care setting only	
• Teriparatide SC biosimilar (note 3,5)	**££**
• Romosozumab SC (TA791) - only if patient has had major osteoporotic fracture (spine, hip, forearm or humerus fracture) within the last 24 months (note 5) ***[HCD; Blueteq form required]***	**£££**
• Abaloparatide SC (TA991) (note 5) ***[HCD; Blueteq form required]***	**£££**

If there is more than one NICE approved treatment available, NICE recommends a discussion between the responsible clinician and the patient about the advantages and disadvantages of each treatment (considering therapeutic need and likely adherence to treatment).
If more than one treatment option is suitable, the least expensive will be chosen (taking into account administration costs, dosage and price per dose) unless an order of preference is stated in the NICE TAs.
All drugs are listed in order of cost (including relevant administration costs, using list price or nationally (NICE) / locally (LPP) agreed contract prices).

Refer to the relevant technology appraisals for further information about eligibility

SWL Drug Pathway – Postmenopausal Osteoporosis: Notes

Version 1.2 (NICE CG146 guidelines, NICE TA464, NICE TA161, NICE TA204, NICE TA791, NICE TA991, NOGG and ROS guidance: with local adaptation)

Note 1 – Intolerance and unsatisfactory response to oral bisphosphonates:
Intolerance is defined as persistent upper gastrointestinal disturbance that is sufficiently severe to warrant discontinuation of treatment, and that occurs even though the instructions for administration have been followed correctly (as per NICE TA161). Contraindications (check Summary of Product Characteristics)- may include moderate or severe cognitive problem, renal impairment (CrCl- ml/min), osteonecrosis of the jaw and atypical fractures of the femur.
Unsatisfactory response is defined as another fragility fracture despite adhering fully to treatment for 1 year and there is evidence of a decline in BMD below pre-treatment baseline (as per NICE TA161).

Note 2 – Hormone replacement therapy (HRT): As per NOGG 2024 guidelines, consider offering HRT to younger postmenopausal women (age ≤ 60 years) with high fracture risk and low baseline risk for adverse malignant and thromboembolic events. Continued use of HRT after the age of 60 years should be based on individual patient risk-benefit analysis.

Note 3 –

- **Teriparatide for patients with high fracture risk**: As per NICE TA161, teriparatide is recommended as an alternative treatment option for the secondary prevention of osteoporotic fragility fractures if:
  - patients are unable to take alendronate and risedronate, or have a contraindication to or are intolerant (note 2) of alendronate and risedronate, or who have had an unsatisfactory response (note 3) to treatment with alendronate or risedronate **and;**
  - who are 65 years or older and have a T-score of -4.0 SD or below, or a T-score of -3.5 SD or below plus more than 2 fractures, **or** who are aged 55 to 64 years and have a T-score of -4 SD or below plus more than 2 fractures **OR**;
  - patients who have other clinical indicators of high fracture risk but a normal to low frax score
- **Teriparatide for patients with very high fracture risk:** NICE TA approval criteria for teriparatide (published 2008) recommends its use only after oral bisphosphonates. The NICE TA restriction seems to be based on the high cost of teriparatide at the time, rather than clinical evidence. Teriparatide is now included in the NHS Payment Scheme and with more affordable biosimilars available, it is the least expensive option among currently available anabolic treatments (teriparatide, romosozumab, abaloparatide) for patients with very high fracture risk. NOGG guidelines show that anabolic therapy has greater anti-fracture efficacy than oral bisphosphonates in postmenopausal individuals with severe osteoporosis and works better in treatment-naïve patients. Considering this clinical evidence and cost-effectiveness, in SWL teriparatide biosimilar can be used in bisphosphonate-naïve patients (with **very high** fracture risk only), in line with its product license.
- Teriparatide is commissioned for a max 24 months in SWL.

Note 4 – Patients with very high fracture risk should be started on bisphosphonate treatment and referred to secondary care for anabolic treatment, without delay.
NOGG (2024) recommends consideration of referral of very high-risk patients to an osteoporosis specialist in secondary care for the following:

- The presence of single but important clinical risk factors, such as,
- A recent vertebral fracture [within the last 2 years]
- ≥2 vertebral fractures [whenever they have occurred]
- BMD T-Score ≤-3.5
- Treatment with high dose glucocorticoids [≥7.5 mg/day of prednisolone or equivalent over 3 months] (refer urgently given rapid loss in bone post initiation of glucocorticoids; if any delay is anticipated, start an oral bisphosphonate in the meantime)
- The presence of multiple clinical risk factors, particularly with a recent fragility fracture indicating high imminent risk of re-fracture,
- or other indicators of very high fracture risk

Note 5 – Subsequent antiresorptive therapy: Following treatment with teriparatide (24 months), romosozumab (12 months) or abaloparatide (18 months), initiate antiresorptive treatment (with alendronate, zoledronate or denosumab) without delay.

SWL Drug Pathway –Postmenopausal Osteoporosis- Drug Information for Specialist Therapies

Version 1.2 (this list is not exhaustive; see summary of product characteristics (SPC) for full information)

Drug Name	NICE	Administration	Contra-indications	Special warnings and precautions
Raloxifene	TA161	60mg PO once a daily	•Hypersensitivity to the active substance or to any of the excipients listed •Must not be used in women with childbearing potential •Active or past history of venous thromboembolic events (VTE), including deep vein thrombosis, pulmonary embolism and retinal vein thrombosis. •Hepatic impairment, including cholestasis. •Severe renal impairment. •Unexplained uterine bleeding. •This medicine should not be used in patients with signs or symptoms of endometrial cancer, as safety in this patient group has not been adequately studied.	• Increased risk for VTE • Not recommended to be used in patients with hepatic insufficiency. • Serum total bilirubin, gamma-glutamyl transferase, alkaline phosphatase, ALT and AST should be closely monitored during treatment if elevated values are observed.
Zoledronic acid	TA464	5mg IV once a year as a single dose	•Hypersensitivity to the active substance, to any bisphosphonates or to any of the excipients listed •Patients with hypocalcaemia •Severe renal impairment with creatinine clearance <35 ml/min • Pregnancy and breast-feeding.	• Renal function • Hypocalcaemia • Osteonecrosis of the jaw • Osteonecrosis of the external auditory canal • Atypical fractures of the femur • Acute phase reactions – e.g. fever, flu-like symptoms
Denosumab	TA204	60mg SC every 6 months	• Hypersensitivity to the active substance or to any of the excipients listed • Hypocalcaemia	• Calcium and vitamin D supplementation • Hypocalcaemia • Renal impairment • Skin infections • Osteonecrosis of the jaw and external auditory canal • Atypical fractures of the femur • Long-term antiresorptive treatment • Concomitant treatment with other denosumab-containing medicinal products • Warnings for excipients – contains sorbitol
Ibandronic acid	TA464	3mg IV once every 3 months	• Hypersensitivity to the active substance or to any of the excipients listed • Hypocalcaemia	• Patients with disturbances of bone and mineral metabolism • Anaphylactic reaction/shock • Osteonecrosis of the jaw and external auditory canal • Atypical fractures of the femur • Patients with renal, hepatic, cardiac impairment • Patients with known hypersensitivity to other bisphosphonates

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SWL Drug Pathway –Postmenopausal Osteoporosis- Drug Information for Specialist Therapies

Version 1.2 (this list is not exhaustive; see summary of product characteristics (SPC) for full information)

Drug Name	NICE	Administration	Contra-indications	Special warnings and precautions
Teriparatide	TA161	20 micrograms SC once daily, max 24 months	• Hypersensitivity to the active substance or to any of the excipients listed • Pregnancy and breast-feeding • Pre-existing hypercalcaemia • Severe renal impairment • Metabolic bone diseases (including hyperparathyroidism and Paget's disease of the bone) other than primary osteoporosis or glucocorticoid-induced osteoporosis. • Unexplained elevations of alkaline phosphatase • Prior external beam or implant radiation therapy to the skeleton • Patients with skeletal malignancies or bone metastases should be excluded from treatment with teriparatide.	• Serum and urine calcium • Urolithiasis • Orthostatic hypotension • Renal impairment • Experience in the younger adult population is limited, and treatment should be initiated with caution • The medicinal product is considered 'sodium-free'
Abaloparatide	TA991	80 micrograms SC once daily, max 18 months	• Hypersensitivity to the active substance or to any of the excipients listed • Pregnancy and breast-feeding (see section • Women of childbearing potential • Pre-existing hypercalcaemia • Severe renal impairment • Unexplained elevations of serum alkaline phosphatase • Patients with known risks for osteosarcoma such as those who have received prior external beam or implant radiation therapy involving the skeleton • Patients with skeletal malignancies or bone metastases	• Orthostatic hypotension and increased heart rate • Hypercalcaemia • Hypercalciuria and urolithiasis • The medicinal product is considered 'sodium-free'
Romosozumab	TA791	210mg SC once a month, max 12 months	• Hypersensitivity to the active substance or to any of the excipients [5] • Hypocalcaemia • History of myocardial infarction or stroke	• Myocardial infarction and stroke • Hypocalcaemia • Hypersensitivity • Osteonecrosis of the jaw • Atypical femoral fractures • Excipients may cause allergic reactions – refer to SPC

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SWL Drug Pathway – Postmenopausal Osteoporosis – References

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1. National Osteoporosis Guideline Group (NOGG) 2024 Clinical Guideline. Available from Full Guideline | NOGG. [Accessed 25/06/25].
2. National Institute for Health and Care Excellence. Bisphosphonates for treating osteoporosis. Technology appraisal guidance [TA464] [Online]. Available from NICE [Accessed: 26/06/25].
3. National Institute for Health and Care Excellence. Raloxifene and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women [TA161] [Online]. Available from NICE [Accessed: 26/06/25].
4. National Institute for Health and Care Excellence. Denosumab for the prevention of osteoporotic fractures in postmenopausal women [TA204] [Online]. Available from NICE [Accessed: 26/06/25].
5. National Institute for Health and Care Excellence. Romosozumab for treating severe osteoporosis [TA791] [Online]. Available from NICE [Accessed: 26/06/25].
6. National Institute for Health and Care Excellence. Abaloparatide for treating osteoporosis after menopause. Technology appraisal guidance [TA991] [Online]. Available from NICE [Accessed: 26/06/2025]
7. Summary of Product Characteristics: Alendronic acid 70mg tablets [Last updated 21/04/202]. Available from EMC [Accessed: 26/06/25].
8. Summary of Product Characteristics: Risedronate sodium 35 mg film-coated tablets [Last updated 10/06/2020]. Available from EMC [Accessed: 26/06/25].
9. Summary of Product Characteristics: Ibandronic acid 150mg film-coated tablets. [Last updated 28/12/2022]. Available from EMC [Accessed: 26/06/25].
10. Summary of Product Characteristics: Raloxifene hydrochloride 60mg film-coated tablets. [Last updated 20/06/2019]. Available from EMC [Accessed: 26/06/25].
11. Summary of Product Characteristics: Zoledronic acid 5 mg/100 ml Solution for infusion [Last updated 15/10/2024]. Available from EMC [Accessed:26/06/2025].
12. Summary of Product Characteristics: Movymia 20 micrograms/80 microliters solution for injection [Last updated 01/01/2021]. Available from EMC [Accessed:26/06/2025].
13. Summary of Product Characteristics: Prolia 60 mg solution for injection in pre-filled syringe [Last updated 03/03/2025]. Available from EMC [Accessed: 26/06/2025].
14. Summary of Product Characteristics: Ibandronic acid 1mg concentrate for solution for infusion [Last updated 19/08/2022]. Available from EMC [Accessed: 26/06/2025].
15. Summary of Product Characteristics: EVENITY 105 mg solution for injection in pre-filled [Last updated 22/08/2024]. Available from EMC [Accessed: 26/06/2025].
16. Summary of Product Characteristics: Eladynos 80 microgram solution for injection in pre-filled pen [Last updated 22/01/2024]. Available from EMC [Accessed: 26/06/2025].

SWL Drug Pathway – Postmenopausal Osteoporosis - Version Control

Version 1.2

Version number	Main amendments	Date of approval
1.0	New pathway	15/10/2025
1.1	Remove from note 1 reference to eGFR. Include ‘check Summary of Product Characteristics' and ‘renal impairment (CrCl-mL/min)’ .	10/12/2025
1.2	Note 3 amendment: access to Teriparatide for patients with indicators of high fracture risk and a normal to low frax score clarified. Change in Teriparatide duration from 18 months to 24 months.	22/04/2026
Date of next review: April 2028 (or earlier if indicated)		