# Initiating denosumab (Prolia®) prescribing checklist

**This checklist should be completed by the clinician initiating prescribing and the completed form scanned into the patient’s notes**

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Patient Name** | | Click here to enter text. | | **Appointment Date** | | Click here to enter text. | |
| **Clinician name** | | Click here to enter text. | | **Clinician Signature** | | Click here to enter text. | |
| Denosumab 60mg injection is licensed for the treatment of osteoporosis in postmenopausal women at increased risk of fractures and is GREEN (suitable for prescribing in primary care) in North Cumbria traffic light system system (<http://medicines.necsu.nhs.uk/cumbria-traffic-light-classification/>) for this indication ONLY when prescribed in line with NICE TA204.  **Dose:** 60mg subcutaneous injection, every 6 months for 3-5 years | | | | | | | |
| **Age** | **Most recent T-Score** | | **Independent clinical risk factors (RFs)** | | **Tick all that apply** | | **Total no. RFs** |
| Click here to enter text. | Click here to enter text. | | Parental history of hip fracture | |  | | Click here to enter text. |
| Alcohol intake of 4 or more units/day | |  | |
| Rheumatoid arthritis | |  | |

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| **NICE criteria for PRIMARY PREVENTION of osteoporotic fractures – ALL CRITERIA MUST BE MET** | **Tick** |
| Post-menopausal |  |
| Increased risk of fractures |  |
| Has an intolerance of, or a contraindication to alendronate **and** either residronate or etidronate, or is unable to comply with the special instructions for administering those treatments – specify details: |  |
| Click here to enter text. | |
| Has a combination of T-score, age and number of independent clinical risk factors for fracture as indicated in the following table – *circle appropriate number* | |

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| **Age** | **0 RFs** | **1 RF** | **2RFs** |  | T-scores (SD) at (or below) which denosumab is recommended when alendronate and either risedronate or etidronate are unsuitable |
| 65-69yrs | X | -4.5 | -4.0 |  |
| 70-74yrs | -4.5 | -4.0 | -3.5 |  |
| 75+yrs | -4.0 | -4.0 | -3.0 |  |

|  |  |
| --- | --- |
| **NICE criteria for SECONDARY PREVENTION of osteoporotic fractures – ALL CRITERIA MUST BE MET** | **Tick** |
| Post-menopausal |  |
| Increased risk of fractures |  |
| Has an intolerance of, or a contraindication to alendronate **and** either residronate or etidronate, or is unable to comply with the special instructions for administering those treatments – specify details: |  |
| Click here to enter text. | |

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| **Before starting treatment with denosumab 60mg (Prolia®)** | | **Tick** |
| Perform baseline measures | * Renal function * Bone profile (serum calcium, alkaline phosphatase, phosphate, albumin) * Vitamin D * Correct any calcium and/or vitamin D insufficiency or deficiency – this may require the use of high dose vitamin D preparations. * See the Cumbria guidance on the management of vitamin D deficiency and insufficiency   (<http://medicines.necsu.nhs.uk/download/cumbria-vitamin-d-guidelines-november-2016>). |  |
| Ensure adequate calcium and vitamin D supplementation throughout treatment | * Recommend use of a calcium calculator tool (<http://www.cgem.ed.ac.uk/research/rheumatological/calcium-calculator>) * Advise to buy/prescribe a combined calcium and vitamin D preparation OR if they have sufficient dietary calcium (700mg/day), advise 800 units vitamin D daily. * Document if supplementation of calcium not felt to be necessary |  |
| Latex allergy | * Ask about latex allergy (latex contained in needle cover). |  |
| Discuss benefits, side effects and provide patients with the package leaflet and the **Patient safety information sheet** (<https://www.gov.uk/drug-safety-update/denosumab-xgeva-prolia-intravenous-bisphosphonates-osteonecrosis-of-the-jaw-further-measures-to-minimise-risk>) | * Advise patients to report symptoms of hypocalcaemia (paraesthesia, muscle spasms, cramps or twitching, tingling or numbness of fingers, toes or around the mouth); of atypical femoral fracture (new, unusual hip or groin pain); any skin infections/symptoms of cellulitis; ear symptoms |  |
| Assess for good oral hygiene and consider dental examination where appropriate | * Ask about risk factors for osteonecrosis of the jaw (corticosteroid use, chemotherapy, smoking, poor oral hygiene, planned invasive dental surgery eg. tooth extraction, dental infection). * Consider dental assessment prior to treatment in patients with risk factors * Withhold treatment until after any planned dental surgery. * Encourage routine dental check-ups and to report any oral symptoms. |  |