Prescribing Protocol SESLHDPR/720
Zoledronic Acid for Osteoporosis with fracture due to minimal trauma

Health
South Eastern Sydney
Local Health District

Title	Zoledronic Acid in the treatment of Osteoporosis with fracture due to minimal trauma
Areas where Protocol/Guideline applicable e.g. District, Hospital, ITU, Ward	SESLHD
Areas where Protocol/Guideline not applicable	Paediatrics
Authorised Prescribers	Medical Officers
Indication for use	Osteoporosis with fracture due to minimal trauma **AND** not receiving concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition **AND** there is evidence (or perceived risk) that the patient will not tolerate or receive an equivalent medication in the immediate post fracture period.
Contraindications	• Hypocalcaemia • CrCl <35mL/min • Hypovitaminosis D
Precautions	• Renal Impairment: CrCl 35-60mL/min: Consider reducing infusion rate • Osteonecrosis of the jaw • Atypical femoral fracture • Pregnancy (or planning pregnancy in the next 12 months) • Breastfeeding
Place in Therapy	Established role as a first-line treatment options for osteoporosis.
Dosage	5mg intravenously every 12 months (or longer)
Duration of therapy	Duration of therapy is individualised based on regular re-assessment of fracture risk.
Important Drug Interactions	Exercise caution when used in conjunction with drugs that can significantly impact renal function (e.g. aminoglycosides or diuretics that may cause dehydration). In patients with renal impairment, the systemic exposure to concomitant medicinal products that are primarily excreted via the kidneys may increase.
Administration instructions	Use the 5 mg/100 mL infusion solution and infuse over at least 15 minutes. Consider slower rate in patients with renal impairment

Monitoring requirements	Monitor renal function (creatinine clearance): Renal impairment has been observed following the administration of zoledronic acid, especially in patients with pre-existing renal impairment or additional risk factors e.g. advanced age, concomitant nephrotoxic medications, concomitant diuretic therapy, severe dehydration. Monitor calcium and Vitamin D to ensure concomitant therapy is optimised. Supplementation is recommended. Ensure 25-hydroxyvitamin D is >50 nmol/L prior to therapy.
Management of complications	Patients must be appropriately hydrated prior to administration of zoledronic acid. This is especially important in the elderly and for patients receiving diuretic therapy. For most patients adequate hydration can be achieved by the patient drinking two glasses of fluid (such as water) before and two glasses of fluid after the infusion. Flu-like symptoms including fever and headache may occur after the infusion and usually resolve within 3 days. Consider administering paracetamol shortly before infusion, and regularly for 1-2 days after infusion, to reduce incidence of these post-dose symptoms.
Basis of Protocol/Guideline (including sources of evidence, references)	MIMS AMH Australian Injectable Drugs Handbook Therapeutic Guidelines Osteoporosis Prevention, Diagnosis and Management in Postmenopausal Women and Men over 50 years of age. RACGP and Osteoporosis Australia. 2017 (Ed 2).
Groups consulted in development of this protocol	Endocrinology Pharmacy

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GOVERNANCE	
Enactment date	October 2021
Expiry date:	September 2024
Ratification date by SESLHD QUM Committee	7th October 2021
Chairperson, QUM Committee	Dr John Shephard
Version Number	1