Safe Administration Therapy Tool for Osteoporosis

For residents who are at HIGH RISK of fractures, these medications are recommended as FIRST LINE therapy, *strong recommendation*

Therapies	Frequency	Safe Administration Guidance Life Expectancy > 1year	Key Cautions*
Alendronate 70 mg	Weekly Oral	• Take tablet with 250ml water 30 min PRIOR to eating/drinking or taking medication and in the morning before breakfast. • **Except** Risedronate Delayed Release (DR): can be taken immediately after breakfast and is not required to be taken first thing in the morning on an empty stomach. • Do NOT crush or chew. • Stay upright. Do not lie down for 30 min after taking the tablet.	**For All Oral Bisphosphonates** • Calcium, antacids, and some other oral medications may interfere with bisphosphonate absorption so should be administered at a different time of day. • Bisphosphonates are NOT recommended for those with renal insufficiency. Obtain Creatinine Clearance, avoid Alendronate if CrCl<35mL/min; avoid Risedronate if CrCl<30mL/min. • For residents who cannot either swallow or have swallowing difficulties, intravenous infusion and injectable therapies are recommended. NOTES • Comparative adverse events - alendronate esophageal adverse events may be severe; risk with risedronate appears to be lower
Risedronate Sodium 35 mg	Weekly Oral		
Risedronate Sodium 150 mg	Monthly Oral		

For residents who are at HIGH RISK of fractures and who have difficulty taking oral medications or when bisphosphonate are unsuitable, these medications are recommended as FIRST LINE therapy, *strong recommendation*

Therapies	Frequency	Safe Administration Guidance Life Expectancy > 1year	Key Cautions
Denosumab 60 ml/mg	Every 6 months subcutaneous Injection	• Subcutaneous (under the skin) injection. • Consider use for residents who cannot sit for 30 minutes post IV treatment. • Consider use for residents with difficulty swallowing or intolerance to oral bisphosphonates.	**Renal Impairment** • Residents with severe renal impairment creatinine clearance <30 mL/min or receiving dialysis may be at greater risk of developing hypocalcemia. Clinical monitoring of calcium levels is recommended. • Consider referral to specialist.
Zoledronic Acid 5 mg/100 ml	Once yearly Intravenous Infusion (IV)	• MUST drink 2 glasses of fluid / water before & after IV infusion. • MUST keep the intravenous infusion intact. • Sit during the entire IV infusion. • Infusion Rate: a minimum of 15 min. Consider 45 min for improved tolerance.	**For zoledronic acid post-IV therapy: there may be flu-like, fever and myalgia symptoms:** • Flu-like, fever, myalgia symptoms can occur within 3 days post-IV and can last 7-14 days. • Acetaminophen or ibuprofen can reduce the likelihood of post dose symptoms. • IV Bisphosphonates are NOT recommended for residents with severe renal impairment and creatinine clearance <30mL/min.

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For residents who are at HIGH RISK of fractures, these medications are suggested, when other agents are unsuitable, *conditional recommendation*

Therapies	Frequency	Safe Administration Guidance Life Expectancy > 1year	Key Cautions*
Teriparatide 20 mcg	Once daily subcutaneous injection	• Injection	• Lifetime maximum duration of use is 24 months due to the potential risk of osteosarcoma • AVOID if creatinine clearance <30 mL/min • Rare adverse events include allergic reaction and anaphylaxis NOTES • Treatment with alendronate may reduce the effectiveness of teriparatide; combination not recommended.
Romosozumab 105mg/1.17mL	Monthly subcutaneous injection	• Injection • Available formulation contains half the recommended monthly dose (210 mg); hence two consecutive injections are required each month	• Lifetime maximum duration of use is 12 months as the anabolic effect declines over time • Do not initiate romosozumab in patients who have had a myocardial infarction or stroke within the preceding year. (from PI) • Consider the benefit-risk in patients at increased risk for MI or stroke. (from PI) • Add something about renal considerations • Hypersensitivity reactions can occur. NOTES • PBS Listed April 2021 (authority required)

For residents who are at HIGH RISK of fractures, it is suggested that Raloxifene and Etidronate NOT be used, *conditional recommendation*

Always check cautions listed in product monographs and relevant prescribing guidelines (eg Therapeutic Guidelines)

Adequate calcium and vitamin D intake is necessary to maintain normal blood calcium levels in residents prescribed these medications (see recommendations for calcium and vitamin D on page 2).

Australian PI –EVENITY® (ROMOSOZUMAB) Solution For Injection.
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2019-PI-01692-1&d=202105241016933
Australian Medicines Handbook 2021
[1]Papaioannou A et al. CMAJ. 2015; 2www.gradeworkinggroup.org; 3www.lucodes.ca
The Royal Australian College of General Practitioners. RACGP aged care clinical guide (Silver Book). 5th edn. East Melbourne, Vic: RACGP, 2019, 2020.

This document is only to be used as a support decision tool.
May 2021

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How to use this tool

1. Assess risk for fracture using a fracture risk tool (e.g. Garvan Risk Calculator, FRAX Score) - ON ADMISSION
2. The 2015 Fracture Prevention Recommendations for Frail Older Adults1 establish HIGH RISK individuals as those who meet one of the following:
   - Had a prior hip fracture
   - Had a prior vertebral fracture
   - Had more than one prior fracture (exclude hands, feet and ankle)
   - Recently used glucocorticoids (e.g. steroids, prednisone) and had one prior fracture
   - Has a vertebral fracture present (if chest x-ray ordered, screen for vertebral fracture)
   - Has been readmitted from hospital (post-fracture).
3. Treat osteoporosis with lifestyle changes and pharmacological treatment.
4. A careful risk–benefit analysis is important prior to initiation of pharmacological treatment for osteoporosis.
5. Pharmacotherapy is not appropriate for individuals with a poor prognosis and/or lifespan < 1 year.
6. Calcium and vitamin D supplements should be offered to people taking osteoporosis treatments if intake/levels are inadequate .
7. Recommendations for calcium and vitamin D :
   - 1000 - 1300 mg/day of calcium through dietary interventions or calcium supplementation up to 500 mg/day (if cannot meet target through diet)
   - Vitamin D supplementation, 800 – 2000 UNITS/day.

What does a strong/conditional recommendation[2] mean?

Implications	Strong Recommendation *(RECOMMEND)*	Conditional Recommendation *(SUGGEST)*
For patients/ residents	Most individuals in this situation would want the recommended course of action, and only a small proportion would not.	The majority of individuals in this situation would want the suggested course of action, but many would not.
For clinicians	Most individuals should receive the intervention.	Clinicians recognize that different choices will be appropriate for each individual and they must help each individual arrive at a management decision consistent with their values and preferences.