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 240ml water 30 min PRIOR to eat/drink/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.
Risedronate Sodium 35 mg **Risedronate DR** 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, 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.

For residents who are at HIGH RISK of fractures, this medication is suggested, *conditional recommendation:*

Therapies	Frequency	Safe Administration Guidance Life Expectancy > 1year	Key Cautions*
Teriparatide 20 mcg subcut	Daily subcutaneous injection	• Injection	✔ REFER to product monograph or CPS* for information. ✔ Cost may restrict access to this medication.

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 provided in *eCPS (Compendium of Pharmaceuticals and Specialties).

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).

 This document is only to be used as a support decision tool. *May 2018, ON*

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How to use this tool

1. Assess risk for fracture – 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. Pharmacotherapy is not appropriate for individuals with a lifespan < 1 year.
4. Recommendations for calcium and vitamin D intake[1]:
   - 1200 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 his/her values and preferences.

What do I need to know about Limited Use Codes[3] (Ontario)?

High Risk for Fracture*

DENOSUMAB

LIMITED USE: Code 428 female 515 males
Failed Other Available Osteoporosis Therapy (fragility fracture or evidence of decline in bone mineral density below pre-treatment baseline levels despite adherence for one year).

LIMITED USE: Code 429 female 516 males
For whom oral bisphosphonates are contraindicated due to hypersensitivity or abnormalities of the esophagus (esophageal stricture or achalasia) or inability to stand or sit upright for at least 30 minutes.

ZOLEDRONIC ACID

LIMITED USE: Code 436
For treatment of osteoporosis in postmenopausal women for whom bisphosphonates are contraindicated due to abnormalities of esophagus (esophagus stricture or achalasia) or inability to stand or sit upright for at least 30 minutes.

* **High Risk defined as:**
A prior fragility fracture and a moderate 10 year fracture risk (10-20%) or
A high 10 year fracture risk (>20%) or
Where a residents 10 year fracture risk is less then the thresholds define above, a high fracture risk based on evaluation of clinical risk factors for fracture.

[1]Papaioannou A et al. CMAJ. 2015; 2www.gradeworkinggroup.org; 3www.lucodes.ca

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May 2018

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