Osteoporosis

Management Guide

Detect to Prevent

Fracture Risk Assessment

Diagnosis [1]

Family History

Clinical fracture risk assessment with FRAX (should be performed in the first assessment)

Physical Examination

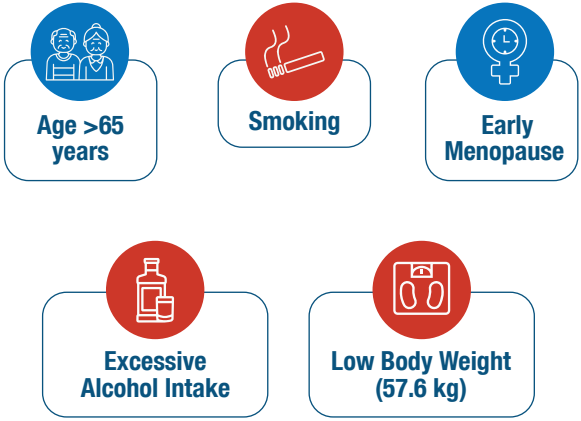
Take note of previous fractures

Bone mineral density testing by DEXA (based on clinical fracture risk profile)

FRAX: Fracture Risk Assessment Tool, DEXA: Dual X-ray Absorptiometry

Fracture Risk Assessment

Risk Factors[1]



Who Should Be Screened for BMD? [1]

All men or women >65 years without risk factors

Secondary Osteoporosis

All postmenopausal women >50 years

- Starting or taking long-term glucocorticoid therapy (≥3 months)
- With osteopenia identified radiographically
- With a history of fracture(s) without trauma

Other peri- or post menopausal women with risk factors

- Low Body Weight (BMI < 20 kg/m^2)
- On long-term systemic glucocorticoid therapy (≥3 months)
- Family history of osteoporotic fractures
- Early menopause
- Current smoking
- Excessive alcohol consumption

BMD: Bone Mineral Density, BMI: Body Mass Index

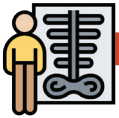
Osteoporosis Evaluation [2-8]

Evaluate for causes of secondary osteoporosis [2-8]

- Type I Diabetes
- Osteogenesis imperfecta in adults
- Untreated long-standing hyperthyroidism
- Premature menopause
- Chronic malnutrition
- Malabsorption
- Hypogonadism
- Chronic liver disease

Consider using bone turnover markers [2-8]

- N-terminal propeptide of type 1 procollagen (P1NP)
- C-terminal telopeptide of type 1 collagen (CTX)



Evaluate for prevalent vertebral fractures [2-8]

How? See Page 6

ISCD/AACE Indications for Spinal Imaging [1]

Lateral spine imaging is indicated when T-score is < -1.0 and one or more of the following is present:

Women ≥ 70 years

Men ≥ 80 years

Self reported but undocumented prior vertebral fracture

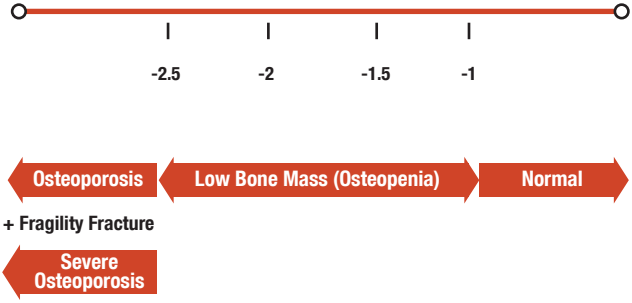
Glucocorticoid therapy equivalent to ≥ 5 mg of prednisone or equivalent per day for ≥ 3 months

Historical height loss of > 4 cm (> 1.5 in)

ISCD: International Society for Clinical Densitometry, AACE: American Association of Clinical Endocrinology

Osteoporosis Classification WHO Criteria[1]

WHO Criteria for Classification of Osteopenia and Osteoporosis[1]



WHO: World Health Organization

Osteoporosis Classification AACE Guidelines[1]

2020 AACE Diagnosis of Osteoporosis in Postmenopausal Women[1]

LOW RISK	HIGH RISK	VERY HIGH RISK
• T-score -1 to -2.5, without trauma fractures	• T-score <-2.5 • FRAX ≥ 3% (hip) or ≥20% (MOF)	• T-score < -3.0 • FRAX >4.5% (hip) or >30% (MOF)

AACE Guidelines for Management of Post Menopausal Osteoporosis[1]

VERY HIGH RISK | **HIGH RISK**

PATIENT CRITERIA[1]

- Recent fracture (<12 months)
- Multiple fractures while on therapy
- Use of drugs that cause skeletal harm (e.g. glucocorticoids)
- BMD: Very low T-score (< -3.0)
- FRAX >4.5% (hip) or >30% (MOF)
- High fall risk
- Previous hip or spine fracture (>12 months)
- BMD T-score <-2.5
- FRAX ≥ 3% (hip) or ≥20% (MOF)
- BMD T-score -1 to -2.5 with high FRAX ≥ 20 % MOF or ≥ 3 % hip

Treatment Options[1]

Abaloparatide | **Denosumab** | **Romosozumab** | **Teriparatide** | **Zoledronate**

If not available:

Alendronate | **Risedronate**

Alendronate | **Denosumab** | **Risedronate** | **Zoledronic Acid**

Alternative therapy:

Ibandronate | **Raloxifene**

Reassessment[1]

Every 1-2 years By DEXA

AACE: American Association of Clinical Endocrinology, BMD: Bone Mineral Density, FRAX: Fracture Risk Assessment Tool, DEXA: Dual X-ray Absorptiometry

Non-Pharmacologic Measures For Bone Health[1]

- **Measure serum** 25-hydroxy Vitamin D in patients who are at risk for Vitamin D insufficiency, particularly those with osteoporosis.[1]
- **Maintain serum** 25-hydroxy Vitamin D = 30 ng/ml in patients with osteoporosis (preferable range 30-50 ng/ml)[1]
- **Supplement** with Vitamin D3 is needed, with a daily dose of 1,000-2,000 IU[1]

Counsel patients to maintain adequate dietary intake of Calcium of 1,200 mg/day for women aged 50 years or older.[1]

Counsel patients to avoid or stop smoking.[1]

Counsel patients to maintain an active lifestyle including resistance exercises.[1]

Counsel patients on reducing the risk of falls, particularly the elderly.[1]

Consider referral for physical therapy.[1]

Denosumab for High-Risk Patients [9]

Indications

Treatment of **osteoporosis** in **postmenopausal women** and in **men** at increased risk of fractures. In postmenopausal women denosumab significantly reduces the risk of vertebral, non-vertebral and hip fractures [9]

Treatment of **bone loss** associated with hormone ablation **in men** with prostate cancer at increased risk of fractures. In men with prostate cancer receiving hormone ablation, denosumab significantly reduces the risk of vertebral fractures [9]

Treatment of **bone loss** associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture [9]

Dose

Single-use prefilled syringe containing **60 mg** in a **1 ml solution.** [9]

Missed Dose?

Administer the injection as soon as the patient is available. Then, schedule injections every 6 months from the date of the last injection. [9]

Contraindication

Hypersensitivity to the active substance or to any of the excipients.
Hypocalcaemia. [9]

Adverse Reactions[9]

Most common:
Back pain
Pain in Extremity
Hypercholesterolemia
Musculoskeletal pain
Arthralgia
Cystitis
Pancreatitis (reported in clinical trials)

Administration

60 mg
Every **6 months**
As **S.C. injection**
In the upper arm, upper thigh, or abdomen. [9]

Precaution

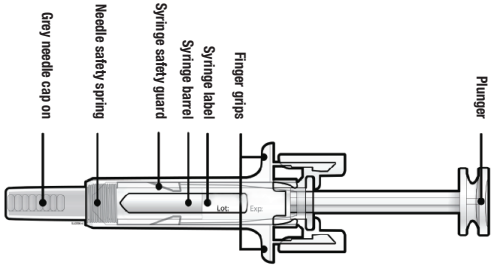
Denosumab should not be used in paediatric patients (age < 18).
Check serum **Calcium** level before treatment. Clinical monitoring of calcium levels is recommended before each dose. For patients at increased risk of hypocalcemia, especially those with advocated CKD-MBD and GFR <30 ml/min, monitor calcium additionally within two weeks of starting treatment. [9]

Renal Patients

No dose adjustment needed.
Monitor serum Calcium in patients with severe renal impairment (GFR <30 ml/min) or receiving dialysis, who are at a higher risk of developing hypocalcemia. Supplement with adequate amount of Calcium and Vitamin D. [9]

S.C.: Subcutaneous

Denosumab
How to Use?

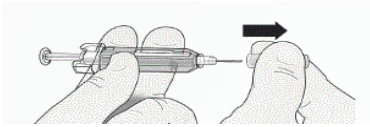


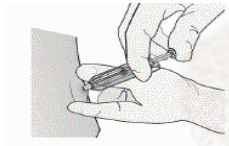
Step 1

Remove Grey Needle Cap.

Step 2

Insert the needle and inject all the liquid.





To view the video, please scan the QR code in the last page

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