



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 Factors¹



**Age >65
years**



Smoking



**Early
Menopause**



**Excessive
Alcohol Intake**



**Low Body Weight
(57.6 kg)**

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/m²)

On long-term systemic
glucocorticoid therapy
(≥ 3 months)

Family history of
osteoporotic fractures

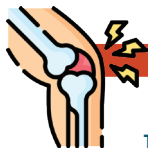
Early menopause

Current smoking

Excessive alcohol
consumption

BMD: Bone Mineral Density, BMI: Body Mass Index

Osteoporosis Evaluation²⁻⁸



Evaluate for causes of secondary osteoporosis²⁻⁸

Type I Diabetes

Osteogenesis imperfecta in adults

Untreated long-standing hyperthyroidism

Premature menopause

Chronic malnutrition

Malabsorption

Hypogonadism

Chronic liver disease



Consider using bone turnover markers²⁻⁸

N-terminal propeptide of type 1 procollagen (P1NP)

C-terminal telopeptide of type 1 collagen (CTX)



Evaluate for prevalent vertebral fractures²⁻⁸

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 Criteria¹



WHO Criteria for Classification of Osteopenia and Osteoporosis¹



Osteoporosis

Low Bone Mass (Osteopenia)

Normal

+ Fragility Fracture

**Severe
Osteoporosis**

Osteoporosis Classification AAACE Guidelines¹



2020 AAACE Diagnosis of Osteoporosis in Postmenopausal Women¹

LOW RISK

- **T-score** -1 to -2.5,
without trauma
fractures

HIGH RISK

- **T-score** <-2.5
- **FRAX** \geq 3% (hip)
or \geq 20% (MOF)

VERY HIGH RISK

- **T-score** < -3.0
- **FRAX** >4.5% (hip)
or >30% (MOF)

AACE Guidelines for Management of Post Menopausal Osteoporosis¹

**VERY
HIGH RISK**

HIGH RISK

PATIENT CRITERIA¹

- 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 Options¹

Abaloparatide

Denosumab

Romosozumab

Teriparatide

Zoledronate

If not available:

Alendronate

Risedronate

Alendronate

Denosumab

Risedronate

Zoledronic Acid

Alternative therapy:

Ibandronate

Raloxifene

Reassessment¹

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 Health¹



- **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 IU¹



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

Romosozumab for Very High-Risk Patients¹⁰



Indication

Treatment of **postmenopausal women with osteoporosis** at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.¹⁰



Precaution

Check serum **Calcium** level before treatment.¹⁰



Contraindications

- In cases of **Hypocalcemia**
- History of systemic **hypersensitivity** to Romosozumab or any component of the formulation.¹⁰



Adverse Reactions¹⁰

Most common:
Arthralgia
Headache



Dose

Two separate prefilled syringes of **105 mg/1.17 ml** each.¹⁰



Administration¹⁰

210 mg
(2 syringes taken one after the other)
Every month
For 1 year only
As S.C. injection



Renal Patients

No dose adjustment needed. Monitor serum Calcium in patients with severe renal impairment or receiving dialysis, who are at a higher risk of developing Hypocalcemia. Supplement with Calcium and Vitamin D, if needed.¹⁰



Missed Dose?

Administer the injection as soon as the patient is available. Then, schedule injections every month from the date of the last injection.¹⁰



Warning

- Potential risk of **myocardial infarction, stroke, and cardiovascular health**. Shouldn't be used with any patient who experienced **MI** or **stroke** in the preceding year.¹⁰

Romosozumab

How to Use?

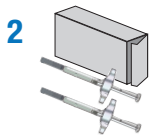
Step 1

Allow the syringe to sit at room temperature for at least 30 minutes before injecting



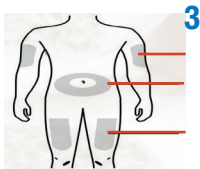
Step 2

Remove the 2 syringes from the carton



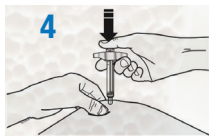
Step 3

Select the injection site and prepare the syringe



Step 4

Insert the needle and inject the liquid subcutaneously.



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

References

- 1- Camacho P, Petak S, Binkley N, et al. AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS/AMERICAN COLLEGE OF ENDOCRINOLOGY CLINICAL PRACTICE GUIDELINES FOR THE DIAGNOSIS AND TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS— 2020 UPDATE. ENDOCRINE PRACTICE May 2020;26 (1): 1-46
- 2- Gehlbach SH, et al. Osteoporos Int. 2000;11:577-582.
- 3- Lindsay R, et al. JAMA. 2001;285:320-323.
- 4- Cooper C, et al. J Bone Miner Res. 1992;7:221-227.
- 5- Cosman F, et al. Osteoporos Int. 2014;25:2359-2381.
- 6- Delmas P, et al. J Bone Miner Res. 2005;20:557-563.
- 7- Adapted with permission from: de Bruijne M, et al. Med Image Anal. 2007;11:503-512. ° Elsevier, Inc.
- 8- Adapted with permission from: Genant H, et al. J Bone Miner Res. 1996;11:984-996. ° John Wiley and Sons, Inc.
- 9- https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125320s5s6lbl.pdf
- 10- https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761062s000lbl.pdf



**Scan the QR code
for Romosozumab**



Scan Me

SC-SAU-AMG162-00142

