FOR YOUR POSTMENOPAUSAL PATIENTS AT HIGH RISK FOR OSTEOPOROTIC FRACTURE[1]

BE AN OSTEOPOROSIS FIRST RESPONDER

Identify postmenopausal osteoporosis

According to AACE guidelines, all postmenopausal women 50 years and older should undergo clinical assessment for osteoporosis and fracture risk.[2]

Use this checklist to help evaluate your postmenopausal patient.

Patient's name:_____ **DOB:**_____ **Ethnicity:**_____

Ask about fractures and identify the clinical risk factors for postmenopausal osteoporosis by checking off all that apply[2]:

- ◯ Prior fracture without major trauma after age 50 (other than fingers, toes, and skull)
- ◯ Age ≥65
- ◯ Low body weight (<127 lb)
- ◯ Family history of osteoporosis or fractures
- ◯ Smoking
- ◯ Early menopause
- ◯ Excessive alcohol intake (≥3 drinks daily)
- ◯ Height loss or kyphosis

For postmenopausal women, osteoporotic fractures are a sentinel event that can lead to subsequent fractures, especially in the first 12 months.[3,4]

A fragility (ie, low-trauma) fracture occurs from low-energy injuries with minimal trauma, such as a fall from standing height or less.[2,5]

Has your patient had a recent fragility fracture? ◯ **Y** ◯ **N** **Fracture site:**_____

INDICATIONS AND USAGE

TYMLOS is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

Limitations of Use

Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of TYMLOS and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF OSTEOSARCOMA

- **Abaloparatide caused a dose-dependent increase in the incidence of osteosarcoma (a malignant bone tumor) in male and female rats. The effect was observed at systemic exposures to abaloparatide ranging from 4 to 28 times the exposure in humans receiving the 80 mcg dose. It is unknown if TYMLOS will cause osteosarcoma in humans.**
- **The use of TYMLOS is not recommended in patients at increased risk of osteosarcoma including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton.**
- **Cumulative use of TYMLOS and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.**

Orthostatic Hypotension: Orthostatic hypotension may occur with TYMLOS, typically within 4 hours of injection. Associated symptoms may include dizziness, palpitations, tachycardia or nausea, and may resolve by having the patient lie down. For the first several doses, TYMLOS should be administered where the patient can sit or lie down if necessary.

Hypercalcemia: TYMLOS may cause hypercalcemia. TYMLOS is not recommended in patients with pre-existing hypercalcemia or in patients who have an underlying hypercalcemic disorder, such as primary hyperparathyroidism, because of the possibility of exacerbating hypercalcemia.

Please see the accompanying full Prescribing Information, including Boxed Warning.

TYMLOS® (abaloparatide) injection

Diagnose

According to AACE guidelines, postmenopausal osteoporosis can be diagnosed if your patient meets any of the following criteria[2]:

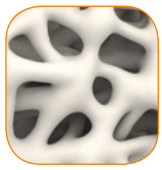
- ◯ Low-trauma spine or hip fracture (regardless of BMD)
- ◯ Osteopenia or low bone mass (T-score between -1.0 and -2.5) with a fragility fracture of the proximal humerus, pelvis, or possibly distal forearm
- ◯ T-score of -2.5 or below in the lumbar spine, femoral neck, total, and/or 33% radius
- ◯ Low bone mass or osteopenia and high FRAX® fracture probability based on country-specific thresholds

Patient T-score from bone density DXA scan:_____ **Site assessed:**_____

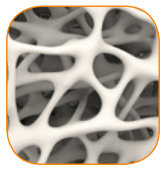
DXA=dual-energy x-ray absorptiometry; FRAX=fracture risk assessment tool.

Bone strength: a measure of quality and BMD[6]

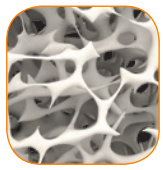
BMD determined by DXA provides a measure of bone quantity, but cannot capture three-dimensional bone geometry or microarchitecture.[6-8]



HEALTHY BONE
T-SCORE -1.0 OR ABOVE[2]



BONE WITH OSTEOPENIA
T-SCORE BETWEEN -1.0 AND -2.5[2]



BONE WITH OSTEOPOROSIS
T-SCORE -2.5 OR BELOW[2]

In a study of postmenopausal women who reported new osteoporotic fractures at 1 year, 82% had peripheral T-scores that were not in the osteoporotic range.[9]*

*The longitudinal, observational National Osteoporosis Risk Assessment study of 149,524 white postmenopausal women aged 50 years and older examined reported fractures in the year following BMD measurement.[9]

Previous postmenopausal osteoporosis treatment?† ◯ **Y** ◯ **N** **Medication:**_____

Duration of treatment:_____

†Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of TYMLOS and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

Treat appropriate patients with TYMLOS

For postmenopausal women at high risk for fracture, TYMLOS significantly reduced the risk of vertebral and nonvertebral fractures.[1]

You are on the front line of postmenopausal osteoporosis. Learn more at TYMLOSfirstresponder.com.

IMPORTANT SAFETY INFORMATION (cont'd)

Hypercalciuria and Urolithiasis: TYMLOS may cause hypercalciuria. It is unknown whether TYMLOS may exacerbate urolithiasis in patients with active or a history of urolithiasis. If active urolithiasis or pre-existing hypercalciuria is suspected, measurement of urinary calcium excretion should be considered.

Adverse Reactions: The most common adverse reactions (incidence ≥2%) are hypercalciuria, dizziness, nausea, headache, palpitations, fatigue, upper abdominal pain and vertigo.

Please see the accompanying full Prescribing Information, including Boxed Warning.

References: 1. TYMLOS® [prescribing information]. Waltham, MA: Radius Health, Inc; 2017. **2.** Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for the diagnosis and treatment of postmenopausal osteoporosis—2016. *Endocr Pract.* 2016;22(suppl 4):1-42. **3.** National Coalition for Osteoporosis and Related Bone Diseases. National Action Plan for Bone Health: Recommendations From the Summit for a National Action Plan for Bone Health. http://www.oif.org/site/DocServer/BoneHealthReport.pdf. Accessed August 27, 2018. **4.** Lindsay R, Silverman SL, Cooper C, et al. Risk of new vertebral fracture in the year following a fracture. *JAMA.* 2001;285(3):320-323. **5.** Giangregorio L, Papaioannou A, Thabane L, et al. Do patients perceive a link between a fragility fracture and osteoporosis? *BMC Musculoskelet Disord.* 2008;9:38. **6.** NIH Consensus Development Panel on Osteoporosis Prevention, Diagnosis, and Therapy. Osteoporosis prevention, diagnosis, and therapy. *JAMA.* 2001;285(6):785-795. **7.** Biver E, Durosier-Izart C, Chevalley T, van Rietbergen B, Rizzoli R, Ferrari S. Evaluation of radius microstructure and areal bone mineral density improves fracture prediction in postmenopausal women. *J Bone Miner Res.* 2018;33(2):328-337. **8.** Unnanuntana A, Gladnick BP, Donnelly E, Lane JM. The assessment of fracture risk. *J Bone Joint Surg Am.* 2010;92(3):743-753. **9.** Siris ES, Chen YT, Abbott TA, et al. Bone mineral density thresholds for pharmacological intervention to prevent fractures. *Arch Intern Med.* 2004;164(10):1108-1112.

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