TYMLOS®
(abaloparatide) injection

Change the trajectory of osteoporosis for your patients.[1]

2020 American Association of Clinical Endocrinologists (AACE) Guidelines support the use of abaloparatide for appropriate patients.[1,2]

INDICATION 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 or multiple risk factors for fracture), or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, TYMLOS reduces the risk of vertebral fractures and nonvertebral fractures.

IMPORTANT SAFETY INFORMATION

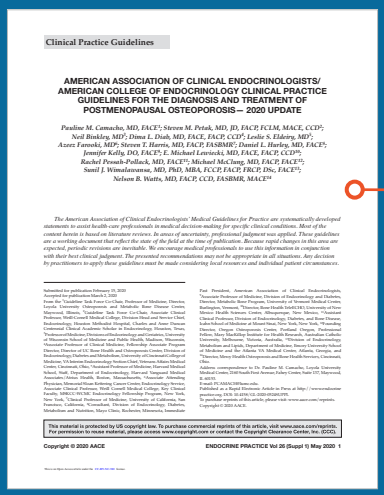
Contraindications: TYMLOS is contraindicated in patients with a history of systemic hypersensitivity to abaloparatide or to any component of the product formulation. Reactions have included anaphylaxis, dyspnea, and urticaria.

Please see Important Safety Information throughout and full Prescribing Information at TYMLOSPI.com.

AACE Guidelines for PMO Support the Use of TYMLOS as an **Initial Anabolic Option for Patients at Very High Fracture Risk**[1,2]

What are the AACE Guidelines?

The American Association of Clinical Endocrinologists (AACE) Guidelines are systematically developed clinical practice recommendations for the diagnosis and treatment of postmenopausal osteoporosis (PMO).[2]



Clinical Practice Guidelines

AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS/ AMERICAN COLLEGE OF ENDOCRINOLOGY CLINICAL PRACTICE GUIDELINES FOR THE DIAGNOSIS AND TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS— 2020 UPDATE

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The American Association of Clinical Endocrinologists' Medical Guidelines for Practice are systematically developed statements to assist health-care professionals in medical decision-making for specific clinical conditions. Most of the content herein is based on literature reviews. In areas of uncertainty, professional judgment was applied. These guidelines are a working document that reflect the state of the field at the time of publication. Because rapid changes in this area are expected, periodic revisions are inevitable. We encourage medical professionals to use this information in conjunction with their best clinical judgment. The presented recommendations may not be appropriate in all situations. Any decision by practitioners to apply these guidelines must be made considering local resources and individual patient circumstances.

The full guidelines can be found at **pro.aace.com** under **Clinical Guidance**.

RECOMMENDATION (R) HIGHLIGHTS

R23

Identifying Very High Fracture Risk Patients[2]

AACE defines patients at very high fracture risk as those with:

- **A very low T-score** (eg, less than -3.0)
- **Fractures while on approved osteoporosis therapy** (eg, bisphosphonates)

Other clinical factors include recent (≤12 months) or multiple fractures, fractures while on drugs causing skeletal harm (eg, long-term glucocorticoids), high risk for falls or history of injurious falls, and very high fracture probability by FRAX® (eg, major osteoporosis fracture >30%, hip fracture >4.5%) or other validated fracture risk algorithm.

According to AACE, some patients who are at very high fracture risk may require more aggressive treatment to achieve an acceptable level of fracture risk.

BMD=bone mineral density; FRAX=fracture risk assessment tool.

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R25

TYMLOS Is Recommended as an Initial Anabolic Option for Patients at Very High Fracture Risk[2]

AACE states that abaloparatide (TYMLOS), denosumab, romosozumab, teriparatide, and zoledronate should be considered for patients unable to use oral therapy and as initial therapy for patients at very high fracture risk.

R43

Anabolic Agents (eg, TYMLOS) With Follow-on Therapy Are Recommended to Prevent Loss of BMD and Fracture Efficacy[2]

AACE advises to follow treatment of an anabolic agent (eg, abaloparatide [TYMLOS], romosozumab, teriparatide) with a follow-on therapy (eg, bisphosphonate or denosumab) to prevent bone density decline and loss of fracture efficacy.

Guidelines Define Increases in BMD and Bone Formation Markers, and Fracture Risk Reduction as Hallmarks of Treatment Response[2]

R31

AACE considers stable or increasing BMD, with no evidence of new fractures or vertebral fracture progression, as a response to therapy for osteoporosis.

R32

AACE considers significant increases in bone formation markers as a pharmacologic response to anabolic therapy.

IMPORTANT SAFETY INFORMATION (cont'd)

Risk of Osteosarcoma: It is unknown whether TYMLOS will cause osteosarcoma in humans. Osteosarcoma has been reported in patients treated with a PTH-analog in the post marketing setting; however, an increased risk of osteosarcoma has not been observed in observational studies in humans. There are limited data assessing the risk of osteosarcoma beyond 2 years of TYMLOS use. Avoid use of TYMLOS for patients at an increased baseline risk for osteosarcoma including patients with open epiphysis (pediatric and young adult patients); metabolic bone diseases other than osteoporosis, including Paget's disease of the bone; bone metastases or a history of skeletal malignancies; prior external beam or implant radiation therapy involving the skeleton; or hereditary disorders predisposing to osteosarcoma.

In managing osteoporosis, AACE emphasizes that patients must understand the potential risk and expected benefits of osteoporosis treatments, and must fully appreciate the risk of fractures and their consequences (eg, pain, disability, loss of independence, and death) when no treatment is given.[2]

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AACE Guidelines recommend considering abaloparatide (TYMLOS) for postmenopausal women at very high risk for fracture.*[1,2]

AACE defines patients at very high fracture risk as those with clinical factors including[2]:

- **Very low T-score: -3.0 or worse**
- **Having fractures while on approved osteoporosis therapy** (eg, bisphosphonates)

According to AACE, patients at very high fracture risk may require more aggressive treatment.†[2]

Abaloparatide (TYMLOS) should be considered as an initial anabolic treatment option for patients at very high fracture risk.*

Follow treatment with an anabolic agent, such as TYMLOS, with a bisphosphonate or denosumab to prevent bone density decline and loss of fracture efficacy.

*Other agents such as denosumab, romosozumab, teriparatide, and zoledronate could also be considered for patients at very high fracture risk.
†According to AACE Guidelines, there is evidence supporting superiority of anabolic agents over antiresorptive agents in reducing vertebral fracture risk in patients at very high risk for fracture.

CONTACT YOUR REPRESENTATIVE OR VISIT TYMLOS.COM/HCP to learn more about TYMLOS

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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.

Pregnancy and Lactation: TYMLOS is not indicated for use in females of reproductive potential.

Adverse Reactions:

The most common adverse reactions (incidence ≥2%) reported with TYMLOS in postmenopausal women with osteoporosis are hypercalciuria (11%), dizziness (10%), nausea (8%), headache (8%), palpitations (5%), fatigue (3%), upper abdominal pain (3%), and vertigo (2%).

Please see full Prescribing Information at TYMLOSPI.com.

References: 1. TYMLOS. Prescribing information. Radius Health, Inc. **2.** Camacho PM, Petak SM, 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. *Endocr Pract.* 2020;26(suppl 1):1-46.

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