

For your postmenopausal patients with osteoporosis at high risk for fracture,

## **BONE UP ON YOUR PA PROCESS FOR TYMLOS**

TYMLOS is a once-daily injection that goes where your patients go



### TYMLOS offers1:

- 30 doses per pen
- No refrigeration after the first dose
- Can be taken with or without food

# Here are 2 fulfillment pathways to help your patients receive TYMLOS:



## **Specialty Pharmacy (SP)**

An SP may provide assistance beyond that of a retail pharmacy, such as investigating your patient's health insurance benefits and assisting you with PA requests. Regardless of which SP your office works with, TYMLOS will likely be available.

TYMLOS may also be available at retail pharmacies.



## Together with Tymlos (TWT) Patient Support Program

TWT can assist your patient with access to treatment with TYMLOS, including coverage determination support and coordination with an in-network SP. You can download the enrollment form for your patient by visiting TYMLOShcp.com/patient-support.

PA: prior authorization.

#### 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.



## THE PATH TO TYMLOS IN 5 STEPS



## ✓ Step 1 Gather relevant patient information

### **Record insurance information**

Record your patient's Member ID and Group, PCN, and Rx BIN numbers (as available) for their primary medical insurance and prescription drug benefit. Also verify whether or not your patient has secondary insurance.\*

## **Record medical history**

- Confirm the following medical history factors. This information will be required to populate a PA form:
  - Diagnosis of osteoporosis (ICD-10-CM codes M80.0, M81.0)
  - BMD T-scores ≤ -2.5 at the lumbar spine, total hip, and femoral neck
  - · Any history of fragility fracture, including fracture of the spine, hip, shoulder, pelvis, or forearm
  - Risk factors for fracture (e.g., fracture risk assessment tool [FRAX®], rheumatoid arthritis, alcohol intake of 4 or more units a day, smoking, high risk for falls, and low body mass)
  - Prior treatments and responses (e.g., contraindications, drug interactions, treatment failures, adverse events)

### Consider prescribing a 90-day supply for your patients.

\*Some insurance plans include medical and prescription drug benefit information on 1 card; others provide 2 cards.



# Step 2 Complete the benefits investigation (BI) for your patient

SPs and TWT case managers will perform a complete BI to confirm TYMLOS coverage, out-of-pocket costs, and if a PA is required.



Ensure all of the appropriate patient information is immediately sent to the SP. SPs may use a third-party service to submit a PA form.



The TWT case manager may reach out to your office if any relevant information is missing.

BMD: bone mineral density.



## Step 3 Submit a PA for TYMLOS, if required

Your patient's health plan will review any submitted documentation (e.g., PA) and determine whether coverage for TYMLOS is approved or denied.



Some SPs may submit the PA request on behalf of the provider.



The patient's TWT case manager may provide your office with a PA form and, if needed, instructions on how to complete a PA for your patient's insurance plan.

## **DID YOU** KNOW?

- You may be able to expedite the submission process by initiating a PA using the CoverMyMeds® tool on our website or by visiting CoverMyMeds.com
- Insurance plans are expanding the use of electronic PAs (ePAs), which offer real-time approval within 24 hours



## Step 4 Appeal a PA denial, if applicable

Not sure what information to include? Visit TYMLOShcp.com/resources-for-your-office to download the sample Letter of Appeal and sample Letter of Medical Necessity (LMN) to view what types of information are often required. You may also file a Formulary Exception using an LMN.



Some SPs may provide assistance with submitting a Letter of Appeal or LMN.



The patient's TWT case manager will contact your office and ask if the provider would like to appeal.

Make sure to attach the denial letter when submitting a Letter of Appeal or the LMN.



## **✓ Step 5** PA approved, TYMLOS dispensed

Once the PA is approved, the TYMLOS prescription can be filled for your patient.



The SP contacts the patient, collects any required payment, fills the prescription, and ships TYMLOS directly to their home.



The TWT case manager informs your office of approval, and the provider submits the prescription to a pharmacy to be filled. The TWT case manager may also triage the prescription directly to the SP along with a savings card if your patient is commercially insured.

**Prepare your** patients to receive 3 important calls from their SP:

- 1. Welcome call
- 2. Prescription delivery call
- 3. Refill reminder

Please see Important Safety Information on front and back covers and accompanying full Prescribing Information, including Boxed Warning.



## There are support options for your patients throughout their treatment with TYMLOS



## **Specialty Pharmacy**

- Clinical counseling and support
- Adherence reminders
- Information on out-of-pocket costs and support



## **Together with Tymlos Patient Support Program**

- Savings card for eligible, commercially insured patients
- Clinical educator network
  - Injection training and support in some areas throughout the treatment process



Clinical educator support is available to patients even if they didn't enroll in TWT. Download the registration form at **TYMLOShcp.com/patient-support** 



## Radius Assist Patient Assistance Program

- RadiusAssist is a patient assistance program for eligible patients who cannot afford their medication
- Visit radiuspharm.com/ radius-assist to download the application

## **IMPORTANT SAFETY INFORMATION**

**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.

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

### 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. In postmenopausal women with osteoporosis, TYMLOS reduces the risk of vertebral fractures and nonvertebral fractures.

### Limitations of Use

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

Please see accompanying full Prescribing Information, including Boxed Warning.

Reference: 1. TYMLOS® [prescribing information]. Waltham, MA: Radius Health, Inc.; 2017.

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