



Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	April 2, 2018

TYMLOS[®] (abaloparatide) Injection

LENGTH OF AUTHORIZATION: UP TO ONE YEAR

REVIEW CRITERIA:

To reduce risk of vertebral and non-vertebral fractures in postmenopausal women at high risk for fracture or who failed or intolerant to other osteoporosis therapy.

INITIATION OF THERAPY:

- Documented diagnosis of osteoporosis with A DXA hip (femoral neck) or spine T-score ≤ -2.5 (dated within the past year). ***(Must be confirmed in medical records.)*** **-OR-**
- History of a fracture of the spine or hip. ***(Must be confirmed in medical records.)*** **-OR-**
- History of T-score between -1.0 and -2.5 if FRAX (WHO Fracture Risk Assessment Tool) major osteoporotic fracture probability is $\geq 20\%$ or hip fracture probability is 3%. ***(Must be confirmed in medical records.)***

-AND-

- Trial (minimum of 12 months) and failure of zoledronic acid
 - Failure may be defined as an intolerance (adverse reaction, contraindication...) to other bisphosphonates, or no increase from baseline bone mineral density (BMD) as indicated by T-score history, or recurring fractures (in the absence of major trauma) following at least one year of therapy.

-AND-

- Trial (minimum of 12 months) and failure to Forteo.

CONTINUATION OF THERAPY:

- Medical records must demonstrate a stable BMD (within interventional goals) or an increasing BMD after a minimum trial of one year of therapy.
 - T-score test results may date back as far as five years.
 - Depending on level of BMD progression retesting may be done from every one to five years.
 - Medical records should demonstrate improvement by providing reference to the sequential progression or stability of the BMD.

DOSING:

- Recommended dose is 80mcg subcutaneously once a day.
- Use of the drug for more than 2 years during a patient's lifetime is not recommended.