Abaloparatide (TYMLOS)
Criteria for Use – Osteoporosis
May 2024

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If the answer to **ANY** item below is met, then the patient should **NOT** receive abaloparatide.

☐ Patient has a history of a hypersensitivity reaction or contraindication to abaloparatide including Paget's disease, hyper or hypocalcemia, hypercalciuria, bone cancer, bone metastases, radiation treatment to the skeleton, and hyperparathyroidism

☐ Pregnancy or lactating

☐ Has received 2 years of treatment with abaloparatide in their lifetime

Inclusion Criteria

All criteria must be met to qualify for abaloparatide^1

☐ Patient has a diagnosis of osteoporosis or is at risk for glucocorticoid-induced osteoporosis

☐ Prescriber is a VA/Community Care endocrinologist, rheumatologist, nephrologist, geriatrician, or locally designated expert

☐ Patient's total daily dietary and supplemental calcium intake is 1000 to 1200 mg/day

☐ Has a 25-hydroxyvitamin D concentration >30 ng/mL or >20 ng/ml and appropriate intake (e.g., cholecalciferol >800 international units per day)

1. Following a 2-year course of abaloparatide, start antiresorptive therapy to maintain bone density gains

Additional Inclusion Criteria

One of the following criteria must be met

☐ Osteoporotic fracture and a T-score at the hip or spine of $\leq$ -2.5

☐ Very high fracture probability by the Fracture Risk Assessment Tool (FRAX) (e.g., major osteoporosis fracture >30%, hip fracture >4.5%)

☐ Patient has a T-score $\leq$ -3.0

☐ More than 2 osteoporotic fractures

☐ Despite treatment with an approved osteoporosis therapy (e.g., a bisphosphonate or denosumab) the patient has continued to lose bone mineral density (BMD) or sustained an osteoporotic fracture while on treatment

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