## ABALOPARATIDE

| Generic | Brand | HICL | GCN | Exception/Other |
|---|---|---|---|---|
| ABALOPARATIDE | TYMLOS | 44231 | | |

### GUIDELINES FOR USE

1. Does the patient have a diagnosis of postmenopausal osteoporosis AND meet **ONE** of the following criteria?
   - High risk for fractures defined as ONE of the following:
     - History of osteoporotic (i.e., fragility, low trauma) fracture(s)
     - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.)
     - No prior treatment for osteoporosis AND FRAX score ≥ 20% for any major fracture OR ≥ 3% for hip fracture
   - Unable to use oral therapy (i.e., upper gastrointestinal [GI] problems unable to tolerate oral medication, lower GI problems unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
   - The patient has an adequate trial of, intolerance to, or a contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva)

   If yes, continue to #2.
   If no, do not approve.
   **DENIAL TEXT:** See the denial text at the end of the guideline.

2. Has the patient received a total of 24 months cumulative treatment with any parathyroid hormone therapy (e.g., Tymlos, Forteo)?

   If yes, do not approve.
   **DENIAL TEXT:** See the denial text at the end of the guideline.

   If no, **approve up to 24 months cumulative lifetime treatment duration by HICL with a quantity limit of #1.56 mL (#1 - 3120 mcg/1.56 mL prefilled pen) per 30 days.**

**CONTINUED ON NEXT PAGE**

## ABALOPARATIDE

### GUIDELINES FOR USE (CONTINUED)

**DENIAL TEXT:** The guideline named **ABALOPARATIDE (Tymlos)** requires that the patient has a diagnosis of postmenopausal osteoporosis and has not received a total of 24 months or more of parathyroid hormone therapy with Tymlos or Forteo. In addition, one of the following criteria must be met:

- High risk for fractures defined as ONE of the following:
  - History of osteoporotic (i.e., fragility, low trauma) fracture(s)
  - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.)
  - No prior treatment for osteoporosis AND FRAX score ≥ 20% for any major fracture OR ≥ 3% for hip fracture
- Unable to use oral therapy (i.e., upper gastrointestinal [GI] problems unable to tolerate oral medication, lower GI problems unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
- The patient has an adequate trial of, intolerance to, or a contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva)

### RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tymlos

### REFERENCES

- Tymlos [Prescribing Information]. Waltham, MA: Radius Health, Inc.; October 2018.

| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A
Commercial Effective: 01/01/20
Created: 04/17
Client Approval: 11/19
P&T Approval: 10/19