STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABALOPARATIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABALOPARATIDE	TYMLOS	44231		GPI-10 (3004400500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of postmenopausal osteoporosis and meet **ONE** of the following criteria?
   - The patient has a 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 Synarel [nafarelin])
     - No prior treatment for osteoporosis AND FRAX score ≥ 20% for any major fracture OR ≥ 3% for hip fracture
   - The patient is 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 had a trial of, intolerance to, or a contraindication to a bisphosphonate (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

     If yes, continue to #3.
     If no, continue to #2.

2. Is the request to increase bone density in a male patient with osteoporosis who meets **ONE** of the following criteria?
   - The patient is at high risk for fracture defined as ONE of the following:
     - History of osteoporotic fracture (e.g., fragility, low trauma)
     - Multiple 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, use of GnRH analogs such as Synarel [nafarelin])
   - The patient has failed or is intolerant to other available osteoporosis therapy (e.g., Forteo [teriparatide], Prolia [denosumab], Fosamax [alendronate], Actonel [risedronate])

     If yes, continue to #3.
     If no, do not approve.
     DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

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

   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 or GPI-10 with a quantity limit of #1.56mL per 30 days.**

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **ABALOPARATIDE (Tymlos)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Postmenopausal osteoporosis (a type of bone condition)
   2. Increase bone density in a male patient with osteoporosis (a type of bone condition)

B. **If the request is for postmenopausal osteoporosis, approval also requires:**
   1. You have NOT received a total of 24 months or more of treatment with any parathyroid hormone therapy (such as Tymlos [abaloparatide], Forteo [teriparatide])
   2. You meet ONE of the following (a, b, or c):
      a. You have high risk for fractures defined as ONE of the following:
         i. History of osteoporotic fracture(s) (broken bones) due to trauma (injury) or fragility (weakness)
         ii. Two or more risk factors for fracture such as history of multiple recent low trauma fractures, bone mineral density T-score (a type of lab test) less than or equal to -2.5, corticosteroid use, or use of GnRH (gonadotropin-releasing hormone) analogs such as Synarel (nafarelin)
         iii. No prior treatment for osteoporosis AND FRAX (Fracture Risk Assessment Tool) score greater than or equal to 20 percent for any major fracture OR greater than or equal to 3 percent for hip fracture
      b. You are unable to use oral therapy due to upper gastrointestinal (stomach and intestine) problems, you cannot tolerate oral medication, you have lower gastrointestinal problems (unable to absorb oral medications), you have trouble remembering to take oral medications or cannot plan to use an oral bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate]) with other oral medications in your daily routine
      c. You had a trial of, intolerance (side effect) to, or a contraindication (harmful for) to a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

(Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

C. **If the request is to increase bone density in a male patient with osteoporosis, approval also requires:**
   1. You have NOT received a total of 24 months or more of treatment with any parathyroid hormone therapy (such as Tymlos [abaloparatide], Forteo [teriparatide])
   2. You meet ONE of the following (a or b):
      a. You have high risk for fractures defined as ONE of the following:
         i. History of osteoporotic fracture (such as fragility [weakness] fracture, low trauma [injury] fracture)
         ii. Multiple risk factors for fracture (such as history of multiple recent low trauma fractures, bone mineral density T-score (a type of lab test) less than or equal to -2.5, corticosteroid use, use of GnRH [gonadotropin-releasing hormone] analogs such as Synarel [nafarelin])
      b. You have failed or are intolerant (side effect) to other available osteoporosis therapy (such as Forteo [teriparatide], Prolia [denosumab], Fosamax [alendronate], Actonel [risedronate])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

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

REFERENCES

- Tymlos [Prescribing Information]. Boston, MA: Radius Health, Inc.; December 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/17/23
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P&T Approval: 01/23