Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

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Tymlos (abaloparatide)

DRUG.00103

Override(s)	Approval Duration
Prior Authorization Quantity Limit	2 years

Medications	Quantity Limit
Tymlos (abaloparatide)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Tymlos (abaloparatide) may be approved for the treatment of osteoporosis to increase bone mass when all of the following criteria are met:

I. Individual is a postmenopausal female with one of the following:
   A. A diagnosis of osteoporosis (defined as a bone mineral density [BMD] T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population): **OR**
   B. A diagnosis of osteoporosis based on history of an osteoporotic low trauma fracture (fragility fracture) and considered at high risk for additional fractures; **AND**
   C. Has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of a preferred oral bisphosphonate;
      - Preferred agents: Alendronate tablet (generic Fosamax), alendronate oral solution (generic Fosamax oral solution)

      OR
   D. The individual has been refractory to a prior trial of a preferred oral bisphosphonate; **OR**
   E. The individual is intolerant to or has a contraindication to oral bisphosphonate therapy as defined by one of the following (1 through 5):
      1. Hypersensitivity to TWO oral bisphosphonates (one of which must be generic alendronate); **OR**
      2. Inability to stand or sit upright for at least 30 minutes; **OR**
      3. A pre-existing gastrointestinal disorder (for example, Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, etc.); **OR**
      4. Uncorrected hypocalcemia; **OR**
      5. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents or creatinine clearance less than 30 mL/min for risedronate and ibandronate;

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Applicable	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

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AND

F. The individual has sustained an osteoporotic low trauma fracture (fragility fracture) while on an oral bisphosphonate or has been refractory to, intolerant of, or has a contraindication to one of the following drugs (1 or 2):
    1. Prolia (denosumab); **OR**
    2. Reclast (zoledronic acid);

AND

G. The individual has been refractory to, or intolerant of, or has a contraindication to Forteo (teriparatide); **AND**

H. The individual is not using abaloparatide in combination with **any** of the following (1through 5):
    1. Prolia (denosumab); **OR**
    2. Bisphosphonates; **OR**
    3. Evista (raloxifene); **OR**
    4. Miacalcin/Fortical (calcitonin nasal spray); **OR**
    5. Reclast (zoledronic acid); **OR**
    6. Forteo (teriparatide);

AND

I. The individual has utilized Tymlos injection **AND** parathyroid hormone analogs (for example, teriparatide [Forteo®]) for a combined total duration of less than 24 months in the individual's lifetime.

Requests for Tymlos (abaloparatide) **may not** be approved for the following:

I. Individual is male; **OR**
II. When abaloparatide (Tymlos) injection has been used for more than a total lifetime duration of 2 years; **OR**
III. If a parathyroid hormone analog (for example, teriparatide [Forteo]) has been used for more than a total lifetime duration of 2 years' time; **OR**
IV. If abaloparatide and a parathyroid hormone analog (for example, teriparatide [Forteo]) have been used for a combined total lifetime duration of 2 years or longer.

Note:
It is unknown whether 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.

Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

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State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

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10. National Osteoporosis Foundation. Clinician's guide to prevention and treatment of osteoporosis. Revised 2013. Available at: https://my.nof.org/bone-soruce/education/clinicians-guide-to-the-prevention-and-treatment-of-osteoporosis. Accessed on July 4, 2017.
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13. U.S. Food and Drug Administration (FDA). TYMLOS (abaloparatide) injection [Prescribing Information]. Radius Health, Inc. Waltham WA. April 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208743lbl.pdf. Accessed on July 4, 2017.
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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.