POLICY
A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Treatment of Postmenopausal Women with Osteoporosis at High Risk for Fracture
Forteo is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

Increase of Bone Mass in Men with Primary or Hypogonadal Osteoporosis at High Risk for Fracture
Forteo is indicated to increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

Treatment of Men and Women with Glucocorticoid-Induced Osteoporosis at High Risk for Fracture
Forteo is indicated for the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

B. REQUIRED DOCUMENTATION
- Bone mineral density (BMD) measured by dual-energy x-ray absorptiometry (DEXA) scan to determine the T-score
- The following may also be required:
  o Imaging studies supporting vertebral, hip, or low impact/fragility fractures
  o Ten-year probability of hip or other osteoporosis-related fracture based on the US-adapted World Health Organization (WHO) fracture risk assessment algorithm (FRAX®)
- For glucocorticoid-induced osteoporosis, documentation supporting treatment with glucocorticoid therapy at a mean daily dose of 5 mg or more of prednisone or its equivalent for at least 3 consecutive months immediately prior to the request for Forteo
• Documentation indicating duration of and supporting compliance with bisphosphonate or
denosumab use, or documentation supporting intolerance and/or contraindication to orally and
intravenously administered bisphosphonates and denosumab

C. EXCLUSIONS
• More than 2 years of total treatment with Forteo will not be covered
• Any of the following exclusions
  o Paget's disease of bone
  o Unexplained elevations of alkaline phosphatase
  o Open epiphyses (i.e. pediatric or young patients)
  o Prior radiation therapy involving the skeleton
  o History of skeletal malignancy
  o Bone metastases
  o Metabolic bone disease other than osteoporosis
  o Pre-existing hypercalcemia

D. CRITERIA FOR APPROVAL
1. Treatment of Osteoporosis in Men and Postmenopausal Women
   Authorization of up to total of 24 months (lifetime) may be granted when the following criteria
   are met:
   a. Member is a postmenopausal woman or man ≥ 50 years of age
   b. History of vertebral or hip fracture; or
   c. Bone mass T-score of less than or equal to −2.5 at the femoral neck, total hip or lumbar
      spine as measured by DEXA scan; or
   d. Bone mass T-score between −1 and −2.5 at the femoral neck, total hip or lumbar spine
      and either of the following:
      i. History of low impact/fragility fracture, i.e., fracture occurring spontaneously or
         from a fall at a height no greater than the patient's standing height (excluding
         fingers and toes); or
      ii. Ten-year probability of hip fracture greater than or equal to 3% or a ten-year
         probability of any major osteoporosis-related fracture greater than or equal to
         20% based on the U.S.-adapted WHO fracture risk assessment algorithm (it is
         important to note that this algorithm can only be applied to previously untreated
         patients); and
   e. Member meets criteria i. or ii. below:
      i. Member is unresponsive to treatment with at least one bisphosphonate or
         denosumab (Prolia). Unresponsiveness is defined as one of the following:
         1. A decrease in BMD of greater than or equal to 5% demonstrated by
            comparable DEXA study results while compliant with bisphosphonate or
            denosumab treatment and on treatment for at least two years
         2. One or more vertebral, hip or low impact/fragility fractures while
            compliant with bisphosphonate or denosumab treatment and on
            treatment for at least one year
ii. Member is intolerant to both oral and intravenously administered bisphosphonates and denosumab; or treatment with bisphosphonates and denosumab is contraindicated. Intolerance is defined as having a recognized and reproducible or repeated adverse reaction that is clearly associated with taking the medication.

2. Treatment of Glucocorticoid-Induced Osteoporosis
Authorization of up to total of 24 months (lifetime) may be granted when the following criteria are met:
   a. Member is currently receiving glucocorticoid therapy at a dose of at least 5 mg per day of prednisone or its equivalent for at least 3 consecutive months immediately prior to the request for Forteo; and
   b. Bone mass T-score at the femoral neck, total hip, or lumbar spine is less than or equal to −2.0 as measured by DEXA scan; or
   c. Bone mass T-score at the femoral neck, total hip, or lumbar spine between −1.0 and −2.0 and member has a history of low impact/fragility fracture during treatment with glucocorticoids

E. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

F. IMPORTANT REMINDER
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

G. REFERENCES