FORTEO® (teriparatide) INJECTION

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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FORTEO (teriparatide) INJECTION (cont.)

Description:

Forteo (teriparatide) is a synthetic form of human parathyroid hormone that is the primary regulator of bone and mineral metabolism. Forteo may be used for treatment of osteoporosis in postmenopausal women, to increase bone mass in men with osteoporosis and for treatment of women and men with osteoporosis associated with sustained systemic glucocorticoid therapy. Generally, Forteo is given as a 2 year course of treatment.

Definitions:

T-Scores are reported as standard deviations (SD) World Health Organization (WHO) criteria:
- Normal: T-score within 1 SD
- Osteopenia: T-score of -1 to -2.5 SD
- Osteoporosis: T-score of -2.5 or worse SD
- Severe Osteoporosis: T-score of -2.5 or worse SD with fragility fractures

High risk for fracture is defined as ONE of the following:
- Osteoporotic fracture
- Multiple risk factors for fracture (significantly low bone mass, frequent falls, limited movement, medical conditions likely to cause bone loss, medicines that may cause bone loss, e.g., seizure medicines, blood thinners, corticosteroids, high doses of vitamins A or D)
- Failed response (as defined by prescribing provider) to previous osteoporosis therapy
- Intolerant to previous osteoporosis therapy

Fragility fracture: A fracture occurring spontaneously or after a minor trauma.

Fracture Risk Assessment Tool (FRAX tool):
The World Health Organization developed a risk assessment tool to assist providers in evaluating osteopenic individuals. The tool uses clinically proven risk factors to determine a 10 year probability of hip fracture and a 10 year probability for a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fractures). Treatment may be considered if the 10-year risk is 3% or more for hip fracture or if the risk for other bone fracture is 20% or more.

The tool can obtained at https://www.sheffield.ac.uk/FRAX/tool.aspx?country=9

Adult: Age 18 years and older
FORTEO (teriparatide) INJECTION (cont.)

Criteria:

See Resources section for FDA-approved dosage and Glucocorticoid Equivalencies table.

Initial Course of Treatment:

- Forteo is considered *medically necessary* with documentation of **ALL** of the following:

  1. **ONE** of the following diagnosis:
     - Postmenopausal female with osteoporosis at high risk for fracture
     - Male with primary OR hypogonadal osteoporosis at high risk for fracture
     - Glucocorticoid-induced osteoporosis associated with current and sustained use of Prednisone (or equivalent glucocorticoid) at a daily dose of 5 mg or more for a minimum of 3 months in men or women at high risk for fracture

  2. **ONE** of the following:
     - A *female* with a T-score of -2.5 or worse (e.g., -3.0, -3.5, etc.), with or without osteoporotic fracture
     - A *male* with a T-score of -2.0 or worse at the lumbar spine or femoral neck, with or without osteoporotic fracture
     - T-score of -1.0 or worse at the lumbar spine or femoral neck with a history of prior fragility fracture
     - A low trauma fragility bone fracture
     - High risk for fracture as evidenced by multiple factors such as significantly low bone mass, frequent falls, limited movement, medical conditions likely to cause bone loss, medicines that may cause bone loss, (e.g., seizure medicines, blood thinners, corticosteroids, high doses of vitamins A or D)
     - A FRAX 10-year probability risk of 3% or more for a hip fracture OR 20% or more for other bone fracture, as assessed by the World Health Organization Fracture Risk Assessment Tool (FRAX tool) that can be obtained at [https://www.sheffield.ac.uk/FRAX/tool.aspx?country=9](https://www.sheffield.ac.uk/FRAX/tool.aspx?country=9)

  3. Individual has failed, or is intolerant to, or has a contraindication to at least **TWO** of the following agents:
     - Alendronate
     - Etidronate
     - Ibandronate
     - Risedronate
     - Zoledronic acid
FORTEO (teriparatide) INJECTION (cont.)

Criteria: (cont.)

Initial Course of Treatment: (cont.)

- Forteo is considered *medically necessary* with documentation of ALL of the following: (cont.)
  
  4. Absence of ALL of the following:
     - Active nephrolithiasis
     - End-stage renal disease
     - Open epiphyses
     - Osteomalacia
     - Paget’s disease of bone
     - Primary or metastatic bone cancer or history of skeletal malignancies
     - Metabolic bone diseases other than osteoporosis
     - Unexplained elevation of serum calcium or alkaline phosphatase prior to initiation of therapy
     - Pre-existing hypercalcemic disorder (e.g., hyperparathyroidism)
     - History of external beam radiation involving the skeleton or for a soft tissue malignancy, such as breast cancer, where the radiation would likely have affected the skeleton around the area
     - History of implant radiation (e.g., brachytherapy, interstitial radiation, intracavitary radiation)
  
  5. Absence of hypersensitivity to teriparatide or any of its excipients
  6. No dual therapy with another parathyroid related peptide hormone analogs such as: Tymlos (abaloparatide), Natpara (parathyroid hormone)
  7. No previous use of another parathyroid related peptide hormone analog of 2 years duration such as: Tymlos (abaloparatide), Natpara (parathyroid hormone)
  8. Individual is receiving supplemental calcium and vitamin D with doses adjusted per usual laboratory monitoring

Repeat Course of Treatment:

- As Forteo is generally a 2 year course of treatment, the second year of Forteo therapy may be approved if the above criteria were met for the initial year.

- Review by the clinical pharmacist, and/or medical director(s) and/or clinical advisor(s) is required for course of therapy beyond 2 years.
FORTEO (teriparatide) INJECTION (cont.)

Criteria: (cont.)

➢ Forteo for all other indications not previously listed or if above criteria not met is considered experimental or investigational based upon:

1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
2. Insufficient evidence to support improvement of the net health outcome.

These indications include, but are not limited to:

- Treatment with dosing or frequency outside the FDA-approved dosing and frequency

Resources:

Literature reviewed 07/05/18. We do not include marketing materials, poster boards and non-published literature in our review.


FORTEO (teriparatide) INJECTION (cont.)

Resources: (cont.)


FORTEO (teriparatide) INJECTION (cont.)

Resources: (cont.)

Forteo Package Insert. 03/2012:

- FDA-approved indication and dosage:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommended Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>The recommended dosage is 20 mcg subcutaneously once a day.</td>
</tr>
<tr>
<td>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.</td>
<td>The recommended dosage is 20 mcg subcutaneously once a day.</td>
</tr>
<tr>
<td>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.</td>
<td>The recommended dosage is 20 mcg subcutaneously once a day.</td>
</tr>
</tbody>
</table>

FORTEO should be administered as a subcutaneous injection into the thigh or abdominal wall. There are no data available on the safety or efficacy of intravenous or intramuscular injection of FORTEO.

Safety and effectiveness of FORTEO have not been established in pediatric patients.

Use of the drug for more than 2 years during a patient’s lifetime is not recommended.

Not used in combination with a bisphosphonate (e.g., Actonel, Fosamax).
FORTEO (teriparatide) INJECTION (cont.)

Resources: (cont.)

Initial Approval Duration:
12 months if previous use of any drug in this drug category is less than 12 months

Renewal Approval Duration:
12 months if previous use of any drug in this drug category is less than 24 months

Glucocorticoid Equivalencies:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Equivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Betamethasone</td>
<td>0.75 mg</td>
</tr>
<tr>
<td>Cortisone</td>
<td>25 mg</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>0.75 mg</td>
</tr>
<tr>
<td>Hydrocortisone</td>
<td>20 mg</td>
</tr>
<tr>
<td>Methylprednisolone</td>
<td>4 mg</td>
</tr>
<tr>
<td>Prednisone</td>
<td>5 mg</td>
</tr>
<tr>
<td>Prednisolone</td>
<td>5 mg</td>
</tr>
<tr>
<td>Triamcinolone</td>
<td>4 mg</td>
</tr>
</tbody>
</table>
FORTEO (teriparatide) INJECTION (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ’s Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ’s Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díi kwe’ę atah nihilngii Blue Cross Blue Shield of Arizona haada yit’éego bina’ídíldigdo éí doodedo Háída bíjá aniyeedígíí t’aadoo le’é yina’ídldigdo beehaz’áanii hólo díí t’áá hazaadk’eží háhá a’doowolgö bee haz’a doo baq̱ah ílígóó. Ata’ halne’ígíí kojj’ bich’į’ hodiilbíí 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thể thông tin bằng ngôn ngữ của mình miễn phí. Đề nghị chuyển với một thống dịch viện, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعدك أسئلة بصورة محددة بناءً على المعلوماتفضل الرجوع إلى مرجع الترجمة 877-475-4799.
FORTEO (teriparatide) INJECTION (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatang ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하의 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 동역사와 매기기 위해서는 877-475-4799 로 전화하시십시오.

French: Si vous, ou quelqu’un que vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: 資料は、またはお客様のの困りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳をお話される場合、877-475-4799 までお電話ください。

Farsi: 
агر شما یا کسی که شما یا کسی که در مورد اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799.

Assyrian: 
877-475-4799

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณหรือคนที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิ์ได้รับความช่วยเหลือและข้อมูลภาษาของคุณโดยไม่ต้องจ่ายค่าสื่อสาร โทร 877-475-4799.