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.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.
FORTEO (teriparatide) INJECTION (cont.)

Description:

Forteo 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:

Adult: Age 18 years and older

Criteria:

See Resources section for FDA-approved dosage.

Osteoporosis:

- FDA-approved dosage of Forteo is considered medically necessary with documentation of ALL of the following:

1. ONE of the following:
   - Postmenopausal female with osteoporosis at high risk for fracture
   - Male with primary osteoporosis OR hypogonadal osteoporosis at high risk for fracture

2. T-score of -2.5 or worse (e.g., -3.0, -3.5)
3. 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)

4. Absence of hypersensitivity to teriparatide or any of its excipients
FORTEO (teriparatide) INJECTION (cont.)

Criteria: (cont.)

Osteoporosis: cont.)

- 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.

Glucocorticoid-Induced Osteoporosis:

- FDA-approved dosage of Forteo is considered medically necessary for treatment of osteoporosis in men or women at high risk for fracture with documentation of ALL of the following:

  1. ONE of the following:
      - T-score of -2.0 or worse (e.g., -2.5, -3.0) at the lumbar spine or total hip
      - T-score of -1.0 or worse (e.g., -1.5, -2.0) and at least 1 fragility fracture during treatment with glucocorticoids

  2. Osteoporosis is associated with sustained glucocorticoid therapy defined as daily Prednisone dosing of 5 mg or greater for a minimum of 3 months

  3. 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)

  4. Absence of hypersensitivity to teriparatide or any of its excipients

- Review by the clinical pharmacist, and/or medical director(s) and/or clinical advisor(s) is required for course of therapy beyond 3 years.
FORTEO (teriparatide) INJECTION (cont.)

Criteria: (cont.)

Other:

- 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.

1 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, steroids, high doses of vitamins A or D)
   - Failed response (as defined by prescribing provider) to previous osteoporosis therapy
   - Intolerant to previous osteoporosis therapy

2 A fracture occurring spontaneously or after a minor trauma.

Resources:

Literature reviewed 12/06/16. 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:

- 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</td>
<td>The recommended dosage is 20 mcg subcutaneously once a day.</td>
</tr>
<tr>
<td>for fracture, defined as a history of osteoporotic fracture, multiple</td>
<td></td>
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<tr>
<td>risk factors for fracture or patients who have failed or are intolerant</td>
<td></td>
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<tr>
<td>to other available osteoporosis therapy.</td>
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</tr>
<tr>
<td>To increase bone mass in men with primary or hypogonadal osteoporosis at</td>
<td>The recommended dosage is 20 mcg subcutaneously once a day.</td>
</tr>
<tr>
<td>high risk for fracture, defined as a history of osteoporotic fracture,</td>
<td></td>
</tr>
<tr>
<td>multiple risk factors for fracture or patients who have failed or are</td>
<td></td>
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<tr>
<td>intolerant to other available osteoporosis therapy.</td>
<td></td>
</tr>
<tr>
<td>For the treatment of men and women with osteoporosis associated with</td>
<td>The recommended dosage is 20 mcg subcutaneously once a day.</td>
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<tr>
<td>sustained systemic glucocorticoid therapy (daily dosage equivalent to</td>
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<tr>
<td>5 mg or greater of prednisone) at high risk for fracture, defined as a</td>
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<tr>
<td>history of osteoporotic fracture, multiple risk factors for fracture or</td>
<td></td>
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<tr>
<td>patients who have failed or are intolerant to other available osteoporosis</td>
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<tr>
<td>therapy.</td>
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<tr>
<td>FORTEO should be administered as a subcutaneous injection into the thigh</td>
<td>Safety and effectiveness of FORTEO have not been established in pediatric</td>
</tr>
<tr>
<td>or abdominal wall. There are no data available on the safety or efficacy</td>
<td>patients.</td>
</tr>
<tr>
<td>of intravenous or intramuscular injection of FORTEO</td>
<td></td>
</tr>
<tr>
<td>Safety and effectiveness of FORTEO have not been established in pediatric</td>
<td></td>
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<tr>
<td>patients.</td>
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<tr>
<td>Use of the drug for more than 2 years during a patient’s lifetime is not</td>
<td></td>
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<tr>
<td>recommended.</td>
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<tr>
<td>Not used in combination with a bisphosphonate (e.g., Actonel, Fosamax).</td>
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</tbody>
</table>
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'é atah niílingíí Blue Cross Blue Shield of Arizona haada yídéégo bina’ídiíldogo éi doodago Háida bítání aniyeedíígi t’áadoo le’é yína’ídziikígi bee hahaz’éíi hólo díí t’áá hazaad’ehí háká a’doowolgo bee haz’a doo baam’iilígóó. Ata’ halné’éigí kojí bích’í’ hodíilníih 877-475-4799.

Chinese: 如果您，或是您正在协助的对象，有关于插入项目的名称 Blue Cross Blue Shield of Arizona 方面的问题，您有权要求以您的母语得到帮助和讯息。请洽一位翻译员。请拨电话 在此插入数字 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. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona أو لديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أي تكلفة للتحدث مع مترجم للحصول على معلومات مترجمية. 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 karapatan 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 귀하는 그러한 동물과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 동역사와 대기하기 위해서는 877-475-4799 로 전화하십시오.

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: ご本人様、またはお客様の身の回りの方でも、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。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:
آگر شما یا کسی که شما به او کمک می‌کنید، سوال در مورد اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799. 

Assyrian:

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: หากคุณหรือผู้ที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถใช้บริการช่วยเหลือและข้อมูลภาษา ของคุณโดยไม่ต้องเสียค่าใช้จ่าย พร้อมกับหมายเลขโทรศัพท์ โทร 877-475-4799