RECLAST® (zoledronic acid)

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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RECLAST (zoledronic acid) (cont.)

Description:

Reclast is a bisphosphonate that inhibits osteoclast-mediated bone resorption. It may be used in postmenopausal women for the prevention and treatment of osteoporosis, in men with osteoporosis to increase bone mass, for prevention and treatment of glucocorticoid-induced osteoporosis in non-pregnant women and men starting or continuing systemic glucocorticoids and for treatment of Paget’s disease in non-pregnant women and men.

Definitions:

Osteonecrosis of the jaw (ONJ): According to the American College of Rheumatology, ONJ can be diagnosed by the presence of exposed bone on oral examination, lasting more than eight weeks.

ONJ risk factors include: invasive dental procedures (e.g., tooth extraction, dental implants, oral surgery), diagnosis of cancer, concomitant therapies (e.g., chemotherapy, corticosteroids, angiogenesis inhibitors), poor oral hygiene, and co-morbid disorders (e.g., periodontal and/or other pre-existing dental disease, anemia, coagulopathy, infection, ill-fitting dentures).

Adult: Age 18 years and older

Criteria:

Osteoporosis:

Initial Course of Treatment:

- Reclast injection for the treatment of osteoporosis in postmenopausal women with osteoporosis is considered medically necessary with documentation of ALL of the following:
  1. T-score of -2.5 or worse (e.g., -3.0, -3.5), with or without osteoporotic fracture or T-score of -1.0 or worse at the lumbar spine or femoral neck with a history of prior fragility fracture
  2. Individual is receiving supplemental calcium and vitamin D
  3. Creatinine clearance is equal to or greater than 35 ml/min
  4. No evidence of hypocalcemia, with calcium or corrected calcium within the normal range
  5. No evidence of hypersensitivity to any component of Reclast
  6. Individual is not receiving another agent with the same active ingredient zoledronic acid
  7. Dental examination with appropriate preventive dentistry, prior to treatment with Reclast in individuals with risk factors for ONJ
RECLAST (zoledronic acid) (cont.)

Criteria: (cont.)

Osteoporosis: (cont.)

Initial Course of Treatment: (cont.)

See Resources section for FDA-approved dosage.

- Reclast injection for the prevention of osteoporosis in postmenopausal women is considered *medically necessary* with documentation of **ALL** of the following:

  1. Postmenopausal women with osteopenia defined as T-score of -1 to -2.5 (i.e., -1.0, -1.5, -2.0, -2.5)
  2. Individual is receiving supplemental calcium **and** vitamin D
  3. Creatinine clearance is equal to or greater than 35 ml/min

- Reclast injection to increase bone mass in men with osteoporosis **or** osteoporosis secondary to hypogonadism is considered *medically necessary* with documentation of **ALL** of the following:

  1. Documentation of **ONE** of the following:
      - 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
      - History of osteoporotic clinical fracture of clavicle or long bone after age 50
  2. Individual is receiving supplemental calcium **and** vitamin D
  3. Creatinine clearance is equal to or greater than 35 ml/min
  4. No evidence of hypocalcemia, with calcium or corrected calcium within the normal range
  5. No evidence of hypersensitivity to any component of Reclast
  6. Individual is not receiving another agent with the same active ingredient zoledronic acid
  7. Dental examination with appropriate preventive dentistry, prior to treatment with Reclast in individuals with risk factors for ONJ
RECLAST (zoledronic acid) (cont.)

Criteria: (cont.)

Osteoporosis: (cont.)

Initial Course of Treatment: (cont.)

- Reclast injection for the treatment and prevention of glucocorticoid-induced osteoporosis in non-pregnant women and men is considered medically necessary with documentation of ALL of the following:

  1. Individual is initiating or continuing systemic glucocorticoids
  2. Daily dose is equal to or greater than 7.5 mg of prednisone (or equivalent)
  3. Individual is expected to remain on glucocorticoids for at least 12 months
  4. Individual is receiving supplemental calcium and vitamin D
  5. Creatinine clearance is equal to or greater than 35 ml/min
  6. No evidence of hypocalcemia, with calcium or corrected calcium within the normal range
  7. No evidence of hypersensitivity to any component of Reclast
  8. Individual is not receiving another agent with the same active ingredient zoledronic acid
  9. Dental examination with appropriate preventive dentistry, prior to treatment with Reclast in individuals with risk factors for ONJ

Repeat Courses of Treatment:

- Repeat courses of Reclast injection is considered medically necessary with documentation of ALL of the following:

  1. The individual has benefited from therapy but remains at high risk for development of osteoporotic fractures
  2. The condition has not progressed or worsened while on therapy
  3. Individual has not developed any contraindications or other exclusions to its continued use
  4. Individual is receiving supplemental calcium and vitamin D
  5. Creatinine clearance is equal to or greater than 35 ml/min
  6. No evidence of hypocalcemia, with calcium or corrected calcium within the normal range
  7. No evidence of hypersensitivity to any component of Reclast
  8. Individual is not receiving another agent with the same active ingredient zoledronic acid
  9. Dental examination with appropriate preventive dentistry, prior to treatment with Reclast in individuals with risk factors for ONJ
RECLAST (zoledronic acid) (cont.)

Criteria: (cont.)

Paget's Disease:

Initial Course of Treatment:

- Reclast injection for non-pregnant women and men with Paget's disease of the bone is considered *medically necessary* with documentation of **ALL** of the following:

1. Documentation of **ONE** of the following:
   - Elevation in serum alkaline phosphatase of two times or higher than the upper limit of the age-specific normal reference range
   - Individual is symptomatic
   - Individual is at risk for complication from the disease

2. Individual is receiving supplemental calcium and vitamin D
3. Creatinine clearance is equal to or greater than 35 ml/min
4. No evidence of hypocalcemia, with calcium or corrected calcium within the normal range
5. No evidence of hypersensitivity to any component of Reclast
6. Individual is not receiving another agent with the same active ingredient zoledronic acid
7. Dental examination with appropriate preventive dentistry, prior to treatment with Reclast in individuals with risk factors for ONJ

Repeat Courses of Treatment:

- Repeat courses of Reclast injection are considered *medically necessary* for non-pregnant women and men with Paget's disease with documentation of **ALL** of the following:

1. Documentation of **ONE** of the following:
   - Individual has relapsed documented by an increase in serum alkaline phosphatase
   - Individual's serum alkaline phosphatase has failed to normalize
   - Individual is symptomatic

2. Individual is receiving supplemental calcium and vitamin D
3. Creatinine clearance is equal to or greater than 35 ml/min
4. No evidence of hypocalcemia, with calcium or corrected calcium within the normal range
5. No evidence of hypersensitivity to any component of Reclast
6. Individual is not receiving another agent with the same active ingredient zoledronic acid
7. Dental examination with appropriate preventive dentistry, prior to treatment with Reclast in individuals with risk factors for ONJ
RECLAST (zoledronic acid) (cont.)

Criteria: (cont.)

Other:

- Reclast injection 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 11/14/17. We do not include marketing materials, poster boards and non-published literature in our review.


RECLAST (zoledronic acid) (cont.)

Resources: (cont.)


Reclast Package Insert:

- FDA-approved indication and dosage:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommended Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment of osteoporosis in Postmenopausal Women</td>
<td>5 mg infusion once a year given intravenously.</td>
</tr>
<tr>
<td>Prevention of osteoporosis in Postmenopausal Women</td>
<td>5 mg infusion given every 2 years intravenously.</td>
</tr>
<tr>
<td>Osteoporosis in Men</td>
<td>5 mg infusion once a year given intravenously.</td>
</tr>
<tr>
<td>Treatment and Prevention of Glucocorticoid-Induced Osteoporosis</td>
<td>5 mg infusion once a year given intravenously.</td>
</tr>
<tr>
<td>Treatment of Paget's disease of Bone</td>
<td>5 mg infusion.</td>
</tr>
<tr>
<td>Re-treatment of Paget's Disease of Bone</td>
<td>After a single treatment an extended remission period is observed. Specific re-treatment data are not available. However, retreatment may be considered in individuals who have relapsed, based on increases in serum alkaline phosphate, or in those who failed to achieve normalization of their serum alkaline phosphatase, or in those with symptoms, as dictated by medical practice. Reclast is contraindicated in patients with a creatinine clearance of &lt; 35mL/min. Acute renal impairment including renal failure has been observed following the administration of Reclast especially in patients with pre-existing renal compromise, advanced age concomitant nephrotoxic medications, concomitant-diuretic therapy, or severe dehydration. Rare reports of hospitalization and/or dialysis or fatal outcome have occurred. Optimal duration of use has not been determined. Patients at low-risk for fracture should be considered for drug discontinuation after 3-5 years of use. Safety and effectiveness of Reclast have not been established in pediatric patients.</td>
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RECLAST (zoledronic acid) (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, HHB 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: Díí kwe’é atah nílínígíí Blue Cross Blue Shield of Arizona haada yit’éeego bina’ídlį́į́dzgo éí doocdag Háída bícį́ anilyeedígíí t’áadoo le’é yina’ídlį́į́dzgo bee haz’áanii hólq díí t’áá hazaad’ehjí háká a’doowolgo bee haz’á doo bąąh ilínígóó. Ata’ halne’íígií kojí’ bíchį’ hodlilhíí 877-475-4799.

Chinese: 如果您或您正在协助的对象，有关于插件项目的名称 Blue Cross Blue Shield of Arizona 方面的问题，您有权利免费、无限制地在我们的帮助和信息。请一位翻译员，拨打电话 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 thống dịch viên, xin gọi 877-475-4799.

Arabic: إن كانت لديك أو لدى شخص تساعدك أسئلة يخص بخصم Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات، اتصل ب 877-475-4799.

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RECLAST (zoledronic acid) (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutuuan ang ay 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 makuasa ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관련해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799로 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 et à votre 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 у вас есть 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、ご希望の言語での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。通訳をお呼びされる場合、877-475-4799までお電話ください。

Farsi: 

در معنی این است که شما به این کمک می‌توانید، سوال‌های مورد اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799.

Assyrian: 

Blue Cross Blue Shield of Arizona

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

Thai: หากคุณปวดกลไกการขยายกลไกเพื่อความสะดวกสบาย Blue Cross Blue Shield of Arizona

ข้อมูลที่คุณต้องการสามารถเรียนรู้ได้จากและสอบถามได้ในภาษาของคุณโดยไม่มีค่าใช้จ่าย ที่เบอร์ 877-475-4799