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:

Adult: Age 18 years and older

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 (WHO) 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 be obtained at [https://www.sheffield.ac.uk/FRAX/tool.aspx?country=9](https://www.sheffield.ac.uk/FRAX/tool.aspx?country=9)
RECLAST (zoledronic acid) (cont.)

Definitions: (cont.)

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).

Albumin-corrected serum calcium [cCa, mg/dL] = individual's serum calcium (mg/dL) + 0.8 (4.0 – individual's serum albumin [g/dL])

Bisphosphonates:
- Alendronate, e.g., Binosto, Fosamax
- Etidronate, e.g., Didronel
- Ibandronate, e.g., Boniva
- Risedronate, e.g., Actonel
- Zolendronate, e.g., Reclast, Zometa
RECLAST (zoledronic acid) (cont.)

Criteria:

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

Osteoporosis:

Initial Course of Treatment:

➢ Reclast for the treatment of osteoporosis is considered medically necessary with documentation of ALL of the following:

1. **ONE** of the following diagnosis:
   - Treatment of postmenopausal females with osteoporosis
   - Prevention of postmenopausal females with osteoporosis
   - Increase bone mass in males with osteoporosis or osteoporosis secondary to hypogonadism
   - Treatment and prevention of glucocorticoid-induced osteoporosis in males and non-pregnant females, when initiating or continuing systemic glucocorticoids in a daily dose that is equal to or greater than 7.5 mg of prednisone (or equivalent), and is expected to remain on glucocorticoids for at least 12 months

2. **ONE** of the following:
   - Females with **ONE** of the following:
     - T-score of -2.5 or worse (e.g., -3.0, -3.5), with or without osteoporotic fracture
     - T-score of -1 to -2.5 (i.e., -1.0, -1.5, -2.0, -2.5)
   - Males with **ONE** of the following:
     - T-score of -2.0 or worse at the lumbar spine or femoral neck, with or without osteoporotic fracture
     - History of osteoporotic clinical fracture of clavicle or long bone after age 50
   - T-score of -1.0 or worse at the lumbar spine or femoral neck with a history of prior fragility fracture
   - 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)
   - 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
RECLAST (zoledronic acid) (cont.)

Criteria: (cont.)

Osteoporosis: (cont.)

Initial Course of Treatment: (cont.)

- Reclast for the treatment of osteoporosis is considered medically necessary with documentation of ALL of the following: (cont.)

3. Individual has failed, or is intolerant to, or has a contraindication to at least TWO of the following agents:
   - Alendronate
   - Etidronate
   - Ibandronate
   - Risedronate

4. Individual is receiving supplemental calcium and vitamin D with doses adjusted per usual laboratory monitoring

5. Creatinine clearance is equal to or greater than 35 mL/min

6. No evidence of hypocalcemia, has a serum calcium or corrected calcium within the normal range

7. No evidence of hypersensitivity to any component of Reclast

8. There is evidence that a female of child bearing potential is not pregnant or is unable to become pregnant

9. Individual is not receiving another agent with the same active ingredient zoledronic acid

10. Reclast is not being used concurrently with another bisphosphonate

11. A routine oral examination must be performed by a medical provider or dentist prior to treatment. Individuals with risk factors for ONJ (see Definition section) should receive appropriate preventive dentistry prior to initiation of Reclast.
RECLAST (zoledronic acid) (cont.)

Criteria: (cont.)

Osteoporosis: (cont.)

Repeat Courses of Treatment:

➤ Repeat courses of Reclast for the treatment of osteoporosis is considered medically necessary with documentation of ALL of the following:

1. Achieved and maintains TWO of the following:
   ▪ Reduced incidence of new vertebral fractures in previously undeformed vertebrae
   ▪ Reduced incidence of non-vertebral fractures (e.g., ankle/foot, hip, humerus, pelvis, wrists, or other sites)
   ▪ Increased bone mineral density (e.g., lumbar spine, femoral neck, or total hip)

2. Individual is receiving supplemental calcium and vitamin D with doses adjusted per usual laboratory monitoring

3. Creatinine clearance is equal to or greater than 35 mL/min

4. There is evidence that a female individual of child bearing potential is not pregnant or is unable to become pregnant

5. Individual is not receiving another agent with the same active ingredient zoledronic acid

6. Reclast (zoledronic acid) is not being used concurrently with another bisphosphonate

7. Individual has not developed any unacceptable drug toxicity (e.g., hypersensitivity, renal toxicity, osteonecrosis, atypical fractures, hypocalcemia, or severe bone/joint/muscle pains), contraindications or other exclusions to its continued use
RECLAST (zoledronic acid) (cont.)

Criteria: (cont.)

Paget’s Disease:

Initial Course of Treatment:

➢ Reclast for males and non-pregnant females 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 has failed, or is intolerant to, or has a contraindication to at least TWO of the following agents:
   • Alendronate
   • Etidronate
   • Ibandronate
   • Risedronate

3. Individual is receiving supplemental calcium and vitamin D with doses adjusted per usual laboratory monitoring
4. Creatinine clearance is equal to or greater than 35 mL/min
5. No evidence of hypocalcemia, has a serum calcium or corrected calcium within the normal range
6. No evidence of hypersensitivity to any component of Reclast
7. There is evidence that a female of child bearing potential is not pregnant or is unable to become pregnant
8. Individual is not receiving another agent with the same active ingredient zoledronic acid
9. Reclast is not being used concurrently with another bisphosphonate
10. A routine oral examination must be performed by a medical provider or dentist prior to treatment. Individuals with risk factors for ONJ (see Definition section) should receive appropriate preventive dentistry prior to initiation of Reclast.
RECLAST (zoledronic acid) (cont.)

Criteria: (cont.)

Paget's Disease:

Repeat Courses of Treatment:

- Repeat courses of Reclast for males or non-pregnant females with Paget's disease of the bone are considered *medically necessary* 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 with doses adjusted per usual laboratory monitoring
3. Creatinine clearance is equal to or greater than 35 mL/min
4. There is evidence that a female of child bearing potential is not pregnant or is unable to become pregnant
5. Individual is not receiving another agent with the same active ingredient zoledronic acid
6. Reclast is not being used concurrently with another bisphosphonate
7. Individual has not developed any unacceptable drug toxicity (e.g., hypersensitivity, renal toxicity, osteonecrosis, atypical fractures, hypocalcemia, or severe bone/joint/muscle pains), contraindications or other exclusions to its continued use.

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
RECLAST (zoledronic acid) (cont.)

Resources:

Literature reviewed 07/05/18. 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 once 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>A single 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.</td>
</tr>
</tbody>
</table>

Reclast is contraindicated in patients with a creatinine clearance of < 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.

Initial Approval Duration: 3 months

Renewal Approval Duration: 12 months
RECLAST (zoledronic acid) (cont.)

Resources: (cont.)

Glucocorticoid Equivalencies:

<table>
<thead>
<tr>
<th>Glucocorticoid</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>
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, 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 kwé’é atah nilínígíí Blue Cross Blue Shield of Arizona haada yit’ëego bíná’íd’líkidgo éí doocado Háída bíjí anliyeeeldíí t’àdoo le’è yíná’íd’ilkidgo beeheaz’áanii hólq díí t’àa hazaadk’e’ehí háká a’doowolgo bee haz’á doo bąąq ilínígíí. Ata’ halné’ígíí koj’ bičí’í’ hodíííhí 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 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 thợ dịch viễn, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعد أسهل بخصوص Blue Cross Blue Shield of Arizona الضرورة بلغتك من دون اية تكلفة. للتحدث مع متزوج اتصل ب 877-475-4799.
RECLAST (zoledronic acid) (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay maaaring katanungan tungkol sa Blue Cross Blue Shield of Arizona, maaaring karapatang na makakuhang tulung ng impormasyon sa iyong wika ng walang gastos. Upang makuasaang ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하의 상담하는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 이용 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 sans 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:

اگر شما، یا کسی که شما به او کمک می‌کنید، سوال نمودید، اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799.

Assyrian:

Blue Cross Blue Shield of Arizona نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نارساد و نар