HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

ZOLEDRONIC ACID (RECLAST)

Generic	Brand	HICL	GCN	Exception/Other
ZOLEDRONIC ACID	RECLAST		25026	

NOTE: Brand-name Reclast would only be covered under the medical benefit.

GUIDELINES FOR USE

1. Is the request for the multisource brand product Reclast?

   If yes, process as PA not required. Please fax the request to Provider Services at 800-232-0816. Send the doctor a provider response letter using reason code HPH75. [The requested medication should only be administered by a healthcare professional and therefore it is not covered under the Harvard Pilgrim Health Care Prescription Drug Benefit but may be covered under the Medical Benefit. For further information, please contact the HPHC Provider Service Center at 1-800-708-4414 or visit the Provider section of our public website at www.HarvardPilgrim.org.]
   If not continue to #2.

2. Does the member have a diagnosis of Paget's disease of the bone?

   If yes, **approve for one fill by GPID.** [The quantity limit is hard-coded] Please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for zoledronic acid has been approved for one 5mg dose.

   If no, continue to #3.

3. Does the member have a diagnosis of osteoporosis?

   If yes, continue to #4.
   If no, do not approve. Please use status code #238 and the denial text provided:
   DENIAL TEXT: Per your health plan's Zoledronic Acid (Reclast) guideline, this medication is only covered when prescribed for Paget's disease of the bone or osteoporosis. Your provider did not indicate that you have one of these diagnoses and therefore your request was denied.

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GUIDELINES FOR USE (CONTINUED)

4. Does the member meet **ALL** of the following criteria?
   - The member is a postmenopausal female **OR** a male
   - The member has had a trial of an oral bisphosphonate **OR** there is a clinical reason to avoid treatment with an oral bisphosphonate (e.g., esophageal abnormality, active upper gastrointestinal condition, inability to stand or sit upright for at least 30 to 60 minutes or wait at least 30 to 60 minutes before first food, drink, or medication of the day, renal insufficiency (creatine clearance < 30mL/min))
   - The member meets **ONE** of the following:
     - o History of an osteoporotic vertebral or hip fracture
     - o A pre-treatment T-score of less than or equal to -2.5
     - o A pre-treatment T-score of less than or equal to -1 and no less than -2.4 **AND** a pre-treatment FRAX score of either greater than or equal to 20% for any major or greater than or equal to 3% for a hip fracture

   If yes, **approve for 12 months by GPID.** [The quantity limit is hard-coded] Please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for zoledronic acid has been approved for a quantity of one 5mg dose per 12 months for a 12-month period.

   If no, continue to #5.

5. Is the member's osteoporosis glucocorticoid-induced and they meet **ALL** of the following criteria?
   - The member is a postmenopausal female **OR** a male
   - The member is 50 years of age or older
   - The member has had a trial of an oral bisphosphonate **OR** there is a clinical reason to avoid treatment with an oral bisphosphonate (e.g., esophageal abnormality, active upper gastrointestinal condition, inability to stand or sit upright for at least 30 to 60 minutes or wait at least 30 to 60 minutes before first food, drink, or medication of the day, renal insufficiency (creatine clearance < 30mL/min))
   - The member is currently receiving or will be initiating glucocorticoid therapy
   - The member meets **ONE** of the following:
     - o History of a fragility fracture
     - o A pre-treatment T-score of less than or equal to -2.5
     - o A FRAX score of either greater than or equal to 20% for any major or greater than or equal to 3% for a hip fracture
     - o Glucocorticoid dose of at least 7.5mg prednisone or equivalent per day for at least 3 months

   If yes, **approve for 12 months by GPID.** [The quantity limit is hard-coded] Please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for zoledronic acid has been approved for a quantity of one 5mg dose per 12 months for a 12-month period.

   If no, continue to #6.

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GUIDELINES FOR USE (CONTINUED)

6. Is the member's osteoporosis glucocorticoid-induced and they meet **ALL** of the following criteria?
   - The member is a premenopausal female **OR** a male
   - The member is less than 50 years of age
   - The member has had a trial with an oral bisphosphonate **OR** there is a clinical reason to avoid treatment with an oral bisphosphonate (e.g., esophageal abnormality, active upper gastrointestinal condition, inability to stand or sit upright for at least 30 to 60 minutes or wait at least 30 to 60 minutes before first food, drink, or medication of the day, renal insufficiency (creatine clearance < 30mL/min))
   - The member has a history of a fragility fracture
   - The member is currently receiving or will be initiating glucocorticoid therapy
   - Glucocorticoid therapy consists of **ONE** of the following:
     - The expected length of therapy is greater than 3 months
     - The expected length of therapy is between 1 to 3 months at a dose of at least 7.5mg prednisone or equivalent per day

   If yes, **approve for 12 months by GPID.** [The quantity limit is hard-coded] Please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for zoledronic acid has been approved for a quantity of one 5mg dose per 12 months for a 12-month period.

   If no, do not approve. Please use status code #238 and the denial text provided:
   DENIAL TEXT: Per your health plan's Zoledronic Acid (Reclast) guideline, this medication is only covered when prescribed for osteoporosis when the member meets the following conditions:
   - You are a postmenopausal female **OR** a male
   - You have had a trial with an oral bisphosphonate **OR** there is a clinical reason to avoid treatment with an oral bisphosphonate
   - You meet any of the following:
     - You have a history of an osteoporotic vertebral or hip fracture
     - You have a pre-treatment T-score of less than or equal to -2.5
     - You have a pre-treatment T-score of less than or equal to -1 and no less than -2.4 **AND** a pre-treatment FRAX score of either greater than or equal to 20% for any major or greater than or equal to 3% for a hip fracture

   (Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

For glucocorticoid-induced osteoporosis, approval requires:

- You have had a trial with an oral bisphosphonate **OR** there is a clinical reason to avoid treatment with an oral bisphosphonate
- You are currently receiving or will be initiating glucocorticoid therapy
- You are a postmenopausal female **OR** a male 50 years of age or older and meet one of the following:
  - History of a fragility fracture
  - A pre-treatment T-score of less than or equal to -2.5
  - A FRAX score of either greater than or equal to 20% for any major or greater than or equal to 3% for a hip fracture
  - A dose of at least 7.5mg prednisone or equivalent per day for at least 3 months
- You are a premenopausal female **OR** a male less than 50 years of age with a history of a fragility fracture and your glucocorticoid therapy consists of **ONE** of the following:
  - The expected length of therapy is greater than 3 months
  - The expected length of therapy is between 1 to 3 months at a dose of at least 7.5mg prednisone or equivalent per day

Your provider did not indicate that you **[specify criteria not met]** and therefore your request was not approved.

RATIONALE

Ensure the appropriate use of zoledronic acid 5 mg/ 100ml for the treatment of glucocorticoid-induced osteoporosis, osteoporosis in men, Paget disease of bone, and postmenopausal osteoporosis.

FDA APPROVED INDICATIONS

Reclast is approved for:

- Glucocorticoid-induced osteoporosis: Treatment and prevention of glucocorticoid-induced osteoporosis in men and women who are initiating or continuing systemic glucocorticoids in a daily dose equivalent to 7.5 mg or more of prednisone and who are expected to remain on glucocorticoids for at least 12 months.
- Osteoporosis in men: To increase bone mass in men with osteoporosis.
- Paget disease of bone: Treatment of Paget disease of bone in men and women.
- Postmenopausal osteoporosis: Treatment and prevention of osteoporosis in postmenopausal women.

Limitations of use: Safety and efficacy for osteoporosis treatment is based on clinical data of 3 years duration; the optimal duration has not been determined. All patients on bisphosphonate therapy for the treatment of osteoporosis should be re-evaluated periodically for the need to continue therapy; consider discontinuing after 3 to 5 years in patients at low-risk for fracture; reevaluate fracture risk periodically in patients who discontinue therapy.

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REFERENCES

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