Zoledronic acid Injection (Zometa, Reclast)

Medical Policy

Section | Original Policy Date
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 | October 1, 2014

Disclaimer

Our medical policies are designed for informational purposes only and are not an authorization, or an explanation of benefits, or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

Description

Zoledronic acid Injection (Zometa) is part of a class of drugs called bisphosphonates that are used to improve bone strength in many diseases associated with bone resorption, such as cancer. The principal action of Zometa is to inhibit bone resorption. Although the mechanism is not completely understood, Zometa inhibits the increased osteoclastic (bone breakdown) activity and skeletal calcium release induced by various stimulatory factors released by tumors. This osteoclastic hyperactivity is the underlying mechanism resulting in hypercalcemia of malignancy (tumor-induced hypercalcemia) and metastatic bone disease.

Zometa is indicated in the treatment of hypercalcemia of malignancy for patients with multiple myeloma or documented bone metastases from solid tumors. It is given in conjunction with standard antineoplastic therapy. Treatment for patients with prostate cancer is indicated only after documented progression of disease following treatment with at least one hormonal therapy.

The safety and efficacy of Zometa in the treatment of hypercalcemia associated with hyperparathyroidism or other non-tumor related conditions has not been established.

Reclast (zoledronic acid) Injection is used to treat osteoporosis in postmenopausal women and Paget's disease in men and women.
Medically Necessary

FCC considers the use of Zometa medically necessary for the treatment of patients with any of the following conditions:

- Hypercalcemia of malignancy
- Diagnosis of multiple myeloma
- Documented bone metastases from a solid tumor in conjunction with standard antineoplastic therapy

Limitation: Treatment for patients with prostate cancer is indicated only after documented progression of disease following treatment with at least one hormonal therapy

- Treatment of osteoporosis in patients intolerant of oral bisphosphonate therapy. To receive coverage for this off-label use, documentation must include:
  - T score of at least –2.5
  - A significant adverse reaction that precludes further use of at least two oral agents used to treat osteoporosis

- Prophylaxis for drug-induced osteopenia, secondary to androgen-deprivation therapy in prostate cancer patients (USP DI August 2005)

FCC considers the use of Reclast medically necessary for the treatment of patients with any of the following conditions:

- Osteoporosis in postmenopausal women intolerant of oral bisphosphonate therapy. The recommended regimen is a single 5 mg infusion once a year given intravenously. To receive coverage, documentation must include:
  - T score of at least –2.5
  - A significant adverse reaction that precludes further use of at least two oral agents used to treat osteoporosis.
- Paget's disease

Not Medically Necessary

FCC considers the use of zoledronic acid not medically necessary when the above criteria for coverage outlined above is not met including, but not limited to the following:

- Use in pediatric patients
- When used to treat the following conditions, including but not limited to:
  - Osteoporosis (see exception above). Osteoporosis therapy is covered under the pharmacy benefit
- To prevent metastases in patients with solid tumors. Superiority to oral bisphosphonates has not been established for this indication
- Hypercalcemia associated with hyperparathyroidism
- Hypercalcemia associated with non-tumor related conditions
Policy Guidelines

This medical policy was developed through consideration of peer reviewed medical literature, FDA approval status, accepted standards of medical practice North Carolina and the concept of medical necessity. FCC reserves the right to make exceptions to policy that benefit the member when advances in technology or new medical information become available.

The purpose of medical policy is to guide coverage decisions and is not intended to influence treatment decisions. Providers are expected to make treatment decisions based on their medical judgment. FirstCarolinaCare recognizes the rapidly changing nature of technological development and welcomes provider feedback on all medical policies.

When using this policy to determine whether a service, supply, drug or device will be covered, please note that member contract language will take precedence over medical policy when there is a conflict.

Medicare National Coverage: None

References:

Codes

HCPCS Codes

J3487 INJECTION ZOLEDRONIC ACID
J3488 ZOLEDRONIC ACID
Q4095 INJECTION, ZOLEDRONIC ACID (RECLAST), 1 MG - HAS BEEN DELETED FOR 2008

This may not be a comprehensive list of procedure codes applicable to this policy.

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