VENTURA COUNTY
HEALTH CARE PLAN

Aredia (pamidronate)

Effective Date: 10/22/13

Date Developed: 9/3/13 by Albert Reeves MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19

(Archived 1/22/19)

Pharmacologic Category: Antidote; Bisphosphonate Derivative

Authorization Criteria: moderate or severe hypercalcemia associated with malignancy, with or without bone metastases, in conjunction with adequate hydration; moderate to severe Paget disease of bone;

Off-Label: Bone loss associated with androgen deprivation treatment in prostate cancer (prevention); hyperparathyroidism; osteogenesis imperfecta; symptomatic bone metastases of thyroid cancer

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Unlabeled

Treatment of osteogenesis imperfecta; treatment of symptomatic bone metastases of thyroid cancer; prevention of bone loss associated with androgen deprivation treatment in prostate cancer

Dosage: **Hypercalcemia of malignancy:** I.V.:

Moderate cancer-related hypercalcemia (corrected serum calcium: 12-13.5 mg/dL): 60-90 mg, as a single dose over 2-24 hours

Severe cancer-related hypercalcemia (corrected serum calcium: >13.5 mg/dL): 90 mg, as a single dose over 2-24 hours

Retreatment in patients who show an initial complete or partial response (allow at least 7 days to elapse prior to retreatment): May retreat at the same dose if serum calcium does not return to normal or does not remain normal after initial treatment.

Multiple myeloma, osteolytic bone lesions: I.V.: 90 mg over 4 hours once monthly:

Lytic disease: American Society of Clinical Oncology (ASCO) guidelines: 90 mg over at least 2 hours once every 3-4 weeks for 2 years; discontinue after 2 years in patients with responsive and/or stable disease; resume therapy with new-onset skeletal-related events (Kyle, 2007)

Newly-diagnosed, symptomatic (unlabeled dose): 30 mg over 2.5 hours once monthly for at least 3 years (Gimsing, 2010)

Breast cancer, osteolytic bone metastases: I.V.: 90 mg over 2 hours once every 3-4 weeks
Paget's disease (moderate-to-severe): I.V.: 30 mg over 4 hours once daily for 3 consecutive days

(total dose = 90 mg); may retreat at initial dose if clinically indicated

Prevention of androgen deprivation-induced osteoporosis (unlabeled use): Males: I.V.: 60 mg over 2 hours once every 3 months (Smith, 2001)

Dosing: Adult

Note: Single doses should not exceed 90 mg.

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Severe cancer-related hypercalcemia (corrected serum calcium: >13.5 mg/dL): 90 mg, as a single dose over 2-24 hours

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Dosing: Geriatric

Refer to adult dosing. Begin at lower end of adult dosing range.

Dosing: Renal Impairment

Patients with serum creatinine >3 mg/dL were excluded from clinical trials; there are only limited pharmacokinetic data in patients with Cl_{cr} <30 mL/minute.

Manufacturer recommends the following guidelines:

Treatment of bone metastases: Use is not recommended in patients with severe renal impairment.

Renal impairment in indications other than bone metastases: Use clinical judgment to determine if benefits outweigh potential risks.

Multiple myeloma: American Society of Clinical Oncology (ASCO) guidelines (Kyle, 2007):

Severe renal impairment (serum creatinine >3 mg/dL **or** Cl_{cr} <30 mL/minute) and extensive bone disease: 90 mg over 4-6 hours. However, a reduced initial dose should be considered if renal impairment was pre-existing.

Albuminuria >500 mg/24 hours (unexplained): Withhold dose until returns to baseline, then recheck every 3-4 weeks; consider reinitiating at a dose not to exceed 90 mg every 4 weeks and with a longer infusion time of at least 4 hours

Dosing adjustment in renal toxicity: In patients with bone metastases, treatment should be withheld for deterioration in renal function (increase of serum creatinine ≥0.5 mg/dL in patients with normal baseline or ≥1 mg/dL in patients with abnormal baseline). Resumption of therapy may be considered when serum creatinine returns to within 10% of baseline.

Dosing: Hepatic Impairment

Mild-to-moderate impairment: No dosage adjustment necessary.

Severe impairment: No dosage adjustment provided in manufacturer's labeling (has not been

Single doses should not exceed 90 mg

Administration: I.V.: Infusion rate varies by indication. Longer infusion times (>2 hours) may reduce the risk for renal toxicity, especially in patients with pre-existing renal insufficiency. The manufacturer recommends infusing over 2-24 hours for hypercalcemia of malignancy; over 2 hours for osteolytic bone lesions with metastatic breast cancer; and over 4 hours for Paget's disease and for osteolytic bone lesions with multiple myeloma. The ASCO guidelines for bisphosphonate use in multiple myeloma recommend infusing pamidronate over at least 2 hours; if therapy is withheld due to renal toxicity, infuse over at least 4 hours upon reintroduction of treatment after renal recovery (Kyle, 2007).

Dosage Forms: U.S.

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Solution, Intravenous, as disodium:

Generic: 30 mg/10 mL (10 mL); 90 mg/10 mL (10 mL)

Solution, Intravenous, as disodium [preservative free]:

Generic: 30 mg/10 mL (10 mL); 6 mg/mL (10 mL); 90 mg/10 mL (10 mL)

Solution Reconstituted, Intravenous, as disodium:

Generic: 30 mg (1 ea); 90 mg (1 ea)

Major adverse reactions and Black Box Warnings:

Adverse Reactions Significant

Note: Actual percentages may vary by indication; treatment for multiple myeloma is associated with higher percentage.

>10%:

Central nervous system: Fever (18% to 39%; transient), fatigue (≤37%), headache (≤26%), insomnia (≤22%)

Endocrine & metabolic: Hypophosphatemia (≤18%), hypokalemia (4% to 18%), hypomagnesemia (4% to 12%), hypocalcemia (≤12%)

Gastrointestinal: Nausea (≤54%), vomiting (≤36%), anorexia (≤26%), abdominal pain (≤23%), dyspepsia (≤23%)

Genitourinary: Urinary tract infection (≤19%)

Hematologic: Anemia (≤43%), granulocytopenia (≤20%)

Local: Infusion site reaction (≤18%; includes induration, pain, redness and swelling)

Neuromuscular & skeletal: Myalgia (≤26%), weakness (≤22%), arthralgia (≤14%), osteonecrosis of the jaw (cancer patients: 1% to 11%)

Renal: Serum creatinine increased (≤19%)

Respiratory: Dyspnea (≤30%), cough (≤26%), upper respiratory tract infection (≤24%), sinusitis (≤16%), pleural effusion (≤11%)

1% to 10%:

Cardiovascular: Atrial fibrillation (≤6%), hypertension (≤6%), syncope (≤6%), tachycardia (≤6%), atrial flutter (≤1%), cardiac failure (≤1%), edema (≤1%)

Central nervous system: Somnolence (≤6%), psychosis (≤4%), seizure (≤2%)

Endocrine & metabolic: Hypothyroidism (≤6%)

Gastrointestinal: Constipation (≤6%), gastrointestinal hemorrhage (≤6%), diarrhea (≤1%), stomatitis (≤1%)

Hematologic: Leukopenia (≤4%), neutropenia (≤1%), thrombocytopenia (≤1%)

Neuromuscular & skeletal: Back pain, bone pain

Renal: Uremia (≤4%)

Respiratory: Rales (≤6%), rhinitis (≤6%)

Miscellaneous: Moniliasis (≤6%)

<1% (Limited to important or life-threatening): Acute renal failure, adult respiratory distress syndrome, allergic reaction, anaphylactic shock, angioedema, bone/joint/muscle pain (severe and occasionally incapacitating), bronchospasm, CHF, confusion, conjunctivitis, electrolyte/mineral abnormality, episcleritis, femoral fractures (atypical subtrochanteric, diaphyseal femoral), fluid overload, flu-like syndrome, focal segmental glomerulosclerosis (including collapsing variant), glomerulonephropathies, hallucinations (visual), hematuria, herpes virus reactivation, hyperkalemia, hypernatremia, hypotension, injection site phlebitis/thrombophlebitis, interstitial pneumonitis, iridocyclitis, iritis, joint and/or muscle pain (sometimes severe and/or incapacitating), left ventricular failure, lymphocytopenia, malaise, nephrotic syndrome, orbital inflammation, osteonecrosis (other than jaw), paresthesia, pruritus, rash, renal deterioration, renal failure, renal tubular disorders, scleritis, tetany, tubulointerstitial nephritis, uveitis, xanthopsia

Contraindications

Hypersensitivity to pamidronate, other bisphosphonates, or any component of the formulation

Warnings/Precautions

Concerns related to adverse effects:

- Bone fractures: Atypical femur fractures (after minimal or no trauma) have been reported. The fractures include subtrochanteric femur (bone just below the hip joint) and diaphyseal femur (long segment of the thigh bone). Some patients experience prodromal pain weeks or months before the fracture occurs. It is unclear if bisphosphonate therapy is the cause for these fractures. Patients receiving long-term (>3-5 years) bisphosphonate therapy may be at an increased risk. Consider discontinuing pamidronate in patients with a suspected femoral shaft fracture. Patients who present with thigh or groin pain in the absence of trauma should be evaluated.

- Musculoskeletal pain: Infrequently, severe (and occasionally debilitating) bone, joint, and/or muscle pain have been reported during bisphosphonate treatment. The onset of pain ranged from a single day to several months. Consider discontinuing therapy in patients who experience severe symptoms; symptoms usually resolve upon discontinuation. Some patients experienced recurrence when rechallenged with same drug or another bisphosphonate; avoid use in patients with a history of these symptoms in association with bisphosphonate therapy.

- Electrolyte abnormalities: Use has been associated with asymptomatic electrolyte abnormalities (including hypophosphatemia, hypokalemia, hypomagnesemia, and

hypocalcemia). Rare cases of symptomatic hypocalcemia, including tetany, have been reported.

- Myelosuppression: Patients with pre-existing anemia, leukopenia, or thrombocytopenia should be closely monitored during the first 2 weeks of treatment.

- Osteonecrosis of the jaw (ONJ): ONJ has been reported in patients receiving bisphosphonates. Risk factors include invasive dental procedures (eg, tooth extraction, dental implants, boney surgery); a diagnosis of cancer, with concomitant chemotherapy, radiotherapy, or corticosteroids; poor oral hygiene, ill-fitting dentures; and comorbid disorders (anemia, coagulopathy, infection, pre-existing dental disease). Most reported cases occurred after I.V. bisphosphonate therapy; however, cases have been reported following oral therapy. A dental exam and preventative dentistry should be performed prior to placing patients with risk factors on chronic bisphosphonate therapy. There is no evidence that discontinuing therapy reduces the risk of developing ONJ (Assael, 2009). The benefit/risk must be assessed by the treating physician and/or dentist/surgeon prior to any invasive dental procedure. Patients developing ONJ while on bisphosphonates should receive care by an oral surgeon.

- Renal deterioration: Single pamidronate doses should not exceed 90 mg. Initial or single doses have been associated with renal deterioration, progressing to renal failure and dialysis. Glomerulosclerosis (focal segmental) with or without nephrotic syndrome has also been reported. Longer infusion times (>2 hours) may reduce the risk for renal toxicity, especially in patients with pre-existing renal insufficiency. Withhold pamidronate treatment (until renal function returns to baseline) in patients with evidence of renal deterioration.

Disease-related concerns:

- Hypercalcemia of malignancy (HCM): Adequate hydration is required during treatment (urine output ~2 L/day); avoid overhydration, especially in patients with heart failure.

- Hypoparathyroidism: Use caution with a history of thyroid surgery; patients may have relative hypoparathyroidism, predisposing them to pamidronate-related hypocalcemia.

- Multiple myeloma: According to the American Society of Clinical Oncology (ASCO) guidelines for bisphosphonates in multiple myeloma, treatment with pamidronate is not recommended for asymptomatic (smoldering) or indolent myeloma or with solitary plasmacytoma (Kyle, 2007). The National Comprehensive Cancer Network® (NCCN) multiple myeloma guidelines (v.2.2013) recommend bisphosphonates for all patients receiving treatment for symptomatic disease; the use of bisphosphonates in stage 1 or smoldering disease may be considered, although preferably as part of a clinical trial. Patients with Bence-Jones proteinuria and dehydration should be adequately hydrated prior to therapy.

- Renal impairment: Patients with serum creatinine >3 mg/dL were not studied in clinical trials; limited data are available in patients with Cl_{cr} <30 mL/minute. Evaluate serum creatinine prior to each treatment. For the treatment of bone metastases, use is not recommended in patients with severe renal impairment. With indications other than bone metastases, use clinical judgment to determine if benefits outweigh potential risks in patients with renal impairment.

Special handling:

- Hazardous agent: Use appropriate precautions for handling and disposal (meets NIOSH, 2012 criteria).

Metabolism/Transport Effects

None known.

Drug Interactions

(For additional information: Launch Lexi-Interact™ Drug Interactions Program)
Lexicomp®

Aminoglycosides: May enhance the hypocalcemic effect of Bisphosphonate Derivatives. *Risk C: Monitor therapy*

Deferasirox: Bisphosphonate Derivatives may enhance the adverse/toxic effect of Deferasirox. Specifically, the risk for GI ulceration/irritation or GI bleeding may be increased. *Risk C: Monitor therapy*

Nonsteroidal Anti-Inflammatory Agents: May enhance the adverse/toxic effect of Bisphosphonate Derivatives. Both an increased risk of gastrointestinal ulceration and an increased risk of nephrotoxicity are of concern. *Risk C: Monitor therapy*

Phosphate Supplements: Bisphosphonate Derivatives may enhance the hypocalcemic effect of Phosphate Supplements. *Risk C: Monitor therapy*

Proton Pump Inhibitors: May diminish the therapeutic effect of Bisphosphonate Derivatives. *Risk C: Monitor therapy*

SUNItinib: Bisphosphonate Derivatives may enhance the adverse/toxic effect of SUNItinib. Specifically, the risk of osteonecrosis of the jaw may be increased. Management: Monitor for development of osteonecrosis of the jaw in patients receiving sunitinib and bisphosphonates. Avoid invasive dental procedures if possible. *Risk C: Monitor therapy*

Thalidomide: May enhance the nephrotoxic effect of Pamidronate. *Risk C: Monitor therapy*

Generic Equivalent Available: U.S.

Yes

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Revision History:

Date Approved by P&T Committee: 10/22/13
Date Reviewed/No Updates: 1/28/14 by C. Sanders MD
Date Approved by P&T Committee: 1/28/14
Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD
Date Approved by P&T Committee: 1/27/15
Date Reviewed/Updated: 1/22/15 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/26/16
Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/24/17
Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/23/18
Date Reviewed/Archived: 1/22/19 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/22/19

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review

1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Archived – check MCG