Arzerra (ofatumumab)

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

Pharmacologic Category: Antineoplastic Agent, Monoclonal Antibody;

Authorization Criteria: previously untreated CLL (in combination with chlorambucil)
when fludarabine-based therapy is considered inappropriate; CLL refractory to fludarabine and
alemtuzumab

Dosage: Adult

Note: Premedicate with acetaminophen, an antihistamine, and a corticosteroid 30-120 minutes prior to
treatment (see Administration).

CLL: I.V. Initial dose: 300 mg week 1, followed 1 week later by 2000 mg once weekly for 7 doses
(doses 2-8), followed 4 weeks later by 2000 mg once every 4 weeks for 4 doses (doses 9-12; for
a total of 12 doses

Administration: Do not administer I.V. push or as a bolus. Premedicate with acetaminophen, an
antihistamine, and a corticosteroid 30-120 minutes prior to administration. Administer with an in-line filter
(supplied) and polyvinyl chloride (PVC) administration sets. Do not mix with or infuse with other
medications. Flush line before and after infusion with NS. Begin infusion within 12 hours of preparation.
The final concentration of dose 1 is 0.3 mg/mL and final concentration of doses 2-12 is 2 mg/mL.

Premedication: Premedicate with oral acetaminophen (1000 mg), an oral or I.V. antihistamine (eg,
cetirizine 10 mg orally or equivalent), and an I.V. corticosteroid. Full dose corticosteroid is
recommended for doses 1, 2, and 9; in the absence of infusion reaction ≥grade 3, may
gradually reduce corticosteroid dose for doses 3-8; administer full or half corticosteroid dose
with doses 10-12 if ≥grade 3 did not occur with dose 9.

Doses 1 and 2: Initiate infusion at 12 mL/hour for 30 minutes, if tolerated (no infusion reaction)
increase to 25 mL/hour for 30 minutes, if tolerated, increase to 50 mL/hour for 30 minutes, if
tolerated, increase to 100 mL/hour for 30 minutes, if tolerated, increase to 200 mL/hour for
duration of infusion.

Doses 3-12: Initiate infusion at 25 mL/hour for 30 minutes, if tolerated (no infusion reaction) increase to
50 mL/hour for 30 minutes, if tolerated, increase to 100 mL/hour for 30 minutes, if tolerated,
increase to 200 mL/hour for 30 minutes, if tolerated, increase to 400 mL/hour for remainder of infusion.

Major adverse reactions and Black Box Warnings:

>10%:

Central nervous system: Fatigue (15%)
Dermatologic: Skin rash (14%)
Gastrointestinal: Diarrhea (18%), nausea (11%)
Hematologic & oncologic: Neutropenia (≥grade 3: 42%; grade 4: 18%; may be prolonged >2 weeks), anemia (16%; grades 3/4: 5%)
Infection: Infection (70%; includes bacterial, fungal, or viral; ≥grade 3: 29%)
Respiratory: Pneumonia (23%), cough (19%), dyspnea (14%), bronchitis (11%), upper respiratory tract infection (11%)
Miscellaneous: Infusion related reaction (first infusion [300 mg]: 44%; second infusion [2000 mg]: 29%), fever (20%)

1% to 10%:

Cardiovascular: Peripheral edema (9%), hypertension (5%), hypotension (5%), tachycardia (5%)
Central nervous system: Chills (8%), insomnia (7%), headache (6%)
Dermatologic: Urticaria (8%), hyperhidrosis (5%)
Infection: Sepsis (8%), herpes zoster (6%)
Neuromuscular & skeletal: Back pain (8%), muscle spasm (5%) Respiratory:
  Nasopharyngitis (8%), sinusitis (5%)

<1% (Limited to important or life-threatening): Angina pectoris, bacteremia, hemolytic anemia, hepatitis B (new onset or reactivation), hepatitis (cytolytic), hypoxia, interstitial pulmonary disease (infectious), intestinal obstruction, peritonitis, progressive multifocal leukoencephalopathy (PML), rigors, sepsis (neutropenic), septic shock, thrombocytopenia

Contraindications

There are no contraindications listed within the manufacturer's labeling.
References:


Revision History:
Date Approved by P&T Committee: 10/22/13
Date Reviewed/No Updates: 1/28/14 by C. Sanders MD
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Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD
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Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD
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