Approval Criteria Department of Pharmacy Services

**Generic Name:** Rituximab

**Brand Name:** Rituxan®

**Medication Class:** CD20-directed cytolytic antibody

**FDA Approved Uses**
- Non-hodgkin’s Lymphoma (NHL)
- Chronic lymphocytic leukemia (CLL)
- Granulomatosis with polyangiitis (Wegener granulomatosis) and Microscopic Polyangiitis (MPA)
- Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to-severely-active RA who have inadequate response to one or more TNF antagonists

**Criteria for use**
- The indicated diagnosis (including any applicable laboratory tests) and medication usage must be supported by documentation from the patient’s medical record
- Must be clinically diagnosed with one of the FDA approved uses noted above
- For Wegener’s Granulomatosis (WG) and Microscopic Polyangiitis (MPA)
  - Must be ordered concomitant therapy with glucocorticoids unless intolerant or contraindicated
- For Rheumatoid Arthritis
  - Must have tried and failed TWO (2) of the following TNF antagonists: Enbrel (etanercept), Humira (adalimumab), Remicade (infliximab), or Simponi (golimumab) in most recent 180 days
  - Member must be ordered concomitant therapy with methotrexate (MTX) unless intolerant or contraindicated

**Not Approved For**
- Graft versus Host Disease (GVHD) – as first or second-line therapy
- Membranous glomerulonephropathy
- Multiple sclerosis

**Required Medical Information**
- Clinical documentation of diagnosis and pertinent laboratory studies
- Claims supporting trial and failure of required previous therapy (dates of treatment and response to treatment)
- Claims supporting concomitant therapy as indicated above

**Contraindications**
- None well documented
Dosing
- **CLL**
  - 375mg/m² IV infusion the day prior to initiation of fludarabine and cyclophosphamide chemotherapy, then 500 mg/m² on day 1 of cycles 2 to 6 (every 28 days)
- **Granulomatosis with polyangiitis (Wegener granulomatosis) and Microscopic polyangiitis:**
  - 375 mg/m² IV infusion once weekly for 4 weeks
- **Non-hodgkin’s lymphoma**
  - Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin lymphoma:
    - 375 mg/m² IV infusion once weekly for 4 or 8 doses (4 doses for re-treatment)
  - Previously untreated, follicular, CD-20 positive, B-cell non-Hodgkin lymphoma:
    - 375 mg/m² IV infusion on day 1 of each cycle of chemotherapy for up to 8 doses
  - Non-progressing, low-grade, CD20-positive, B-cell non-Hodgkin lymphoma:
    - 375 mg/m² IV infusion once weekly for 4 doses every 6 months to a maximum of 16 doses following completion of 6 to 8 cycles of cyclophosphamide, vincristine, and prednisone chemotherapy
- **Rheumatoid Arthritis**
  - Two 1,000 mg IV infusions separated by 2 weeks in combination with methotrexate
  - May administer subsequent doses every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks

Authorization
- According to dosages identified above

Approved by P&T: 07/16/2013 Reviewed: 3/18/2014

References


66. Actemra (tocilizumab) injection, for intravenous infusion [package insert]. South San Francisco, CA: Genentech, Inc; 2010