Policy: MBP 48.0
Section: Medical Benefit Pharmaceutical Policy
Subject: Rituxan (rituximab) and Truxima (rituximab-abbs)

I. Policy:
Rituxan (rituximab) and Truxima (rituximab-abbs)

II. Purpose/Objective:
To provide a policy of coverage regarding Rituxan (rituximab) and Truxima (rituximab-abbs)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and

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d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and

e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.
DESCRIPTION:
Rituxan (rituximab) and Truxima (rituximab-abbs) are genetically engineered chimeric murine/human monoclonal antibodies directed against the CD20 antigen found on the surface of normal and malignant B lymphocytes. Rituximab has been shown to be effective in rheumatoid arthritis in three randomized controlled trials and is now FDA-approved for use in combination with methotrexate (MTX) for reducing signs and symptoms in adult patients with moderately- to severely-active rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Rituxan (rituximab) and Truxima (rituximab-abbs) will be considered medically necessary when all of the following criteria are met:

1. For Rheumatoid Arthritis:
   All of the following criteria must be met:
   - Physician documentation of a diagnosis of moderate to severe rheumatoid arthritis in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis; AND
   - At least 18 years of age or older; AND
   - Prescription written by a rheumatologist; AND
   - Medical record documentation that an effective dose of methotrexate will be continued during rituximab therapy; AND
   - Medical record documentation that Rituxan is not being used concurrently with a TNF blocker AND
   - Physician documentation of an inadequate response to 12 weeks of therapy with Humira*, Rinoq*, OR Xeljanz*

2. For Chronic Immunothrombocytopenia (ITP):
   All of the following criteria must be met:
   - Diagnosis of primary chronic ITP AND
   - Platelet count of < 30,000/mm³ with active bleeding or < 20,000/mm³ with increased risk of bleeding AND
   - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids AND IVlg* AND splenectomy (*prior authorization required)

   Authorization Duration*: If patient meets criteria for coverage, authorization will be given for one month of treatment with rituximab.

3. For Chronic Lymphoid Leukemia:
   Note: Prior authorization is not required for diagnosis codes C91.10, C91.11 and C91.12. In the event a requestor would like a medical necessity review completed the following criteria would apply:
   - Medical record documentation of a diagnosis of Chronic Lymphocytic Leukemia (CLL)

4. For Microscopic Polyarteritis Nodosa (PAN)
   - Medical record documentation of a diagnosis of microscopic polyarteritis nodosa used in combination with glucocorticoids

5. For Granulomatosis with Polyangiitis (GPA) (Wegener’s Granulomatosis) and Microscopic Polyangiitis (MPA)
   - Medical record documentation of a diagnosis of Granulomatosis with Polyangiitis (GPA) (Wegener’s granulomatosis) or Microscopic Polyangiitis (MPA) used in combination with glucocorticoids
6. **For Non-Hodgkin Lymphoma**
   Note: Prior authorization is not required for diagnosis codes C82.00 through C85.99 and C86.0 through C88.9. In the event a requestor would like a medical necessity review completed the following criteria would apply:
   - Medical record documentation of a diagnosis of Non-Hodgkin Lymphoma

7. **For Multiple Sclerosis (MS)**
   Note: Prior authorization is not required for diagnosis code G35. In the event a requestor would like a medical necessity review completed the following criteria would apply:
   - Medical record documentation of a diagnosis of Multiple Sclerosis

8. **For Refractory Chronic Debilitating Myasthenia Gravis**
   - Medical record documentation of refractory Chronic Debilitating Myasthenia Gravis AND
   - Prescribed by or in consultation with a neuromuscular specialist AND
   - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one corticosteroid AND
   - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one cholinesterase inhibitor AND
   - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one non-steroidal immunosuppressive therapy

   *Note: Corticosteroids: betamethasone, dexamethasone, methylprednisolone, prednisone
    Cholinesterase inhibitors: pyridostigmine, neostigmine
    Immunosuppressants: azathioprine, mycophenolate, cyclosporine, Rituxan

9. **For Pemphigus Vulgaris (PV)**
   - Prescription written by a dermatologist AND
   - Member is 18 years of age or older AND
   - Medical record documentation of a diagnosis of moderate to severe pemphigus vulgaris AND
   - Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on corticosteroids AND a 12-week trial of at least one (1) nonsteroidal immunomodulatory medication (e.g. azathioprine, cyclophosphamide, or mycophenolate).

**AUTHORIZATION DURATION:**
For Multiple Sclerosis: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

For all other indications: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate (*except for the diagnosis for ITP*). Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

**LINE OF BUSINESS:**
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 8/2/06

**Revised:** 1/10, 09/16/14, 11/18/2014, 12/31/14 (updated formulary alternatives criteria for RA) 03/30/14 – Non-Hodgkin Lymphoma indication, 09/15/15 (removed joint counts), 9/20/16 (added MS indication), 7/17/18 (PV, and MG), 9/18/18 (RA for alt, CLL and MS removal), 11/19/19 (GPA, MPA), 1/21/20 (Truxima, RA form alt)

**Reviewed:** 11/18/2014, 7/31/17, 8/29/19