Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 48.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Rituxan (rituximab), Truxima (rituximab-abbs), Ruxience (rituximab-pvvr), and Riabni (rituximab-arrx)

I. Policy:
Rituxan (rituximab), Truxima (rituximab-abbs), Ruxience (rituximab-pvvr), and Riabni (rituximab-arrx)

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

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
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. 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
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
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. 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), Truxima (rituximab-abbs), Ruxience (rituximab-pvvr), and Riabni (rituximab-arrx) 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), Truxima (rituximab-abbs), Ruxience (rituximab-pvvr), and Riabni (rituximab-arrx) will be considered medically necessary for commercial, exchange, CHIP and Medicaid lines of business 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*, Enbrel*, Rinvoq*, OR Xeljanz*

   AND
   - For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

2. **For Chronic Immunothrombocytopenia (ITP):**
   All of the following criteria must be met:
   - Diagnosis of primary chronic ITP **AND**
   - Platelet count of < 30,000/mm^3 with active bleeding; or platelet count < 30,000/mm^3 and a documented history of significant bleeding**;** or platelet count < 20,000/mm^3 **AND**
   - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids and/or IVIG* AND splenectomy (*prior authorization required)

   AND
   - For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

3. **For Chronic Lymphoid Leukemia:**
   Note: Prior authorization is not required for Ruxience, Riabni or Truxima for diagnosis codes C91.10, C91.11 and C91.12. In the event of a request for the rituximab reference product (i.e. Rituxan), OR 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)

   AND
   - For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

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

   AND
   - For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

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

AND

- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

6**. For Non-Hodgkin Lymphoma**

Note: Prior authorization is not required for Ruxience, Riabni or Truxima for diagnosis codes C82.00 through C85.99 and C86.0 through C88.9. In the event of a request for the rituximab reference product (i.e. Rituxan),OR 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

AND

- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

7. For Multiple Sclerosis (MS)

Note: Prior authorization is not required for Ruxience, Riabni or Truxima for diagnosis code G35. In the event of a request for the rituximab reference product (i.e. Rituxan), OR 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

AND

- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

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

AND

- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

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 use in combination with corticosteroids or a contraindication or intolerance to corticosteroids.

AND

- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

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 **AND**
- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

For all other indications: Initial approval will be for 6 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 **AND**
- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

Rituxan (rituximab), Truxima (rituximab-abbs), Ruxience (rituximab-pvvr), and Riabni (rituximab-arrx) will be considered medically necessary for the Medicare line of business 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**

   AND
   - For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two (2) of the following: rituximab-pvvr (Ruxience), rituximab-arrx (Riabni), and/or rituximab-abbs (Truxima).

2. **For Chronic Immunothrombocytopenia (ITP):**
   All of the following criteria must be met:
   - Diagnosis of primary chronic ITP **AND**
   - Platelet count of < 30,000/mm^3 with active bleeding; or platelet count < 30,000/mm^3 and a documented history of significant bleeding**;** or platelet count < 20,000/mm^3 **AND**
   - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids AND/OR IVIG* (*prior authorization required)

   AND
   - For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two (2) of the following: rituximab-pvvr (Ruxience), rituximab-arrx (Riabni), and/or rituximab-abbs (Truxima).

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   Note: Prior authorization is not required for Ruxience, Riabni or Truxima for diagnosis codes C91.10, C91.11 and C91.12. In the event of a request for the rituximab reference product (i.e. Rituxan), OR in the event a requestor would like a medical necessity review completed, the following criteria would apply:
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AND

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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. 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.

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), 1/18/22 (+Ruxience & Riabni, +failure of biosimilars, reauth extension to 12 months), 1/21/22 (PV removal of immunomodulatory medication, in combo with corticosteroids), 7/19/22 (auth duration), 9/20/22 (LOB carve out, ITP duration/alternative, RA limitation delete, Medicaid Business Segment), 9/12/23 (added Enbrel RA form alt)

Reviewed: 11/18/2014, 7/31/17, 8/29/19, 1/1/21, 12/21/21