Reference number(s)
1704-A

SPECIALTY GUIDELINE MANAGEMENT

RITUXAN (rituximab)
RUXIENCE (rituximab-pvvr)
TRUXIMA (rituximab-abbs)
RIABNI (rituximab-arrx)

Treatment of Hematologic and Oncologic Conditions

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Rituxan, Ruxience, Truxima, and Riabni are indicated for:
1. Non-Hodgkin's lymphoma (NHL) in adult patients with:
   a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent
   b. Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy
   c. Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL, as a single agent after first-line CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy
   d. Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens
2. Chronic lymphocytic leukemia (CLL), in combination with fludarabine and cyclophosphamide (FC), for the treatment of adult patients with previously untreated and previously treated CD20-positive CLL.
3. Granulomatosis with polyangiitis (Wegener's Granulomatosis) and microscopic polyangiitis (MPA)
(Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other SGM)

Rituxan and Truxima are also indicated for:
Moderately to severely active rheumatoid arthritis in adult patients who have had an inadequate response to one or more TNF antagonist therapies
(Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other SGM)

Rituxan is also indicated for:
Moderate to severe pemphigus vulgaris in adult patients
(Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other SGM)

B. Compendial Uses
1. Autoimmune hemolytic anemia
2. B-cell acute lymphoblastic leukemia (ALL)
3. B-cell lymphomas
   a. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma
   b. B-cell lymphoblastic lymphoma

c. Burkitt lymphoma
d. Castleman's disease
e. High-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma)
f. High-grade B-cell lymphoma, not otherwise specified
g. Histological transformation from follicular lymphoma to diffuse large B-cell lymphoma
h. Histological transformation from nodal marginal zone lymphoma to diffuse large B-cell lymphoma
i. Mantle cell lymphoma
j. Marginal zone lymphomas
    i. Nodal marginal zone lymphoma
    ii. Gastric mucosa associated lymphoid tissue (MALT) lymphoma
    iii. Nongastric MALT lymphoma
    iv. Splenic marginal zone lymphoma
k. Post-transplant lymphoproliferative disorder (PTLD)

4. Central nervous system (CNS) cancers
    a. Leptomeningeal metastases from lymphomas
    b. Primary CNS lymphomas
5. Chronic graft-versus-host disease (GVHD)
6. CLL/Small lymphocytic lymphoma (SLL)
7. Hairy cell leukemia
8. Hodgkin's lymphoma, nodular lymphocyte-predominant
9. Immune checkpoint inhibitor-related toxicities
10. Prevention of Epstein-Barr virus (EBV)-related PTLD in high risk patients
11. Primary cutaneous B-cell lymphoma
12. Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)
13. Thrombotic thrombocytopenic purpura
14. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)
15. For other compendial uses, refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other SGM

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Testing or analysis confirming CD20 protein on the surface of the B-cell (if applicable)

III. CRITERIA FOR INITIAL APPROVAL

A. Oncologic indications

Authorization of 12 months may be granted for treatment of any of the following oncologic disorders that are CD20-positive as confirmed by testing or analysis:

1. B-cell acute lymphoblastic leukemia (ALL)
2. B-cell lymphomas:
    i. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma
    ii. B-cell lymphoblastic lymphoma
    iii. Burkitt lymphoma
    iv. Castleman's disease
    v. Diffuse large B-cell lymphoma
    vi. Follicular lymphoma

vii. High-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma)
viii. High-grade B-cell lymphoma, not otherwise specified
ix. Histological transformation from follicular lymphoma to diffuse large B-cell lymphoma
x. Histological transformation from nodal marginal zone lymphoma to diffuse large B-cell lymphoma
xi. Mantle cell lymphoma
xii. Marginal zone lymphomas
    a. Nodal marginal zone lymphoma
    b. Gastric mucosa associated lymphoid tissue (MALT) lymphoma
    c. Nongastric MALT lymphoma
    d. Splenic marginal zone lymphoma
xiii. Post-transplant lymphoproliferative disorder (PTLD)

3. Central nervous system (CNS) cancers:
    i. Leptomeningeal metastases from lymphomas
    ii. Primary CNS lymphoma
4. CLL/Small lymphocytic lymphoma (SLL)
5. Hairy cell leukemia
6. Hodgkin's lymphoma, nodular lymphocyte-predominant
7. Primary cutaneous B-cell lymphoma
8. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)

B. Hematologic indications

Authorization of 12 months may be granted for treatment of any of the following indications:

1. Refractory immune or idiopathic thrombocytopenic purpura (ITP)
2. Autoimmune hemolytic anemia
3. Thrombotic thrombocytopenic purpura
4. Chronic graft-versus-host disease (GVHD)
5. Prevention of Epstein-Barr virus (EBV)-related PTLD

C. Immune checkpoint inhibitor-related toxicities

Authorization of 3 months may be granted for treatment of immune checkpoint inhibitor-related toxicities.

IV. CONTINUATION OF THERAPY

For oncologic indications: Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an oncologic indication listed in Section III A. when there is no evidence of unacceptable toxicity.

For immune checkpoint inhibitor-related toxicities: Authorization of 3 months may be granted for continued treatment in members requesting reauthorization for treatment of immune checkpoint inhibitor-related toxicities who are experiencing benefit from therapy.

For all other indications: Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III B.-C. who are experiencing benefit from therapy.

V. REFERENCES

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5. Arber D, Orazi A, Vardiman J, et al. The 2016 revision to the World Health Organization classification of myeloid neoplasms and acute leukemia. *Blood*. May 19, 2016;127(20):2391-2405.
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10. Riabni [package insert]. Thousand Oaks, CA: Amgen Inc.; December 2020.