Clinical Policy Title:	rituximab, rituximab/hyaluronidase
Policy Number:	RxA.673
Drug(s) Applied:	Rituxan Hycela®, Ruxience®, Truxima®
Original Policy Date:	03/09/2021
Last Review Date:	09/03/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Follicular Lymphoma (Rituxan Hycela)

1. Diagnosis of follicular lymphoma;
2. Patient meets one of the following (a, b, or c):
    a. Disease is relapsed or refractory;
    b. Disease is non-progressing or stable following prior treatment with first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy;
    c. Disease is previously untreated and used in combination with first-line chemotherapy;
3. Trial and failure of Ruxience, unless contraindicated or clinically significant adverse events are experienced.

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Diffuse Large B-cell Lymphoma (Rituxan Hycela)

1. Diagnosis of diffuse large B-cell lymphoma;
2. Disease is previously untreated and is being used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy;
3. Trial and failure of Ruxience, unless contraindicated or clinically significant adverse events are experienced.

Approval Duration

All Lines of Business (except Medicare): 12 months

C. Chronic Lymphocytic Leukemia (Ruxience, Rituxan Hycela, Truxima)

1. Diagnosis of Chronic Lymphocytic Leukemia
2. Medication is being used in combination with fludarabine and cyclophosphamide;
3. Trial and failure of Ruxience, unless contraindicated or clinically significant adverse events are experienced.

Approval Duration

All Lines of Business (except Medicare): 12 months

D. Non-Hodgkin's Lymphoma (Ruxience, Truxima)

1. Patient meets one of the following (a or b):
    a. Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma (i, ii, or iii);

i. First-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens;
ii. First-line treatment in combination with chemotherapy;
iii. Patient has had a response to treatment following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy;

b. Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma.

2. Trial and failure of Ruxience, unless contraindicated or clinically significant adverse events are experienced.

Approval Duration
All Lines of Business (except Medicare): 12 months

E. Rheumatoid arthritis (Truxima, Ruxience) (must meet all):
1. Member has a diagnosis of moderate to severe active RA;
2. Prescribed in combination with methotrexate;
3. Trial and failure of at least two (2) of the following: adalimumab (adalimumab-adaz, Amjevita, Hadlima, Humira, Yusimry), Cimzia, Enbrel, Simponi, Rinvoq, Xeljanz or Xeljanz XR, unless contraindicated or clinically significant adverse effects are experienced.

Trial and failure of Ruxience, unless contraindicated or clinically significant adverse events are experienced.**Approval Duration**
All Lines of Business (except Medicare): 12 months

F. Autoimmune mucocutaneous blistering disease (Ruxience, Truxima) (must meet all):
1. Diagnosis of moderate to severe Pemphigus Vulgaris (PV) or Pemphigus Foliaceus (PF);
2. Prescribed in combination with a tapering course of glucocorticoids;
3. Trial and failure of Ruxience, unless contraindicated or clinically significant adverse events are experienced.

Approval Duration
All Lines of Business (except Medicare): 12 months

G. Wegener's Granulomatosis (GPA) and Microscopic Polyangiitis (Ruxience, Truxima) (must meet all):
1. Diagnosis of GPA or Microscopic Polyangiitis;
2. Prescribed in combination with glucocorticoids;
3. Trial and failure of Ruxience, unless contraindicated or clinically significant adverse events are experienced.

Approval Duration
All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval (all indications):
1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration
All Lines of Business (except Medicare): 12 months

References
1. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 24, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/15/2021	03/09/2021
Policy was reviewed: 1. Initial Approval Criteria, I.B.3: Updated age criteria from Member is 2 years of age or older to For Rituxan® age ≥ 2 years or, For Ruxience®, Truxima®, Riabni™ age ≥ 18 years. 2. References were reviewed and updated.	12/15/2021	01/17/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.2, I.B.3, I.D.3, I.G.3: Updated to include new criteria Request is for Rituxan®/Riabni™/Ruxience®/Truxima®. 2. Initial Approval Criteria I.J.1: Updated to include new off-label indication Rosai-Dorfman Disease – Histiocytic Neoplasms. 3. References were reviewed and updated.	09/20/2022	10/19/2022
Policy was reviewed: 1. Initial Approval Criteria, I.D.5: Updated to remove prior trial and failure criteria "Member has failed at least one anti-TNF therapy (e.g., adalimumab, etanercept)." 2. Initial Approval Criteria, I.D.6: Updated to include new trial and failure criteria For Ruxience®: Member meets one of the following (a or b): a. Trial and failure of at least two (2) of the following: Cimzia®, Enbrel®, Humira®, Simponi®, Rinvoq®, Xeljanz® or Xeljanz XR® unless contraindicated or clinically significant adverse effects are experienced or attestation demonstrating a trial may be inappropriate; b. Trial and failure of two TNF inhibitors: Cimzia®, Enbrel®, Humira®, Simponi®, Remicade®, Avsola®, Inflectra® or Renflexis®. 3. Initial Approval Criteria, I.D.7: Updated	01/04/2023	01/17/2023

to include new trial and failure criteria For Riabni™/Rituxan®/ Truxima® request, member meets ALL of the following (a, b and c): a. Member meets one of the following (i or ii): i. Trial and failure of at least two (2) of the following: Cimzia®, Enbrel®, Humira®, Simponi®, Rinvoq®, Xeljanz® or Xeljanz XR® unless contraindicated or clinically significant adverse effects are experienced or attestation demonstrating a trial may be inappropriate; ii. Trial and failure of two TNF inhibitors: Cimzia®, Enbrel®, Humira®, Simponi®, Remicade®, Avsola®, Inflectra® or Renflexis®. b. Trial and failure, contraindication, or intolerance to BOTH of the following: Actemra® and Orencia®; c. Trial and failure or intolerance to Ruxience®. 4. References were reviewed and updated		
Policy was reviewed: 1. Initial Approval Criteria, I.D.7.a.i and I.D.7.a.ii: Updated trial and failure criteria to include new drug Amjevita™. 2. References were reviewed and updated.	04/05/2023	04/13/2023
Policy was reviewed: 1. Updated trial and failure criteria to include Humira biosimilar. 2. Updated Approval duration. 3. Removed responding positively criteria. 4. References were reviewed and updated.	11/10/2023	10/19/2023
Policy reviewed: 1. Removed dose and age restriction 2. Clinical review 3. Removed off label use 4. Added T/F of Ruxience based on indication 5. Removed Rituxan from policy	3/1/2024	2/28/2024

Policy was reviewed. 1. Removed trial and failure of Actemra and Orencia under rheumatoid arthritis. 2. Update trial and failure language. 3. Updated continued therapy approval language to 120 days.	9/3/2024	09/12/2024