Drug Policy:

Rituximab Products (Rituxan, Rituxan Hycela, Truxima, Ruxience, Riabni)

POLICY NUMBER UM ONC_1132	**SUBJECT** Rituximab Products (Rituxan, Rituxan Hycela, Truxima, Ruxience, Riabni)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 07/22/11, 01/02/13, 03/13/13, 07/24/14, 12/16/15, 12/21/16, 12/03/17, 11/08/18, 01/09/19, 08/14/19, 12/11/19, 02/12/20, 03/11/20, 04/08/20, 10/14/20, 02/10/21	**APPROVAL DATE** February 10, 2021	**EFFECTIVE DATE** February 26, 2021	**COMMITTEE APPROVAL DATES** (latest version listed last) 07/22/11, 01/02/13, 03/13/13, 07/24/14, 12/16/15, 12/21/16, 12/03/17, 11/08/18, 01/09/19, 08/14/19, 12/11/19, 02/12/20, 03/11/20, 04/08/20, 10/14/20, 02/10/21	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Rituximab Products (Rituxan, Rituxan Hycela, Truxima, Ruxience, Riabni) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR
3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When available, generic alternatives are preferred over brand name drugs AND
6. Truxima (rituximab-abbs) and Ruxience (rituximab-pvvr) are the PREFERRED products whenever Rituximab, Rituxan Hycela, or Riabni are requested.
7. Non-preferred Rituximab will be approved only if there is a contraindication/intolerance to the PREFERRED medication.

B. CD-20 positive B-Cell Non-Hodgkin's Lymphomas

1. The member has CD20 positive B-cell NHL and rituximab (Truxima or Ruxience) is being used as a single agent or in combination with chemotherapy for ANY of the following:
    a. Initial therapy OR
    b. Treatment of relapsed or refractory disease OR
    c. Maintenance therapy:
        i. For up to two years for Indolent B-Cell Lymphomas (Follicular B Cell Lymphoma and all subtypes of Marginal Zone Lymphoma).
        ii. For up to disease progression on intolerable toxicity for Mantle Cell Lymphoma.

C. Chronic Lymphocytic Leukemia (CLL)

1. Rituximab (Truxima or Ruxience) is being used for first or subsequent line of therapy:
    a. In combination with chemotherapy OR
    b. As maintenance therapy for up to 2 years.

D. Hodgkin's Lymphoma

1. The member has nodular lymphocyte predominant Hodgkin's Lymphoma and rituximab (Truxima or Ruxience) is being used as a single agent or in combination with chemotherapy for initial or subsequent therapy OR
2. For maintenance therapy for up to 2 years.

E. Idiopathic Thrombocytopenic Purpura (ITP)

1. The member has acute ITP and rituximab (Truxima or Ruxience) is being used as a single agent AND
2. The member has ITP that is refractory to corticosteroids and IVIG AND
3. The platelet count is < 30,000 OR
4. There are other clinical indications for therapy.

III. EXCLUSION CRITERIA

A. Use of Rituximab products (Rituxan, Rituxan Hycela, Truxima, Ruxience, Riabni) as maintenance therapy after primary treatment of Diffuse Large B-Cell Lymphoma (DLBCL).

B. Dosing exceeds single dose limit of rituximab 500 mg/m² and Rituxan Hycela 1600 mg (CLL) and 1400 mg (NHL).

C. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Riabni prescribing information. Amgen. Thousand Oaks, CA 2020.

B. Rituxan Hycela prescribing information. Genetech, Inc. San Francisco, CA 2019.

C. Truxima (rituximab-abbs) prescribing information. Teva Pharmaceuticals USA, Inc. North Wales, PA 2020.

D. Rituxan prescribing information. Genetech, Inc. San Francisco, CA 2020.

E. Ruxience (rtuximab-pvvr) prescribing information. Pfizer Inc. NY, NY 2020.

F. Clinical Pharmacology Elsevier Gold Standard 2021.

G. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.

H. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2021.

I. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2021.