Blue Cross Blue Shield Blue Care Network of Michigan

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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 04/11/2024

Rituximab Class Policy

Riabni™ (rituximab-arrx)
Rituxan® (rituximab)
Rituxan Hycela® (rituximab and hyaluronidase human)
Ruxience™ (rituximab-pvvr)
Truxima™ (rituximab-abbs)

HCPCS: Riabni Q5123**;** Rituxan: J9310, J9312; Rituxan Hycela: J9311; Ruxience: Q5119; Truxima: Q5115

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. Rituxan Hycela
      i. FDA approved indications
      ii. Please provide a medical rationale as to why you need to use Rituxan Hycela over rituximab or a rituximab biosimilar
   b. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the BCBSM/BCN utilization management medical drug list

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
   c. Renewal Criteria: Treatment continued until disease progression or unacceptable toxicity

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Rituxan Hycela is a combination of rituximab and hyaluronidase human, an endoglycosidase, indicated for the treatment of adult patients with:
    - Follicular lymphoma (FL)
        - Relapsed or refractory follicular lymphoma as a single agent
        - Previously untreated follicular lymphoma in combination with first line chemotherapy and in patients achieving a complete or partial response to rituximab in combination with chemotherapy as single agent maintenance therapy
        - Non-progressing follicular lymphoma as a single agent after first-line CVP chemotherapy
    - Previously untreated diffuse large B-cell lymphoma (DLBCL) in combination with CHOP or other anthracycline-based chemotherapy regimens
    - Previously untreated and previously treated CLL in combination with FC
    - Limitations of use:
        - Treatment should only be initiated after patients have received at least one full dose of a rituximab product by intravenous infusion
        - Rituxan Hycela is not indicated for the treatment of non-malignant conditions
- Rituxan Hycela is a combination of rituximab and hyaluronidase, an enzyme that helps deliver rituximab under the skin, and can be given subcutaneously versus intravenously as with Rituxan. Rituxan Hycela cannot be given before a patient has received at least one full dose of intravenous Rituxan without adverse effects and, because of this, there would be no clinical necessity for a patient to switch from Rituxan to Rituxan Hycela as it offers no clinical safety or efficacy advantages over the intravenous product.
- NCCN guidelines state an FDA approved biosimilar can be substituted for Rituxan. The guidelines do not specify what biosimilars are appropriate for a specific tumor type which allows for use of any of the biosimilars to be used for any indication the innovator product is FDA approved for.

References:

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Policy History		
#	Date	Change Description
2.5	Effective Date: 04/11/2024	Annual review of criteria was performed, no changes were made
2.4	Effective Date: 04/06/2023	Updated the approval duration to allow for at least 60 days and up to 6 months of therapy
2.3	Effective Date: 04/14/2022	Annual review of criteria was performed, no changes were made.
2.2	Effective Date: 04/08/2021	Updated to remove FDA approved indication from the Rituxan and rituximab biosimilar products
2.1	Effective Date: 04/01/2021	UM medical management system update for Rituxan and Truxima for BCBS, BCN, BCNA, and MAPPO
2.0	Effective Date: 02/04/2021	Updated to remove prescriber requirement, not allow use with other medications for the treatment of NMOSD, remove the bullet saying Rituxan Hycela cannot be used for non-cancer indications, removed bullet stating the drugs should not be used in cases of severe infection, and added Riabni
1.9	Effective Date: 2/06/2020	Updated to add new Truxima indications
1.8	Effective Date: 12/05/2019	Updated to remove age requirements for Rituxan and added FDA approved age for age requirements
1.7	Effective Date: 08/15/2019	Updated to add new Truxima indications and Ruxience
1.6	Effective Date: 02/14/2019	Added Criteria for Truxima
1.5	Effective Date: 09/07/2018	The Treatments for RA Policy is being retired; adding RA criteria back in this document.
1.4	Effective Date: 02/08/2018	Added Criteria for Rituxan Hycela
1.3	Effective Date: 11/01/2018	Pemphigus Vulgaris indication added
1.2	Effective Date: 05/04/2017	Update to include neuromyelitis optica
1.1	Effective Date: 02/09/2017	Annual review of criteria was performed, no changes were made.
1.0	Effective date: 11/05/2015	New Policy

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*