Pharmacy Management Drug Policy

SUBJECT: Rituxan (rituximab), Truxima (rituximab-abbs), Ruxience (rituximab-pvvr), Rituxan Hycela (rituximab and hyaluronidase)
POLICY NUMBER: PHARMACY-76
EFFECTIVE DATE: 10/2018
LAST REVIEW DATE: 2/6/2020

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. Medical or drug policies apply to commercial and Health Care Reform products only when a contract benefit for the specific service exists.

DESCRIPTION:

Rituximab, a chimeric human-murine anti-human antigen CD20 monoclonal antibody, is an antineoplastic agent that binds specifically to antigen CD20 which is a hydrophobic transmembrane protein located on normal pre-B and mature B lymphocytes. Antigen CD20 also is expressed on greater than 90% of B-cell non-Hodgkin's lymphomas (NHLs) but is not found on hematopoietic stem cells, early pre-B cells, normal plasma cells, or other normal tissues. Antigen CD20 is involved in the regulation of cell cycle initiation and differentiation and also may function as a calcium ion channel. Rituximab destroys the CD20+ cells by augmenting complement-mediated lysis and participates in antibody-dependent cell-mediated cytotoxicity. This results from its ability to bind the CD20 antigen with a high affinity.

Truxima (rituximab-abbs) and Rixuence (rituximab-pvvr) are biosimilars to Rituxan (rituximab). For a biological product to be labeled as a biosimilar, it must be shown that it is highly similar and has no differences from an existing FDA approved reference product (i.e. Rituxan) by extensively analyzing the structure, purity, chemical identity, and bioactivity. It has been concluded that there are no clinically meaningful differences demonstrated through human pharmacokinetic/exposure and pharmacodynamic/responses, and assessment of immunogenicity. Biosimilars may be approved for all or a subset of the same indications as the reference product, depending on patent exclusivity. Biosimilars differ from generics in complexity, manufacturing processes, and in the data needed to demonstrate similarity for approval.

Please note: the below criteria apply to –

- **Requests for Rituxan IV, Truxima, Ruxience, and Rituxan Hycela for Managed Medicaid (MMC)/Child Health Plus (CHP)**

Rituxan IV Policy:

Based upon our assessment and review of the peer-reviewed literature, Rituxan IV has been medically proven to be effective and, therefore, medically appropriate for all FDA-approved indications and those indications which satisfy the Off-Label Use of FDA Approved Drugs policy. Due to the large range of acceptable uses for Rituxan IV and because of the complex and fluid nature of the drug regimen recommendations employed in various clinical circumstances, a list of acceptable indications is not contained in this policy. Requests for Rituxan IV use inconsistent with FDA labeling will be reviewed based on the Off-Label Use of FDA Approved Drugs policy.

Truxima Policy
Based upon our assessment and review of the peer-reviewed literature, Truxima has been medically proven to be effective and, therefore, medically appropriate for all FDA-approved indications and those indications which satisfy the Off-Label Use of FDA Approved Drugs policy. Due to the large range of acceptable uses for Truxima and because of the complex and fluid nature of the drug regimen recommendations employed in various clinical circumstances, a list of acceptable indications is not contained in this policy. Requests for Truxima use inconsistent with FDA labeling will be reviewed based on the Off-Label Use of FDA Approved Drugs policy.
In addition, Truxima will be covered for any FDA-approved indication and any indication which satisfies the Off-Label Use of FDA Approved Drugs policy for rituximab (Rituxan).

Ruxience Policy:
Based upon our assessment and review of the peer-reviewed literature, Ruxience has been medically proven to be effective and, therefore, medically appropriate for all FDA-approved indications and those indications which satisfy the Off-Label Use of FDA Approved Drugs policy. Due to the large range of acceptable uses for Ruxience and because of the complex and fluid nature of the drug regimen recommendations employed in various clinical circumstances, a list of acceptable indications is not contained in this policy. Requests for Ruxience use inconsistent with FDA labeling will be reviewed based on the Off-Label Use of FDA Approved Drugs policy.

In addition, Ruxience will be covered for any FDA-approved indication and any indication which satisfies the Off-Label Use of FDA Approved Drugs policy for rituximab (Rituxan).

Rituxan Hycela (SC) Policy:
Based upon our assessment and review of the peer-reviewed literature, **Rituxan Hycela** has been medically proven to be effective and therefore, **medically appropriate** for the following:

1. Chronic lymphocytic leukemia: Treatment of adult patients with previously untreated and previously treated chronic lymphocytic leukemia (CLL) (in combination with fludarabine and cyclophosphamide)
2. Diffuse large B-cell lymphoma: Treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL) in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens
3. Follicular lymphoma: Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) as a single agent; previously untreated FL (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); or non-progressing (including stable disease) FL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy
4. Mantle Cell lymphoma
5. AIDS related B-Cell lymphoma
6. Castleman's Disease
7. Post-Transplant lymphoproliferative disorders
8. Histologic Transformation of Marginal Zone Lymphoma to Diffuse Large B-Cell Lymphoma
9. Nongastric MALT lymphoma
10. Gastric MALT lymphoma
11. Burkitt Lymphoma
12. Nodal/Splenic Marginal Zone Lymphoma
13. Hairy Cell Leukemia

APPROVAL TIME PERIODS:

Line of Business	Medical Initial approval	Medical recertification
Medicaid Managed Care (MMC)/Child Health Plus (CHP)	6 months	12 months

POLICY GUIDELINES:

1. Prior authorization is contract-dependent.
2. Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e.; generics, biosimilars, or other guideline-supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations
3. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
    a. The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
    b. The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
    c. The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
    d. The required prescription drug(s) is (are) not in the patient’s best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
    e. The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
    f. The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
4. Rituxan carrier a Black Box warning documenting the incidence of the following:
    a. Fatal infusion reactions within 24 hours of Rituxan infusions have been reported
    b. Tumor Lysis Syndrome (TLS)- Acute renal failure requiring dialysis with instances of fatal outcomes has been reported following treatment of non- Hodgkin’s lymphoma (NHL).
    c. Severe mucocutaneous reactions with some fatal outcomes have been reported

   d. Progressive multifocal leukoencephalopathy (PML)- JC virus resulting in PML and death has been reported (thus far in patients with SLE).
5. Hepatitis B virus (HBV) reactivation with hepatic failure has been reported in patients receiving Rituxan with hematologic malignancies. Patients at high risk for HBV should be screened prior to the initiation of treatment.
6. Abdominal pain, bowel obstruction and perforation, in some cases leading to death, have been observed in patients receiving concomitant chemotherapy for DLBCL.
7. The use of Rituxan in patients w/ Rheumatoid Arthritis who have not had prior inadequate response to one or more TNF antagonists is not recommended.

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.
Codes may not be covered under all circumstances. Please read the policy and guidelines statements carefully.
Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

HCPCS:
J9310 Rituxan IV
J9311 Rituxan Hycela
Q5115 Truxima

UPDATES:

Date	Revision
2/2020	Revision
10/2019	Annual Review/P&T Approval
6/2019	Annual Review
8/2018	Created

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