Reference number(s)
2099-A

SPECIALTY GUIDELINE MANAGEMENT

RITUXAN HYCELA (rituximab and hyaluronidase human)

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
1. Adult patients with follicular lymphoma (FL):
   a. Relapsed or refractory, follicular lymphoma as a single agent
   b. 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
   c. Non-progressing (including stable disease), follicular lymphoma as a single agent after first-line CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy
2. Adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL) in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens
3. Adult patients with previously untreated and previously treated chronic lymphocytic leukemia (CLL), in combination with fludarabine and cyclophosphamide (FC)

Limitations of Use:
Initiate treatment with Rituxan Hycela only 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.

B. Compendial Uses
1. B-cell lymphomas:
   a. Castleman's disease (CD)
   b. High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
   c. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma
   d. 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
   e. Mantle cell lymphoma
2. Post-transplant lymphoproliferative disorder (PTLD)Hairy cell leukemia
3. Primary cutaneous B-cell lymphoma (e.g., cutaneous marginal zone lymphoma or cutaneous follicle center lymphomas)
4. Small lymphocytic lymphoma (SLL)
5. Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma

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

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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

III. CRITERIA FOR INITIAL APPROVAL

Prior to initiating therapy, all members must receive at least one full dose of a rituximab product by intravenous infusion without experiencing severe adverse reactions.

A. Chronic lymphocytic leukemia (CLL)/ Small lymphocytic lymphoma (SLL)
Authorization of 12 months may be granted for treatment of CD20 positive CLL or SLL.

B. Hairy cell leukemia (HCL)
Authorization of 12 months may be granted for treatment of CD20 positive HCL.

C. B-cell lymphomas
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. Castleman's disease (CD)
2. Diffuse large B-cell lymphoma (DLBCL)
3. Follicular lymphoma
4. High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
5. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma
6. Mantle cell lymphoma
7. Nodal marginal zone lymphoma
8. Post-transplant lymphoproliferative disorder (PTLD)
9. 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

D. Primary cutaneous B-cell lymphoma
Authorization of 12 months may be granted for treatment of CD20 positive primary cutaneous B-cell lymphoma (e.g., cutaneous marginal zone lymphoma or cutaneous follicle center lymphomas).

E. Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma
Authorization of 12 months may be granted for treatment of CD20 positive Waldenström macroglobulinemia/ lymphoplasmacytic lymphoma

IV. CONTINUATION OF THERAPY

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

V. REFERENCES

1. Rituxan Hycela [package insert]. South San Francisco, CA: Genentech, Inc.; March 2021.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 5, 2021.