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]
1. Adult patients with follicular lymphoma (FL):
   i. Relapsed or refractory, follicular lymphoma as a single agent
   ii. 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
   iii. 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[2]
1. Acquired immune deficiency syndrome (AIDS)-related B-cell lymphoma
2. Burkitt lymphoma
3. Castleman's disease (CD)
4. Small lymphocytic lymphoma (SLL)
5. Gastric MALT lymphoma
6. Mantle cell lymphoma
7. Nodal marginal zone lymphoma
8. Nongastric MALT lymphoma
9. Primary Cutaneous B-cell lymphoma (e.g., Cutaneous Marginal Zone lymphoma or Cutaneous Follicle Center lymphomas)
10. Post-transplant lymphoproliferative disorder (PTLD)
11. Splenic marginal zone lymphoma

All other indications are considered experimental/investigational and are not a covered benefit.

II. 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. Follicular lymphoma (FL)[1]
Authorization of 12 months may be granted for treatment of CD20 positive FL.

B. Diffuse large B-cell lymphoma (DLBCL)[1]
Authorization of 12 months may be granted for treatment of CD20 positive DLBCL.

C. Chronic lymphocytic leukemia (CLL)/ Small lymphocytic lymphoma (SLL)[1-2]
Authorization of 12 months may be granted for treatment of CLL or SLL.

D. B-cell lymphomas[2]
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. Acquired immune deficiency syndrome (AIDS)-related B-cell lymphoma
2. Burkitt lymphoma
3. Castleman's disease (CD)
4. Gastric MALT lymphoma
5. Mantle cell lymphoma
6. Nodal marginal zone lymphoma
7. Nongastric MALT lymphoma
8. Primary Cutaneous B-cell lymphoma (e.g., Cutaneous Marginal Zone lymphoma or Cutaneous Follicle Center lymphomas)
9. Post-transplant lymphoproliferative disorder (PTLD)
10. Splenic marginal zone lymphoma

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Rituxan Hycela [package insert]. South San Francisco, CA: Genentech, Inc.; March 2018.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 30, 2018.