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.

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:

1. Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion.
2. Rituxan Hycela is not indicated for the treatment of non-malignant conditions.

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. Diffuse large B-cell lymphoma (DLBCL)
Authorization of 12 months may be granted for treatment of CD20 positive DLBCL in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens in previously untreated disease.

B. Chronic lymphocytic leukemia (CLL)
Authorization of 12 months may be granted for treatment of CLL in combination with fludarabine and cyclophosphamide.

C. Follicular lymphoma (FL)

Authorization of 12 months may be granted for treatment of CD20 positive FL when used in any of the following settings:

1. As a single agent for relapsed or refractory disease
2. In combination with first line chemotherapy in previously untreated disease
3. As a single agent for maintenance therapy when member has achieved a complete or partial response to rituximab in combination with chemotherapy
4. As a single agent in non-progressing disease after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy

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.; June 2017.