Reference number
1997-A

SPECIALTY GUIDELINE MANAGEMENT

IMBRUVICA (ibrutinib)

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. Mantle Cell Lymphoma (MCL)
   Imbruvica is indicated for the treatment of adult patients with MCL who have received at least one prior therapy.

2. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)
   i. Imbruvica is indicated for the treatment of adult patients with CLL/SLL.
   ii. Imbruvica is indicated for the treatment of adult patients with CLL/SLL with 17p deletion.

3. Waldenström's Macroglobulinemia (WM)
   Imbruvica is indicated for the treatment of adult patients with WM.

4. Marginal Zone Lymphoma (MZL)
   Imbruvica is indicated for the treatment of adult patients with MZL who require systemic therapy and have received at least one prior anti-CD20-based therapy.

5. Chronic Graft versus Host Disease (cGVHD)
   Imbruvica is indicated for the treatment of adult patients with cGVHD after failure of one or more lines of systemic therapy.

B. Compendial Use

1. Mantle cell lymphoma, in combination with rituximab as pretreatment in order to limit the number of cycles of less aggressive induction therapy with RHyperCVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen
2. Gastric MALT lymphoma, second-line or subsequent therapy for recurrent or progressive disease
3. Non-gastric MALT lymphoma, second-line or subsequent therapy for refractory or progressive disease
4. Hairy cell leukemia, for progression
5. Lymphoplasmacytic lymphoma (LPL)
6. Primary central nervous system lymphoma, for relapsed or refractory disease
7. Follicular lymphoma
8. Nodal marginal zone lymphoma, second-line or subsequent therapy for refractory or progressive disease
9. Splenic marginal zone lymphoma, second-line or subsequent therapy for refractory or progressive disease
10. Histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma in patients who have received prior chemoimmunotherapy

11. Diffuse large B-cell lymphoma, second-line or subsequent therapy for refractory or progressive disease
12. AIDS-related B-cell lymphoma, for second-line or subsequent therapy for relapsed disease
13. Post-transplant lymphoproliferative disorders, subsequent therapy for patients with partial response, persistent, or progressive disease after receiving chemoimmunotherapy

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

II. CRITERIA FOR INITIAL APPROVAL

A. Mantle Cell Lymphoma (MCL)
Authorization of 12 months may be granted to members with MCL who meet one of the following criteria:
1. The patient has received at least one prior therapy.
2. Imbruvica will be used in combination with rituximab as pretreatment to induction therapy with RHyperCVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen.

B. Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL)
Authorization of 12 months may be granted to members with CLL/SLL.

C. Waldenström's Macroglobulinemia/lymphoplasmacytic lymphoma (WM/LPL)
Authorization of 12 months may be granted to members with WM/LPL.

D. Marginal Zone Lymphoma (MZL)
Authorization of 12 months may be granted to members with MZL who require systemic therapy and who have received at least one prior anti-CD20-based therapy.

E. Chronic Graft-Versus-Host Disease (cGVHD)
Authorization of 12 months may be granted to members with cGVHD who have failed one or more lines of systemic therapy.

F. Gastric MALT Lymphoma and Non-gastric MALT Lymphoma
Authorization of 12 months may be granted to members with recurrent, refractory, or progressive gastric or non-gastric MALT lymphoma as second-line or subsequent therapy.

G. Hairy Cell Leukemia
Authorization of 12 months may be granted to members with hairy cell leukemia when Imbruvica is used for disease progression.

H. Primary central nervous system lymphoma
Authorization of 12 months may be granted to members with relapsed or refractory primary central nervous system lymphoma.

I. Follicular lymphoma
Authorization of 12 months may be granted to members with follicular lymphoma.

J. Nodal marginal zone lymphoma
Authorization of 12 months may be granted to members with refractory or progressive nodal marginal zone lymphoma when Imbruvica is used as second-line or subsequent therapy.

K. Splenic marginal zone lymphoma

Authorization of 12 months may be granted to members with refractory or progressive splenic marginal zone lymphoma when Imbruvica is used as second-line or subsequent therapy.

L. Histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma
Authorization of 12 months may be granted to members with histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma in patients who have received prior chemoimmunotherapy.

M. Diffuse large B-cell lymphoma
Authorization of 12 months may be granted to members with refractory or progressive diffuse large B-cell lymphoma when Imbruvica is used as second-line or subsequent therapy.

N. AIDS-related B-cell lymphoma
Authorization for 12 months may be granted to members with relapsed AIDS-related B-cell lymphoma when Imbruvica is used as second-line or subsequent therapy.

O. Post-transplant lymphoproliferative disorders
Authorization for 12 months may be granted to members with partial response, persistent, progressive post-transplant lymphoproliferative disorders after receiving chemoimmunotherapy.

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

1. Imbruvica [package insert]. Sunnyvale, CA: Pharmacyclics LLC; February 2018.
2. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed August 2, 2018.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: B-cell Lymphomas. Version 4.2018. https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed August 28, 2017.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia. Version 4.2018. https://www.nccn.org/professionals/physician_gls/pdf/hairy_cell.pdf. Accessed August 2, 2018.