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 aggressive induction therapy with RHyperCVAD (rituximab, 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 or induction therapy
7. Follicular lymphoma, second-line or subsequent therapy
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
10. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma in members who have received prior chemoimmunotherapy
11. Histologic transformation of follicular lymphoma to diffuse large B-cell lymphoma

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

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

II. CRITERIA FOR INITIAL APPROVAL

A. Mantle Cell Lymphoma (MCL)
Authorization of 12 months may be granted for the treatment of MCL when any of the following criteria is met:
1. The member has received at least one prior therapy when the requested medication is used as a single agent or in combination with rituximab.
2. The requested medication will be used in combination with rituximab as pretreatment to induction therapy with RHyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen.

B. Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL)
Authorization of 12 months may be granted for the treatment of CLL/SLL as a single agent, in combination with rituximab or obinutuzumab, or in combination with bendamustine and rituximab.

C. Waldenström's Macroglobulinemia/lymphoplasmacytic lymphoma (WM/LPL)
Authorization of 12 months may be granted for the treatment of WM/LPL when the requested medication is used as a single agent or in combination with rituximab.

D. Marginal Zone Lymphoma (MZL)
Authorization of 12 months may be granted for the treatment of MZL, such as gastric or non-gastric MALT lymphoma, nodal marginal zone lymphoma, or splenic marginal zone lymphoma when the member has received at least one prior therapy.

E. Chronic Graft-Versus-Host Disease (cGVHD)
Authorization of 12 months may be granted for the treatment of cGVHD when the member has failed one or more lines of therapy.

F. Hairy Cell Leukemia
Authorization of 12 months may be granted for the treatment of hairy cell leukemia when the requested medication is used as a single agent for disease progression.

G. Primary central nervous system lymphoma
Authorization of 12 months may be granted for treatment of primary central nervous system lymphoma when any of the following criteria is met:
1. The requested medication is used for relapsed or refractory disease as either a single agent, or in combination with high-dose methotrexate and rituximab.
2. The requested medication is used for induction therapy as a single agent.

H. Follicular lymphoma (FL)
Authorization of 12 months may be granted for the treatment of follicular lymphoma when the requested medication is used as a single agent, as second line or subsequent therapy.

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

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

K. Diffuse large B-cell lymphoma
Authorization of 12 months may be granted for the treatment of diffuse large B-cell lymphoma when the requested medication is used as second-line or subsequent therapy.

L. High-grade B-cell lymphoma
Authorization of 12 months may be granted for the treatment of high-grade B-cell lymphoma when the requested medication is used as second-line or subsequent therapy.

M. AIDS-related B-cell lymphoma
Authorization of 12 months may be granted for the treatment of relapsed AIDS-related B-cell lymphoma when the requested medication is used as a single agent and as second-line or subsequent therapy.

N. Post-transplant lymphoproliferative disorders
Authorization of 12 months may be granted for the treatment of post-transplant lymphoproliferative disorders in members who have received prior chemoimmunotherapy.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Imbruvica [package insert]. Sunnyvale, CA: Pharmacyclics LLC; April 2020.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed July 1, 2020.