Reference number
2073-A

SPECIALTY GUIDELINE MANAGEMENT

ARZERRA (ofatumumab)

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
Chronic lymphocytic leukemia (CLL):
1. Arzerra is indicated in combination with chlorambucil, for the treatment of previously untreated patients with CLL for whom fludarabine-based therapy is considered inappropriate.
2. Arzerra is indicated in combination with fludarabine and cyclophosphamide for the treatment of patients with relapsed CLL.
3. Arzerra is indicated for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL.
4. Arzerra is indicated for the treatment of patients with CLL refractory to fludarabine and alemtuzumab.

B. Compendial Uses
1. CLL
2. Small lymphocytic lymphoma (SLL) (managed in the same manner as CLL)
3. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma
4. Follicular lymphoma, substitute for rituximab or obinutuzumab in patients experiencing intolerance or rare complications from rituximab or obinutuzumab
5. Gastric MALT lymphoma, substitute for rituximab or obinutuzumab in patients experiencing intolerance or rare complications from rituximab or obinutuzumab
6. Non-gastric MALT lymphoma, substitute for rituximab or obinutuzumab in patients experiencing intolerance or rare complications from rituximab or obinutuzumab
7. Nodal marginal zone lymphoma, substitute for rituximab or obinutuzumab in patients experiencing intolerance or rare complications from rituximab or obinutuzumab
8. Splenic marginal zone lymphoma, substitute for rituximab or obinutuzumab in patients experiencing intolerance or rare complications from rituximab or obinutuzumab
9. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma, substitute for rituximab or obinutuzumab in patients experiencing intolerance or rare complications from rituximab or obinutuzumab
10. Mantle cell lymphoma, substitute for rituximab or obinutuzumab in patients experiencing intolerance or rare complications from rituximab or obinutuzumab
11. Diffuse large B-cell lymphoma, substitute for rituximab or obinutuzumab in patients experiencing intolerance or rare complications from rituximab or obinutuzumab
12. High-grade B-cell lymphomas, substitute for rituximab or obinutuzumab in patients experiencing intolerance or rare complications from rituximab or obinutuzumab
13. Burkitt lymphoma, substitute for rituximab or obinutuzumab in patients experiencing intolerance or rare complications from rituximab or obinutuzumab
14. AIDS-related B-cell lymphomas, substitute for rituximab or obinutuzumab in patients experiencing intolerance or rare complications from rituximab or obinutuzumab

15. Post-transplant lymphoproliferative disorders, substitute for rituximab or obinutuzumab in patients experiencing intolerance or rare complications from rituximab or obinutuzumab
16. Castleman's disease, substitute for rituximab or obinutuzumab in patients experiencing intolerance or rare complications from rituximab or obinutuzumab

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

II. CRITERIA FOR INITIAL APPROVAL

A. Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL)
Authorization of 6 months may be granted for the treatment of CLL or SLL.

B. Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL)
Authorization of 6 months may be granted for the treatment of Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma when all of the following criteria are met:
1. The disease is relapsed, refractory, or progressive, and
2. The member is intolerant to rituximab.

C. Follicular Lymphoma (FL), Gastric and Non-Gastric MALT Lymphoma, Nodal Marginal Zone Lymphoma, Splenic Marginal Zone Lymphoma, Histologic Transformation of Nodal Marginal Zone Lymphoma to Diffuse Large B-Cell Lymphoma, Mantle Cell Lymphoma, Diffuse Large B-Cell Lymphoma, High-Grade B-Cell Lymphomas, Burkitt Lymphoma, AIDS-Related B-Cell Lymphomas, Post-Transplant Lymphoproliferative Disorders, and Castleman's Disease
Authorization of 6 months may be granted for the treatment of follicular lymphoma (FL), gastric or non-gastric MALT lymphoma, nodal marginal zone lymphoma, splenic marginal zone lymphoma, histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma, mantle cell lymphoma, diffuse large B-cell lymphoma, high-grade B-cell lymphomas, Burkitt lymphoma, AIDS-related B-cell lymphomas, post-transplant lymphoproliferative disorders, or Castleman's disease when the requested medication is used as a substitute for rituximab or obinutuzumab in members experiencing intolerance or rare complications from rituximab or obinutuzumab such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis.

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. Arzerra [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2016.
2. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed June 1, 2021.