Mass General Brigham
Health Plan

Lymphoma and Leukemia Agents
Arzerra (ofatumumab vial)
Gazyva (obinutuzumab)
Zynlonta (loncastuximab tesirine-lpyl)
Effective 06/01/2025

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	Zynlonta is also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview

Arzerra (ofatumumab) is indicated:

- in combination with chlorambucil, for the treatment of previously untreated patients with CLL for whom fludarabine-based therapy is considered inappropriate
- in combination with fludarabine and cyclophosphamide for the treatment of patients with relapsed CLL
- for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL
- for the treatment of patients with CLL refractory to fludarabine and alemtuzumab

Gazyva (obinutuzumab) is indicated:

- in combination with chlorambucil, is indicated for the treatment of patients with previously untreated chronic lymphocytic leukemia
- in combination with bendamustine followed by Gazyva monotherapy, is indicated for the treatment of patients with follicular lymphoma who relapsed after, or are refractory to, a rituximab-containing regimen.
- in combination with chemotherapy followed by Gazyva monotherapy in patients achieving at least a partial remission, is indicated for the treatment of adult patients with previously untreated stage II bulky, III or IV follicular lymphoma.

Zynlonta (loncastuximab) is indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low-grade lymphoma, and high-grade B-cell lymphoma.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Gazyva (obinutuzumab)
Follicular Lymphoma
1. Diagnosis of FL
2. Member is ≥ 18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing
5. **ONE** of the following:
    a. Paid claims or physician attestation of a relapsed or refractory FL after treatment with a rituximab-containing regimen
    b. Concurrent therapy with first-line chemotherapy agent

Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma
1. Diagnosis of CLL or SLL
2. Member is ≥ 18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing
5. **ONE** of the following:
    a. Member has CLL or SLL without del(17p)/TP53 mutation
    b. Member has CLL or SLL with del(17p)/TP53 mutation AND is treatment naive

Arzerra (ofatumumab vial)
Chronic lymphocytic leukemia (CLL) (relapsed or refractory)
1. Diagnosis of CLL (relapsed or refractory)
2. Member is ≥ 18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing
5. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to **BOTH** of the following:
    a. fludarabine
    b. Campath (alemtuzumab) *(available for CLL treatment free of charge through the Campath Distribution Program)*

CLL (untreated)
1. Diagnosis of CLL (untreated)
2. Member is ≥ 18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing
5. Contraindication to fludarabine
6. **ONE** of the following:
    a. Requested agent will be used in combination with chlorambucil
    b. Clinical rationale why it will not be used with chlorambucil

Zynlonta (loncastuximab tesirine-lpyl)
Large B-Cell Lymphoma (Relapsed or Refractory)

1. Diagnosis of relapsed or refractory large B-cell lymphoma
2. Member is ≥ 18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing
5. Prior therapy with at least TWO prior chemotherapy regimens, or contraindication to ALL recommended chemotherapy regimens

Members who have already started treatment and are currently stable on any of the medications above may be approved for any FDA-approved indication.

Continuation of Therapy

For **Arzerra** (ofatumumab vial), clinical rationale for use of the agent beyond the FDA-approved duration of therapy is required.

For **all other agents**, reauthorization requires physician attestation that indicates a positive response to therapy.

Limitations

1. Initial approvals and reauthorizations will be for 6 months.

References

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Review History

07/20/22 – Reviewed and created for July P&T; matched MH UPPL. Separated out Comm/Exch vs MassHealth (Brukinsa policy). Added Aliqopa (copanlisib), Calquence (acalabrutinib), Copiktra (duvelisib), Imbruvica (ibrutinib), Venclexta (venetoclax), and Zydelig (idelalisib) to criteria. Criteria was renamed to Lymphoma and Leukemia agents. Effective 9/01/22.

01/11/2023 – Reviewed and updated for Jan P&T. Admin update to note that Aliqopa is available through medical benefit only. Guideline updated to include two off label indications (Venclexta for MM, Imbruvica for CNS Lymphoma). Updated appendix: "First-line chemo-immunotherapy for CLL/SLL". Effective 3/1/23.

04/12/23 – Reviewed and updated for P&T. Added Arzerra (ofatumumab vial), Gazyva (obinutuzumab), Leukeran(chlorambucil), Zynlonta (loncastuximab tesirine-lpyl) to criteria. Added appendix for members stable on Copiktra or Zydelig for a withdrawn indication. Effective 5/1/23.

09/13/23 – Reviewed and updated for P&T. Imbruvica suspension added to policy using the existing Imbruvica criteria. Criteria for Imbruvica for MCL and MZL was moved to an appendix section due to voluntary withdrawal

by the manufacturer. Added criteria for Calquence for MZL off-label use based on NCCN guideline. Criteria for Brukinsa for CLL/SLL added to reflect expanded FDA approval. Updated Calquence CLL/SLL criteria to remove requirement that the agent be used in combination with obinutuzumab based on NCCN guideline recommendations. Zydelig criteria for
CLL updated to be consistent with the NCCN guideline. Criteria for Imbruvica for cGVHD was updated to reflect expansion to pediatric patients 1 year of age and older. Venclexta criteria for AML updated to be consistent with NCCN guidelines. Brand preferred and mandatory generic language was added under Limitations. Formatting updates made throughout. Effective 10/2/23.
12/13/23 – Reviewed and updated for P&T. Added Jaypirca to criteria requiring PA and QL. Effective 1/2/24
05/15/25 – Reviewed and updated for P&T. Updated formatting and references. Only applicable medical benefit drugs remain while other Rx drugs should be available on the MHDL. Aliqopa has been removed due to FDA withdrawal. Effective 6/1/25