Mass General Brigham
Health Plan

Lymphoma and Leukemia Agents:
Aliqopa (copanlisib)
Arzerra (ofatumumab vial)
Brukinsa (zanubrutinib)
Calquence (acalabrutinib)
Copiktra (duvelisib)
Gazyva (obinutuzumab)
Imbruvica (ibrutinib)
Jaypirca (pirtobrutinib)
Leukeran (chlorambucil)
Venclexta (venetoclax)
Zydelig (idelalisib)
Zynlonta (loncastuximab tesirine-lpyl)
Effective 01/02/2024

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications**		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	Aliqopa, Arzerra, Gazyva are available through medical benefit only. Zynlonta is available through both pharmacy and medical benefits.		

Overview

No PA	Drugs that require PA
There are therapeutic alternatives recommended by the NCCN guidelines for treatment of AML, cGVHD, CLL, FL, MCL, MCL, MZL, SLL, and WM.	Aliqopa (copanlisib) [MB] Arzerra (ofatumumab vial) [MB] Brukinsa (zanubrutinib) Calquence (acalabrutinib) Copiktra (duvelisib) Gazyva (obinutuzumab) [MB] Imbruvica (ibrutinib) Jaypirca (pirtobrutinib) Leukeran (chlorambucil) ‡ Venclexta (venetoclax) Zydelig (idelalisib) Zynlonta (loncastuximab tesirine-lpyl)[DUAL]

cGVHD=chronic graft versus host disease, CLL=chronic lymphocytic leukemia, FL=follicular lymphoma, MCL=mantle cell lymphoma, MZL=marginal zone lymphoma, NCCN=National Comprehensive Cancer Network, SLL=small lymphocytic lymphoma, WM=Waldenström's macroglobulinemia, AML= Acute myeloid leukemia
MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. The plan does not pay for this drug to be dispensed through the retail pharmacy.
DUAL – Available through pharmacy and medical benefits
‡ This product does not participate in the federal drug rebate program. Please see the Non-FDA and Non-rebate products guideline for more information

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:

Follicular lymphoma (FL)

Aliqopa (copanlisib)

ALL of the following:

1. Diagnosis of FL
2. Member is ≥18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing
5. Paid claims or physician attestation of prior therapy for the treatment of FL with at least **TWO** systemic therapies (*See Appendix III for appropriate therapy)*

Gazyva (obinutuzumab)
ALL of the following:

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 *(See Appendix III for appropriate prior therapy)*
    b. Concurrent therapy with first-line chemotherapy agent *(See Appendix III)*

Leukeran (chlorambucil)
ALL of the following:

1. Diagnosis of FL
2. Member is ≥ 18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing
5. Physician attestation of inadequate response, adverse reaction or contraindication to rituximab monotherapy.

Chronic lymphocytic leukemia (CLL) (relapsed or refractory)

Arzerra (ofatumumab vial)
ALL of the following:

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)*

<u>CLL (untreated)</u>
Arzerra (ofatumumab vial)
ALL of the following:

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

<u>Mantle cell lymphoma (MCL)</u>
Brukinsa (zanubrutinib)
Calquence (acalabrutinib)
Jaypirca (pirtobrutinib)
ALL of the following:

1. Diagnosis of MCL
2. Member is ≥18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing
5. **ONE** of the following:
    a. For **Brukinsa** or **Calquence**, Paid claims or physician attestation of prior therapy with at least ONE systemic therapy *(See Appendix I for appropriate prior therapy)*
    b. For **Jaypirca**, Prior therapy for the treatment of MCL with at least two lines of systemic therapy one of which should be a BTK inhibitor *(e.g., Calquence® [acalabrutinib], Imbruvica® [ibrutinib], or Brukinsa® [zanubrutinib]))*
        i. Requested quantity is ≤ 2 tablets/day

<u>Marginal zone lymphoma (MZL)</u>
Brukinsa (zanubrutinib)
ALL of the following:

1. Diagnosis of MZL
2. Member is ≥18 years of age
3. Prescriber is an oncologist or hematologist

4. Appropriate dosing
5. Paid claims or physician attestation of prior therapy for with at least ONE anti-CD20 monoclonal antibody based regimen *(e.g., Gazyva (obinutuzumab) and Rituxan (rituximab) as well as all rituximab biosimilars)*

Calquence (acalabrutinib)
ALL of the following:
1. Diagnosis of MZL *(off-label)*
2. Member is ≥ 18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing
5. Physician attestation of prior therapy with at least ONE systemic therapy (See Appendix V for appropriate prior therapy)

Leukeran (chlorambucil)
ALL of the following:
1. Diagnosis of MZL
2. Member is ≥ 18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing
5. Physician attestation of inadequate response, adverse reaction or contraindication to rituximab monotherapy.

<u>Waldenstrom's macroglobulinemia (WM)</u>
Brukinsa (zanubrutinib)
Imbruvica (ibrutinib)
ALL of the following:
1. Diagnosis of WM
2. Member is ≥18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing

<u>Chronic lymphocytic leukemia (CLL) or Small lymphocytic lymphoma (SLL)</u>
Brukinsa (zanubrutinib)
ALL of the following:
1. Diagnosis of ONE of the following:
    a. CLL
    b. SLL
2. Member is ≥ 18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing

Calquence (acalabrutinib)
ALL of the following:
1. Diagnosis of CLL or SLL
2. Member is ≥ 18 years of age
3. Prescriber is an oncologist or hematologist

4. Appropriate dosing

Copiktra (duvelisib)
ALL of the following:
1. Diagnosis of CLL or SLL (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 prior therapy with at least TWO systemic therapies* (*See Appendix II for appropriate prior therapy*)

**Radiation therapy can be counted as one prior therapy*

Gazyva (obinutuzumab)
ALL of the following:
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

Imbruvica (ibrutinib)
ALL of the following:
1. Diagnosis of CLL or SLL
2. Member is ≥18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing

Leukeran (chlorambucil)
ALL of the following:
1. Diagnosis of CLL or SLL
2. Member is ≥ 18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing
5. Paid claims or physician attestation of prior therapy at least TWO systemic therapies *(See Appendix II for appropriate prior therapy)*

Venclexta (venetoclax)
ALL of the following:
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 not received treatment for CLL or SLL AND requested agent will be used in combination with Gazyva (obinutuzumab)

b. Paid claims or physician attestation of prior therapy with at least ONE systemic therapy *(See Appendix II for appropriate prior therapy)*

Zydelig (idelalisib)
ALL of the following:
1. Diagnosis of CLL
2. Member is ≥18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing
5. **ONE** of the following:
    a. Relapsed or refractory CLL
    b. Paid claims or physician documentation of prior therapy with at least ONE systemic therapy *(See Appendix II for appropriate prior therapy)*

Chronic graft versus host disease (cGVHD)
Imbruvica (ibrutinib)
ALL of the following:
1. Diagnosis of cGVHD
2. Member is ≥ 1 year of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing
5. Physician attestation of inadequate response or adverse reaction to ONE or contraindication to ALL systemic glucocorticoids

Acute myeloid leukemia (AML)
Venclexta (venetoclax)
ALL of the following:
1. Diagnosis of AML
2. Prescriber is an oncologist or hematologist
3. Appropriate dosing
4. **ONE** of the following:
    a. Member is not a candidate for intensive induction therapy
    b. Member has poor-risk AML
    c. Clinical rationale for use of requested agent instead of intensive induction chemotherapy
5. Requested agent will be used in combination with azacitidine, decitabine, or low-dose cytarabine

Central Nervous System (CNS) Lymphoma
Imbruvica (ibrutinib)
ALL of the following:
1. Diagnosis of CNS lymphoma *(off-label)*
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 a methotrexate-based regimen

Multiple Myeloma

Venclexta (venetoclax)
ALL of the following:

1. Diagnosis of multiple myeloma *(off-label)*
2. Member is ≥ 18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing
5. Documentation of t(11;14) mutation
6. Paid claims or physician attestation of prior therapy with at least **ONE** prior chemotherapy regimen

Large B-Cell Lymphoma (Relapsed or Refractory)

Zynlonta (loncastuximab tesirine-lpyl)

ALL of the following:

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 *(See Appendix VI for appropriate prior therapy)*

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), need clinical rationale for use of the agent beyond the FDA-approved duration of therapy.

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.
2. **Requests for Brand Name when generic is preferred:** In addition to any prior authorization requirements that may be listed above, if an A-rated generic equivalent is available, such prior authorization requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the generic equivalent drug (history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug is acceptable).
3. **Requests for generic when Brand Name is preferred:** There are some drugs for which the Plan has determined it will be cost effective to prefer the use of the Brand Name formulation. In this case, the generic equivalent formulation is considered non-preferred and requires prior authorization. These requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the Brand Name formulation. For the most up to date list of drugs where the Brand Name formulation is preferred, see the MassHealth Brand Name Preferred Over Generic Drug List (BOGL) at www.mass.gov/druglist.
4. The following quantity limits apply:

Brukinsa 80 mg	120 capsules per 30 days
Calquence 100 mg	120 capsules per 30 days

Imbruvica 70 mg, 420 mg, 560 mg	30 units per 30 days
Imbruvica 140 mg	90 capsules per 30 days
Jaypirca 50 mg, 100 mg	60 tablets per 30 days
Venclexta 100 mg	180 tablets per 30 days
Venclexta 10 mg, 50 mg	120 tablets per 30 days
Venclexta starter pack	1 pack per 28 days
Zydelig 100 mg, 150 mg	60 tablets per 30 days

Appendix

Appendix I: First-line induction therapy for MCL

The NCCN Guidelines for the treatment of B-Cell Lymphomas (section on MCL) note that first-line therapy for patients with MCL are stratified into aggressive and less aggressive regimens. Examples of acceptable induction chemo-immunotherapy regimens (both aggressive and less aggressive) are listed below. Please note this list is **not** all inclusive.

a. Rituximab, dexamethasone, and cytarabine + platinum (carboplatin, cisplatin, or oxaliplatin) (RDHAP)
b. Alternating RCHOP and rituximab, dexamethasone, cisplatin and cytarabine (RDHAP)
c. Rituximab plus cyclophosphamide, vincristine, doxorubicin, and prednisone (maxi-CHOP) alternating with rituximab plus high dose cytarabine (NORDIC regimen)
d. Cyclophosphamide, vincristine, doxorubicin and dexamethasone alternating with high-dose methotrexate and cytarabine (HyperCVAD) and rituximab
e. Bendamustine and rituximab
f. Bortezomib, rituximab, cyclophosphamide, doxorubicin, and prednisone (VR-CAP)
g. Rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone (RCHOP)
h. Lenalidomide plus rituximab
i. Modified HyperCVAD and rituximab
j. Rituximab, bendamustine, plus cytarabine (RBAC500)

Members may receive other lines of therapy not indicated in the latest update of the NCCN guidelines.

Appendix II: First-line chemo-immunotherapy for CLL/SLL

Examples of acceptable chemo-immunotherapy regimens recommended by the NCCN guidelines are listed below. Please note this list is not all inclusive.

First-line treatment options for CLL/SLL (without del[17p]/TP53 mutation) include:
Preferred Regimens:

- Calquence (acalabrutinib) with or without Gazyva (obinutuzumab) (category 1)
- Venclexta (venetoclax) plus Gazyva (obinutuzumab) (category 1)
- Brukinsa(zanubrutinib) (category 1)

Other Recommended Regimens:

- Imbruvica (ibrutinib) monotherapy (category 1)
- Bendamustine plus an anti-CD20 monoclonal antibody
- Leukeran (chlorambucil) plus Gazyva (obinutuzumab)
- Gazyva (obinutuzumab) monotherapy
- High-dose methylprednisolone plus rituximab or Gazyva (obinutuzumab)
- Imbruvica (ibrutinib) plus Gazyva (obinutuzumab) (category 2B)
- Imbruvica (ibrutinib) plus rituximab (category 2B)

- Imbruvica (ibrutinib) plus Venclexta (venetoclax) (category 2B)

First-line treatment options for CLL/SLL (with del[17p]/TP53 mutation) include:
Preferred Regimens:
- Calquence (acalabrutinib) with or without Gazyva (obinutuzumab)
- Venclexta (venetoclax) plus Gazyva (obinutuzumab)
- Brukinsa(zanubrutinib)

Other Recommended Regimens:
- Alemtuzumab with or without rituximab
- High-dose methylprednisolone plus rituximab
- Imbruvica (ibrutinib)
- Gazyva (obinutuzumab) monotherapy
- Imbruvica (ibrutinib) plus Venclexta (venetoclax)

Appendix III: First-line chemo-immunotherapy for FL

Examples of acceptable chemo-immunotherapy regimens recommended by the NCCN guidelines are listed below. Please note this list is not all inclusive.

First-line treatment options for FL include:

a. Radioimmunotherapy
b. Bendamustine plus obinutuzumab or rituximab
c. Cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) plus obinutuzumab or rituximab
d. Cyclophosphamide, vincristine, prednisone (CVP) plus obinutuzumab or rituximab
e. Lenalidomide plus rituximab or obinutuzumab
f. Rituximab monotherapy
g. Chlorambucil with or without rituximab
h. Cyclophosphamide with or without rituximab
i. Ibritumomab tiuxetan

Appendix IV: Systemic Therapies for Chronic Graft-versus-Host Disease

Treatment is not clearly defined for cGVHD but often includes use of corticosteroids as first-line treatment. In treating resistant disease, the following may be used (however, data is mixed):

a. Calcineurin inhibitors (cyclosporine, tacrolimus)
b. Mycophenolate mofetil
c. Sirolimus
d. Ruxolitinib
e. Rituximab
f. imatinib
h. Interleukin-2
i. Abatacept
j. Alemtuzumab
k. Belumosudil
l. Etanercept
m. Hydroxychloroquine

n. Ibrutinib
o. Low-dose methotrexate
p. Extracorporeal photopheresis (ECP)

Appendix V: First- and Second-Line Therapies for Marginal Zone Lymphomas

Examples of acceptable chemo-immunotherapy regimens recommended by the NCCN guidelines are listed below. Please note this list is not all inclusive.

First line treatments for MZL include:

a. Bendamustine plus rituximab
b. RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)
c. RCVP (rituximab, cyclophosphamide, vincristine, prednisone)
d. Rituximab monotherapy
f. Lenalidomide plus rituximab
g. Single-agent alkylators with or without rituximab (elderly or infirm patients)

Second-line and subsequent therapy includes acalabrutinib, bendamustine plus obinutuzumab or rituximab, ibrutinib, lenalidomide with or without rituximab or with obinutizimab and zanubrutinib in addition to first-line chemoimmunotherapy.

Appendix VI: Copiktra (duvelisib), Imbruvica (ibrutinib), and Zydelig (idelalisib) Withdrawn Indications

Members stable on therapy

For members previously approved by the plan for Zydelig (idelalisib), Imbruvica (ibrutinib) or Copiktra (duvelisib) for a withdrawn indication, the request can be recertified for up to **6 months**.

For members stable on Zydelig (idelalisib), Imbruvia (ibrutinib), or Copiktra (duvelisib) for a withdrawn indication who have not previously been approved by the plan, requests will be reviewed on a case by case basis and approval is strongly considered.

New Starts

Requests for members not yet stable on Zydelig (idelalisib), Imbruvia (ibrutinib), or Copiktra (duvelisib) should be reviewed using the criteria below:

Copiktra (duvelisib) and Zydelig (idelalisib) for FL

ALL of the following:

1. Diagnosis of FL
2. Member is ≥18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing
5. Paid claims or physician documentation of prior therapy for the treatment of FL with at least two systemic therapies *(See Appendix III for appropriate therapy)*
6. Compelling clinical rationale for use of the requested agent instead of **ALL** FDA-approved regimens.

Zydelig (idelalisib) for SLL

ALL of the following:

1. Diagnosis of SLL

2. Member is ≥18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing
5. Paid claims or physician documentation of prior therapy for the treatment of SLL with at least two systemic therapies *(See Appendix II for appropriate prior therapy)*
6. Compelling clinical rationale for use of the requested agent instead of **ALL** FDA-approved regimens.

Imbruvica (ibrutinib) for MCL/MZL
ALL of the following:
1. Diagnosis of ONE of the following:
    a. MCL
    b. MZL
2. Member is ≥ 18 years of age
3. Appropriate dosing
4. Prescriber is an oncologist or hematologist
5. Prior therapy for the treatment of MCL or MZL with at least systemic therapy
6. Compelling clinical rationale for use of the requested agent instead of ALL FDA-approved regimens.

Dosing:
Copiktra (duvelisib): Relapsed or refractory FL: 25 mg orally twice daily
Imbruvica (ibrutinib): MCL, MZL: 560 mg QD
Zydelig (idelalisib): FL, SLL: 150 mg twice daily

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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