



Lymphoma and Leukemia Agents
Aliqopa (copanlisib)
Brukinsa (zanubrutinib)
Calquence (acalabrutinib)
Copiktra (duvelisib)
Imbruvica (ibrutinib)
Venclexta (venetoclax)
Zydelig (idelalisib)
Effective 3/1/2023

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		<input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	These medications has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
Exchange	Phone: 855-582-2022	Fax: 855-245-2134	
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	Aliqopa is available through medical benefit only.		

Overview

Approval Diagnosis:

- Acute myeloid leukemia (AML) - Venclexta® (venetoclax)
- Chronic graft versus host disease (cGVHD) - Imbruvica® (ibrutinib)
- Chronic lymphocytic leukemia (CLL) - Calquence® (acalabrutinib), Copiktra® (duvelisib), Imbruvica® (ibrutinib), Venclexta® (venetoclax), Zydelig® (idelalisib)
- Follicular lymphoma (FL) - Aliqopa® (copanlisib), Zydelig® (idelalisib)
- Mantle cell lymphoma (MCL) - Brukinsa® (zanubrutinib), Calquence® (acalabrutinib), Imbruvica® (ibrutinib)
- Marginal zone lymphoma (MZL) - Brukinsa® (zanubrutinib), Imbruvica® (ibrutinib)
- Small lymphocytic lymphoma (SLL) - Calquence® (acalabrutinib), Copiktra® (duvelisib), Imbruvica® (ibrutinib), Venclexta® (venetoclax)
- Waldenstrom’s macroglobulinemia (WM) - Brukinsa® (zanubrutinib), Imbruvica® (ibrutinib)

No PA	Drugs that require PA
There are therapeutic alternatives recommended by the NCCN guidelines for treatment of AML,	Aliqopa® (copanlisib)
	Brukinsa® (zanubrutinib)



cGVHD, CLL, FL, MCL, MCL, MZL, SLL, and WM.	Calquence [®] (acalabrutinib)
	Copiktra [®] (duvelisib)
	Imbruvica [®] (ibrutinib)
	Venclexta [®] (venetoclax)
	Zydelig [®] (idelalisib)

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

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)

Prescriber provides documentation of **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)*

Mantle cell lymphoma (MCL)

Brukinsa[®] (zanubrutinib)

Calquence[®] (acalabrutinib)

Prescriber provides documentation of **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. Paid claims or physician attestation of prior therapy for the treatment of MCL *(See Appendix I for appropriate prior therapy)*

Imbruvica[®] (ibrutinib)

Prescriber provides documentation of **ALL** of the following:

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

Marginal zone lymphoma (MZL)

Brukinsa[®] (zanubrutinib)

Prescriber provides documentation of **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 the treatment of MZL with at least one anti-CD20 monoclonal antibody based regimen (e.g., *Gazyva*[®] (obinutuzumab) and *Rituxan*[®] (rituximab) as well as all rituximab biosimilars)

Imbruvica[®] (ibrutinib)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of MZL
2. Member is ≥ 18 years of age
3. Appropriate dosing
4. Prescriber is an oncologist or hematologist
5. Paid claims or physician attestation of prior therapy for the treatment of MZL with at least one systemic therapy (See Appendix I and V for appropriate prior therapy)

Waldenstrom's macroglobulinemia (WM)

Brukinsa[®] (zanubrutinib)

Imbruvica[®] (ibrutinib)

Prescriber provides documentation of **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

Chronic lymphocytic leukemia (CLL) or Small lymphocytic lymphoma (SLL)

Calquence[®] (acalabrutinib)

Prescriber provides documentation of **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 is treatment-naive **AND ONE** of the following:
 - i. Requested agent will be used in combination with *Gazyva*[®] (obinutuzumab)
 - ii. Clinical rationale for use of the requested agent as monotherapy
 - b. Paid claims or physician attestation of member having a relapsed or refractory disease OR prior therapy for the treatment of CLL/SLL (See Appendix II for appropriate prior therapy)

Copiktra[®] (duvelisib)

Prescriber provides documentation of **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 for the treatment of CLL/SLL with at least two prior therapies* (*See Appendix II for appropriate prior therapy*)

*Radiation therapy can be counted as one prior therapy

Imbruvica[®] (ibrutinib)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of CLL/SLL, CLL/SLL with 17p deletion
2. Member is ≥ 18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing

Venclexta[®] (venetoclax)

Prescriber provides documentation of **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 BOTH** of the following:
 - i. Requested agent will be used in combination with Gazyva[®] (obinutuzumab)
 - ii. Contraindication to Imbruvica[®] (ibrutinib)
 - b. Paid claims or physician attestation of prior therapy for the treatment of CLL or SLL with at least one systemic therapy (*See Appendix II for appropriate prior therapy*) **AND** requested agent will be used in combination with Rituxan[®] (rituximab)

Zydelig[®] (idelalisib)

Prescriber provides documentation of **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 for the treatment of CLL with at least one systemic therapy (*See Appendix II for appropriate prior therapy*)
6. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to Imbruvica[®] (ibrutinib)

Chronic graft versus host disease (cGVHD)

Imbruvica[®] (ibrutinib)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of cGVHD
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 systemic glucocorticoids

Acute myeloid leukemia (AML)

Venclexta[®] (venetoclax)

Prescriber provides documentation of **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 ≥ 60 years of age
 - b. 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)

Prescriber provides documentation of **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 for the treatment of CNS lymphoma

Multiple Myeloma

Venclexta[®] (venetoclax)

Prescriber provides documentation of **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 inadequate response or adverse reaction to at least **ONE** prior chemotherapy regimen for multiple myeloma

Members currently stable on Brukinsa[®] (zanubrutinib), Calquence[®] (acalabrutinib), Copiktra[®] (duvelisib), Imbruvica[®] (ibrutinib), Venclexta[®] (venetoclax), and Zydelig[®] (idelalisib) may be approved for any FDA-approved indication.

Continuation of Therapy

Reauthorization requires physician attestation that indicates a positive response to therapy.

Limitations

1. Initial approvals and reauthorizations will be for 6 months.
2. The following quantity limits apply:

Brukina 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
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 is radiation therapy alone or radiation therapy in combination with chemo-immunotherapy. 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, cisplatin, and cytarabine (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)
- Brukina® (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. Tyrosine kinase inhibitors (imatinib)
- g. Ursodeoxycholic acid
- h. Interleukin-2 may be used
- i. Abatacept

- j. Alemtuzumab
- k. Belumosudil
- l. Etanercept
- m. Hydroxychloroquine
- n. Ibrutinib
- o. Low-dose methotrexate
- p. Pentostatin

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
- e. Ibritumomab tiuxetan
- f. Lenalidomide plus rituximab
- g. Single-agent alkylators with or without rituximab (elderly or infirm patients)

Second-line and subsequent therapy includes ibrutinib, lenalidomide with or without rituximab, bendamustine plus obinutuzumab, copanlisib, duvelisib, and idelalisib, in addition to first-line chemoimmunotherapy.

Appendix VI: Copiktra® (duvelisib) and Zydelig® (idelalisib) for FL or SLL

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

Copiktra® (duvelisib) and Zydelig® (idelalisib) for FL

Prescriber provides documentation of **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

Prescriber provides documentation of **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.

Dosing:

Copiktra® (duvelisib): Relapsed or refractory FL: 25 mg orally twice daily

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.

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