Lymphoma and Leukemia Agents
Aliqopa (copanlisib)
Brukinsa (zanubrutinib)
Calquence (acalabrutinib)
Copiktra (duvelisib)
Imbruvica (ibrutinib)
Venclexta (venetoclax)
Zydelig (idelalisib)
Effective 9/01/2022

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication 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	N/A		

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 documentation 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 documentation 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 documentation 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 documentation 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 documentation 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 documentation 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 documentation 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 documentation 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 documentation of inadequate response, adverse reaction, or contraindication to Imbruvica® (ibrutinib)

<u>Chronic graft versus host disease (cGVHD)</u>
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 documentation 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

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:

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
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

Requests for over the quantity limit should be reviewed against the Global Quantity Limit criteria.

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:

a. Imbruvica® (ibrutinib) monotherapy
b. Venclexta® (venetoclax) plus Gazyva® (obinutuzumab)
c. Calquence® (acalabrutinib) with or without Gazyva® (obinutuzumab)
d. Bendamustine plus an anti-CD20 monoclonal antibody
e. Leukeran® (chlorambucil) plus Gazyva® (obinutuzumab)
f. High-dose methylprednisolone plus rituximab or Gazyva® (obinutuzumab)
g. Imbruvica® (ibrutinib) plus Gazyva® (obinutuzumab)
h. Gazyva® (obinutuzumab) monotherapy
i. Leukeran® (chlorambucil) monotherapy
j. Rituximab monotherapy
k. Fludarabine, cyclophosphamide, rituximab (FCR)

First-line treatment options for CLL/SLL (with del[17p]/TP53 mutation) include:

a. Imbruvica® (ibrutinib) monotherapy
b. Calquence® (acalabrutinib) with or without Gazyva® (obinutuzumab)
c. Venclexta® (venetoclax) plus Gazyva® (obinutuzumab)
d. Alemtuzumab with or without rituximab
e. High-dose methylprednisolone plus rituximab
f. Gazyva® (obinutuzumab) monotherapy
g. Brukinsa® (zanubrutinib)

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: Imbruvica® (ibrutinib) for CNS Lymphoma

The NCCN guideline for the treatment of primary central nervous system (CNS) lymphoma recommends induction therapy with high dose methotrexate-based regimens followed by consolidation therapy with high dose chemotherapy with stem cell rescue. For those with relapsed or refractory disease the following agents are recommended:

- Retreatment with high-dose methotrexate
  - With or without rituximab
  - With rituximab and ibrutinib
- Ibrutinib
- Temozolomide
- Rituximab with or without temozolomide
- Lenalidomide with or without rituximab
- High-dose cytarabine
- Pemetrexed
- Pomalidomide

While Imbruvica® (ibrutinib), is not FDA-approved for the treatment of CNS lymphoma, given that the NCCN guideline recommends ibrutinib monotherapy or in combination with high-dose methotrexate and rituximab for those with relapsed or refractory CNS lymphoma, use may be appropriate in some patients.

Requests for **Imbruvica®** (ibrutinib) for CNS lymphoma may be reviewed using the following criteria:
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of CNS lymphoma
2. Member is ≥18 years of age
3. Prescriber is an oncologist or hematologist
4. Appropriate dosing
5. Paid claims or physician documentation of inadequate response, adverse reaction, or contraindication to a methotrexate-based regimen for the treatment of CNS lymphoma

For members meeting all criteria, prior authorization may be issued for 6 months.
Resubmission by prescriber will infer a positive response to therapy and request can be recertified for up to 6 months.

Appendix VII: Venclexta® (venetoclax) for Multiple Myeloma

The NCCN guideline for multiple myeloma (MM) includes Venclexta® (venetoclax) in combination with dexamethasone as a regimen that is useful in certain circumstances for previously treated multiple myeloma specifically in patients with t(11;14) mutation. While not FDA-approved for MM, Venclexta® (venetoclax) may be appropriate in certain patients.

Requests for **Venclexta®** (venetoclax) for Multiple Myeloma may be reviewed using the following criteria:
Prescriber provides documentation of ALL of the following:

1. Diagnosis of multiple myeloma
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 documentation of inadequate response or adverse reaction to at least **ONE** prior chemotherapy regimen for multiple myeloma

For members meeting all criteria, prior authorization may be issued for 6 months.

Resubmission by prescriber will infer a positive response to therapy and request can be recertified for up to 6 months.

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

Requests for members not yet stable on Zydelig® (idelalisib) or Copiktra® (duvelisib) should be reviewed by the Clinical Reviewer of the day 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

References

1. Aliqopa (copanlisib) [prescribing information]. Whippany, NJ: Bayer Healthcare Pharmaceuticals Inc; February 2022.
2. Dreyling M, Santoro A, Mollica L, et al. Phosphatidylinositol 3-kinase inhibition by copanlisib in relapsed or refractory indolent lymphoma. J Clin Oncol. 2017;35(35):3898-3905. doi:10.1200/JCO.2017.75.4648
3. Brukinsa (zanubrutinib) [prescribing information]. San Mateo, CA: BeiGene USA Inc; September 2021.
4. Dimopoulos M, Sanz RG, Lee HP, et al. Zanubrutinib for the treatment of MYD88 wild-type Waldenström macroglobulinemia: a substudy of the phase 3 ASPEN trial. Blood Adv. 2020;4(23):6009-6018. doi:10.2337/dci18-0033[PubMed 33284944]
5. Opat S, Tedeschi A, Linton K, et al. The MAGNOLIA trial: zanubrutinib, a next-generation bruton tyrosine kinase inhibitor, demonstrates safety and efficacy in relapsed/refractory marginal

zone lymphoma. Clin Cancer Res. 2021;27(23):6323-6332. doi:10.1158/1078-0432.CCR-21-1704[PubMed 34526366]
6. Song Y, Zhou K, Zou D, et al. Treatment of patients with relapsed or refractory mantle-cell lymphoma with zanubrutinib, a selective inhibitor of Bruton's tyrosine kinase. Clin Cancer Res. 2020;26(16):4216-4224. doi:10.1158/1078-0432.CCR-19-3703[PubMed 32461234]
7. Tam CS, Opat S, D'Sa S, et al. A randomized phase 3 trial of zanubrutinib vs ibrutinib in symptomatic Waldenström macroglobulinemia: the ASPEN study. Blood. 2020;136(18):2038-2050. doi:10.1182/blood.2020006844[PubMed 32731259]
8. Calquence (acalabrutinib) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; March 2022.
9. Byrd JC, Harrington B, O'Brien S, et al. Acalabrutinib (ACP-196) in relapsed chronic lymphocytic leukemia. N Engl J Med. 2016;374(4):323-332.[PubMed 26641137]
10. Castillo JJ, Advani RH, Branagan AR, et al. Consensus treatment recommendations from the tenth International Workshop for Waldenström Macroglobulinaemia. Lancet Haematol. 2020;7(11):e827-e837. doi:10.1016/S2352-3026(20)30224-6[PubMed 33091356]
11. Ghia P, Pluta A, Wach M, et al. ASCEND: phase III, randomized trial of acalabrutinib versus idelalisib plus rituximab or bendamustine plus rituximab in relapsed or refractory chronic lymphocytic leukemia. J Clin Oncol. 2020;38(25):2849-2861. doi:10.1200/JCO.19.03355[PubMed 32459600]
12. Owen RG, McCarthy H, Rule S, et al. Acalabrutinib monotherapy in patients with Waldenström macroglobulinemia: a single-arm, multicentre, phase 2 study. Lancet Haematol. 2020;7(2):e112-e121. doi:10.1016/S2352-3026(19)30210-8[PubMed 31866281]
13. Sharman JP, Egyed M, Jurczak W, et al. Acalabrutinib with or without obinutuzumab versus chlorambucil and obinutuzumab for treatment-naive chronic lymphocytic leukaemia (ELEVATE TN): a randomised, controlled, phase 3 trial. Lancet. 2020;395(10232):1278-1291. doi:10.1016/S0140-6736(20)30262-2[PubMed 32305093]
14. Wang M, Rule S, Zinzani PL, et al. Acalabrutinib in relapsed or refractory mantle cell lymphoma (ACE-LY-004): a single-arm, multicentre, phase 2 trial. Lancet. 2018;391(10121):659-667. doi:10.1016/S0140-6736(17)33108-2[PubMed 29241979]
15. Copiktra (duvelisib) [prescribing information]. Las Vegas, NV: Secura Bio Inc; December 2021.
16. Flinn IW, Hillmen P, Montillo M, et al. The phase 3 DUO trial: duvelisib vs ofatumumab in relapsed and refractory CLL/SLL. Blood. 2018;132(23):2446-2455. doi:10.1182/blood-2018-05-850461[PubMed 30287523]
17. Imbruvica (ibrutinib) [prescribing information]. South San Francisco, CA: Pharmacyclics LLC; May 2022.
18. Dimopoulos MA, Tedeschi A, Trotman J, et al; iNNOVATE Study Group and the European Consortium for Waldenström's Macroglobulinemia. Phase 3 trial of ibrutinib plus rituximab in Waldenström's macroglobulinemia. N Engl J Med. 2018;378(25):2399-2410. doi:10.1056/NEJMoa1802917.[PubMed 29856685]
19. Dreyling M, Jurczak W, Jerkeman M, et al. Ibrutinib versus temsirolimus in patients with relapsed or refractory mantle-cell lymphoma: an international, randomised, open-label, phase 3 study. Lancet. 2016;387(10020):770-778.[PubMed 26673811]
20. Miklos D, Cutler CS, Arora M, et al. Ibrutinib for chronic graft-versus-host disease after failure of prior therapy. Blood. 2017;130(21):2243-2250. doi: 10.1182/blood-2017-07-793786.[PubMed 28924018]
21. Moreno C, Greil R, Demirkan F, et al. Ibrutinib plus obinutuzumab versus chlorambucil plus obinutuzumab in first-line treatment of chronic lymphocytic leukaemia (iLLUMINATE): a

multicentre, randomised, open-label, phase 3 trial. Lancet Oncol. 2019;20(1):43-56. doi: 10.1016/S1470-2045(18)30788-5.[PubMed 30522969]
22. Noy A, de Vos S, Thieblemont C, et al. Targeting Bruton tyrosine kinase with ibrutinib in relapsed/refractory marginal zone lymphoma. Blood. 2017;129(16):2224-2232. doi: 10.1182/blood-2016-10-747345.[PubMed 28167659]
23. Treon SP, Tripsas CK, Meid K et al. Ibrutinib in previously treated Waldenström's macroglobulinemia. N Engl J Med. 2015;372(15):1430-1440.[PubMed 25853747]
24. Wang ML, Blum KA, Martin P, et al. Long-term follow-up of MCL patients treated with single-agent ibrutinib: updated safety and efficacy results. Blood. 2015;126(6):739-745.[PubMed 26059948]
25. Wang ML, Rule S, Martin P, et al. Targeting BTK with ibrutinib in relapsed or refractory mantle-cell lymphoma. N Engl J Med, 2013;369(6):507-516.[PubMed 23782157]
26. Venclexta (venetoclax) [prescribing information]. North Chicago, IL: AbbVie Inc; December 2021.
27. Basali D, Chakraborty R, Rybicki L, et al. Real-world data on safety and efficacy of venetoclax-based regimens in relapsed/refractory t(11;14) multiple myeloma. Br J Haematol. 2020;189(6):1136-1140. doi:10.1111/bjh.16454[PubMed 32012228]
28. Eyre TA, Walter HS, Iyengar S, et al. Efficacy of venetoclax monotherapy in patients with relapsed, refractory mantle cell lymphoma after Bruton tyrosine kinase inhibitor therapy. Haematologica. 2019;104(2):e68-e71. doi: 10.3324/haematol.2018.198812.[PubMed 30190341]
29. Fischer K, Al-Sawaf O, Bahlo J, et al. Venetoclax and obinutuzumab in patients with CLL and coexisting conditions. N Engl J Med. 2019;380(23):2225-2236. doi: 10.1056/NEJMoa1815281.[PubMed 31166681]
30. Kater AP, Wu JQ, Kipps T, et al. Venetoclax plus rituximab in relapsed chronic lymphocytic leukemia: 4-year results and evaluation of impact of genomic complexity and gene mutations from the MURANO phase III study. J Clin Oncol. 2020;38(34):4042-4054. doi:10.1200/JCO.20.00948[PubMed 32986498]
31. Kaufman JL, Gasparetto C, Schjesvold FH, et al. Targeting BCL-2 with venetoclax and dexamethasone in patients with relapsed/refractory t(11;14) multiple myeloma. Am J Hematol. 2021;96(4):418-427. doi:10.1002/ajh.26083[PubMed 33368455]
32. Kumar SK, Harrison SJ, Cavo M, et al. Venetoclax or placebo in combination with bortezomib and dexamethasone in patients with relapsed or refractory multiple myeloma (BELLINI): a randomised, double-blind, multicentre, phase 3 trial. Lancet Oncol. 2020;21(12):1630-1642. doi:10.1016/S1470-2045(20)30525-8[PubMed 33129376]
33. Kumar S, Kaufman JL, Gasparetto C, et al. Efficacy of venetoclax as targeted therapy for relapsed/refractory t(11;14) multiple myeloma. Blood. 2017;130(22):2401-2409. doi:10.1182/blood-2017-06-788786[PubMed 29018077]
34. Roberts AW, Davids MS, Pagel JM, et al. Targeting BCL2 with Venetoclax in Relapsed Chronic Lymphocytic Leukemia. N Engl J Med. 2016;374(4):311-22.[PubMed 26639348]
35. Seymour JF, Kipps TJ, Eichhorst B, et al. Venetoclax-rituximab in relapsed or refractory chronic lymphocytic leukemia. N Engl J Med. 2018;378(12):1107-1120. doi: 10.1056/NEJMoa1713976.[PubMed 29562156]
36. Stilgenbauer S, Eichhorst B, Schetelig J, et al. Venetoclax in relapsed or refractory chronic lymphocytic leukaemia with 17p deletion: a multicentre, open-label, phase 2 study. Lancet Oncol. 2016;17(6):768-778.[PubMed 27178240]
37. Tam CS, Anderson MA, Pott C, et al. Ibrutinib plus venetoclax for the treatment of mantle-cell lymphoma. N Engl J Med. 2018;378(13):1211-1223. doi: 10.1056/NEJMoa1715519.[PubMed 29590547]

38. Wei AH, Montesinos P, Ivanov V, et al. Venetoclax plus LDAC for newly diagnosed AML ineligible for intensive chemotherapy: a phase 3 randomized placebo-controlled trial. Blood. 2020;135(24):2137-2145. doi:10.1182/blood.2020004856[PubMed 32219442]
39. Zydelig (idelalisib) [prescribing information]. Foster City, CA: Gilead Sciences Inc; February 2022.
40. Furman RR, Sharman JP, Coutre Se, et al. Idelalisib and rituximab in relapsed chronic lymphocytic leukemia. N Engl J Med. 2014; 370(11):997-1007.[PubMed 24450857]
41. Hallek M, Cheson BD, Catovsky D, et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. Blood. 2018;131(25):2745-2760. doi:10.1182/blood-2017-09-806398[PubMed 29540348]
42. Sharman JP, Coutre SE, Furman RR, et al. Final results of a randomized, phase III study of rituximab with or without idelalisib followed by open-label idelalisib in patients with relapsed chronic lymphocytic leukemia. J Clin Oncol. 2019;37(16):1391-1402. doi: 10.1200/JCO.18.01460.[PubMed 30995176]

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.

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.