Clinical Policy: Sonrotoclax (Beqalzi)

Reference Number: CP.PHAR.786
Effective Date: 09.01.26
Last Review Date: 08.26
Line of Business: Commercial, HIM/ICHRA, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Sonrotoclax (Beqalzi™) is a B-cell lymphoma 2 (BCL-2) inhibitor.

FDA Approved Indication(s)

Beqalzi is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor.

This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Beqalzi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Mantle Cell Lymphoma (must meet all)**:**

1. Diagnosis of relapsed, refractory, or progressive MCL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. For Beqalzi requests, member must use sonrotoclax, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. Member meets both of the following (a and b; *see Appendix B*):
   a. Received ≥ 2 prior systemic therapies;
   b. Received a prior BTK inhibitor (e.g., Imbruvica®, Brukinsa®, Calquence®, Jaypirca®);
6. Request meets one of the following (a or b):*
   a. Dose does not exceed both of the following after initial 4-week dose ramp-up^ (i and ii):
      i. 320 mg per day;
      ii. 4 tablets per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*
^See Section V Dosage and Administration for 4-week dose ramp-up schedule

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Mantle Cell Lymphoma (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Beqalzi for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For Beqalzi requests, member must use sonrotoclax, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed both of the following (i and ii):
      i. 320 mg per day;
      ii. 4 tablets per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BCL-2: B-cell lymphoma 2
BTK: Bruton's tyrosine kinase
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
RDHA/RCHOP (rituximab, dexamethasone, cytarabine) + platinum (carboplatin, cisplatin, or oxaliplatin)/(rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies
NORDIC (rituximab + cyclophosphamide, vincristine, doxorubicin, prednisone/rituximab + cytarabine)	Varies	Varies
RCHOP/RDHAP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)/(rituximab, dexamethasone, cisplatin, cytarabine)	Varies	Varies
bendamustine + rituximab	Varies	Varies
VR-CAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, prednisone)	Varies	Varies
RCHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + rituximab	Varies	Varies
Revlimid® (lenalidomide) + rituximab	Varies	Varies
RBAC500 (bendamustine, low-dose cytarabine) + rituximab	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
T-cell mediated therapy examples include Tecartus® (brexucabtagene autoleucel), Breyanzi® (lisocabtagene maraleucel), Columvi™ (glofitamab-gxbm)	Varies	Varies
BTK inhibitor examples include Calquence® (acalabrutinib), Brukinsa® (zanubrutinib), Imbruvica® (ibrutinib), Jaypirca® (pirtobrutinib)	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): concomitant use with strong CYP3A inhibitors at initiation and during the ramp-up phase
- Boxed warning(s): none

V. Dosage and Administration

<table>
<tr><th>Indication</th><th>Dosing Regimen</th><th>Maximum Dose</th></tr>
<tr><td>MCL</td><td>Maintenance dose of 320 mg PO once daily following completion of a 4-week dose ramp-up schedule

Dosing schedule for 4-week dose ramp-up phase:
<table>
<tr><th>Dosing Regimen</th><th>Dosing Regimen</th><th>Dosing Regimen</th><th>Dosing Regimen</th></tr>
<tr><td rowspan="2">Week 1</td><td>Days 1 to 3</td><td>1 mg</td><td>One 1 mg tablet</td></tr>
<tr><td>Days 4 to 7</td><td>2 mg</td><td>Two 1 mg tablets</td></tr>
<tr><td rowspan="2">Week 2</td><td>Days 1 to 3</td><td>5 mg</td><td>One 5 mg tablet</td></tr>
<tr><td>Days 4 to 7</td><td>10 mg</td><td>Two 5 mg tablets</td></tr>
<tr><td rowspan="2">Week 3</td><td>Days 1 to 3</td><td>20 mg</td><td>One 20 mg tablet</td></tr>
<tr><td>Days 4 to 7</td><td>40 mg</td><td>Two 20 mg tablets</td></tr>
<tr><td rowspan="2">Week 4</td><td>Days 1 to 3</td><td>80 mg</td><td>One 80 mg tablet</td></tr>
<tr><td>Days 4 to 7</td><td>160 mg</td><td>Two 80 mg tablets</td></tr>
</table></td><td>320 mg/day</td></tr>
</table>

VI. Product Availability

Oral tablets: 1 mg, 5 mg, 20 mg, 80 mg

VII. References

1. Beqalzi Prescribing Information. Pennington, NJ: BeOne Medicines USA, Inc.; May 2026. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/220711Orig1s000lbl.pdf. Accessed June 4, 2026.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed June 8, 2026.

3. National Comprehensive Cancer Network. B-Cell Lymphomas Version 4.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed June 8, 2026.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	06.05.26	08.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.