PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – BCL-2 Inhibitor) – Beqalzi Prior Authorization Policy
- Beqalzi™ (sonrotoclax tablets – BeOne Medicines)

REVIEW DATE: 06/03/2026; selected revision 06/17/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Beqalzi, a B-Cell Lymphoma-2 (BCL-2) inhibitor, is indicated for the treatment of **relapsed or refractory mantle cell lymphoma** after at least two lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor in adults.[1]

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).

Guidelines

National Comprehensive Cancer Network (NCCN) B-Cell Lymphoma guidelines (version 4.2026 – May 20, 2026) recommend Beqalzi as third-line and subsequent therapy for mantle cell lymphoma, after at least two lines of systemic therapy, including a BTK inhibitor (category 2A). Multiple chemotherapy regimens are listed for induction therapy; BTK inhibitors and Venclexta® (venetoclax tablets) in

combination with other agents can also be used in certain scenarios as induction therapy. In the second-line or subsequent therapy setting, "Preferred" agents include lenalidomide+ rituximab and covalent BTK inhibitors (Brukinsa® [zanubrutinib tablets and capsules], Calquence® [acalabrutinib tablets]) [all category 2] and "Other Recommended" agents include Imbruvica® (ibrutinib tablets, capsules, and oral suspension).± rituximab (category 2A). There are several therapies recommended in the second-line or subsequent setting for progressive disease as "Useful in Certain Circumstances"; such as Venclexta ± rituximab; Jaypirca® (pirtobrutinib tablets)and T-cell mediated therapies are recommended after prior covalent BTK inhibitor (all category 2A).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Beqalzi. All approvals are provided for the duration noted below.

Beqalzi™ (sonrotoclax tablets - BeOne Medicines) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Mantle Cell Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C,):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has relapsed or refractory disease; AND
   - **C)** Patient meets BOTH of the following (i and ii):
     - **i.** Patient has tried at least two systemic regimens; AND
       Note: Examples of a systemic regimen contain one or more of the following products: rituximab, cytarabine, carboplatin, cisplatin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, methotrexate, bendamustine, bortezomib, lenalidomide, Gazyva (obinutuzumab intravenous infusion), or Venclexta (venetoclax tablets).
     - **ii.** At least one of the systemic regimens included a Bruton's tyrosine kinase (BTK) inhibitor for mantle cell lymphoma.
       Note: Examples of a BTK inhibitor indicated for mantle cell lymphoma includes: Brukinsa (zanubrutinib tablets and capsules), Calquence (acalabrutinib tablets), Imbruvica (ibrutinib capsules, tablets, and oral suspension), and Jaypirca (pirtobrutinib tablets).

CONDITIONS NOT COVERED

Beqalzi™ (sonrotoclax tablets - BeOne Medicines) is(are) considered not medically necessary for ANY other use(s) including the following (this list

may not be all inclusive. Criteria will be updated as new published data are available.

REFERENCES

1. Beqalzi™ tablets [prescribing information]. Pennington, NJ: BeOne Medicines; May 2026
2. The NCCN B-Cell Lymphomas Guidelines in Oncology (version 4.2026 - May 20, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 15, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	06/03/2026
Selected Revision	**Mantle Cell Lymphoma:** The requirement of trial of "at least one systemic chemotherapy regimen" was changed to "at least two systemic regimens." Venclexta (venetoclax tablets) was added to the Note. The requirement that the patient has tried one Bruton's tyrosine kinase inhibitor was changed to "at least one of the systemic regimens included a Bruton's tyrosine kinase (BTK) inhibitor for mantle cell lymphoma.	06/17/2026