**Original Effective Date: 05/31/2023**
**Current Effective Date: 12/06/2024**
**Last P&T Approval/Version: 04/30/2025**
**Next Review Due By: 04/2026**
**Policy Number: C25200-A**

# NexoBrid (anacaulase-bcdb)

## PRODUCTS AFFECTED

NexoBrid (anacaulase-bcdb)

## COVERAGE POLICY

*Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.*

***Documentation Requirements:***
*Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.*

**DIAGNOSIS:**
Deep partial thickness and/or full thickness thermal burns

**REQUIRED MEDICAL INFORMATION:**
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. THERMAL BURNS:
   1. Documented diagnosis of deep partial thickness and/or full thickness thermal burns
      AND
   2. Member does not have any of the following: Chemical or electrical burns, burns on the face, perineum, or genitalia, burns on the feet of patients with diabetes mellitus or

on the feet of patients with occlusive vascular disease, circumferential burns, burns in patients with significant cardiopulmonary disease, including inhalation injury OR wounds contaminated with radioactive and other hazardous substances to avoid unforeseeable reactions with the product and an increased risk of spreading the noxious substance OR treatment of wounds where medical devices or vital structures could become exposed during eschar removal AND

3. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to NexoBrid (anacaulase-bcdb) include: Known hypersensitivity to anacaulase-bcdb, bromelain, pineapples, or to any of the other components, and known hypersensitivity to papayas or papain because of the risk of cross sensitivity]

**CONTINUATION OF THERAPY:**
NA

**DURATION OF APPROVAL:**
Initial authorization: 1 month, Continuation of therapy: NA

**PRESCRIBER REQUIREMENTS:**
Prescribed by or in consultation with a burn specialist, pain management or emergency medicine specialist. [If prescribed in consultation, consultation notes must be submitted with initial request]

**AGE RESTRICTIONS:**
No restriction

**QUANTITY:**
Adults:
First application may be applied to an area of up to 15% body surface area (BSA), a second application may be applied 24 hours later. The total treated area for both applications must not exceed 20% BSA.

Pediatric Patients 6 years of age and older:
One application to a wound area up to 15% BSA. A second application is not recommended.

Pediatric Patients less than 6 years of age:
One application to a wound area up to 10% BSA. A second application is not recommended.

**Maximum Quantity Limits –**
Total treated area must not exceed 20% BSA (adults only)
Use 1.94g of anacaulase-bcdb in 2g powder mixed with 20g gel for up to 180 $cm^2$ of treated burn area, OR 4.85g of anacaulase-bcdb in 5g powder mixed with 50g gel for up to 450 $cm^2$ of treated burn area

**PLACE OF ADMINISTRATION:**
The recommendation is that the topical medication in this policy will be for medical benefit coverage and the topical product administered in a place of service that is a hospital facility-based location. Nexobrid is only to be administered by a healthcare provider.

## DRUG INFORMATION

**ROUTE OF ADMINISTRATION:**
Topical Use Only

**DRUG CLASS:**
Enzymes – Topical

**FDA-APPROVED USES:**
Indicated for eschar removal in adults and pediatric patients with deep partial thickness and/or full thickness thermal burns
*Limitations of Use:*
*The safety and effectiveness of Nexobrid have not been established for treatment of:*
- *Chemical or electrical burns.*
- *Burns on the face, perineum, or genitalia.*
- *Burns on the feet of patients with diabetes mellitus or on the feet of patients with occlusive vascular disease*
- *Circumferential burns*
- *Burns in patients with significant cardiopulmonary disease, including inhalation injury*

*Nexobrid is not recommended for:*
- *Wounds contaminated with radioactive and other hazardous substances to avoid unforeseeable reactions with the product and an increased risk of spreading the noxious substance*
- *Treatment of burn wounds where medical devices (e.g., implants, pacemakers, shunts) or vital structures (e.g., large vessels) could become exposed during eschar removal*

**COMPENDIAL APPROVED OFF-LABELED USES:**
None

## APPENDIX

**APPENDIX:**
None

## BACKGROUND AND OTHER CONSIDERATIONS

**BACKGROUND:**
NexoBrid is a topically administered, bromelain-based biological product containing a sterile mixture of proteolytic enzymes. The product selectively removes burn eschar within 4 hours without harming surrounding viable tissue. NexoBrid (anacaulase-bcdb) is a botanical drug product containing proteolytic enzymes indicated for the removal of eschar in adults with deep partial- and/or full-thickness thermal burns. A severe burn is one that is complicated by major trauma or inhalation injury, a chemical burn (table 1), high-voltage electrical burn, and, in general for adults, any burn encompassing >20 percent of the total body surface area (TBSA), excluding superficial burns (epidermal; first-degree burns) (table 2). For older adults and young children, a burn encompassing less than 20 percent of the TBSA may be considered severe. The approval of NexoBrid was based on data from 2 clinical trials. The phase 3 DETECT trial (ClinicalTrials.gov Identifier: NCT02148705) compared NexoBrid to gel vehicle placebo or standard of care (SOC) in 175 adults with deep partial and full thickness thermal burns up to 30% of total body surface area (BSA). Results showed the incidence of ≥95% eschar removal at the end of the topical treatment period for patients in the NexoBrid group was 93% vs 4% for the gel vehicle group (treatment difference, 89% [95% CI, 74-96]). NexoBrid was also associated with a lower incidence of surgical eschar removal (4% vs 72% for SOC). The median time to eschar removal was reported to be 1 day with NexoBrid and 3.8 days with SOC. The estimated median time to 95% or greater wound closure was 31 days for the NexoBrid arm and 36 days for the SOC arm.

Use of NexoBrid in pediatric patients is supported by one open label, randomized, controlled, two arm trial that compared NexoBrid to standard of care in pediatric patients up to 18 years of age (Study 3, NCT02278718). The median time to ≥ 95% eschar removal was 0.99 days (95% confidence interval 0.88, 1.04) for the NexoBrid group, compared to 5.99 days (95% confidence interval 2.71, 9.84) in the standard of care group. The incidence of surgical excision for eschar removal was 8% in the NexoBrid group versus 64% in the standard of care group (-56% [95% confidence interval -68%, -42%]). Adverse reactions that occurred in > 5% of NexoBrid treated patients and in greater incidence than the standard of care group

were pruritus, pyrexia, and vomiting.

**CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:**
All other uses of NexoBrid (anacaulase-bcdb) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to NexoBrid (anacaulase-bcdb) include: Known hypersensitivity to anacaulase-bcdb, bromelain, pineapples, or to any of the other components, and known hypersensitivity to papayas or papain because of the risk of cross sensitivity.

**OTHER SPECIAL CONSIDERATIONS:**
Nexobrid is only to be administered by a healthcare provider. Healthcare providers should take precautions to avoid exposure to Nexobrid during preparation and handling (e.g., use of gloves, surgical masks, other protective coverings, as needed).

## CODING/BILLING INFORMATION

***CODING DISCLAIMER.*** *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

| HCPCS CODE | DESCRIPTION |
|---|---|
| J7353 | Anacaulase-bcdb, 8.8% gel, 1 gram |

**AVAILABLE DOSAGE FORMS**:
One glass vial of 2 g lyophilized powder (containing 1.94 grams of anacaulase-bcdb) and one glass jar of 20 g gel vehicle per carton (NDC 69866-2002-3)
One glass vial of 5 g lyophilized powder (containing 4.85 grams of anacaulase-bcdb) and one glass jar of 50 g gel vehicle per carton (NDC 69866-2005-3)

## REFERENCES

1. NexoBrid (anacaulase- bcdb) for topical gel [prescribing information]. Cambridge, MA: Vericel Corporation; August 2024.
2. Wallner C, Kern P, Teig N, Lehnhardt M, Behr B. The interdisciplinary management of severe burns in pregnancy. Burns Open. 2017;1(2):74-77. https://www.sciencedirect.com/science/article/pii/S2468912217300044
3. ISBI Practice Guidelines Committee; Steering Subcommittee; Advisory Subcommittee. (2016). ISBI Practice Guidelines for Burn Care. Burns, 42(5), 953–1021. https://doi.org/10.1016/j.burns.2016.05.013

| SUMMARY OF REVIEW/REVISIONS | DATE |
|---|---|
| REVISION- Notable revisions:<br>Required Medical Information<br>FDA-Approved Uses | Q2 2025 |

| | |
|---|---|
| REVISION- Notable revisions:<br>Age restrictions<br>Quantity<br>FDA-Approved Uses<br>Background<br>References | Q4 2024 |

| | |
|---|---|
| REVISION- Notable revisions:<br>Place of Administration<br>Coding/Billing Information<br>References | Q2 2024 |
| NEW CRITERIA | Q2 2023 |