



Original Effective Date: 05/31/2023
Current Effective Date: 05/31/2023
Last P&T Approval/Version: 04/26/2023
Next Review Due By: 04/2024
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.

A. THERMAL BURNS

1. Documented diagnosis of deep partial thickness and/or full thickness thermal burns
AND
2. Prescriber attests 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

Drug and Biologic Coverage Criteria

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
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 and reauthorization requests]

AGE RESTRICTIONS:

18 years and older

QUANTITY:

Maximum 40g lyophilized powder (38.8 grams anacaulase-bcdb)

Maximum Quantity Limits – 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.

Use 1.94g of anacaulase-bcdb in 2g powder mixed with 20g gel per 1% BSA, OR

4.85g of anacaulase-bcdb in 5g powder mixed with 50g gel per 2.5% BSA

PLACE OF ADMINISTRATION:

The recommendation is that the topical medication in this policy will be for medical benefit coverage and the administered in a place of service that is a hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Topical Use Only

DRUG CLASS:

Enzymes – Topical

FDA-APPROVED USES:

Indicated for eschar removal in adults 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.*

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- 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

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.

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

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Drug and Biologic Coverage Criteria

HCPCS CODE	DESCRIPTION
NA	

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) [prescribing information]. Cambridge, MA: Vericel Corporation; January 2023.
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>

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA	Q2 2023