

## Wound Treatment, Medical 343

### Table of Content

[Description & Definitions](#)[Criteria](#)[Document History](#)[Coding](#)[Special Notes](#)[References](#)[Keywords](#)[Effective Date](#) 8/1/2025[Next Review Date](#) 5/2026[Coverage Policy](#) Medical 343[Version](#) 4

**Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details [\\*](#).**

### Description & Definitions:

NEXOBRID® contains anacaulase-bcdb, a mixture of proteolytic enzymes extracted from the stems of pineapple plants that has been sterile filtered and lyophilized. The mixture of enzymes in NEXOBRID® dissolves burn wound eschar.

MIST therapy utilizes a noncontact, low-frequency ultrasound debridement device directed at the wound bed via saline mist.

MuGard™ is indicated for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces. The mucoadhesive polymers in the hydrogel formulation adhere to the oral mucosa and form a protective coating.

### Criteria:

NexoBrid (anacaulase-bcdb) is medically necessary for **1 or more** of the following:

- Deep partial thickness (DPT) thermal burns
- full thickness (FT) thermal burns

NexoBrid is not covered for **ANY** of the following due to lack of proven clinical utility:

- Chemical or electrical burns,
- burns on the face, perineum
- genitalia
- burns on the feet of patients with diabetes mellitus or occlusive vascular disease
- circumferential burns
- burns in patients with significant cardiopulmonary disease, including inhalation injury
- wounds contaminated with radioactive and other hazardous substances to avoid unforeseeable reactions

There is insufficient scientific evidence to support the medical necessity of this service as it is not shown to improve health outcomes upon technology review.

- MIST Therapy (i.e. noncontact, low-frequency ultrasound debridement)
- MuGard™

## Document History:

### Revised Dates:

2025: May – Updated definitions. No change to coverage criteria. Go live 8.1.2025.

2025: January – Mist therapy reviewed and added to not medically necessary section. Coding and references updated.

### Reviewed Dates:

2024: October – no changes references updated.

2023: October

Origination Date: 10/2023

## Coding:

### Medically necessary with criteria:

Coding	Description
J7353	Anacaulase-bcdb, 8.8% gel, 1 gm

### Considered Not Medically Necessary:

Coding	Description
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day
A9156	Oral mucoadhesive, any type (liquid, gel, paste, etc.), per 1 ml

U.S. Food and Drug Administration (FDA) - approved only products only.

The preceding codes are included above for informational purposes only and may not be all inclusive. Additionally, inclusion or exclusion of a treatment, procedure, or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

## Special Notes: \*

- Coverage: See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.
- Application to Products: Policy is applicable to Commercial products.
- Authorization Requirements: Pre-certification by the Plan is required.
- Special Notes:
  - Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.
  - Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services

section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

## References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

Federal Register. National Archives. Medical Devices; General and Plastic Surgery Devices; Classification of Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Creams, or Ointment; and Liquid Wound Washes. 11.30.2023. Retrieved 4.21.2025. <https://www.federalregister.gov/documents/2023/11/30/2023-26209/medical-devices-general-and-plastic-surgery-devices-classification-of-certain-solid-wound-dressings>

US Food and Drug Administration. Drug Trials Snapshot: NEXOBRID. 1.23.2024. Retrieved 4.21.2025. <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshot-nexobrid>

US Food and Drug Administration. Classification of Absorbable Synthetic Wound Dressings. 10.26.2022. Retrieved 4.21.2025. <https://www.fda.gov/media/162807/download>

Hayes. A symplr Company. Health Technology Assessment. Annual Review: Jun 8, 2018. Noncontact Low-Frequency Ultrasound Using the MIST Therapy System (Celleration Inc.) for Treatment of Venous Leg Ulcers. Retrieved 4.21.2025. <https://evidence.hayesinc.com/report/htb.noncontactmist3774>

Hayes. A symplr Company. Health Technology Assessment. Annual Review: Jun 8, 2018. Noncontact Low-Frequency Ultrasound Using the MIST Therapy System (Celleration Inc.) for Treatment of Lower Extremity Arterial and Diabetic Foot Ulcers. Retrieved 4.21.2025. <https://evidence.hayesinc.com/report/htb.MIST>

Centers for Medicare and Medicaid Services. CMS.gov. Palmetto Billing and Coding: Low frequency, non-contact, non-thermal ultrasound. A53773. 1.1.2024. Retrieved 4.21.2025. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=53773&ver=20&keyword=&keywordType=starts&areaid=all&docType=6,3,5,1,F,P&contractOption=all&hcpcsOption=code&hcpcsStartCode=97610&hcpcsEndCode=97610&sortBy=title&bc=1>

Commonwealth of Virginia. Department of Medical Assistance Services. DME Manual, Revision Date: 10/24/2024, Chapter IV: Covered Services and Limitations. Retrieved 4.21.2025. <https://vamedicaid.dmas.virginia.gov/sites/default/files/2024-10/DME%20Chapter%20IV%20%28updated%2010.24.24%29%20Final.pdf>

MCG Informed Care Strategies. 28<sup>th</sup> Edition. 2024. Retrieved 4.21.2025. <https://careweb.careguidelines.com/ed28/index.html>

National Comprehensive Cancer Network. Retrieved 4.21.2025. <https://www.nccn.org/search-result?indexCatalogue=nccn-search-index&searchQuery=WOUND%20TREATMENT>

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE. Wounds UK. The MIST Therapy system for the promotion of wound healing in chronic and acute wounds. 2.2023. Retrieved 4.21.2025. [https://wounds-uk.com/wp-content/uploads/2023/02/content\\_9837.pdf](https://wounds-uk.com/wp-content/uploads/2023/02/content_9837.pdf)

Lin Wu, Z. Q., Bulla, A., Aguirrezabala Del Río, J. A., Rivas Nicolls, D. A., Aguilera Sáez, J., Serracanta Domènech, J., & Barret, J. P. (2024). Enzymatic Debridement (Nexobrid) on Burned Hands: Retrospective Review from a Burn Referral Center in Spain. Plastic and reconstructive surgery. Global open, 12(6), e5886. Retrieved 4.21.2025. <https://doi.org/10.1097/GOX.0000000000005886>

Shoham, Y., Rosenberg, L., Narayan, R. P., Staubach, R., Bene, R., Kakola, M., Monstrey, S. J., Wilson, Y., Jha, M., Lewis, G. M., Larson, S., & Singer, A. J. (2025). Open label randomized controlled trial of the efficacy and safety of Nexobrid compared to standard of care in children with burns. *Burns : journal of the International Society for Burn Injuries*, 51(4), 107417. Retrieved 4.21.2025. <https://doi.org/10.1016/j.burns.2025.107417>

### **Keywords:**

SHP, Oral Mucoadhesive, Oral Wound Rince, MuGard, NEXOBIRD, burns