

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

<u>Coverage Policy</u> Medical 343

Version 4

All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.

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

Medical 343 Page 1 of 4

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.

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 Medicaid products.
- Authorization Requirements: Pre-certification by the Plan is required.
- · Special Notes:
 - This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.
 - 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

Medical 343 Page 2 of 4

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.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.

References:

Including but not limited to: 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. <a href="https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=53773&ver=20&keyword=&keywordType=starts&areald=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 Final.pdf

MCG Informed Care Strategies. 28th 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

Medical 343 Page 3 of 4

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

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.000000000000000000000000886

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

Medical 343 Page 4 of 4