

Wound Treatment, Medical 343

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<u>Coverage Policy</u> Medical 343

Version 5

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:

Collagen dressings help create and maintain a moist wound environment, necessary for wound healing. Additionally, they can also absorb excess fluids, helping to protect the wound from infection, while supporting new tissue growth.

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.

Topical hyperbaric oxygen therapy, also known as HTOB or TOB, delivers 100% oxygen directly to a wound at a pressure slightly higher than atmospheric pressure. These are disposable topical hyperbaric oxygen chambers ,and can be used for home use. Designed to fit around a limb, TOBs deliver oxygen at a controlled pressure, thereby increasing local oxygen levels in the wound.

Criteria:

Wound Treatment request is for **1 or more** of the following:

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- Collagen Dressing or Wound Fillers (IE: Biobrane, Biostep, Integra, etc) that stay in place for up to 7 days are
 medically necessary for 1 or more of the following:
 - Full thickness wounds (e.g., stage 3 or 4 ulcers)
 - o Wounds with light to moderate exudate
 - Wounds that have stalled or have not progressed toward a healing goal
- NexoBrid (anacaulase-bcdb) is medically necessary for 1 or more of the following:
 - Deep partial thickness (DPT) thermal burns
 - full thickness (FT) thermal burns

There is insufficient scientific evidence to support the medical necessity of the services noted below as they have not been shown to improve health outcomes upon technology review, and are therefore considered **Not Medically Necessary**, to include, but not limited to:

- Collagen dressing or wound fillers for ANY of the following:
 - Wound with heavy exudate
 - Third-degree burns
 - Individual with active vasculitis
- MIST Therapy (i.e. noncontact, low-frequency ultrasound debridement)
- MuGard™
- NexoBrid utilized for ANY of the following:
 - Chemical or electrical burns,
 - Burns on the face, perineum or genitalia
 - o 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
 - o Wounds contaminated with radioactive and other hazardous substances to avoid unforeseeable reactions
- Topical hyperbaric oxygen therapy, also known as HTOB or TOB
- Topical oxygen delivery system

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™
- Topical hyperbaric oxygen therapy, also known as HTOB or TOB
- Topical oxygen delivery system

Document History:

Revised Dates:

- 2025: June Implementation date of September 1, 2025. Criteria updated references updated.
- 2025: May Updated definitions and criteria. Add CPT codes A6010, A6011, A6021-A6024 and criteria for coverage for Collagen Dressings or Wound Fillers. Add A4575 and E0446 to Not Medically Necessary section of the policy. No change to coverage criteria. Go live 7.1.2025.
- 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
 Date: October 2023

Origination Date: October 2023

Coding:

Medically necessary with criteria:

Wedically necessa	ry with official.
Coding	Description
A6010	Collagen based wound filler, dry form, sterile, per g of collagen

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A6011	Collagen based wound filler, gel/paste, per g of collagen
A6021	Collagen dressing, sterile, size 16 sq in or less, each
A6022	Collagen dressing, sterile, size more than 16 sq in but less than or equal to 48 sq in,each
A6023	Collagen dressing, sterile, size more than 48 sq in, each
A6024	Collagen dressing wound filler, sterile, per 6 in
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
A4575	Topical hyperbaric oxygen chamber, disposable
A9156	Oral mucoadhesive, any type (liquid, gel, paste, etc.), per 1 ml
E0446	Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories

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 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.

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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. Regulatory Information. Code of Federal Regulations Annual Edition. AE 2.106/3:21/21. Titel 21 – Food and Drugs. CFR § 868.5470 - Hyperbaric chamber. 4.1.2024. Retrieved 5.15.2025. https://www.govinfo.gov/app/details/CFR-2024-title21-vol8/CFR-2024-title21-vol8-sec868-5470/summary

US Food and Drug Administration. Title 21 - Food and Drugs. Chapter I - FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED). Subchapter H - MEDICAL DEVICES. Part 868 - ANESTHESIOLOGY DEVICES. Subpart F - Therapeutic Devices. Section § 868.5470 - Hyperbaric chamber. 4.1.2024. Retrieved 5.15.2025. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-868

Hayes. A symplr Evidence Review. Evolving Evidence Review. Topical Hyperbaric Oxygen Therapy for Venous Ulcers. 11.22.2024. Retrieved 5.15.2025. https://evidence.hayesinc.com/report/eer.topicalhbot5580

Hayes. A symplr Evidence Review. Health Technology Assessment. Topical Oxygen Therapy for Chronic Wound Healing. 1.6.2022. Retrieved 5.15.2025. https://evidence.hayesinc.com/report/dir.topicaloxwound311

Centers for Medicare and Medicaid Services. CMS.gov. LCD L33797 Oxygen and Oxygen Equipment. 4.1.2023. Retrieved 5.15.2025. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33797

Frykberg, R., Andersen, C., Chadwick, P., Haser, P., Janssen, S., Lee, A., Niezgoda, J., Serena, T., Stang, D., Agarwal, A., Cole, W., Dissemond, J., Kirby, J., Lantis, J., Lavery, L., Martinez, J. L., & Wild, T. (2023). Use of Topical Oxygen Therapy in Wound Healing. Journal of wound care, 32(Sup8b), S1–S32. https://doi.org/10.12968/jowc.2023.32.Sup8b.S1

Kasprzyk-Kucewicz, T., Cholewka, A., Englisz-Jurgielewicz, B., Mucha, R., Relich, M., Kawecki, M., Sieroń, K., Onak, P., & Stanek, A. (2021). Thermal Effects of Topical Hyperbaric Oxygen Therapy in Hard-to-Heal Wounds-A Pilot Study. International journal of environmental research and public health, 18(13), 6737. https://doi.org/10.3390/ijerph18136737

Pasek, J., Szajkowski, S., Travagli, V., & Cieślar, G. (2023). Topical Hyperbaric Oxygen Therapy Versus Local Ozone Therapy in Healing of Venous Leg Ulcers. International journal of environmental research and public health, 20(3), 1967. https://doi.org/10.3390/ijerph20031967

Undersea and Hyperbaric Medical Society. UHMS Position Statement: Topical Oxygen for Chronic Wounds. 2018. Retrieved 5.15.2025. https://www.uhms.org/component/edocman/uhm-journal-vol-45/number-3/uhms-position-statement-topical-oxygen-for-chronic-wounds.html

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

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Commonwealth of Virginia. Department of Medical Assistance Services. Procedure Fee Files & CPT Codes. 2025. Retrieved 5.15.2025. https://www.dmas.virginia.gov/for-providers/rates-and-rate-setting/procedure-fee-files-cpt-codes/

MCG Informed Care Strategies. 28th Edition. 2024. Retrieved 5.15.2025. https://careweb.careguidelines.com/ed28/index.html

Keywords:

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

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