

Wound Treatment and Care Supplies (i.e. dressings, barriers and fillers)

Table of Content

<u>Purpose</u>

Description & Definitions

<u>Criteria</u> Coding

Document History

References

Special Notes

Keywords

Effective Date 4/1/2024

<u>Next Review Date</u> 10/15/2024

<u>Coverage Policy</u> Medical 343

<u>Version</u> 1

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

Purpose:

This policy addresses various wound treatment options.

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.

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 considered **not medically necessary** for any use other than those indicated in clinical criteria, to include but not limited to:

- 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.

MuGard™ is considered not medically necessary for any indication.

Coding:

Medical 343 Page 1 of 4

Medically necessary with criteria:

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

Considered Not Medically Necessary:

Coding	Description
A9156	Oral mucoadhesive, any type (liquid, gel, paste, etc.), per 1 ml

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

Document History:

Revised Dates:

•

Reviewed Dates:

2023: October

Effective Date:

April 1, 2024

References:

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

(2023). Retrieved Sep 19, 2023, from Hayes, Inc:

https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522Mugard%2522,%2522title%2522:null,%2522ter msource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%2522:0,%2522size%2522:50%257D,%2522type%2522:%2522all%2522,%2522sources%2522:%255B%2522

(2023). Retrieved Sep 19, 2023, from Centers for Medicare and MedicareServices: https://www.cms.gov/medicare-coverage-database/search-

results.aspx?keyword=Mugard&keywordType=starts&areald=s53&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance

(2023). Retrieved Sep 19, 2023, from National Comprehensive Cancer Network: https://www.nccn.org/search-result?indexCatalogue=nccn-search-index&searchQuery=mucoadhesive%20hydrogel

(2023, Jun 27). Retrieved Sep 20, 2023, from MCG: https://careweb.careguidelines.com/ed27/index.html

(2023). Retrieved Sep 20, 2023, from InterQual: https://prod.cue4.com/caas/review/login

(2023). Retrieved Sep 20, 2023, from Department of Medical Assistance Services: https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=Mugard&gsc.sort=

Evidence-Based Management of Oral Mucositis. (2020, Feb 20). Retrieved Sep 20, 2023, from American Society of Clinical Oncology: https://ascopubs.org/doi/full/10.1200/JOP.19.00766?role=tab

Galloway, T., & Amdur, R. (2023, Jan 05). Management and prevention of complications during initial treatment of head and neck cancer. Retrieved Sep 19, 2023, from UpToDate: https://www.uptodate.com/contents/management-and-prevention-of-complications-during-initial-treatment-of-head-and-neck-

cancer?search=Mugard%E2%84%A2§ionRank=1&usage_type=default&anchor=H4014997&source=machineLearning&selectedTitle=2~3&display_rank=2#H

Management of Cancer Therapy—Associated Oral Mucositis. (2020, Feb 03). Retrieved Sep 20, 2023, from American Society of Clinical Oncology: https://ascopubs.org/doi/full/10.1200/JOP.19.00652

Medical 343 Page 2 of 4

MUGARD MUCOADHESIVE ORAL WOUND RINSE. (2023, Sep 18). Retrieved Sep 18, 2023, from U.S. Food and Drug Administration: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K062795

Centers for Medicare & MedicareServices' (CMS') Healthcare Common Procedure Coding System (HCPCS) Level II Final Coding, Benefit Category and Payment Determinations - First Biannual (B1), 2023 HCPCS Coding Cycle. (2023). Retrieved Sep 18, 2023, from Department of Health and Human Services - Centers for Medicare and MedicareServices: https://www.cms.gov/files/document/2023-hcpcs-application-summary-biannual-1-2023-non-drug-and-non-biological-items-and-services.pdf

(2023), Retrieved Sep 15, 2023, from Haves, Inc.

https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522NEXOBRID%2522,%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%2522:0,%2522size%2522:50%257D,%2522type%2522:%2522all%2522,%2522sources%2522:%255B%25

(2023). Retrieved Sep 15, 2023, from Centers for Medicare and Medicaid Services: https://www.cms.gov/medicare-coverage-database/search-

results.aspx?keyword=Anacaulase&keywordType=starts&areald=s53&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance

(2023, Jun 27). Retrieved Sep 15, 2023, from MCG: https://careweb.careguidelines.com/ed27/index.html

(2023). Retrieved Sep 18, 2023, from Department of Medical Assistance Services:

https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=burn%20treatment&gsc.sort=

About Nexobrid. (2023). Retrieved Sep 15, 2023, from Vericel Corporation (Nexobrid): https://www.nexobrid-us.com/about-nexobrid/

BLA APPROVAL - r NexoBrid (anacaulase-bcdb) gel. (2023, May). Retrieved Sep 18, 2023, from U.S. Food and Drug Administration: https://www.accessdata.fda.gov/drugsatfda docs/appletter/2022/761192Orig1s000ltr.pdf

Hirche, C. (2020, Mar 30). Eschar removal by bromelain based enzymatic debridement (Nexobrid®) in burns: European consensus guidelines update. Retrieved Sep 18, 2023, from PubMed: https://pubmed.ncbi.nlm.nih.gov/?term=Static+progressive+stretch+or+patient-actuated+serial+stretch&filter=simsearch1.fha&filter=simsearch2.ffrft&filter=vears.2022-2022

NexoBrid (anacaulase-bcdb). (2023, May 31). Retrieved Sep 15, 2023, from Molina Healthcare: https://www.molinamarketplace.com/marketplace/oh/en-us/Providers/-/media/4BC8D756A26A4D5D886F42E2411A0014.ashx

NexoBrid® (anacaulase-bcdb) – New orphan drug approval. (2023). Retrieved Sep 18, 2023, from Optum Rx: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval nexobrid 2023-1229.pdf

Phelan, H., & Bernal, E. (2022, May 18). Treatment of deep burns. Retrieved Sep 18, 2023, from UpToDate: https://www.uptodate.com/contents/treatment-of-deep-

burns?search=NEXOBRID%C2%AE&source=search_result&selectedTitle=1~3&usage_type=default&display_rank=1#H3 710518805

Second Quarter, 2023 HCPCS Coding Cycle - Final Determinations for the Second Quarter 2023 Drug and Biological HCPCS Applications. (2023). Retrieved Sep 15, 2023, from Centers for Medicare and Medicaid Services: https://www.cms.gov/medicare-coverage-database/search-

results. aspx? hcpcsOption = code & hcpcsStartCode = E0618 & hcpcsEndCode = E0618 & sortBy = title & areald = s53 & docType = 6, 3, 5, 1, F, P & contractOption = all

Special Notes: *

This medical policy expresses Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. 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 343 Page 3 of 4

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.

Keywords:

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

Medical 343 Page 4 of 4