

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

Table of Content

<u>Purpose</u>

Description & Definitions

Criteria

Coding

Document History

References

Special Notes

Keywords

Effective Date 4/1/2024

Next Review Date 10/15/2024

Coverage Policy Medical 343

Version 1

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.*.

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

Medical 343 Page 1 of 4

- 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:

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:

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).

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

https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522Mugard%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%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, Fa, 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=

Medical 343 Page 2 of 4

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-

 $cancer? search=Mugard\% E2\%84\% A2\§ion Rank=1\&usage_type=default\& anchor=H4014997\& source=machine Learning\& selected Title=2~3\&display_rank=2\#H$

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

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 Hayes, 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=years.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

Medical 343 Page 3 of 4

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&areaId=s53&doc Type=6,3,5,1,F,P&contractOption=all

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.

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.

Keywords:

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

Medical 343 Page 4 of 4