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Original Effective Date: 05/15/17

Reviewed: 03/28/24

Revised: 04/15/24

Subject: ProThelial™ for the Treatment of Oral Mucositis

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

Oral mucositis is a common and often debilitating complication of cancer treatment. Oral mucositis describes inflammation of the oral mucosa and typically manifests as erythema or ulcerations that appear 7 to 10 days after initiation of high-dose cancer therapy. Oral mucositis can cause significant pain and increased risk of systemic infection, dependency on total parenteral nutrition, and use of narcotic analgesics. There are a number of interventions for oral mucositis that may partially control symptoms, but none is considered a criterion standard treatment. When uncomplicated by infection, oral mucositis is self-limited and usually heals within 2 to 4 weeks after cessation of cytotoxic chemotherapy.

One intervention proposed is the use of ProThelial™. ProThelial is polymerized sucralfate malate paste that forms a protective layer over the oral mucosa by adhering to the mucosal surface to protect against further irritation and relieve pain. The paste may be used in the management of mouth lesions of all types, including stomatitis and mucositis. Though ProThelial contains sucralfate, it has been approved by the U.S. Food and Drug Administration (FDA) and is classified as a medical device. The device uses sucralfate as the active component to achieve the clinical effect and requires the facilitated polymerization of sucralfate in order for the devices to function. It requires direct application, transient contact with the patient and multiple administrations for use.

POSITION STATEMENT:

ProThelial™ is considered **experimental or investigational** for all indications, including as an adjunct to standard oral care for the treatment of oral mucositis. The evidence is insufficient to determine the effects of the technology on health outcomes.

BILLING/CODING INFORMATION:

There is no specific HCPCS code to report ProThelial. It may be billed using code J3490.

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) or Local Coverage Determination (LCD) was found at the time of the last guideline reviewed date.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

None applicable.

OTHER:

None applicable

REFERENCES:

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11. ProThelial™ Polymerized Sucralfate Malate Paste, accessed at prothelial.com.
12. Russo G, Haddad R, et al, Radiation Treatment Breaks and Ulcerative Mucositis in Head and Neck Cancer, Oncologist. 2008 Aug;13(8):886-98.
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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 03/28/24.

GUIDELINE UPDATE INFORMATION:

05/15/17	New Medical Coverage Guideline.
03/15/18	Annual review; investigational position maintained and references updated.
03/15/19	Annual review; position statement maintained and references updated.
03/15/20	Annual review; investigational position statement maintained and references updated.
03/15/21	Annual review; position statement maintained and references updated.
02/15/22	Annual review: position statement maintained; references updated.
01/01/24	Position statements maintained.
04/15/24	Review: position statement maintained; references updated.