Medica Central Coverage Policy

Policy Name:	**Chemiluminescent Testing (ViziLite™) for Oral Cancer Screening MP9569**
Effective Date:	**09/01/2024**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

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Note: This policy is no longer scheduled for regular review of the scientific literature.

Chemiluminescent testing (ViziLite®) for oral cancer screening is investigative unproven, and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Description

ViziLite® (Zila Inc., Phoenix, AZ) is a chemiluminescent test, which has been proposed as an adjunct to visual examination to increase identification, evaluation, and monitoring of oral mucosal abnormalities in individuals at increased risk for oral cancer. ViziLite is a single-use product that consists of an acetic acid rinse, retractor, and light stick. The patient rinses with the acetic acid solution and expectorates. The ViziLite light stick is activated and inserted into the hollow end of the retractor. After dimming the lights, the provider examines the oral cavity using the ViziLite device. The light is purported to impart a blue hue to normal tissue, while lesions take on an "acetowhite" appearance, thus becoming clinically discernable.

FDA Approval

The ViziLite® test kit is classified by the FDA as a dental operating light and regulated as a Class II (moderate risk) device. This test system received FDA 510(k) premarket approval on January 31, 2005 (K033033). According to 510(k) approval, a standard visual examination must always be performed before use of the ViziLite® test kit.

Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

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Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:

82397 - chemiluminescent assay

	Committee/Source	Date(s)
Document Created:	Medical Policy Committee/Health Services Division	July 20, 2022
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