



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Oral Cancer Screening Systems (e.g., ViziLite™ and VELscope®)**

**Effective Date ..... 10/15/2010**  
**Next Review Date ..... 10/15/2011**  
**Coverage Policy Number ..... 0372**

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## Hyperlink to Related Coverage Policies

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

## Coverage Policy

**CIGNA does not cover oral cancer screening systems (e.g., ViziLite™ or VELscope®) because they are considered experimental, investigational or unproven.**

## General Background

Oral carcinomas may occur anywhere in the oral cavity, including the posterolateral margin of the tongue and floor of the mouth. Early detection of potentially malignant oral lesions can improve clinical outcome and quality of life. In more than 50% of cases, however, there is evidence of spreading to regional lymph nodes and metastases at the time of diagnosis. The most common method of screening for oral cancer is visual inspection. Visual detection of oral cancer at an early stage is difficult, since premalignant and malignant lesions cannot be easily differentiated from benign lesions. Clinical characteristics such as induration, elevation, bleeding and cervical adenopathy are associated with advanced oral cancers but are typically absent in early-stage lesions. Diagnosis has traditionally been based on histopathological evaluation of a full-thickness incisional scalpel biopsy of the lesion. The ViziLite™ and VELscope® systems have been proposed as adjunctive methods to improve current oral screening methods by assisting in the identification, evaluation and monitoring of oral mucosal abnormalities.

### U.S. Food and Drug Administration (FDA) ViziLite™

The ViziLite Comprehensive Exam Tray (Zila Inc., Phoenix, AZ) received U.S. Food and Drug Administration (FDA) approval through the 510(k) process in November 2001. ViziLite (OralLite) was approved for use in combination with conventional visual oral mucosal examination by healthcare providers to improve identification, evaluation and monitoring of oral mucosal abnormalities in a patient population at increased risk of oral cancer. ViziLite is a single-use product that consists of an acetic acid rinse, retractor, and light stick. The patient rinses with the ViziLite acetic acid solution and expectorates. The ViziLite light stick is activated by bending until the inner capsule breaks. The examiner shakes the stick until it glows, then inserts the light stick into the hollow end of the retractor. After dimming the lights, the oral cavity is examined using the ViziLite device. The technology used in this device is based on similar technology utilizing chemiluminescent light to evaluate dysplastic and malignant squamous cell lesions in the cervix. The light is reported to impart a blue hue to normal tissue, while lesions become clinically discernible and take on an "acetowhite" appearance.

In November 2004, the FDA approved the ViziLite Blue Oral Lesion Identification and Marking System, a three-component swab system used as an adjunct to the ViziLite Test. This system consists of three swab components: two swabs of 1% acetic acid rinse, including a post-dye decolorizer and one swab with a metachromatic vital tissue dye, toluidine chloride (also called toluidine blue). The dye is applied to ViziLite-identified white lesions to allow the healthcare provider to visualize the lesions with incandescent light.

### **VELscope®**

VELscope (LED Medical Diagnostics, White Rock, BC, Canada) received approval through the 510(k) process on April 7, 2006. According to the 510(k) summary, the device was determined to be substantially equivalent to the predicate device, ViziLite. VELscope is intended to be used by a dentist or health-care provider as an adjunct to traditional oral examination by incandescent light to enhance the visualization of oral mucosal abnormalities that may not be apparent or visible to the naked eye, such as oral cancer or premalignant dysplasia. VELscope is further intended to be used by a surgeon to help identify diseased tissue around a clinically apparent lesion and thus aid in determining the appropriate margin for surgical excision. The summary also states that VELscope is complementary to, and is intended to be used in combination with, a traditional oral mucosal examination with white light. The difference between VELscope system and the predicate device is that VELscope uses filters to block the reflected blue light to allow the visualization of the natural tissue fluorescence.

### **Literature Review**

**ViziLite™**: Epstein et al. (2008) evaluated the adjunctive value of ViziLite and application of toluidine blue to further assess lesions identified during a conventional oral soft tissue examination (97 lesions/84 patients). The ViziLite exam improved the brightness and/or sharpness of margin in 61.8% of identified lesions. No lesions that had not previously been identified by oral exam, however, were identified by the adjunctive use of ViziLite. Toluidine blue staining reduced the number of false positive biopsies by 55.26%; approximately two-thirds of lesions with no dysplasia, and 41.18% of lesions with mild or moderate dysplasia were identified as true negative when TBlue staining was used. The authors stated that further research is needed to confirm these results in other populations using different study designs before practitioners can be confident that specificity is improved significantly over conventional visual examination while the negative predictive value remains near 100%.

Farah and McCullough (2007) evaluated the efficacy of ViziLite in enhancing visualization of oral mucosal white lesions and in highlighting malignant and potentially malignant lesions (n=55). Patients referred to an oral medicine specialist service over a three month period for evaluation of an oral mucosal white lesion were examined by two oral medicine specialists under routine incandescent light. The examination was repeated with ViziLite chemiluminescent illumination. Although chemiluminescence subjectively enhanced visualization of 26 white lesions, there was no significant difference in lesions size, ease of visibility or border distinctness for oral lesions examined with or without ViziLite. In addition, ViziLite could not distinguish between epithelial hyperplasia, dysplasia, carcinoma or inflammatory mucosal conditions; all appeared aceto-white under chemiluminescent light and were considered ViziLite-positive. The examination with ViziLite did not change the provisional diagnosis or alter the biopsy site. The authors noted that the updated product, ViziLite Plus, includes a staining solution similar to toluidine blue that is used to further delineate ViziLite positive lesions. The authors stated that this is unlikely to make a significant change to the usefulness of the product, given the documented inherent problem with toluidine blue staining as a diagnostic adjunct in the detection of epithelial dysplasia, and its high false-negative rate for carcinoma in site and mild to moderate dysplasia.

Oh et al. (2007) investigated the efficacy of the individual components of the ViziLite system in providing improved visualization of early oral mucosal lesions in 100 patients who presented to a dental school for screening. The oral cavity was examined under incandescent light for soft tissue abnormalities. Re-examination was performed following a one-minute rinse with 1% acetic acid. The mouth was examined a third time using ViziLite chemiluminescent light. Any lesions detected by these three examinations that were clinically undiagnosable were brush biopsied (Oral CDx) for determination. In the original examination of 100 patients, 57 clinically diagnosable (i.e., recognizable) benign lesions, such as linea alba, leukoedema, were found, and 29 clinically undiagnosable lesions were found. Six additional diagnosable lesions and three undiagnosable lesions were found following the rinse. No additional lesions were found using chemiluminescent light. Of the 32 undiagnosable lesions that were brush biopsied, two were characterized as atypical and were scalpel biopsied. Neither lesion was found to be premalignant or malignant. The authors stated that most of the lesions were found during the initial examination under incandescent light. The acetic acid rinse allowed detection of three new undiagnosable lesions which were found to be benign. No additional lesions were found with ViziLite illumination, and this illumination was reported to make visualization more difficult due to distracting highlights on the oral mucosa.

Epstein et al. (2006) evaluated the use of ViziLite in a group of 134 patients with identified oral lesions or those seen for follow-up of previously treated upper aerodigestive tract cancer. All patients received a routine oral examination using conventional projected incandescent light, with documentation of any lesions found. Patients then rinsed with 15 milliliters of 1% acetic acid solution, and the oral cavity was re-examined using the ViziLite light source. Of 138 lesions seen with incandescent light, 123 (89%) were clinically diagnosed as leukoplakia. Of the 138 lesions seen with incandescent light, 135 (98%) were also seen with ViziLite illumination. Of the three lesions not seen with chemiluminescence, two were red lesions with clinical features not suspicious for malignancy. The third was a flat leukoplakia lesion later diagnosed as consistent with lichen planus on biopsy. Two lesions were visible only with ViziLite illumination; one was diagnosed as recurrent cancer and one was benign. There was no statistically significant difference in lesion detection between the two methods ( $p=0.10$ ). The authors stated that the use of chemiluminescent light or lesion localization, possibly identifying dysplasias and malignancy, will depend on the analysis of an appropriately designed study comparing biopsy in two lesion types: 1) lesions identified by ViziLite only, and 2) visually identified lesions with lesion parameters enhanced by ViziLite.

Kerr et al. (2006) evaluated the utility of ViziLite as an adjunct to enhance visualization of mucosal lesions, especially those considered to be clinically suspicious for oral cancer or pre-cancer. A total of 501 consecutive patients with a positive tobacco history received a standard visual exam with incandescent lighting followed by chemiluminescent lighting. All lesions were recorded, and lesions detected with both exams were compared in terms of lesion brightness, sharpness, surface texture and relative size. The standard visual exam identified 410 epithelial lesions in 270 patients, with 127 lesions considered clinically suspicious and 360 considered non-suspicious. Of the suspicious lesions, 77 (61%) were also seen with chemiluminescence, compared to 21 (5.8%) of the non-suspicious lesions. In addition to the 98 lesions seen by both methods, six aceto-white lesions were seen only with oral chemiluminescence. Upon re-examination, these lesions were visible with standard lighting and met the criteria for suspicious. Compared to standard lighting, chemiluminescence demonstrated improved sharpness ( $p=0.015$ ); there was a trend toward improved brightness ( $p=0.112$ ) and no significant improvement in surface texture. Red-only lesions were least likely to be detected and lesions with a white component were more likely to be detected with chemiluminescence. Two suspicious lesions were not detected with chemiluminescence. The authors acknowledge that the clinical significance and predictive value of oral chemiluminescence to detect oral cancer or pre-cancer remains unknown, and additional studies with tissue biopsy pathologic endpoints are underway. The authors also state that the high prevalence of oral lesions in this population suggests that the performance of oral chemiluminescence in finding new lesions may be lower in the general population.

**VELscope®**: Lane et al. (2006) evaluated the use of a handheld device (presumed to be VELscope, although the copyrighted device name was not mentioned) that facilitates direct visualization of oral cavity fluorescence for the detection of high-risk precancerous and early cancerous lesions. Blue excitation light is used to excite green-red fluorescence in the oral tissues. The device enables direct visualization of fluorescence in the context of surrounding tissue. This small pilot study evaluated the use of the device in 44 patients with a history of biopsy-confirmed oral dysplasia or SCC who were recruited from the Oral Health Study at the British Columbia Cancer Agency. During each visit, an assessment of the oral mucosa under white light was conducted to identify new lesions or alterations to previously identified lesions. After turning off the room light, the oral cavity was

viewed with direct fluorescence visualization (FV). The clinicians then decided whether the lesions required biopsy based on standard clinical features (patient history, clinical appearance, and toluidine blue staining results) and not based on the direct FV examination. Biopsied lesions were evaluated by oral pathologists and a histological diagnosis was assigned. The association with direct FV changes in the oral mucosa of biopsy-confirmed sites of normal and severe dysplasia, carcinoma in situ, and invasive SCC was then assessed. Using histology as the gold standard, the device achieved a sensitivity of 98% and a specificity of 100% when discriminating normal lesions from high-risk pre-malignant lesions and invasive SCC. The authors stated that these preliminary results suggest this direct FV device has potential as an adjunct to conventional white-light screening to increase the sensitivity of white-light screening alone but not reduce the specificity.

VELscope has also been suggested as a method to identify subclinical high-risk fields with precancerous or cancerous changes in the operating room setting (Poh, et al., 2006-1). This proposed application is not addressed in this Coverage Policy. Additional published information on the use of VELscope consists of case reports (Poh, et al., 2006-2; Kois and Truelove, 2006).

### **ViziLite and VELscope**

Mehrotra et al. conducted a cross-sectional study to evaluate the use of ViziLite Plus with TBlue (n=102) and VELscope (n=156) as adjunct aids in diagnosing lesions deemed clinically innocuous according to conventional light examination. Patients were screened with an overhead examination light and with VELscope or ViziLite. Patients with clinically innocuous lesions underwent a biopsy, and the results of tissue pathological analysis were compared with findings from the screening aid tests. Three dysplasias and one cancer were found Of 102 patients in the ViziLite group who underwent biopsy. None of these were detected with the adjunctive screening device, ViziLite. The sensitivity of ViziLite was 0%. ViziLite findings were negative in 74 patients with benign lesions and positive in 24 patients with benign lesions, with a specificity of 75.5%. The positive predictive value was 0 %, and the negative predictive value was 94.8%. Eleven dysplasias and one cancer were found in 156 patients in the VELscope group who underwent a biopsy. Five dysplasias and one cancer were also detected with VELscope. The sensitivity of VELscope was 50%. VELscope findings were negative in 56 patients with benign lesions and positive in 88 patients with benign lesions. The specificity was 38.9%; the positive predictive value was 6.4%, and the negative predictive value was 90.3 percent. Neither adjunctive technique identified any lesions that were not already apparent during the conventional overhead light exam.

Patton et al. (2008) conducted a systematic review to evaluate the effectiveness of adjunctive techniques for oral cancer examination and lesion diagnosis. The review evaluated various techniques that are promoted to improve earlier detection and diagnosis of oral malignancies, including toluidine blue, ViziLite Plus with toluidine blue, ViziLite, VELscope, and OralCDx brush biopsy. A total of 23 studies met the inclusion criteria. The authors concluded that there is insufficient evidence to support or refute the use of visually-based examination adjuncts. The review concluded that, given the lack of effectiveness data in general dental practice settings, clinicians must rely on a thorough oral mucosal examination supported by specialty referral and/or tissue biopsy for oral premalignant and malignant lesions.

### **Professional Societies/Organizations**

**American Dental Association (ADA):** The ADA published evidence-based clinical recommendations regarding screening for oral squamous cell carcinomas in 2010 (Rethman et al., or the ADA Council on Scientific Affairs Expert Panel on Screening for Oral Squamous Cell Carcinoma). The authors concluded that screening by means of visual and tactile examination to detect potentially malignant and malignant lesions may result in detection of oral cancers at earlier stages, but there is insufficient evidence to determine if screening alters disease-specific mortality in asymptomatic people seeking dental care.

The guideline includes the following conclusion regarding autofluorescence devices (e.g., VELscope)

- There is insufficient evidence that commercial devices based on autofluorescence enhance visual detection of potentially malignant lesions beyond that achieved through a conventional visual and tactile examination. (Level of evidence: III [evidence from non experimental descriptive studies, such as comparative studies, correlation studies, cohort studies and case-control studies])

The guideline includes the following conclusion regarding tissue reflectance devices (e.g., ViziLite)

- There is insufficient evidence that commercial devices based on tissue reflectance enhance visual detection of potentially malignant lesions beyond that achieved through a conventional visual and tactile examination. (Level of evidence: III [evidence from non experimental descriptive studies, such as comparative studies, correlation studies, cohort studies and case-control studies])

The authors noted that additional research regarding oral cancer screening and the use of adjuncts is needed.

**U.S. Preventive Services Task Force (USPSTF):** In a recommendation issued in 2004, the USPSTF concluded that the evidence is insufficient to recommend for or against routinely screening adults for oral cancer. They found no new good-quality evidence that screening for oral cancer leads to improved health outcomes for either high-risk adults (i.e., those over the age of 50 who use tobacco) or average-risk adults in the general population. It is unlikely that controlled trials of screening for oral cancer will ever be conducted in the general population because of the very low incidence of oral cancer in the United States. There is also no new evidence for the harms of screening. As a result, the USPSTF could not determine the balance between benefits and harms of screening for oral cancer.

### Summary

There is no clear evidence that oral cancer screening programs provide early detection of oral cancer earlier and reduce the number of deaths from this disease. The ViziLite™ oral screening system and the VELscope System have been proposed as methods to improve current oral screening methods by assisting in the identification, evaluation and monitoring of oral mucosal abnormalities. There is insufficient information in the published medical literature, however, to demonstrate that the use of these devices as an adjunct to conventional oral screening provides additional benefit compared to conventional oral cancer screening alone or that their use results in improved health outcomes.

## Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**Experimental, investigational, unproven and not covered when used to report the ViziLite oral screening system or the VELscope® system.**

HCCPS/ CDT*Codes	Description
D0431	Adjunctive pre-diagnostic test that aids in detection of mucosal abnormalities including premalignant and malignant lesions, not to include cytology or biopsy procedures

ICD-9-CM Diagnosis Codes	Description
V76.42	Screening for malignant neoplasm of the oral cavity
	All codes

\*Current Dental Terminology (CDT®) ©2009 American Dental Association, Chicago, IL.

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## Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	9/15/2008	0372	ViziLite™ and VELscope® Oral Screening Systems
Great-West Healthcare	11/30/2007	05.325.02	ViziLite Oral Screening for Cancer

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