



# 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 ViziLite™ and VELscope® Oral Screening Systems**

**Effective Date ..... 10/15/2008**  
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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 ©2008 CIGNA

## Coverage Policy

**CIGNA does not cover the ViziLite™ oral screening system or the VELscope® system because they are considered experimental, investigational or unproven.**

It is estimated that 35,310 new cases of oral cancer will be diagnosed in the United States in 2008 and approximately 7590 individuals will die of the disease. Oral cancer accounts for about 3% of cancers in men and 2% in women. The incidence of oral cancer increases with age until approximately age 65, when the rate levels off. More than 90% of oral cancers occur in patients over age 45, although recent increases in the incidence of oral cancer, especially oral cancer of the tongue, have been reported in adults under age 40. The major risk factors for oral cancer in the United States are tobacco use, including smokeless tobacco, and alcohol. Infection with human papillomavirus has been linked to an excess risk of developing squamous cell carcinoma of the oropharynx (American Cancer Society, 2008).

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.

## **ViziLite™**

### **U.S. Food and Drug Administration (FDA)**

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.

### **Literature Review**

Huber et al. (2004) published a pilot study designed to collect data to support the hypothesis that oral soft tissues exhibit features similar to cervical epithelium following an acetic acid wash and visual inspection under chemiluminescent illumination. In this case series, a conventional visual oral soft tissue examination was performed on 100 consecutive patients, ages 18–70, using incandescent overhead and halogen dental illumination as well as palpation. The examiner then repeated the exam under chemiluminescent illumination using the ViziLite system to detect abnormal epithelial changes. Most “acetowhite lesions” in this study were evaluated and found to be benign and, according to the researchers, could have been diagnosed accurately based on history, clinical features, bilateral distribution and anatomical location, with the exception of one lesion classified as mild atypia. The authors concluded that oral epithelium exhibits features similar to cervical epithelium, but that further studies are required to refine issues related to the selectivity and specificity of ViziLite in conjunction with the clinical cytological and histological features of oral epithelial lesions.

Ram et al. (2005) conducted a small case series to evaluate chemiluminescence and toluidine chloride as diagnostic aids in the detection of oral cancer and potentially malignant epithelial lesions (PMELs). A total of 46 clinically identified lesions were examined with the ViziLite chemiluminescence kit and a 1% toluidine chloride rinse. The 46 lesions examined consisted of 14 primary squamous cell carcinomas (SCCs), 26 PMELs, and six benign lesions in 40 patients. The authors stated that the SCC cases were clinically obvious malignant lesions that could be recognized without the aid of adjunctive diagnostic tools. ViziLite screening was done to determine the characteristics of clinically obvious SCC when visualized under chemiluminescent light and to screen for the possibility of change in other apparently normal mucosa. Biopsy and histological verification of 31 lesions disclosed 14 SCC lesions, 10 epithelial dysplasias, five lichen planus and two benign lesions. Biopsies were not performed on 15 lesions due to lack of patient consent or ill health. The five cases of normal oral mucosa that tested normal for both tools were not biopsied. Sensitivity for ViziLite and toluidine chloride was 100% and 70.3%, respectively, and specificity was 14.2% and 25%, respectively. The authors stated that chemiluminescent light or ViziLite is useful as an adjunctive diagnostic tool for the detection of oral cancer and PMELs and follow-up of patients treated for these conditions, and that further studies are required to evaluate the full potential of these techniques for target screening of high-risk individuals. It is difficult to draw conclusions from this study, however, because of its small size, incomplete biopsy and histological data, and the fact that patients with obvious lesions from previously diagnosed oral cancer and PMEL were included.

A Cochrane systematic review, published in 2003 and amended in 2006, evaluated screening programs for the early detection and prevention of oral cancer (Kujan, et al.) and concluded that there is insufficient evidence to support or refute the use of visual examination as a screening method in the general population and that there is no evidence that methods of screening, such as toluidine blue, fluorescence imaging and brush biopsy are either beneficial or harmful. The Cochrane review recommended systematic examination of the oral cavity by the general dental practitioner or physician should remain an integral part of the routine daily work, with

particular attention paid to high-risk individuals, but that randomized controlled trials are needed to determine whether screening programs can detect oral cancer earlier and reduce the number of deaths from the disease.

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 examination of the oral cavity using conventional projected incandescent light. If a mucosal lesion was seen, the examiner recorded the location, an assessment of the brightness of the lesion, sharpness of the borders, texture, and size of the lesion. Patients then rinsed with 15 milliliters of 1% acetic acid solution, and the oral cavity was re-examined using the ViziLite light source. Examiners recorded the same data documented in the standard exam and compared each parameter. Results were graded as decreased, no change, slight improvement or marked improvement. A total of 138 lesions were seen with incandescent light. The majority of lesions (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. Both patients had a history of oral squamous cell carcinoma. One lesion was diagnosed as recurrent cancer and one was benign. Examiners reported improved brightness with the use of ViziLite in 54.1% of cases and improved sharpness in 40.9% of cases. Improvement in visualization of lesion texture and size was reported in 36.2% and 15.3% of cases, respectively, using ViziLite. Based on brightness, sharpness and texture, lesion visibility was enhanced using ViziLite ( $p=0.001$ ). The slight increase in mean lesion size was not significant ( $p=0.06$ ). 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.

Oh et al. (2007) investigated the efficacy of the individual components of the ViziLite system in providing improved visualization of early oral mucosal lesions. A total of 100 patients who presented to a dental school for screening were examined. 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.

Kerr et al. (2006) evaluated the utility of ViziLite as an adjunct to standard visual examination 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 for lesions detected with both exams, comparisons of lesion brightness, sharpness, surface texture and relative size were made. The standard visual exam identified 410 epithelial lesions in 270 patients, with 127 lesions considered to be 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.

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 situ and mild to moderate dysplasia.

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%.

There is insufficient evidence to demonstrate the specificity or sensitivity of the ViziLite oral screening system or its impact on health outcomes. There is no evidence that the use of ViziLite as an adjunct to conventional oral screening provides additional benefit compared to conventional oral cancer screening alone.

## **VELscope®**

### **U.S. Food and Drug Administration (FDA)**

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.

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 objective was to verify the effectiveness of the direct FV device in differentiating

high-risk oral premalignant lesions and invasive SCC from normal oral mucosa. 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 therefore 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 Position.

Additional published information on the use of VELscope consists of case reports (Poh, et al., 2006-2; Kois and Truelove, 2006). Although VELscope is a promising technology, there is insufficient evidence to demonstrate that its use as an adjunct to conventional oral screening provides additional benefit compared to conventional oral cancer screening alone.

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, 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

The American Dental Association (ADA) policy on prevention and early oral cancer detection states that because early detection is critical for decreasing the morbidity and mortality associated with oral and pharyngeal cancer, periodic extraoral and intraoral examinations are recommended. In a recommendation statement published in 2004, the U.S. Preventive Services Task Force (USPSTF) concluded that the evidence is insufficient to recommend for or against routinely screening adults for oral cancer.

### Summary

Systematic examination of the oral cavity for signs of oral cancer is recommended, especially in high-risk individuals, although there is no clear evidence that oral cancer screening programs can detect 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.

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## Coding/Billing Information

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

### Experimental/Investigational/Unproven/Not Covered:

HCPCS Codes	Description
D0431 <sup>†</sup>	Adjunctive pre-diagnostic test that aids in detection of mucosal abnormalities including premalignant and malignant lesions, not to include cytology or biopsy procedures

<sup>†</sup>**Note: Experimental, investigational, unproven and not covered when used to report the ViziLite oral screening system or the VELscope® system.**

ICD-9-CM Diagnosis Codes	Description
V76.42	Screening for malignant neoplasm of the oral cavity
	Multiple/varied

**\*Current Procedural Terminology (CPT®) ©2007 American Medical Association: Chicago, IL.**

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## Policy History

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
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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