BlueCross BlueShield of Alabama

Name of Policy:
Oral Lesion Identification System (ViziLite™, Velscope™)

Policy #: 332
Category: Medical/Dental

Latest Review Date: October 2010
Policy Grade: **Active Policy but no longer scheduled for regular literature reviews and updates.**

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Proprietary Information of Blue Cross and Blue Shield of Alabama

Description of Procedure or Service:

Cancer is defined as the uncontrollable growth of cells that invade and cause damage to surrounding tissue. Oral cancer, which includes cancers of the lips, tongue, cheeks, floor of the mouth, hard and soft palate, sinuses, and pharynx (throat), can be life threatening if not diagnosed and treated early. The overall 1-year survival rate for patients with all stages of oral cavity and pharynx cancers is 81%. The 5- and 10-year survival rates are 56% and 41%, respectively. As part of a routine dental examination, the dentist will conduct an oral cancer screening exam. More specifically, the dentist will feel for any lumps or irregular tissue changes in the neck, head, face, and oral cavity. When examining the mouth, the dentist will look for any sores or discolored tissue as well as check for any signs and symptoms mentioned above. A dentist may perform an oral brush biopsy if he or she sees tissue in the mouth that looks suspicious. This test is painless and involves taking a small sample of the tissue and analyzing it for abnormal cells. Alternatively, if the tissue looks more suspicious, the dentist may recommend a scalpel biopsy. This procedure usually requires local anesthesia and may be performed by a dentist or a specialist. These tests are necessary to detect oral cancer early, before it has had a chance to progress and spread. The American Cancer Society recommends oral cancer screening exams every 3 years for persons over age 20 and annually for those over age 40. Risk factors include smoking, smokeless tobacco, excessive alcohol consumption, family history and/or excessive sun exposure.

ViziLite™, by Zila Pharmaceuticals, is a single-use product that is made up of a single acetic acid rinse, retractor and light stick. After rinsing with the acetic acid solution, the patient expectorates. The dentist then activates the ViziLite™ stick by bending until the inner capsule is broken. After shaking the light stick until it glows, it is inserted into the hollow end of the retractor and, with the lights dimmed; the oral cavity is examined with the ViziLite™ device. This light is reported to impart a blue hue to normal tissue, while lesions become clinically discernible by taking on an "acetowhite" appearance. The ViziLite™ test kit has been further updated by the addition of a three-component swab system, known as the ViziLite™ Blue Oral Lesion Identification and Marking System. The system contains two swabs of 1% acetic acid rinse and one swab with a metachromatic vital tissue dye, toluidine blue. The dye is applied to ViziLite™-identified white lesions to allow the examiner to visualize the lesions with incandescent light.

VELscope™ received 510(k) market clearance in April 2006 and was deemed equivalent to Vizilite. VELscope is intended to be used by dentists or health-care providers 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 pre-malignant dysplasia. It is further intended to be used by surgeons to help identify diseased tissue around a clinically apparent lesion and thus aid in determining the appropriate margin for sugical excision. VELscope uses visible light in the 430 nm wavelength in order to cause fluorescent excitation of certain compounds in the tissues.

Policy:

Oral lesion identification systems (such as ViziLite™ or Velscope™) **do not meet** Blue Cross Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

Head and neck cancer accounts for 3.2% of all cancers in the U.S. The primary risk factors are smoking and alcohol use. Infection with human papilloma virus (HPV) has been linked to a greater risk of developing squamous cell carcinoma, which accounts for 90-95% of the oral cavity and laryngeal tumors. Rarely the cancer will be adenocarcinoma, mucoepidermoid carcinoma or adenoid cystic carcinoma. Patients who present with oral cavity tumors will often complain of nonhealing mouth ulcers, ill-fitting dentures, loosening of teeth, weight loss, bleeding, odynophagia, and dysphagia or referred otalgia. Up to 66% of patients with primary tongue lesions have cervical nodal involvement. In hard palate and lip cancers the incidence is substantially lower.

The process from premalignant to frank malignancy involves a series of pathology changes. Among the premalignant are leukoplakia, erythroplakia and dysplasia. The standard diagnostic approach for suspected head and neck cancer begins with the history and physical that includes palpation of the neck and endoscopic exam of nasopharynx and larynx. Bimanual exam of the floor of the mouth is important to determine the local extent of the tumors of the oral cavity. Flexible fiberoptic endoscopy allows visualization of the nasal vault, nasopharynx, base of the tongue, hypopharynx and larynx as well as assessment of vocal cord mobility. Histologic diagnosis of cancer is mandatory prior to treatment. This is most often accomplished by fine needle aspiration or brush/scalpel biopsy.

A pilot study was published by Huber et al (2004) that compared conventional visual oral exam to an acetic wash and visual inspection under chemiluminescent illumination in 100 consecutive patients 18 to 70 years of age. Most “acetowhite lesions” in this study were found to be benign on evaluation 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 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.

In a study conducted by Ram et al. (2005) stated the chemiluminescent light or ViziLite™ is useful as an adjunctive diagnostic tool for the detection of oral cancer and potentially malignant epithelial lesions (PMEL) 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.

Oh et al. (2007) investigated the efficacy of the individual components of the ViziLite™ system in providing improved visualization of early oral mucosal. Most of the lesions were found 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.

The 2004 update from 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.

October 2009
Farah and McCullough (2007) reported on a pilot case control study evaluating the efficacy of using acetic acid wash and chemiluminescent illumination in the visualization of oral mucosal white lesions. Fifty-five patients were referred for assessment of an oral white lesion with prospective screening via Vizilite and then an incisional biopsy. The Vizilite tool enhanced intra-oral visualization of 26 white lesions, but did not change the provisional diagnosis nor alter the biopsy site. Vizilite illumination does not discriminate between keratotic, inflammatory, malignant or potentially malignant oral mucosal white lesions. Therefore, a high index of suspicion, expert clinical judgment, and scalpel biopsy are still essential for proper patient care.

Patton et al (2008) published the results the results of a systematic review of the literature on adjunctive techniques for oral cancer exam and lesion diagnosis. A number of techniques were evaluated in the 23 articles identified for the literature review that included toluidine blue (TB), ViziLite with TBlue, ViziLite, Microlux DL, Orascoptic DK, BELscope, and OralCDx brush biopsy. The authors reported that there was evidence that TB is effective as a diagnostic adjunct for use in high-risk populations and suspicious mucosal lesions. OralCDx is useful in assessment of dysplastic changes in clinically suspicious lesion; however, there was insufficient data meeting the inclusion criteria to assess usefulness in innocuous mucosal lesions. Overall, there is insufficient evidence to support or refute the use of visually based examination adjuncts. Due to the lack of data on the effectiveness of adjunctive cancer detection techniques 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 (OPML) diagnosis.

Trullenque-Eriksson et al (2009) published the results of a review of publications related to examination techniques that might improve the visualization of suspicious lesions of the oral mucosa (ViziLite and VELscope system) or that might facilitate the cytological identification of suspicious (OralCDx). The authors found that clinical examination and histopathological confirmation with biopsy remain the gold standard for the detection of oral cancer. More randomized controlled studies are needed to confirm the positive cost-benefit relationship and the true usefulness of these “new diagnostic methods” in oral mucosal pathology.

October 2010 Update
No new peer reviewed literature was identified in a recent literature search. Therefore there is no change in the coverage statement of this policy.

Key Words:
Oral cancer screening, ViziLite™, VELscope system™, ViziLite Plus™, ViziLite Plus with TBlue630™, Zila Inc., ViziLite™ Blue Oral Lesion Identification and Marking System, chemiluminescent, Zila Technical, Inc.

Approved by Governing Bodies
ViziLite™---510K FDA approved 2005
Velscope™---510K FDA approved 4/7/2006

Benefit Application:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.
Pre-certification requirements: Not applicable

Current Coding:
CDT:

D0431	Adjunctive pre-diagnostic test that aids in detection of mucosal abnormalities including premalignant and malignant lesions, not to include cytology or biopsy procedures.
D0502	Other pathology procedures, by report
D0999	Unspecified diagnostic procedure, by report

CPT codes:

40899	Unlisted procedure, vestibule of mouth
41599	Unlisted procedure, tongue, floor of mouth
41899	Unlisted procedure, dentoalveolar structures
82397	Chemiluminescent assay

References:
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2. Downer MD. *A systematic review of measures of effectiveness in screening for oral cancer and precancer*. Oral Oncology, July 2006; 42(6): 551-560.
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13. U.S. Preventive Services Task Force. S*creening for oral cancer.* Agency for Healthcare Research and Quality, February 2004. http://www.ahrq.gov/clinic/uspstf/uspsoral.htm.

Policy History:

Medical Policy Group, October 2008 **(4)**
Medical Policy Administration Committee, November 2008
Available for comment November 20, 2008-January 5, 2009
Medical Policy Group, October 2009 **(1)**
Medical Policy Group, October 2010 **(1)** Update to Description, no policy change
Medical Policy Group, September 2012 **(3)**: **Effective September 14, 2012 this policy is no longer scheduled for regular literature reviews and updates.**

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date

hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review)in Blue Cross and Blue Shield's administration of plan contracts.