Coverage Policy

Cigna does not cover oral cancer screening systems, including, but not limited to the following, because they are considered experimental, investigational or unproven:

- ViziLite™ (Zila Inc., Phoenix, AZ)
- VELscope® (LED Medical Diagnostics, White Rock, BC, Canada)
- Microlux™/DL (AdDent, Inc., Danbury, CT)
- Orascoptic™ DK™ (Sybron Dental Specialties, Inc., Orange, CA)
- OraRisk® HPV Salivary Diagnostic Test (OralDNA Labs, Brentwood, TN)
- TRIMIRA™ Identafi™ 3000 (TRIMIRA, LLC, Houston, TX)
- Dentlight Oral Exam Light Kit (DentLight, Inc., Richardson, TX)

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. Screening has not been demonstrated to reduce mortality in cancer of the oral cavity, however. In more than 50% of cases 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 and palpation. 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 scalp biopsy of the
A number of light-based visualization adjuncts have been developed in an effort to improve evaluation of oral mucosal abnormalities. Chemilluminescence, blue-white LED, and autofluorescence are used as light sources in light-based systems, including ViziLite™ (Zila Inc., Phoenix, AZ) VELscope® (LED Medical Diagnostics, White Rock, BC, Canada) MicroLux™/DL (AdDent, Inc., Danbury, CT); Orascoptic DK™ (Sybron Dental Specialties, Inc., Orange, CA); TRIMIRA™ Identiﬁ™ 3000 (TRIMIRA, LLC, Houston, TX); and Dentlight Oral Exam Light Kit (DentLight, Inc., Richardson, TX).

Human papillomavirus (HPV) are a group of more than 150 related viruses. Persistent HPV infections have been recognized as the cause of essentially all cervical cancers, as well as most cases of anal cancer. At least 15 high-risk HPV types have been identified, including HPV types 16 and 18. Recent data indicates that HPV, specifically HPV-16, is also an independent risk factor for the oropharyngeal cancer. HPV may modulate the malignancy process in some tobacco and alcohol induced tumors of the oropharynx, and may also be associated with development of oropharyngeal cancer in some non-smokers. The OraRisk® HPV test (OralDNA Labs, Brentwood, TN) is a screening tool used to identify types of oral HPV. The patient swishes and gurgles a sterile saline solution and expectorates into a collection tube. The sample is then sent to OralDNA Labs for DNA polymerase chain reaction analysis.

There is insufficient information in the published medical literature to demonstrate that the use of light-based visualization adjuncts or testing of saliva for the presence of HPV provides additional benefit compared to conventional visual and tactile oral cancer screening alone or that their use results in improved health outcomes.

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 blue (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 healthcare 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.

MicroLux™/DL (AdDent, Inc., Danbury, CT): Microlux/DL received FDA 510(k) clearance on March 28, 2005. It was considered to be substantially equivalent to ViziLite. According to the FDA summary, the only difference between the MicroLux DL and ViziLite is that the former uses a blue-white LED as a light source and the latter uses a blue-white chemical luminescent light source. The associated 1% acetic rinse and diagnostic procedures
are identical. The device is used as an aid to improve the visualization of oral lesions. It is designed to be used by a dentist or health care provider, in combination with a traditional examination by incandescent light.

**Orascoptic DK™ (Sybron Dental Specialties, Inc., Orange, CA):** The Orascoptic DK is a 510(K) exempt Class I device intended for various purposes, including oral lesion screening. It is a battery operated hand-held LED instrument with an oral lesion screening attachment, and is used in conjunction with a 1% acetic acid solution. The examination process is similar to that used with ViziLite and MicroLux, above.

**TRIMIRA™ Identafi™ 3000 (TRIMIRA, LLC, Houston, TX):** The TRIMIRA Identafi 3000 received FDA 510(k) clearance on February 17, 2009. The device is a battery operated, hand-held multispectral oral examination light used in conventional and specialized oral examination. It is intended to be used by qualified health-care providers to enhance the identification and visualization of oral mucosal abnormalities that may not be apparent or visible to the naked eye, such as oral cancer or premalignant dysplasia.

**Dentlight Oral Exam Light Kit (DentLight, Inc., Richardson, TX):** The Dentlight Oral Exam Light Kit received FDA 510(k) clearance on July 15, 2010. The device is a rechargeable-battery-powered cordless unit with interchangeable light head (white and violet) and accessories. It is indicated for providing illumination to aid visualization during oral procedures and as an adjunct to enhance the visualization for oral examination of mucosal abnormalities and oral lesions.

**Literature Review:**

**ViziLite:** Awan et al. (2011) conducted a case series (n=126) to evaluate the utility of ViziLite examination as an adjunct in the identification of oral potentially malignant disorders. Patients underwent ViziLite examination followed by surgical biopsy. Of 126 lesions, 70 were clinically diagnosed as oral leukoplakia/erythroplakia, 32 lichen planus, 9 hyperplastic candidiasis, 13 frictional keratosis, and 2 were diagnosed with submucous fibrosis. A total of 95 (75.4%) showed aceto-whitening. Following biopsy, 44 had oral epithelial dysplasia (29 mild, 8 moderate, 7 severe). Although aceto-whitening was seen in the majority of dysplastic lesions, the device failed to distinguish between dysplastic and non-dysplastic lesions. The sensitivity and specificity of chemiluminescence for detecting a dysplastic lesion were 77.3% and 27.8%, respectively. The authors concluded that although ViziLite has the ability to detect oral potentially malignant disorders, it does not accurately delineate dysplastic lesions.

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 scalp 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 leukoplasia. 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 leukoplasia 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: McNamara et al. (2012) evaluated the benefit of direct visual fluorescent examination (DVFE) using VELscope in screening for potentially malignant mucosal lesions in 130 consecutive patients presenting to a dental clinic for initial oral evaluation and routine dental care. A comprehensive oral examination (COE) was performed under regular dental incandescent (white) light, followed by a DVFE examination. Clinically suspicious areas based on COE or with positive DVFE exam (i.e., visual fluorescence loss) were surgically biopsied. The association between COE and DVFE was assessed and compared to histopathology. A total of 42 patients had one or more areas of visual fluorescence loss, yet histologic evidence of premalignancy or malignance was only identified in one patient. In addition, one lesion negative for DVFE exhibited epithelial
dysplasia. DVFE was statistically different from a scalpel biopsy (p=0.0001) No difference was found between
COE and scalpel biopsy (p=1.0). The authors noted that, as has been seen in other studies, common
inflammatory conditions, such as traumatic ulceration, benign migratory glossitis, inflammatory papillary
hyperplasia and chronic mucositis consistently demonstrated visual fluorescence loss, as did areas rich in
lymphoid tissue or melanin pigmentation. As a result of these and other factors that result in reduced
fluorescence, the significance of a given VFL area would appear to ultimately rest on conventional oral exam
and the knowledge or experience of the clinician. If DVFE does not yield useful independent or additive
information beyond COE alone, the benefit of VELscope in the routine practice of dentistry is unclear. The
authors stated that the results suggest that a comprehensive oral examination is more valid than DVFE in
discrimination benign mucosal alterations form premalignancy and do not support use of this technology as an
adjunct to oral cancer screening.

Rana et al. (2012) evaluated the use of VELscope for oral cancer detection in patients with premalignant lesions
(n=289). All patients were evaluated using a conventional oral examination with light, but because of time
restrictions in the daily diagnostic process, only 123 of 289 patients were examined with VELscope in addition to
the white light examination. Biopsies were performed on all suspicious areas identified in both groups (n=52).
The use of VELscope led to higher sensitivity compared to white light alone (100% vs. 17%) but lower specificity
(74% vs. 97%). A loss of fluorescence was detected in all dysplastic lesions, but 37.84% of cases of
leukoplakia/erythroplakia and 81.08% of cases of lichen planus also showed loss of tissue fluorescence. Of all
examined lesions, 64.23% showed loss of fluorescence, while only 4.88% of the lesions could be identified as
dysplasia.

A case series conducted by Farah et al. (2011) assessed the efficacy of direct tissue autofluorescence imaging
using VELscope in detection of oral mucosal lesions. Patients referred to an oral medicine specialist unit
(n=112) with a potentially malignant oral mucosal lesion were examined under routine incandescent light,
followed by examination with VELscope. Incisional biopsies were performed for definitive histopathological
diagnosis. VELscope enhanced the visibility of 41 lesions and helped detect 5 clinically undetected lesions.
VELscope examination alone demonstrated a sensitivity of 30% and a specificity of 63%. The accuracy of
dysplasia identification was 55%. The authors concluded that VELscope examination cannot provide a definitive
diagnosis regarding the presence of epithelial dysplasia. Loss of autofluorescence is not useful in diagnosing
epithelial dysplasia without relevant clinical interpretation.

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).

Mehrotra et al. (2010) 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.

Microlux/DL: McIntosh et al. (2009) conducted a case series to assess the efficacy of acetic acid mouthwash and diffused light illumination (Microlux/DL) as a diagnostic aid in visualizing oral mucosal lesions, and to assess its ability to highlight malignant and potentially malignant lesions. Patients referred to an oral medicine specialist unit for assessment of an oral white lesion (n=50) were initially examined using routine incandescent light. The location, size, ease of visibility, border distinctness, and presence of satellite lesions were documented. Examination was then repeated using Microlux/DL diffused light illumination kit. An excisional biopsy was performed to obtain definitive histopathological diagnosis. Microlux/DL enhanced visibility of 34 lesions, but it did not help detect any clinically undetected lesions, change the provisional diagnosis, or alter the biopsy site. Microlux/DL demonstrated a sensitivity of 77.8% and a specificity of 70.7%, and a positive predictive value of 36.8%. The authors stated that although Microlux/DL appears useful at enhancing visibility of lesions, it is a poor discriminator of inflammatory, traumatic, and malignant lesions.

OraRisk® HPV Salivary Diagnostic Test:: A case control study conducted by Saheb Jamee et al. ((2009) evaluated the presence of HPV in saliva rinses of patients with oral squamous cell carcinoma to assess the possibility of using saliva as a diagnostic method for screening high-risk patients. Saliva samples were obtained from 22 patients with oral squamous cell carcinoma (OSCC) and 20 age-and sex-matched healthy controls. The presence of HPV 6, 11, 16, 18, 31 and 33 was evaluated by polymerase chain reaction (PCR). Saliva was positive for HPV in 40.9% of OSCC patients and in 25% of controls. Saliva was positive for HPV 16 in 27.3% of OSCC patients and 20% of controls. HPV 16 was present in the saliva of 1 OSCC patient and no controls. Neither OSCC patients nor controls were positive for HPV 31 or 33. There were no statistically significant differences between groups. The authors stated that the results of this study were unable to support the detection of HPV in saliva rinses as a diagnostic method for OSCC.

No studies evaluating Orascoptic DK, TRIMIRA Identafi, or Dentilight were found in a search of the published peer-reviewed literature.

Systematic Review: 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, MicroLux/DL, Orascoptic DK, and OralCDx brush biopsy. A total of 23 studies met the inclusion criteria. The largest evidence base was for toluidine blue. The authors identified no studies of MicroLux/DL or Orascoptic DK. 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 evaluated adjunctive screening aids based on tissue reflectance (i.e., ViziLite Plus, MicroLux/DL, Orascoptic DK), autofluorescence (i.e., VELscope), and autofluorescence and tissue reflectance (i.e., TRIMIRA Identafi). The guideline includes the following conclusions:
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])

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.

**Use Outside of the US**
No relevant guidelines or recommendations for oral cancer screening were found.

Several oral cancer screening devices have been awarded the CE mark for use in Europe, including, but not limited to Velscope, Microlux/DL, and Saphire Plus Lesion Detection (DenMat, Lompoc, CA).

**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. Various light-based adjunctive methods (e.g., ViziLite®, VELscope®, MicroLux™/DL, Orascoptic DK™), TRIMIRA™ Identafi™ 3000, and Dentlight Oral Exam Light Kit) have been proposed as methods to improve current oral screening methods by assisting in the identification, evaluation and monitoring of oral mucosal abnormalities. Evaluation of saliva for the presence of human papillomavirus (HPV) has also been proposed as a method to identify patients at increased risk for oral cancer, based on data that demonstrates an association between certain types of HPV and the development of oropharyngeal carcinoma. There is insufficient information in the published medical literature, however, to demonstrate that the use of these provides additional benefit compared to conventional visual and tactile oral cancer screening alone or that their use results in improved health outcomes.

**Coding/Billing Information**

**Note:**
1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

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<td>Adjunctive pre-diagnostic test that aids in detection of mucosal abnormalities including premalignant and malignant lesions, not to include cytology or biopsy procedures</td>
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### References


