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

Policy #: 332          Latest Review Date: November 2019
Category: Medical/Dental  Policy Grade: Active policy but no longer scheduled for regular literature reviews and updates.

BACKGROUND:
Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. Safe and effective;
2. Not experimental or investigational*;
3. Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:
   • Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member;
   • Furnished in a setting appropriate to the patient’s medical needs and condition;
   • Ordered and furnished by qualified personnel;
   • One that meets, but does not exceed, the patient’s medical need; and
   • At least as beneficial as an available medically appropriate alternative.

*Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill Original Medicare for covered services that are related to clinical trials that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).
POLICY:

Effective for dates of service on or after January 15, 2009:
Blue Advantage will treat oral lesion identification systems (such as ViziLite™ or Velscope™) as a non-covered benefit and as investigational.

Blue Advantage 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 Advantage administers benefits based on the members' contract and 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.

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 premalignant 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 surgical excision. VELscope uses visible light in the 430 nm wavelength in order to cause fluorescent excitation of certain compounds in the tissues.

KEY POINTS:
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:

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.

CURRENT CODING:
CDT:

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<th>Code</th>
<th>Description</th>
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<td>D0431</td>
<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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<td>D0502</td>
<td>Other pathology procedures, by report</td>
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<td>D0999</td>
<td>Unspecified diagnostic procedure, by report</td>
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CPT codes:

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<th>Code</th>
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<td>Unlisted procedure, vestibule of mouth</td>
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<td>41599</td>
<td>Unlisted procedure, tongue, floor of mouth</td>
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<td>41899</td>
<td>Unlisted procedure, dentoalveolar structures</td>
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REFERENCES:

POLICY HISTORY:
Adopted for Blue Advantage, December 2008
Available for comment December 1, 2008-January 14, 2009
Medical Policy Group, October 2009
Medical Policy Group, October 2010
Medical Policy Group, September 2012: **Effective September 14, 2012 this policy is no longer scheduled for regular literature reviews and updates.**

Medical Policy Group, November 2019

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.