DELTA DENTAL

Delta Dental of Virginia Clinical Policy # 701

Subject	**Originating Department**
Oral Brush Biopsy	Clinical Professional Services
	Signature Authority
	Dental Director

Type: ☐ New ☐ Replacement ☒ Revision ☐ Clarification

Date: 11/09/2009 **Revision Date:** 11/15/2011

Preamble:	The Clinical Policy Bulletin is an expression of Delta Dental of Virginia's (DDVA) determination regarding whether certain services or supplies are medically or dentally necessary. DDVA bases its conclusions on a review of currently available clinical literature. This includes, but is not limited to, clinical outcome studies published in the peer-reviewed medical and dental literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians and dentists practicing in relevant clinical areas, and other relevant factors. DDVA reserves the right to revise these policies as new clinical information is available and we welcome submission of further relevant information. A group may define covered dental services under their dental plan, as well as those services that may be subject to dollar caps or other limits. The plan documents outline covered benefits, exclusions and limitations. DDVA advises dentists and enrollees to consult the plan documents to determine if there are exclusions or other benefit limitations applicable to the service request. The conclusion that a particular service is medically or dentally necessary does not constitute an indication or warranty that the service requested is a covered benefit payable by DDVA. Some plans exclude coverage for services that DDVA considers either medically or dentally necessary. When there is a discrepancy between DDVA's clinical policy and the group's plan documents, DDVA is to defer to the group's plan documents as to whether the dental service is a covered benefit. In addition, if state or federal regulations mandate coverage then DDVA will adhere to the applicable regulatory requirement.
History:	The use of the oral brush biopsy is an attempt to introduce a non-invasive, simple biopsy technique into the clinical setting that is acceptable to the patient and requires a modicum of specialized knowledge by the practitioner. The oral brush biopsy is an improvement over historical efforts to diagnose pathological processes in the mouth, particularly oral cancers and dysplastic lesions, by an exfoliative cytological smear technique. False negative rates for oral exfoliative cytology have been reported as high as 63%(1). The reason is primarily due to the keratinized nature of many oral lesions, the inability to access deep areas of the epithelial layers, difficulties in recovering representative samples, and the subjective evaluation of the cytological samples(1,2). Although simple in concept, the oral brush biopsy is technique sensitive and requires familiarity with the principles involved. The procedure must be sufficiently aggressive to represent adequate sampling of the basal cell layer, and clinically, the endpoint is the appearance of pink microhemmorhage(2,13).

DELTA DENTAL

	When properly used, the brush biopsy has been shown to have the ability to extract cells from all epithelial layers, including the basal cell layer, and upper portions of the lamina propria(1,11). Further, advances in evaluation methods have improved the sensitivity and specificity of the oral brush biopsy. Computer assisted image analysis, DNA cytometry, molecular biological analysis, and protein profiling have all been shown to improve detection results with the brush biopsy(3,4,5,6,7). In spite of the ease of use and improved results, the deficiencies of the oral brush biopsy include the continued problem of sub-optimal samples and false positive and negative results when compared to scalpel biopsy samples. In one study, 7% of brush biopsy specimens were shown to be non-diagnostic(8). False negatives have been shown to be 3.5% and time delays averaging 117 days until an accurate diagnosis could be made or confirmed by scalpel biopsy have been reported(9). Research has shown the sensitivity of the brush biopsy to be 71% while the specificity was 32%. The positive predictive value of an abnormal brush biopsy approximates 44% while the negative predictive value was 60%(10). The conclusion of these and other researchers is that even though the oral brush biopsy can enhance the oral pathology screening process, this technique will miss some oral cancers(3,12). The oral brush biopsy is intended for evaluation of small, obvious alterations in the oral mucosal surface and is not intended to replace the need for surgical scalpel biopsy and histopathologic examination, which remains the gold standard in determining the diagnosis of suspicious oral lesions(14).
Policy:	DDVA Guidelines for Therapy: 1. The brush biopsy may be used to evaluate small non-specific alterations in appearance of the surface of the oral mucosa. 2. The brush biopsy is not to be used for obviously suspicious areas of pathology, areas of ulceration, areas of erythroplakia or erythroleukoplakia, pigmented lesions, or submucosal masses. 3. Documentation of the oral brush biopsy procedure must include a copy of the biopsy report.
Code(15):	D7288 – Brush biopsy – transepithelial sample collection
References:	1. Oral Cancer foundation. From exfoliative cytology to oral brush biopsy: An advance in the early detection of oral precancers and cancers. ©2001-2008 OCF Inc. 2. Mehotra R, Gupta A, Singh M, Ibrahim R. Application of cytology and molecular biology in diagnosing premalignant or malignant oral lesions.Mol Cancer 2006;5:11. 3. Hullman M, Reichert TE, et al. Oral cytology: historical development, current status, and perspectives. Mund Keifer Gesich 2007;11:1-9. 4. Dreimel O, Dahse R, et al. Laminin-5 immunocytochemistry: a new toolfor identifying dysplastic cells in oral brush biopsies. Cytopathology 2007;18:348-355. 5. Schwartz JL, Panda S, et al. RNA from brush oral cytology to measure squamous cell carcinoma gene expression. J Oral Pathol Med 2008:37:70-77.

6. Dreimel O, Murzik U, et al. Protein profiling of oral brush biopsies: S100A8 and S100A9 can differentiate between normal, premalignant, and tumor cells. Proteonomics 2007;1:486-493.

7. Oral Cancer Foundation. Oral brush biopsy in the early detection of oral precancers and cancers. ©20012-2008 OCF Inc.

8. Sciubba JJ, et al. Improving detection of precancerous and cancerous oral lesions. Computer-assisted analysis of the oral brush biopsy. U.S. Collaborative OralCDx Study Group. J Amer Dent Assoc 999;130:1445 -1457.

9. Potter TJ, Summerlin DJ and Campbell JH. Oral malignancies associated with negative transepithelial brush biopsy. J Oral Maxillofac Surgery 2003; 61:674-677.

10. Poate TW, Buchanan JA, et al. An audit of the efficacy of the oral brush Biopsy technique in a specialist oral medicine unit. Oral Oncol 2004:40: 829-834.

11. Sciubba JJ. Oral brush biopsy with computer-assisted analysis. eMedicine.com/derm/topic701 Diseases of the oral mucosa. Feb 26, 2007.

12. Scheifele C, Schmidt-Westhausen AM, et al. The sensitivity and Specificity of the OralCDx technique: evaluation of 103 cases. Oral Oncol 2005;40:824-828.

13. Hall DL. Oral brush biopsy technique instruction outcomes for senior dental students. J Dent Educ 2006;70:820-824.

14. Mendes SF, Ramos GO, et al. Techniques for precancerous lesion diagnosis. J Oncol 2011;2011:326094.

15. American Dental Association. *Current Dental Terminology. CDT 2011-2012;*59 (©ADA 2010).