



If a conflict arises between a Clinical Payment and Coding Policy (“CPCP”) and any plan document under which a member is entitled to Covered Services, the plan document will govern. If a conflict arises between a CPCP and any provider contract pursuant to which a provider participates in and/or provides Covered Services to eligible member(s) and/or plans, the provider contract will govern. “Plan documents” include, but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions, and other coverage documents. BCBSNM may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSNM has full and final discretionary authority for their interpretation and application to the extent provided under any applicable plan documents.

Providers are responsible for submission of accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from Health Insurance Portability and Accountability Act (“HIPAA”) approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing (“UB”) Editor, American Medical Association (“AMA”), Current Procedural Terminology (“CPT®”), CPT® Assistant, Healthcare Common Procedure Coding System (“HCPCS”), ICD-10 CM and PCS, National Drug Codes (“NDC”), Diagnosis Related Group (“DRG”) guidelines, Centers for Medicare and Medicaid Services (“CMS”) National Correct Coding Initiative (“NCCI”) Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services/procedures billed. Claim submissions are subject to claim review including but not limited to, any terms of benefit coverage, provider contract language, medical policies, clinical payment and coding policies as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

## **Oral Screening Lesion Identification Systems and Genetic Screening**

**Policy Number: CPCPLAB032**

**Version 1.0**

**Plan CMO Approval Date: July 27, 2022**

**Plan Effective Date: January 1, 2023**

### **Description**

BCBSNM has implemented certain lab management reimbursement criteria. Not all requirements apply to each product. Providers are urged to review Plan documents for eligible coverage for services rendered.

### **Reimbursement Information:**

1. For individuals with oropharyngeal squamous cell carcinoma, high-risk HPV testing by one of the following methods **may be reimbursable**:
  - a. HPV E6/E7 mRNA expression testing OR
  - b. Expression of p16 as detected by immunohistochemistry

2. Oral screening, lesion identification systems and genetic testing **is not reimbursable** for all uses. This includes, but is not limited, to the following:
  - a. OraRisk® HPV Complete Genotyping Test and OraRisk® HPV 16/18/HR Test (OralDNA labs, Brentwood, TN)
  - b. MOP™ testing
  - c. SaliMark OSCC® (PeriRx)
  
3. The use of salivary biomarkers to screen, detect, or diagnose oral cancer **is not reimbursable**. This includes, but is not limited, to the following:
  - a. Salivary peptides and proteins, such as protein 14, Mac-2 binding protein, profilin 1, CD59, defensin-1, IL-1 $\beta$ , IL-8, lactate dehydrogenase, and catalase
  - b. Salivary nucleic acids, such as methylated DNA testing, mRNAs, modified nucleotides (such as 8-OHdG), microRNA (miRNAs)
  - c. Salivary metabolites, such as valine, lactic acid, and phenylalanine

## Procedure Codes

Codes
81599, 82397, 87623, 87624, 87625, 88341, 88342

## References:

ACS. (2020). Key Statistics for Oral Cavity and Oropharyngeal Cancers. Retrieved from <https://www.cancer.org/cancer/oral-cavity-and-oropharyngeal-cancer/about/key-statistics.html>

ACS. (2021, March 23 ). Key Statistics for Oral Cavity and Oropharyngeal Cancers. Retrieved from <https://www.cancer.org/cancer/oral-cavity-and-oropharyngeal-cancer/about/key-statistics.html>

AdDent. (2020). MICROLUX TRANSILLUMINATOR. Retrieved from <https://www.addent.com/microlux/>

Alsarraf, A. H., Kujan, O., & Farah, C. S. (2018). The utility of oral brush cytology in the early detection of oral cancer and oral potentially malignant disorders: A systematic review. *J Oral Pathol Med*, 47(2), 104-116. doi:10.1111/jop.12660

Apteryx. (2020). VELscope Vx Enhanced Oral Assessment. Retrieved from <https://apteryx.com/velscope/>

Borsetto, D., Cheng, J., Payne, K., Nankivell, P., Batis, N., Rao, K., . . . Wong, D. (2018). Surveillance of HPV-Positive Head and Neck Squamous Cell Carcinoma with Circulating and Salivary DNA Biomarkers. *Crit Rev Oncog*, 23(3-4), 235-245. doi:10.1615/CritRevOncog.2018027689

CDC. (2021, January 19). Human Papillomavirus (HPV) Fact Sheet. Retrieved from <https://www.cdc.gov/std/hpv/stdfact-hpv.htm>

DenMat. (2020a). ViziLite PRO® Oral Lesion Screening System. Retrieved from <https://www.denmat.com/vizilite-pro-oral-lesion-screening-system.html>

DenMat. (2020b). ViziLite® TBlue Annual Oral Cancer Screening System. Retrieved from <https://www.denmat.com/vizilite-tblue-annual-oral-cancer-screening-system.html>

Dhanuthai, K., Rojanawatsirivej, S., Thosaporn, W., Kintarak, S., Subarnbhesaj, A., Darling, M., . . . Aminishakib, P. (2018). Oral cancer: A multicenter study. *Med Oral Patol Oral Cir Bucal*, 23(1), e23-e29. doi:10.4317/medoral.21999

Fakhry, C., Lacchetti, C., Rooper, L. M., Jordan, R. C., Rischin, D., Sturgis, E. M., . . . Perez-Ordóñez, B. (2018). Human Papillomavirus Testing in Head and Neck Carcinomas: ASCO Clinical Practice Guideline Endorsement of the College of American Pathologists Guideline. *J Clin Oncol*, 36(31), 3152-3161. doi:10.1200/jco.18.00684

Fedele, S. (2009). Diagnostic aids in the screening of oral cancer. *Head Neck Oncol*, 1, 5. doi:10.1186/1758-3284-1-5

Fuller, C., Camilon, R., Nguyen, S., Jennings, J., Day, T., & Gillespie, M. B. (2015). Adjunctive diagnostic techniques for oral lesions of unknown malignant potential: Systematic review with meta-analysis. *Head Neck*, 37(5), 755-762. doi:10.1002/hed.23667

Gross, N., Lee, N., Okuno, S., & Rao, S. (2020, February 4). Treatment of stage I and II (early) head and neck cancer: The oral cavity. UpToDate. Retrieved from <https://www.uptodate.com/contents/treatment-of-stage-i-and-ii-early-head-and-neck-cancer-the-oral-cavity>

Kaur, J., Jacobs, R., Huang, Y., Salvo, N., & Politis, C. (2018). Salivary biomarkers for oral cancer and pre-cancer screening: a review. *Clin Oral Investig*, 22(2), 633-640. doi:10.1007/s00784-018-2337-x

Lewis, J. S., Jr., Beadle, B., Bishop, J. A., Chernock, R. D., Colasacco, C., Lacchetti, C., . . . Faquin, W. C. (2018). Human Papillomavirus Testing in Head and Neck Carcinomas: Guideline From the College of American Pathologists. *Arch Pathol Lab Med*, 142(5), 559-597. doi:10.5858/arpa.2017-0286-CP

Lim, Y., Wan, Y., Vagenas, D., Ovchinnikov, D. A., Perry, C. F., Davis, M. J., & Punyadeera, C. (2016). Salivary DNA methylation panel to diagnose HPV-positive and HPV-negative head and neck cancers. *BMC Cancer*, 16(1), 749. doi:10.1186/s12885-016-2785-0

Lingen, M. W., Abt, E., Agrawal, N., Chaturvedi, A. K., Cohen, E., D'Souza, G., . . . Carrasco-Labra, A. (2017). Evidence-based clinical practice guideline for the evaluation of potentially malignant disorders in the oral cavity: A report of the American Dental Association. *The Journal of the American Dental Association*, 148(10), 712-727. doi:10.1016/j.adaj.2017.07.032

Lingen, M. W., Kalmar, J. R., Karrison, T., & Speight, P. M. (2008). Critical evaluation of diagnostic aids for the detection of oral cancer. *Oral Oncol*, 44(1), 10-22. doi:10.1016/j.oraloncology.2007.06.011

Liyanage, C., Wathupola, A., Muraleetharan, S., Perera, K., Punyadeera, C., & Udagama, P. (2019). Promoter Hypermethylation of Tumor-Suppressor Genes p16(INK4a), RASSF1A, TIMP3, and PCQAP/MED15 in Salivary DNA as a Quadruple Biomarker Panel for Early Detection of Oral and Oropharyngeal Cancers. *Biomolecules*, 9(4). doi:10.3390/biom9040148

Lodi, G. (2020, November 24). Oral Lesions. UpToDate. Retrieved from <https://www.uptodate.com/contents/oral-lesions>

Macey, R., Walsh, T., Brocklehurst, P., Kerr, A. R., Liu, J. L., Lingen, M. W., . . . Scully, C. (2015).

Diagnostic tests for oral cancer and potentially malignant disorders in patients presenting with clinically evident lesions. *Cochrane Database Syst Rev*(5), Cd010276.  
doi:10.1002/14651858.CD010276.pub2

Machiels, J. P., René Leemans, C., Golusinski, W., Grau, C., Licitra, L., & Gregoire, V. (2020). Squamous cell carcinoma of the oral cavity, larynx, oropharynx and hypopharynx: EHNS-ESMO-ESTRO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Ann Oncol*, 31(11), 1462-1475. doi:10.1016/j.annonc.2020.07.011

Maghami, E., Ismaila, N., Alvarez, A., Chernock, R., Duvvuri, U., Geiger, J., . . . Caudell, J. (2020). Diagnosis and Management of Squamous Cell Carcinoma of Unknown Primary in the Head and Neck: ASCO Guideline. *J Clin Oncol*, 38(22), 2570-2596. doi:10.1200/jco.20.00275

Mascitti, M., Orsini, G., Tosco, V., Monterubbianesi, R., Balercia, A., Putignano, A., . . . Santarelli, A. (2018). An Overview on Current Non-invasive Diagnostic Devices in Oral Oncology. *Frontiers in physiology*, 9, 1510-1510. doi:10.3389/fphys.2018.01510

Moyer, V. A. o. b. o. t., U. S. Preventive Services Task Force. (2014). Screening for Oral Cancer: U.S. Preventive Services Task Force Recommendation Statement. *Annals of Internal Medicine*, 160(1), 55-60. doi:10.7326/M13-2568

Nagi, R., Reddy-Kantharaj, Y. B., Rakesh, N., Janardhan-Reddy, S., & Sahu, S. (2016). Efficacy of light based detection systems for early detection of oral cancer and oral potentially malignant disorders: Systematic review. *Med Oral Patol Oral Cir Bucal*, 21(4), e447-455.  
doi:10.4317/medoral.21104

NCCN. (2021, March 26). NCCN Clinical Practice Guidelines in Oncology - Head and Neck Cancers Version 2.2021 Retrieved from [https://www.nccn.org/professionals/physician\\_gls/pdf/head-and-neck.pdf](https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf)

OralDNA. (2020a). OraRisk® HPV 16/18/HR. Retrieved from <https://www.oraldna.com/test/ohpv/>

OralDNA. (2020b). OraRisk® HPV Complete Genotyping. Retrieved from <https://www.oraldna.com/test/ohpv-complete/>

Patton, L. L., Epstein, J. B., & Kerr, A. R. (2008). Adjunctive techniques for oral cancer examination and lesion diagnosis: a systematic review of the literature. *J Am Dent Assoc*, 139(7), 896-905; quiz 993-894. Retrieved from [https://jada.ada.org/article/S0002-8177\(14\)65381-2/fulltext](https://jada.ada.org/article/S0002-8177(14)65381-2/fulltext)

Paul Brocklehurst, O. K., Anne-Marie Glenny, Richard Oliver, Philip Sloan, Graham Ogden, Simon Shepherd. (2017). Screening programmes for the early detection and prevention of oral cancer. The Cochrane Library. Retrieved from <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004150.pub3/full>

PCG. (2014). PCG Molecular. Retrieved from <https://www.linkedin.com/company/pcg-molecular/about/>

PeriRx. (2020). SaliMark™ OSCC: Oral Cancer Salivary Diagnostic Test. Retrieved from <http://perirx.com/>

Rashid, A., & Warnakulasuriya, S. (2015). The use of light-based (optical) detection systems as

adjuncts in the detection of oral cancer and oral potentially malignant disorders: a systematic review. *J Oral Pathol Med*, 44(5), 307-328. doi:10.1111/jop.12218

Rethman, M. P., Carpenter, W., Cohen, E. E., Epstein, J., Evans, C. A., Flaitz, C. M., . . . Meyer, D. M. (2010). Evidence-based clinical recommendations regarding screening for oral squamous cell carcinomas. *J Am Dent Assoc*, 141(5), 509-520.

Scully, C., & Porter, S. (2000). ABC of oral health. Oral cancer. *BMJ*, 321(7253), 97-100.

Seoane Leston, J., & Diz Dios, P. (2010). Diagnostic clinical aids in oral cancer. *Oral Oncol*, 46(6), 418-422. doi:10.1016/j.oraloncology.2010.03.006

Siegel, R. L., Miller, K. D., & Jemal, A. (2019). Cancer statistics, 2019. *CA Cancer J Clin*, 69(1), 7-34. doi:10.3322/caac.21551

Speight, P. M., Epstein, J., Kujan, O., Lingen, M. W., Nagao, T., Ranganathan, K., & Vargas, P. (2017). Screening for oral cancer-a perspective from the Global Oral Cancer Forum. *Oral Surg Oral Med Oral Pathol Oral Radiol*, 123(6), 680-687. doi:10.1016/j.oooo.2016.08.021

van der Waal, I. (2009). Potentially malignant disorders of the oral and oropharyngeal mucosa; terminology, classification and present concepts of management. *Oral Oncol*, 45(4-5), 317-323. doi:10.1016/j.oraloncology.2008.05.016

Vijayakumar, V., Reghunathan, D., Edacherian, B., & Mukundan, A. (2019). Role of Toluidine Blue Staining in Suspicious Lesions of Oral Cavity and Oropharynx. *Indian J Otolaryngol Head Neck Surg*, 71(Suppl 1), 142-146. doi:10.1007/s12070-017-1161-y

Warnakulasuriya, S., Johnson, N. W., & van der Waal, I. (2007). Nomenclature and classification of potentially malignant disorders of the oral mucosa. *J Oral Pathol Med*, 36(10), 575-580. doi:10.1111/j.1600-0714.2007.00582.x

### Policy Update History:

1/1/2023	New policy
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