SALIVARY TESTING

Policy Number: DCG037.03 **Effective Date**: January 1, 2019

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Related Dental Policy

- Miscellaneous Diagnostic Procedures

INSTRUCTIONS FOR USE

This Dental Coverage Policy provides assistance in interpreting UnitedHealthcare dental benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Dental Coverage Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Dental Coverage Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Dental Coverage Policy. Other Clinical Policies and Coverage Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Dental Coverage Policy is provided for informational purposes. It does not constitute medical advice.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group health plans (inside and outside of Exchanges) to provide coverage for Pediatric Dental Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for Pediatric Dental EHBs. However, if such plans choose to provide coverage for benefits which are deemed Pediatric Dental EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute Pediatric Dental EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Collection, Preparation and Analysis of Saliva Sample for Laboratory Diagnostic Testing

Collection, preparation and analysis of saliva sample for laboratory diagnostic testing may be indicated as part of oral disease Risk Assessment and management, including but not limited to caries, periodontal disease, oral cancers and xerostomia.

DEFINITIONS

Risk Assessment: Analysis of risks involved prior to action being taken.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Clinical Policies and Coverage Guidelines may apply.

CDT Code	Description
D0417	Collection and preparation of saliva sample for laboratory diagnostic testing
D0418	Analysis of saliva sample

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DESCRIPTION OF SERVICES

Saliva is made of water, mucus, proteins, minerals, and an enzyme called amylase (which breaks down starch as the first stage of digestion). It functions to lubricate the mouth, and provides protection to the teeth from the bacteria that produce acid in dental plaque. Saliva also carries minerals that help rebuild the enamel and neutralize acids. Low and poor quality saliva (which may be due to medications, systemic disease or radiation therapy to the head and neck) increases risk for dental diseases. The information gathered from saliva testing (bacteria, biomarkers, quality and quantity of saliva) can be an additional diagnostic tool to lower incidence and/or severity of disease, more effectively guide preventive care, and may result in earlier diagnosis. Furthermore, technologies that will enable saliva to be used as a window into the body are being explored for their ability to detect diseases and monitor health.

CLINICAL EVIDENCE

Caries

Chokshi et al (2016) conducted a study to estimate the salivary levels of Streptococcus mutans, Lactobacilli and Actinomyces and to correlate it with dental caries experience in mixed and permanent dentition. The sample size comprised 110 subjects. The decayed, missing and filled teeth (DMFT) index of all the individuals participating in the study was calculated. Saliva samples were collected from patients and samples were inoculated on specific culture media and incubated for a period of 48 hours, and colony characteristics, S. mutans, Lactobacilli and Actinomyces were identified. A positive correlation exists between DMFT and S. mutans, Lactobacilli and Actinomyces in mixed dentition and permanent dentition group samples ($P < 0.001$). The conclusion from the results obtained was that S. Mutans, lactobacilli and Actinomyces which are the components of the normal microbial flora of the oral cavity play an important role in the pathogenesis of dental caries and increased number of microorganisms is associated with an increased caries frequency.

Edelstein et al (20016). The purpose of this retrospective cohort study was to examine mutans streptococci (MS) from children's saliva, and its ability in predicting caries progression and determine sensitivity, specificity, and likelihood ratios of a very high "too numerous to count" (TNTC) MS test result. There were 200 preschoolers (50 percent no recoverable MS, 50 percent TNTC MS at first dental visit) followed for five or more years, and caries experience of both groups was compared to identify predictors of caries presence and its progression. Controlling for demographic, oral health, and dental visit factors, TNTC preschoolers had both greater presence and extent of caries at the first dental visit and caries progression at five or more years. Fewer TNTC preschoolers remained caries free over five years or longer (13 percent versus 77 percent for no MS). Overall, sensitivities and specificities exceeded 75 percent. This study showed that despite engagement in preventive dental care, children with TNTC MS were six times more likely to experience cavity increments than preschoolers with no recoverable MS at first visit.

Ghasempour et al (2014). One of the causative factors in development of dental caries is microorganisms. Two species of mutans streptococci including Streptococcus mutans and Streptococcus sobrinus are associated with dental caries in human beings. The aim of this analytical case-control study was to investigate the frequency of S. mutans and S. sobrinus in saliva of children with different caries activity and ability to form biofilm and acid susceptibility of these microorganisms. 83 preschool children, 4-6 years old were selected and divided into two groups: 41 caries-active and 42 caries-free children. Non-stimulated saliva samples were collected and culture and polymerase chain reaction techniques were used. Statistical analysis was performed using t-test, Chi-square, ANOVA, and Kappa tests. S. mutans and S. sobrinus were found in 65% and 21.6% of the samples respectively. S. mutans was isolated from 75.6% of caries-active and 54.8% of caries-free children. Figures for S. sobrinus were 29.2% and 14.3% respectively. Acid susceptibility of microorganisms isolated from saliva was 87.43 in caries-active children and 94.30 for caries-free children. Biofilm formation of microorganisms in caries-active and caries-free children was 0.77 and 0.73, respectively. This study showed the frequency of S. mutans in caries-active children to be significantly higher than caries-free children, but the difference in frequency of S. sobrinus was not significant. Acid susceptibility of

microorganisms in caries-active children was significantly lower, but the ability to form biofilm was not significantly different in two groups.

Yang et al (2015) The purpose of this study was to determine the relationships among early childhood caries (ECC), root caries (RC), the quantity of Streptococcus mutans in saliva, and the concentrations of total and specific secretory IgA (sIgA). Saliva samples were collected from 70 children, 3-4 years of age, with and without ECC, and from 43 adults, ≥60 years of age, with and without RC. The decayed, missing, and filled teeth (DMFT) and decayed, missing, and filled surfaces (DMFS) scores of each child, and the root decayed and filled teeth (RDFT) and root decayed and filled surfaces (RDFS) scores of each elderly subject, were determined. The S. mutans levels, total sIgA, and specific sIgA against two virulence antigens of S. mutans in saliva were analyzed using quantitative real-time PCR (qPCR) and ELISAs. The quantity of S. mutans was significantly higher in caries-positive subjects within the two populations than in the caries-free subjects; and a positive correlation was found between the quantity of S. mutans and the DMFT, DMFS, RDFT, and RDFS scores. In addition, the salivary total sIgA was significantly higher in children with severe early childhood caries (SECC) and in the elderly subjects with RC. Moreover, although the S. mutans level was significantly higher, the concentrations of specific sIgA against S. mutans antigens were significantly lower in samples from elderly subjects than in samples from children. The authors concluded that these results support the concept that S. mutans is positively associated with ECC and RC.

Periodontal Disease

Kuboniwa et al (2016). In this pilot study, the authors explored the use of salivary metabolites to reflect periodontal inflammation severity with a recently proposed parameter-periodontal inflamed surface area (PISA)-used to quantify the periodontal inflammatory burden of individual patients with high accuracy. Following PISA determination, whole saliva samples were collected from 19 subjects before and after removal of supragingival plaque and calculus (debridement) with an ultrasonic scaler to assess the influence of the procedure on salivary metabolic profiles. Metabolic profiling of saliva was performed with gas chromatography coupled to time-of-flight mass spectrometry, followed by multivariate regression analysis with orthogonal projections to latent structures (OPLS) to investigate the relationship between PISA and salivary metabolic profiles. Sixty-three metabolites were identified. OPLS analysis showed that postdebridement saliva provided a more refined model for prediction of PISA than did predebridement samples, which indicated that debridement may improve detection of metabolites eluted from subgingival areas in saliva, thus more accurately reflecting the pathophysiology of periodontitis. Based on the variable importance in the projection values obtained via OPLS, 8 metabolites were identified as potential indicators of periodontal inflammation, of which the combination of cadaverine, 5-oxoproline, and histidine yielded satisfactory accuracy (area under the curve = 0.881) for diagnosis of periodontitis. The authors' findings identified potential biomarkers that may be useful for reflecting the severity of periodontal inflammation as part of monitoring disease activity in periodontitis patients.

Morozumi et al (2016). A diagnosis of periodontitis progression is presently limited to clinical parameters such as attachment loss and radiographic imaging. The aim of this multicenter study was to monitor disease progression in patients with chronic periodontitis during a 24-month follow-up program and to evaluate the amount of bacteria in saliva and corresponding IgG titers in serum for determining the diagnostic usefulness of each in indicating disease progression and stability. A total of 163 patients with chronic periodontitis who received trimonthly follow-up care were observed for 24 months. The clinical parameters and salivary content of Porphyromonas gingivalis, Prevotella intermedia and Aggregatibacter actinomycetemcomitans were assessed using the modified Invader PLUS assay, and the corresponding serum IgG titers were measured using ELISA. The changes through 24 month period were analyzed using cut-off values calculated for each factor. One-way ANOVA or Fisher's exact test was used to perform between-group comparison for the data collected. Diagnostic values were calculated using Fisher's exact test. Of the 124 individuals who completed the 24-month monitoring phase, 62 exhibited periodontitis progression, whereas 62 demonstrated stable disease. Seven patients withdrew because of acute periodontal abscess. The ratio of P. gingivalis to total bacteria and the combination of P. gingivalis counts and IgG titers against P. gingivalis were significantly related to the progression of periodontitis. The combination of P. gingivalis ratio and P. gingivalis IgG titers was significantly associated with the progression of periodontitis. The authors suggest this study shows that the combination of P. gingivalis ratio in saliva and serum IgG titers against P. gingivalis may be associated with the progression of periodontitis.

Sexton et al (2011) conducted a 6-month case-controlled study of adults with chronic periodontitis to longitudinally assess salivary biomarkers of periodontitis to determine response to therapy. 33 participants received oral hygiene instructions (OHI) alone and 35 with scaling and root planing (SRP) combined with OHI. Saliva samples collected at week 0, 16 and 28 were analysed for interleukin (IL)-1β, IL-8, macrophage inflammatory protein (MIP)-1α, matrix metalloproteinase-8 (MMP-8), osteoprotegerin (OPG), and tumour necrosis factor-α (TNF)-α. Clinical measures of periodontal disease were recorded at each visit. The results showed all parameters of periodontal health improved significantly in both groups by week 16, with the SRP group demonstrating greater benefit at week 16 and 28. Baseline OPG and TNF-α levels changed significantly at both follow-up visits regardless of treatment group. IL-1β and MMP-8 levels decreased significantly from baseline in the SRP group only. OPG, MMP-8, and MIP-1α were significantly reduced in responders compared with non-responders. In receiver-operating characteristic analyses, MMP-8 produced

the highest area under the curve .The authors concluded salivary levels of IL-1β, MMP-8, OPG, and MIP-1α reflected disease severity and response to therapy, suggesting their potential utility for monitoring periodontal disease status.

Zhang et al (2016). In periodontitis, activated macrophages not only initiate immune responses to periodontal-pathogen infections, but also damage the periodontal tissues by releasing a series of inflammatory cytokines. Macrophage-activating factor (MAF) and macrophage-chemotactic factor (MCF) are two important mediators involved in macrophage accumulation, activation and function. This study analyzed the levels of salivary MAF and MCF in healthy individuals and those with different periodontal diseases, and assessed the usefulness of salivary MAF and MCF as diagnostic biomarkers in periodontal tissue health status. Ninety-five saliva specimens were collected from healthy individuals and patients with gingivitis, mild periodontitis, moderate periodontitis, and severe periodontitis. Pocket probing depth (PPD) and alveolar bone loss (ABL) were recorded via periodontal probing and dental radiography, respectively. Salivary MAF and MCF concentrations were assayed using enzyme-linked immunosorbent assays. MAF level tended to increase in saliva as periodontal diseases progressed. The concentration of salivary MAF in periodontitis correlated positively with ABL and PPD. In contrast, salivary MCF levels increased significantly only in periodontitis. The authors concluded that salivary MAF levels correlate positively with tissue destruction in periodontal diseases. It is a potential valuable biomarker that could be used to assess periodontal health status.

Oral Cancer

Guerra et al (2015). The purpose of this systematic review and meta-analysis was to evaluate the diagnostic value of salivary biological markers in the diagnosis of head and neck carcinoma. Studies were gathered by searching Cochrane, EMBASE, LILACS, MEDLINE, and PubMed. The references were also crosschecked and a partial grey literature search was undertaken using Google Scholar. The methodology of selected studies was evaluated using the 14-item Quality Assessment Tool for Diagnostic Accuracy Studies. 15 articles were identified and subjected to qualitative and quantitative analyses. The studies were homogeneous, and all had high methodological quality. Combined biomarkers demonstrated better accuracy with higher sensitivity and specificity than those tested individually. Furthermore, the salivary biomarkers reviewed predicted the early stages of head and neck carcinoma better than the advanced stages. A restricted set of five single biomarkers (interleukin-8, choline, pipecolinic acid, l-phenylalanine, and S-carboxymethyl-l-cysteine) as well as combined biomarkers demonstrated excellent diagnostic test accuracy. The results of this systematic review confirm the potential value of a selected set of salivary biomarkers as diagnostic tools for head and neck carcinoma.

Ishikawa et al (2016). The objective of this study was to explore salivary metabolite biomarkers by profiling both saliva and tumor tissue samples for oral cancer screening. Patients with oral cancer and healthy controls were recruited at the Department of Dentistry, Oral and Maxillofacial Plastic and Reconstructive Surgery of Yamagata University Hospital from 2012 to 2014. None had received any prior treatment such as chemotherapy or radiotherapy. All oral cancer patients provided both tumor tissues and saliva samples. No controls had a history of prior malignancy or autoimmune disorders. Paired tumor and control tissues were obtained from oral cancer patients and whole unstimulated saliva samples were collected from patients and healthy controls. The comprehensive metabolomic analysis for profiling hydrophilic metabolites was conducted using capillary electrophoresis time-of-flight mass spectrometry. In total, 85 and 45 metabolites showed significant differences between tumor and matched control samples, and between salivary samples from oral cancer and controls, respectively ($P < 0.05$ correlated by false discovery rate); 17 metabolites showed consistent differences in both saliva and tissue-based comparisons. Of these, a combination of only two biomarkers yielded a high area under receiver operating characteristic curves (0.827; 95% confidence interval, 0.726-0.928, $P < 0.0001$) for discriminating oral cancers from controls. Various validation tests confirmed its high generalization ability. The demonstrated approach, integrating both saliva and tumor tissue metabolomics, helps eliminate pseudo-molecules that are coincidentally different between oral cancers and controls. These combined salivary metabolites could be the basis of a clinically feasible method of non-invasive oral cancer screening.

Polz-Dacewicz et al (2016). Each year approximately 6,000 new cases of head and neck cancer are registered in Poland. Human papillomavirus (HPV) and Epstein-Barr virus (EBV) have been associated with tumour formation. Cytokines have been shown to play an important role both in inflammation and carcinogenesis and they can be detected in saliva and serum with ELISA assays. Salivary biomarkers may be used as markers of early cancer detection. The aim of this study was the analysis of the serum and salivary levels of IL-10, TNF-α, TGF-β and VEGF in patients with oropharyngeal cancer and in healthy individuals. The level of these biomarkers was also analyzed in HPV- and EBV-related cases. The study involved 78 patients with histopathologically confirmed oropharyngeal squamous cell carcinoma and 40 healthy controls. Serum and salivary levels of IL-10, TNF-α, TGF-β and VEGF were analyzed both in patients and in healthy individuals by ELISA method using Diaclone SAS commercially available kits (France). EBV DNA was detected by the nested PCR for amplification of EBNA-2. HPV detection and genotyping was performed using the INNO-LiPA HPV Genotyping Extraassay (Innogenetics N. V, Gent, Belgium). The obtained results were subjected to statistical analysis using Mann-Whitney and Kruskal Wallis tests. The level of tested cytokines was higher in patients than in controls both in serum as well as in saliva. EBV DNA was detected in 51.3 % of patients and 20 % of controls, HPV DNA was present in 30.8 % of patients and 2, 5 % of controls. The level of IL-10 was

statistically higher in patients infected with EBV, HPV and co-infected with EBV/HPV. The level of TNF-α was significantly higher in patients infected with EBV, while TGF-β in patients with HPV infection and EBV/HPV co-infection. The authors concluded that the detection of salivary cytokines may be very helpful in early diagnosis, treatment and prognosis of OSCC.

Professional Societies

American Academy of Pediatric Dentistry (AAPD)

In the Guideline on Caries-Risk Assessment and Management for Infants, Children, and Adolescents, revised in 2014, the AAPD recommends the following:

- Due to a child's Mutans Streptococci (MS) levels and the age at which a child becomes colonized with cariogenic flora as being valuable in assessing risk, especially in preschool children, baseline testing on all children regardless of other risk factors/ risk level through the age of 5 is recommended.

American Dental Association (ADA) Council on Scientific Affairs

In a report by the ADA Council on Scientific Affairs, the following recommendation was made:

- Initial evaluation of patients with dry mouth should include a detailed health history to facilitate early detection and identify underlying causes. Comprehensive evaluation, diagnostic testing and periodic assessment of salivary flow, followed by corrective actions, may help prevent significant oral disease. A systematic approach to xerostomia management can facilitate interdisciplinary patient care, including collaboration with physicians regarding systemic conditions and medication usage. Comprehensive management of xerostomia and hyposalivation should emphasize patient education and lifestyle modifications. It also should focus on various palliative and preventive measures (Plemons et al 2014)

American Dental Association (ADA) Statement on Salivary Diagnostics

Large-scale, multicenter clinical trials and independent validation studies are required to establish evidence of clinical utility of salivary and oral fluid diagnostics in the early diagnosis and/or monitoring of oral cancer and other diseases or conditions. Current challenges include identification of disease-specific markers, establishing sensitivity and specificity of developed tests, and standardization of collection/storage of salivary samples.16 Refinement of oral fluid screening and diagnostic tests may further elucidate our understanding of the relationship between oral health and overall health. Presently, as of August 2018, there are no FDA approved salivary diagnostic tests for evaluating risk of periodontal disease, dental caries, or head and neck cancer.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Examples of salivary diagnostic devices include, but are not limited to the following:

- MyPerioPath® (Oral DNA Labs, Inc.)
- DentocultSM® Strip Mutans (Orion Diagnostica)
- CRT® Bacteria (Ivoclar)
- Saliva-Check Mutans (GC America)
- Saliva-Check BUFFER (GC America)

The FDA has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties referred to as "panels". Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device:

- Class I General Controls
  - With Exemptions
  - Without Exemptions
- Class II General Controls and Special Controls
  - With Exemptions
  - Without Exemptions
- Class III General Controls and Premarket Approval

Select testing devices are a Class I device. The FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the Federal Registers of December 7, 1994, and January 16, 1996. If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and FDA clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the following website for additional information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=31793.

Specific information regarding classification of dental devices may be found here: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?start_search=1&submission_type_id=&de

vicename=&productcode=&deviceclass=&thirdparty=&panel=de&regulationnumber=&pagenum=500&sortcolumn=devicename.

Laboratories that perform salivary diagnostic tests are regulated under the Clinical Laboratory Improvement Amendments (CLIA) Act of 1988. More information is available at: https://www.cms.gov/clia/.

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
01/01/2019	• Updated supporting information to reflect the most current description of services, clinical evidence, and references; no change to coverage rationale or list of applicable codes • Archived previous policy version DCG037.02