MISCELLANEOUS DIAGNOSTIC PROCEDURES

Policy Number: DCP040.03 **Effective Date**: January 1, 2019

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Related Policies

None

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

In-Office HbA1c and Blood Glucose Level Tests

The link between periodontal disease and diabetes has been well established, and the clinical utility of chairside dental office screening with subsequent referral to primary care has been explored as a means to improve the diagnosis of prediabetes and diabetes. There is a lack of high quality evidence that testing in the dental office setting results in improved outcomes.

Caries Susceptibility Tests

There is a lack of objective, high quality evidence to support or refute the efficacy or superiority of this specific testing method as a tool for Caries risk assessment and management.

Adjunctive Pre-Diagnostic Tests that Aid in the Detection of Mucosal Abnormalities Including Premalignant and Malignant Lesions (Not to Include Cytology or Biopsy Procedures)

Based on current evidence, these devices should be utilized as part of a comprehensive approach to screening for oral cancer. The gold standard for definitive diagnosis remains surgical biopsy with histopathological examination.

Pulp Vitality Tests

Pulp vitality tests are indicated for the following:

- For traumatic injuries to teeth
- Teeth with deep Caries or defective restorations

Pulp vitality tests are not indicated for the following:

- Sensitivity of exposed dentin without evidence of Pulp pathosis
- Teeth with no evidence of Caries, resorption, defective restorations, or are otherwise asymptomatic
- As part of routine dental examinations

Diagnostic Casts

Combined with clinical and radiographic findings, Diagnostic Casts may be useful for select cases, as they can provide a further understanding of the overall dentition. They may be helpful in developing the treatment plan without the patient present, and can serve as an additional tool for educating the patient. They provide an opportunity for a more thorough evaluation of the following:

- Tooth interdigitation
- Functional occlusion, and any occlusal abnormalities
- Wear facets and defective restorations, coronal contours, proximal contacts and embrasure spaces between teeth

DEFINITIONS

Caries: Commonly used term for tooth decay.

Diagnostic Cast: A replica of teeth and adjoining tissues created digitally or by a casting process (e.g., plaster into an impression). "Study model" is another term used for such a replica.

HbA1c/A1C: A blood test measures average blood glucose (blood sugar) control for the past 2 to 3 months.

Pulp: Connective tissue that contains blood vessels and nerve tissue which occupies the pulp cavity of a tooth.

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
D0411	HbA1c in-office point of service testing
D0412	Blood glucose level test – in-office using a glucose meter
D0425	Caries susceptibility tests
D0431	Adjunctive pre-diagnostic test that aids in detection of mucosal abnormalities including premalignant and malignant lesions, not to include cytology or biopsy procedures
D0460	Pulp vitality tests
D0470	Diagnostic casts

DESCRIPTION OF SERVICES

Pulp vitality testing involves thermal or electrical stimulation of a tooth in order to obtain a subjective response from the patient, to aid in the diagnosis of pulpal pathology, indicating the need for endodontic therapy. The fabrication of diagnostic casts or study models are most often inclusive in restorative, prosthodontic and orthodontic treatment planning, however they can have use in select cases for definitive treatment planning. Caries susceptibility testing can be done with a variety of diagnostic tools. The use of this code relates to a proprietary device to screen plaque

samples for bacteriologic activity using adenosine triphosphate (ATP) driven bioluminescence. This technology has wide use in rapid monitoring of microbiologic activity, hygiene effectiveness, and finished product testing in various environments, such as hospitals, the food industry, and laboratories. There are several adjunctive tests to aid in the detection of mucosal abnormalities using lights, and dye. There is a lack of high quality evidence to support or refute the efficacy of these devices and a traditional physical and tactile examination, with histopathological examination of suspicious lesions via surgical biopsy remains the "gold standard" for detecting oral cancer (Rethman et al. 2010). Many patients visit their dentist more often than their primary care providers, and as periodontal disease is associated with diabetes, the clinical utility of chairside dental office screening with subsequent referral to primary care has been explored as a means to improve the diagnosis of prediabetes and diabetes and reducing associated comorbidities. The American Diabetes Association provides a simple 7 question screening for risk of Type 2 diabetes. This can be completed and brought to patient's primary care provider for testing. The screening tool can be found at: http://www.diabetes.org/are-you-at-risk/diabetes-risk-test/.

CLINICAL EVIDENCE

HbA1c Testing

Lalla et al. (2015) conducted a randomized clinical trial to assess an approach to improving behavioural and glycaemic outcomes in dental patients who present with diabetes risk factors and previously unrecognized hyperglycaemia. The authors randomized 101 individuals identified with potential diabetes or pre-diabetes into two interventions. In the basic/control intervention, participants were informed about their diabetes risk factors and blood test result, and advised to see a physician. In the enhanced/test intervention, patients received a detailed explanation of findings and their implications, a written report for the physician, and were contacted at 2 and 4 months to inquire whether medical follow-up had occurred. At a 6-month re-evaluation, outcome measures included visit to physician, positive lifestyle changes and reduction in HbA1c. 73 subjects returned for the 6-month reevaluation, and the results showed that the two intervention groups did not significantly differ in any of the outcome variables. Eighty-four percent of subjects reported having visited a physician post-randomization, and 49% reported at least one positive lifestyle change as a result of our intervention. In subjects identified with potential diabetes (baseline HbA1c ≥ 6.5%), HbA1c was reduced 1.46 ± 0.28% compared to baseline ($p < 0.01$). The authors' concluded that diabetes risk assessment and education by dental professionals of affected individuals unaware of their status may contribute to improved patient outcomes. This study is limited to a small amount of participants.

In a 2014 field study, Genco et al. sought to assess the feasibility of screening for diabetes and prediabetes in dental practices, and in a community health center. Dental patients 45 years and older who were not aware of their diabetic status underwent evaluation for diabetes risk with an American Diabetes Association Diabetes Risk Test and with hemoglobin (Hb) A1C measurement. (Participants with an HbA1c level of 5.7 percent or greater were referred to their physicians for diagnosis). Of the 1,022 patients screened, 416 (40.7 percent) had an HbA1c blood level of 5.7 percent or greater and were referred for diagnosis. The HbA1c and the American Diabetes Association Diabetes Risk Test were correlated. Of the 416 participants who were referred, 35.1 percent received a diagnosis from their physicians within one year; 78.8 percent of these patients were seen in the community health center and 21.4 percent were seen in private dental offices. The diagnoses were diabetes (12.3 percent of patients), high risk of developing diabetes (that is, prediabetes) (23.3 percent) and no diabetes (64.4 percent). The study results show that screening for prediabetes and diabetes is feasible in a dental office, with acceptance by the dentist and dental office staff members, patients' physicians and patients. Patients from the community health center demonstrated good compliance with referrals to physicians; however, compliance was poor among those in the private dental offices.

Teeuw et al. (2017) conducted a study on the use of diabetic screening on patients with diagnosed periodontal disease. A total of 313 individuals from a university dental clinic participated. From 126 patients with mild/moderate periodontitis, 78 patients with severe periodontitis and 109 subjects without periodontitis, HbA1c values were obtained by the analysis of dry blood spots. Differences in mean HbA1c values and the prevalence of (pre)diabetes between the groups were analyzed. The mild/moderate and severe periodontitis groups showed significantly higher HbA1c values (6.1%±1.4% (43 mmol/mol±15 mmol/mol) and 6.3% ±1.3% (45 mmol/mol±15 mmol/mol), respectively) compared with the control group (5.7%±0.7% (39 mmol/mol±8 mmol/mol), p=0.003). In addition, according to the American Diabetes Association (ADA) guidelines for diagnosis, there was a significant overrepresentation of subjects with suspected diabetes (23% and 14%) and pre-diabetes (47% and 46%) in the severe periodontitis group and mild/moderate periodontitis groups, respectively, compared with the control group (10% and 37%, p=0.010). Notably, 18.1% of patients with suspected new diabetes were found among subjects with severe periodontitis compared with 9.9% and 8.5% among subjects with mild/moderate periodontitis and controls, respectively (p=0.024). Conclusions: The dental office, with particular focus on patients with severe periodontitis, proved to be a suitable location for screening for (pre)diabetes; a considerable number of suspected new diabetes cases were identified. The early diagnosis and treatment of (pre)diabetes help to prevent more severe complications and benefit the treatment of periodontitis.

Kalladka et al. (2014) used screening strategy to facilitate early identification of individuals at increased disease risk in a single Indian dental institute. 158 patients >30 years old, with no reported heart disease or diabetes, and unaware of any increased disease risk were enrolled. Blood pressure, total cholesterol, high-density lipoprotein levels and body mass index were collected. The Framingham Risk Score (FRS) was calculated as an indication of global risk of developing a coronary heart disease (CHD) event within 10 years; hemoglobin A1c level was used to determine DM risk. The results showed 11% had increased risk of heart disease (FRS >10%) and 32% had abnormal A1c levels (>5.7%). At least one risk factor was present in 61 patients, and 39% presented with two or more risk factors. Hypertension and obesity were the most common risk factors. The authors concluded that the use of a dental setting in a developing country could serve as a resource for early identification of patients at increased risk of developing CHD and DM, yet unaware of their increased risk. The dental setting can also serve as an entry point into the medical care system by identifying asymptomatic patients at increased risk of disease and referring these individuals to a primary care provider.

Caries Susceptibility Tests

Fazilat et al (2010) The authors conducted a cross-sectional study to demonstrate the use of adenosine triphosphate (ATP) driven bioluminescence as an innovative tool for the rapid chairside enumeration of oral bacteria (including plague streptococci) and assessment of oral hygiene and caries risk. Thirty-three pediatric patients (7- to 12-year-old males and females) were examined, and plague specimens, in addition to stimulated saliva, were collected from representative teeth within each quadrant. Oral specimens (n=150 specimens) were assessed by plating on enriched and selective agars, to enumerate total bacteria and streptococci, and subjected to adenosine triphosphate- (ATP-) driven bioluminescence determinations using a luciferase-based assay system. Statistical correlations, linking ATP values to numbers of total bacteria, oral streptococci and mutans streptococci, yielded highly significant r values of 0.854, 0.840, and 0.796, respectively. The authors concluded that ATP measurements have a strong statistical association with bacterial number in plague and saliva specimens, including numbers for oral streptococci, and may be used as a potential assessment tool for oral hygiene and caries risk in children.

Gilbert et al (2014) Mutans streptococci (MS) are one of the major microbiological determinants of dental caries. The objectives of this study are to identify distinct MS and Non-MS Streptococci strains that are located at carious sites and non-carious enamel surfaces in children with severe early childhood caries (S-ECC), and assess if cariogenic MS and non-cariogenic streptococci might independently exist as primary bacterial strains on distinct sites within the dentition of individual children. Dental plaque from 20 children aged 3-6 with S-ECC was collected from carious lesions (CLs), white spot lesions (WSLs) and non-carious enamel surfaces. Streptococcal isolates from each site were subjected to polymerase chain reaction (PCR) to identify MS, and arbitrarily primed-PCR for assignment of genetic strains. Primary strains were identified as ≥50% of the total isolates surveyed at any site. In several cases, strains were characterized for acidity using ATP-driven bioluminescence and subjected to PCR-determination of potential MS virulence products. Identification of non-MS was determined by 16S rRNA gene sequencing. The results showed 64 independent MS or non-MS streptococcal strains identified. All children contained 1-6 strains. In 11 patients, single primary MS strains were identified throughout the dentition. In 4 patients, primary MS strains were identified within CLs that were distinct from primary strains found on enamel. Streptococcus gordonii strains were identified as primary strains on enamel or WSLs in four children, and in general were less acidic than MS strains. The authors concluded that many children with S-ECC contained only a single primary MS strain that was present in both carious and non-carious sites. In some cases, MS and non-cariogenic S. gordonii strains were found to independently exist as dominant strains at different locations within the dentition of individual children, and the acidic potential (using ATP-driven bioluminescence) of these strains may influence susceptibility in the development of CLs.

Hallett et al (2013) Conducted a study to evaluate a chairside caries risk assessment protocol utilizing a caries prediction instrument, adenosine triphosphate (ATP) activity in dental plaque, mutans streptococci (MS) culture, and routine dental examination in five- to 10-year-old children at two regional Australian schools with high caries experience. Clinical indicators for future caries were assessed at baseline examination using a standardized prediction instrument. Plaque ATP activity was measured directly in relative light units (RLU) using a bioluminescence meter, and MS culture data were recorded. Each child's dentition was examined clinically and radiographically, and caries experience was recorded using enamel white spot lesions and decayed, missing, and filled surfaces for primary and permanent teeth indices. Univariate one-way analysis of variance between selected clinical indicators, ATP activity, MS count at baseline, and future new caries activity was performed, and a generalized linear model for prediction of new caries activity at 24 months was constructed. The results showed future new caries activity was significantly associated with the presence of visible cavitations, reduced saliva flow, and orthodontic appliances at baseline ($R(2)=0.2$, $P<.001$), but baseline plaque adenosine triphosphate activity and mutans streptococci counts were not significantly associated with caries activity at 24 months.

Pellegrini et al (2009) Enamel decalcification is a common problem in orthodontics, and can lead to tooth decay. The objectives of this randomized clinical study were to enumerate and compare plaque bacteria surrounding 2 bracket types, self-ligating (SL) vs elastomeric ligating (E), and to determine whether adenosine triphosphate (ATP)-driven bioluminescence could be used for rapid assessment of bacterial load in plaque. 14 patients (ages 11-17 years) were

bonded with SL and E brackets in 14 maxillary and 12 mandibular arches by using a split-mouth design. Recall visits were at 1 and 5 weeks after bonding. Plaque specimens were assayed for oral bacteria and subjected to ATP-driven bioluminescence determinations with a luciferin-based assay. In most patients, teeth bonded with SL attachments had fewer bacteria in plaque than did teeth bonded with E brackets. At 1 and 5 weeks after bonding, the means for SL vs E brackets were statistically lower for total bacteria and oral streptococci ($P < 0.05$). ATP bioluminescence values were statistically correlated to the total oral bacteria and oral streptococci, with correlation coefficients of 0.895 and 0.843, respectively. SL appliances promote reduced retention of oral bacteria, and ATP bioluminescence might be a useful tool in the rapid quantification of bacterial load and the assessment of oral hygiene during orthodontic treatment.

Adjunctive Pre-Diagnostic Testing

Nagi et al. (20016). In a systematic review, the authors evaluated the effectiveness of devices that utilise the principles of chemiluminescence and tissue autofluorescence as adjuncts in the detection of oral squamous cell carcinoma (OSCC) and oral potentially malignant disorders (OPMD). Relevant articles were found in PubMed [MEDLINE] and Science direct, and were limited to articles published in English or with an English abstract, from January 2005 to April 2014. Clinical trials utilized ViziLite, Microlux TM/DL and Visual Enhanced Light scope (VELscope) for early detection of OPMD and OSCC. Twenty primary studies published satisfied the criteria for selection, and 10 utilised chemiluminescence and 10 tissue autofluorescence. Sensitivity of Vizilite for detecting OSCC and OPMD ranged from 77.1 % to 100% and specificity was low and ranged from 0% to 27.8%.Most showed that chemiluminescence increases the brightness and margins of oral mucosal white lesions and thus assists in identification of mucosal lesions not considered under conventional visual examination. However, it preferentially detects leukoplakia and may fail to spot red patches. Clinical trials demonstrated that sensitivity of VELscope in detecting malignancy and OPMD ranged from 22 % to 100 % and specificity ranged from 16 % to 100%. Most studies concluded that VELscope can help the experienced clinician to find oral precursor malignant lesions. But it could not differentiate between dysplasia and benign inflammatory conditions. The authors concluded that while both devices are simple, non-invasive test of the oral mucosa, they are best suited for clinicians with sufficient experience and training. More clinical trials in future should be conducted to establish optical imaging as an efficacious adjunct tool in early diagnosis of OSCC and OPMD.

Chainani-Wu et al. (2015) conducted a cross-sectional, observational study to evaluate the assessment methods that predict the presence of higher-risk oral premalignant lesions or higher-risk areas within lesions. Patients diagnosed with oral leukoplakia, erythroleukoplakia, or erythroplakia were selected and visual oral examination, ViziLite® examination, toluidine blue staining (TBlue®), and a biopsy were completed in a single clinic visit. There were 77 of 100 examined lesions in 43 patients biopsied. Sensitivity, specificity, and positive and negative predictive values were computed for visual examination, ViziLite, and TBlue using biopsy results as the gold standard.
The results showed the sensitivity of TBlue in detecting high-risk lesions (carcinoma in situ or carcinoma) was 94 (71-100, $P < 0.0003$) and specificity 45 (32-58, $P < 0.53$), while for carcinoma, sensitivity was 100 (54-100, $P < 0.032$) and specificity 39 (28-52, $P < 0.097$). The results of ViziLite(®) testing either by itself or in combination with the information from toluidine blue testing revealed low sensitivity for the detection of high-risk lesions.
The authors concluded that clinical examination of leukoplakia, erythroplakia, or erythroleukoplakia lesions combined with toluidine blue staining may aid in the identification of severe dysplasia (carcinoma in situ) or carcinoma. This may help in determining whether, when, and where (the site within a lesion) a biopsy should be taken.

Chhabra et al. (2015) conducted an extensive literature review of the various diagnostic modalities available at for the detection of squamous cell carcinomas and oral epithelial dysplasias. An advanced PUBMED search from 1972 to present was conducted and selected based on the desired criteria of being non-invasive, highly specific and sensitive, economically viable, having a scope to be used for mass screening, easy to process, having low inter examiner variability and possibly not requiring high expertise to conduct and interpret the results. After reviewing various diagnostic modalities, the authors concluded that toluidine blue staining emerges as a valuable adjunct to incisional biopsy in detection of oral cancer but may not substitute it except in certain circumstances when its results are carefully correlated with the patient history and clinical characteristics of the mucosal disorder (considering the fact that incisional biopsy has been reported to cause dissemination of cancer cells in the circulation there by increasing the possibility of metastasis). The authors emphasize that toluidine blue is a screening modality and not a diagnostic procedure like biopsy and hence cannot replace a confirmatory biopsy as a whole, and that more detailed studies with large study samples are needed to investigate the reliability of toluidine blue staining and other screening methods in detection of oral cancer.

To evaluate the effectiveness of devices that utilise the principles of chemiluminescence and tissue autofluorescence as adjuncts in the detection of oral cancer and oral potentially malignant disorders (OPMDs), Rashid et al. (2015) conducted a systematic review of the published literature to evaluate the effectiveness of the ViziLite and ViziLite Plus with toluidine blue, MicroLux™/DL and the VELscope™. Twenty-five primary studies published between 2004 and 2013 satisfied the criteria for selection - 13 utilised chemiluminescence and 12 tissue autofluorescence, and several had utilised both study methods on the same population. The results showed chemiluminescence shows good sensitivity at detecting any OPMDs and oral cancer. However, it preferentially detects leukoplakia and may fail to spot red patches. The additive use of toluidine blue may improve specificity. Tissue autofluorescence is sensitive at

detecting white, red and white and red patches, and the area of fluorescence visualisation loss (FVL) often extends beyond the clinically visible lesion. However, in addition to OPMDs, VELScope may detect erythematous lesions of benign inflammation resulting in false-positive test results. The authors concluded that there is limited evidence for the use of these devices as a primary diagnostic tool. Additionally, they may be better suited to use by specialists in clinics in which there is a higher prevalence of disease, and where experienced clinicians may better discriminate between benign and malignant lesions.

Professional Societies

American Dental Association (ADA)

Evidence-Based Clinical Practice Guideline for the Evaluation of Potentially Malignant Disorders in the Oral Cavity states that no available adjuncts demonstrated sufficient diagnostic test accuracy to support their routine use as triage tools during the evaluation of lesions in the oral cavity. For patients seeking care for suspicious lesions, immediate performance of a biopsy or referral to a specialist remains the single most important recommendation for clinical practice. In exceptional cases, when patients decline a biopsy or live in rural areas with limited access to care, the panel suggested that cytologic testing may be used to initiate the diagnostic process until a biopsy can be performed (Lingen et al. 2017).

- The panel does not recommend autofluorescence, tissue reflectance, or vital staining adjuncts for the evaluation of potentially malignant disorders among adult patients with clinically evident, seemingly innocuous or suspicious lesions.
- The panel does not recommend cytologic adjuncts for the evaluation of potentially malignant disorders among adult patients with clinically evident, seemingly innocuous or suspicious lesions. Should a patient decline the clinician's* recommendation for performing a biopsy of the lesion or referral to a specialist, the clinician can use a cytologic adjunct to provide additional lesion assessment.
  - A positive or atypical cytologic test result reinforces the need for a biopsy or referral.
  - A negative cytologic test result indicates the need for periodic follow-up of the patient. If the clinician* detects persistence or progression of the lesion, immediately performing a biopsy of the lesion or referral to a specialist is indicated.
- The panel does not recommend autofluorescence, tissue reflectance, or vital staining adjuncts for the evaluation of potentially malignant disorders among adult patients with clinically evident, seemingly innocuous or suspicious lesions.
- The panel suggests that for adult patients with no clinically evident lesions or symptoms, no further action is necessary at that time.
- The panel does not recommend commercially available salivary adjuncts for the evaluation of potentially malignant disorders among adult patients with or without clinically evident, seemingly innocuous or suspicious lesions and their use should be considered only in the context of research.

American Diabetes Association (ADA)

American Diabetes Association Standards of Medical Care in Diabetes 2018:

- Because periodontal disease is associated with diabetes, the utility of chairside screening and referral to primary care as a means to improve the diagnosis of prediabetes and diabetes has been explored, with one study estimating that 30% of patients 30 years of age and older seen in general dental practices had dysglycemia. Further research is needed to demonstrate the feasibility, effectiveness, and cost-effectiveness of screening in this setting.
- Components of the comprehensive diabetes medical evaluation should include screening for the presence of dental diseases and referrals to a dentist for comprehensive dental and periodontal examination.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

CariScreen is a device used for ATP bioluminescence testing of dental plaque. According to the Office of In Vitro Diagnostics and Radiological Health (OIR), non-selective and differential culture media testing devices are considered to be Class I devices, and are exempted from the premarket notification requirement, and do not require FDA clearance before marketing in the U.S.; however, these manufacturers are required to register their establishment. See the following website for additional information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=jsh. (Accessed August 24, 2018)

Also see the following consensus standard document. Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard - Third Edition. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=31793. (Accessed August 24, 2018)

Examples of adjunctive diagnostic devices used to detect mucosal abnormalities include Vizilite®, VELscope®, and Identafi®. Please see the following website and search for additional products using Product Code EAZ: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm. (Accessed August 24, 2018)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
01/01/2019	• Changed policy type classification from "Coverage Guideline" to "Clinical Policy" • Revised coverage rationale: ○ Updated content sub-heading; replaced "HbA1c In Office *Testing*" with "In-Office HbA1c *and Blood Glucose Level Tests*" ○ Updated information pertaining to clinical evidence/study findings: **In-Office HbA1c and Blood Glucose Level Tests** ▪ Modified language to indicate the link between periodontal disease and diabetes has been well established, and the clinical utility of chairside

Date	Action/Description
	dental office screening with subsequent referral to primary care has been explored as a means to improve the diagnosis of prediabetes and diabetes; there is a lack of high quality evidence that testing in the dental office setting results in improved outcomes **Caries Susceptibility Tests** ▪ Replaced reference to "high quality *clinical* evidence" with "high quality evidence" • Added definition of "HbA1c/A1C" • Updated list of applicable CDT codes to reflect annual code edits; added D0412 • Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references • Archived previous policy version DCG040.02