NON-IONIZING DIAGNOSTIC PROCEDURES

Policy Number: DCP041.03 **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

There is inadequate evidence demonstrating the efficacy of these devices, limiting their use as a principal diagnostic tool. A non-ionizing diagnostic procedure refers to a device specifically designed to identify, quantify, monitor, and record changes in structure of enamel, dentin and cementum. These devices may be used as an adjunctive tool by the dental provider to identify high caries risk areas, and create non-invasive treatment plans for remineralization before caries begins. Visual and radiographic examinations remain the standard diagnostic methods for diagnosing active caries.

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
D0600	Non-ionizing diagnostic procedure capable of quantifying, monitoring, and recording changes in structure of enamel, dentin, and cementum

DESCRIPTION OF SERVICES

Non-ionizing diagnostic procedures refer to devices used in dentistry to record changes in tooth structures to detect caries before it can be diagnosed clinically or radiographically. There are several such devices currently on the market for use by dental practitioners. Some caries detection units feature lasers that cause fluorescence of the mineral structure of the tooth, while others use transillumination to see through the enamel. The intent is for dental providers to use this information to design preventive based dental programs to heal or remineralize these areas without using invasive techniques. Additionally, devices that use laser technology may be used to detect the presence and content of subgingival calculus deposits.

CLINICAL EVIDENCE

Ghoncheh et al (2017) performed an in vitro study to compare the diagnostic accuracy of DIAGNOdent and digital radiography for detection of secondary proximal caries adjacent to composite restorations. Sixty extracted molars were randomly selected; 30 teeth had carious lesions restored with composite resin and the other 30 teeth were without cavities. All cavities were restored with composite resin. The teeth were examined for caries using DIAGNOdent and digital radiographs and evaluated by four observers. The study showed no statistically significant difference between the diagnostic accuracy of DIAGNOdent and digital radiography for detection of the secondary proximal caries. Thus it was concluded that DIAGNOdent may be used as an adjunct diagnostic tool for detection of secondary proximal caries.

Menem et al (2017) studied the diagnostic accuracy of a pen-type laser fluorescence (LFpen) device in detecting approximal caries lesions, in posterior permanent teeth, and compare it to digital bitewing radiography. Thirty patients in the age range of 18-37 years were screened for participation. Ninety permanent teeth were selected and examined using the LFpen (DIAGNOdent pen) and digital bitewing radiography. One potential limitation of the study was that only one trained examiner performed all the examinations. The findings of this study could be considered a first step in establishing the diagnostic accuracy of the LFpen device in detecting caries lesions in posterior permanent teeth. Future studies with larger sample sizes are needed to confirm the current findings that would have major implications in evidence-based dental practice guidelines.

Ari et al (2013) compared in vitro the diagnostic performance of low-powered magnification with light-emitting diode headlight (LPMLED) using ICDAS-II criteria and AC Impedance Spectroscopy (ACIS) device, on occlusal surfaces of primary molars. The occlusal surfaces of 18 extracted primary molars were examined blindly by two examiners. The teeth were sectioned and examined under light microscopy using Downer's histological criteria as gold standard. Good to excellent inter- and intraexaminer reproducibility, higher sensitivity, specificity, and AUC values were achieved by LPMLED at D1 threshold. Also the relationship between histology and LPMLED was statistically significant. In conclusion visual aids have the potential to improve the performance of early caries detection and clinical diagnostics in children. Despite its potential, ACIS device should be considered as an adjunct method in detecting caries on primary teeth.

Bader and Shugers (2004) conducted a systematic review of the literature to assess the diagnostic performance of the DIAGNOdent (DD). Of 115 articles identified in the search, 25 studies were included in the review according to criteria requiring histologic validation and outcomes expressed as sensitivity and specificity values. For detection of dentinal caries, sensitivity values ranged widely (0.19 to 1.0), although most tended to be high. Specificity values exhibited a similar pattern, ranging from 0.52 to 1.0. In comparison with visual assessment methods, the DD exhibited a sensitivity value that was almost always higher and a specificity value that was almost always lower. The body of evidence is characterized largely by in vitro studies, so that generalization to the clinical setting is uncertain. The DD clearly is more sensitive than traditional diagnostic methods; however, the increased likelihood of false-positive diagnoses compared with that with visual methods limits its usefulness as a principal diagnostic tool.

Bahrololoomi et al (2015) compared the efficacy of three diagnostic methods of bitewing radiography, laser fluorescence (DIAGNOdent), and visual examination in diagnosing incipient occlusal caries of permanent first molars. In this diagnostic cross-sectional study, 109 permanent first molar teeth of 31 patients aged 7-13 years were examined visually, on bitewing radiographs, and using DIAGNOdent. Scoring of visual and radiographic examinations was based on Ekstrand's classification. Visual examination after pit and fissure opening served as the gold standard.

The results identified visual examination as the first choice for diagnosis of incipient caries. In suspicious cases, radiography and laser DIAGNOdent can be used as adjunct procedures.

Castilho et al (2016) conducted a study to validate the DIAGNOdent laser fluorescence method and the International Caries Detection and Assessment System (ICDAS) for caries classification against the gold standard, histological examination, for detecting occlusal caries on permanent molars. The thresholds used were the outer enamel, the inner enamel and outer third of the dentine, and the inner two-thirds of the dentine. 43 patients with non-impacted third molars were recruited from a university clinic. A trained examiner performed the examinations. After the teeth were extracted, the histological criterion was used to determine the severity of the lesions. Intra-examiner agreement for ICDAS was 0.60 and reliability for DIAGNOdent was 0.968. ICDAS and DIAGNOdent proved to be reproducible methods with similar performance in the detection of occlusal carious lesions in dentine. The ability of DIAGNOdent to detect initial enamel lesions was higher than that of ICDAS, but with low specificity. The usefulness of DIAGNOdent as an adjunct method for assessment of initial occlusal caries in permanent molars is questionable.

Cınar et al (2013) performed an in vivo study to evaluate the performance of fluorescence-based devices in detecting occlusal caries lesions in primary molars compared with conventional methods. Two examiners assessed 44 occlusal surfaces of first and second primary molars in 20 patients using two fluorescence devices: DIAGNOdent and DIAGNOdent pen. Teeth were also assessed by visual examination and bitewing radiograph. Histological examination served as the gold standard after extraction. All methods presented similar performance in detecting all lesions considering the area under the receiver operating curve. The DIAGNOdent pen showed better performance than DIAGNOdent. Furthermore, visual examination and the DIAGNOdent pen device seem to be sufficient for detection of occlusal caries in primary molars.

Diniz et al (2012) conducted an in vivo study to determine clinical cutoffs for a laser fluorescence (LF) device, an LF pen and a fluorescence camera (FC), as well as to evaluate the clinical performance of these methods and conventional methods in detecting occlusal caries in permanent teeth by using the histologic gold standard for total validation of the sample. One trained examiner assessed 105 occlusal surfaces by using the LF device, LF pen, FC, International Caries Detection and Assessment System (ICDAS) criteria and bitewing (BW) radiographic methods. After tooth extraction, the authors assessed the teeth histologically. They determined the optimal clinical cutoffs by means of receiver operating characteristic curve analysis. The specificities and sensitivities for enamel and dentin caries detection versus only dentin caries detection thresholds were 0.60 and 0.93 and 0.77 and 0.52 (ICDAS), 1.00 and 0.29 and 0.97 and 0.44 (BW radiography), 1.00 and 0.85 and 0.77 and 0.81 (LF device), 0.80 and 0.89 and 0.71 and 0.85 (LF pen) and 0.80 and 0.74 and 0.49 and 0.85 (FC), respectively. The accuracy values were higher for ICDAS, the LF device and the LF pen than they were for BW radiography and the FC. The ICDAS, the LF device and the LF pen demonstrated good performance in helping detect occlusal caries in vivo. Occlusal caries detection should be based primarily on visual inspection; fluorescence-based methods may be used to provide a second opinion in clinical practice.

Gomez et al (2012) conducted a comparison of in vitro performance of the International Caries Detection and Assessment System (ICDAS), digital photographs scored with ICDAS (ICDAS photographs), fibre-optic transillumination (FOTI), optical coherence tomography (OCT), SoproLife(®) camera and two implementations of quantitative light-induced fluorescence a commercial (QLF-Inspektor Research systems) and a custom (QLF-Custom) system, to detect early and intermediate occlusal lesions. One hundred and twelve permanent extracted teeth were selected and assessed with each detection method. Histological validation was used as a gold standard. The detection methods were compared by means of sensitivity, specificity, areas under receiver operating characteristic (AUROC) curves for enamel and dentine levels and with the Spearman's rank correlation coefficient against histology. Even though all methods present similar performance in detecting occlusal caries lesions, visual inspection seems to be sufficient to be used in clinical practice for detection and assessment of lesion depth. Other methods may be useful in monitoring caries lesion behavior.

Herzog et al (2015) assessed the feasibility and ease of use of the Canary System in approximal carious lesion detection in primary molars in this study. Forty healthy five- to 12-year-olds, who presented to the Center for Pediatric Dentistry in Seattle, Wash., U.S.A., for initial or recall exams, were enrolled. Participants had one to two primary molars, with or without approximal radiographic radiolucencies. Four Canary System scans were performed at the approximal area of each study tooth. The maximum Canary number of the four scans was compared to bitewing radiographs. Seventy-five teeth were included in the final analysis. The overall sensitivity and specificity of the Canary System, when compared to bitewing radiographs, was 81 percent and 35 percent, respectively. Among teeth without radiographic radiolucencies, the Canary System identified 65 percent (31 of 48) of study teeth as having carious lesions. It was concluded the Canary System is a safe approximal caries detection device in five- to 12-year-olds. When compared to bitewing radiographs, the specificity of the Canary System for approximal carious lesion detection in primary molars was low. However, this could indicate that the Canary System is detecting lesions earlier than radiographs.

Jan et al (2015) investigated the accuracy of the Canary System (CS) to detect proximal caries lesions in vitro, and compared it with conventional methods: International Caries Detection and Assessment System (ICDAS) II and bitewing radiography (BW). Visible proximal surfaces of extracted human teeth were assessed by ICDAS-II before setting them in five manikin mouth models. Then contacting proximal surfaces in mouth models were assessed by BW and CS. Histological validation with polarized-light microscopy served as a gold standard. Pairwise comparisons were performed on area under the curve (AUC), sensitivity, and specificity of the three methods, and corrected using Bonferroni's method. The CS presented significantly higher sensitivity (0.933) than ICDAS-II (0.733, $P = 0.01$) and BW (0.267, $P < 0.001$), and ICDAS-II higher sensitivity than BW ($P < 0.001$). There were no significant differences between their specificity values. It was concluded the CS demonstrated greater accuracy in detecting proximal lesions than ICDAS-II and BW, although without significantly higher specificity.

Lenzi et al (2016) conducted an in vitro study to compare the performance of different conventional and quantitative light-induced fluorescence-based (QLF) methods in detecting secondary caries around occlusal resin composite restorations in primary molars. Two examiners evaluated independently 42 sites adjacent to tooth-colored restorations using visual inspection (ICDAS-CARS), radiographic examination, and QLF. Histological examination was used as reference standard method. Area under the ROC curve (Az), sensitivity, specificity, and accuracy of the methods were calculated at enamel (D1) and dentin caries (D3) lesions thresholds. There was no difference among the methods considering Az at D1 threshold. Visual inspection, radiograph, and QLF (scores) methods presented similar sensitivities and significantly higher than those obtained with the QLF (ΔF%). At D3 threshold, there were no differences among the methods regarding sensitivities, specificities, and accuracy, except for the examiner 2 with the QLF (ΔF%) who achieved a very low sensitivity value. Conventional methods are similar to QLF methods for detecting caries around tooth-colored restorations in primary teeth.

Mansour et al (2016) compared the results of screening for coronal dental caries in a general dental practice using clinical observations, radiographs, laser fluorescence (DIAGNOdent™) (LF), and optical coherence tomography (OCT). Forty patients with >1 coronal carious lesion as determined by prescreening using clinical examination and radiographs were enrolled in this study. Subjects with gross caries were excluded. Subsequently each patient underwent a full detailed dental examination by an experienced clinician, using visual examination and radiographs according to standard clinical practice. The coronal surfaces of a total of 932 teeth were examined and charted. Teeth were then photographed, re-diagnosed using the LF system, and imaged using OCT. Two blinded pre-standardized examiners reviewed radiographic and OCT images and assigned caries status. The findings support the usefulness of LF for primary caries detection, and the clinical utility of OCT for early caries detection and monitoring under dental resin restorations and sealants.

Sichani et al (2016) compared the accuracy of radiographs and DIAGNOdent in detecting caries under restorations in primary teeth using histologic evaluation. A total of 74 previously extracted primary molars (37 with occlusal caries and 37 without caries) were used. Class 1 cavity preparations were made on each tooth by a single clinician and then the preparations were filled with composite resin. The accuracy of radiographs and DIAGNOdent in detecting caries was compared using histologic evaluation. The data were analyzed by SPSS version 21 using Chi-square, Mc Namara statistical tests and receiver operating characteristic curve. The sensitivity and specificity for DIAGNOdent were 70.97 and 83.72, respectively. Few false negative results were observed, and the positive predictive value was high and the area under curve was more than 0.70 therefore making DIAGNOdent a great method for detecting caries. DIAGNOdent showed a greater accuracy in detecting secondary caries under primary molar restorations, compared to radiographs. Although DIAGNOdent is an effective method for detecting caries under composite restorations, it is better to be used as an adjunctive method alongside other detecting procedures.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Laser Fluorescence Technology

A laser fluorescence caries detection device is a laser, a fluorescence detector housed in a dental handpiece, and a control console that performs device calibration, as well as variable tone emitting and fluorescence measurement functions. The intended use of the device is to aid in the detection of tooth decay by measuring increased laser induced fluorescence.

Examples of laser fluorescence technology include, but are not limited to the following:

- DIAGNOdent®,
- DIAGNOdent 2190 with Periodontal Probe®,
- The Canary System®, and
- CarieScan PRO

Transillumination Technology

Transillumination uses non-ionizing radiation and is thought to be more sensitive to early demineralization than dental radiography.

Examples of transillumination technology include, but are not limited to the following:

- Dexis CariVu™,
- Ti2200 Transillumination Cable,
- DIANGOcam 2170, and
- D-Carie

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

These devices can be found at the FDA website (www.fda.gov); some of these are class I and others are class II devices. For information on device classification or a specific device or manufacturer, search the Center for Devices and Radiological Health (CDRH) 510(k) database by product and/or manufacturer name then check for the appropriate indication in the Summary section of the results: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

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U.S. Food and Drug Administration. Medical Devices/Products and Medical Procedures/Device Approvals and Clearances/510(k) Clearances.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
01/01/2019	• Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or list of applicable codes • Archived previous policy version DCP041.02