NON-IONIZING DIAGNOSTIC PROCEDURES

Policy Number: DCP041.04

Effective Date: October 1, 2019

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**Coverage Rationale**

**Non-Ionizing Diagnostic Procedures**

Non-ionizing diagnostic procedures are not indicated due to insufficient evidence of efficacy.

**Exclusions**

- Dental Services that are not Necessary
- Procedures that are considered to be Experimental, Investigational or Unproven
- Any Dental Procedure not directly associated with dental disease

**Definitions**

**Necessary**: Dental Care Services and supplies which are determined through case-by-case assessments of care based on accepted dental practices to be appropriate; and
- Needed to meet basic dental needs; and
- Rendered in the most cost-efficient manner and type of setting appropriate for the delivery of the dental care service; and
- Consistent in type, frequency and duration of treatment with scientifically based guidelines of national clinical, research, or health care coverage organizations or governmental agencies that are accepted by us; and
- Consistent with the diagnosis of the condition; and
- Required for reasons other than the convenience of the member, or dental provider; and
- Demonstrated through prevailing peer-reviewed dental literature to be either:
  - Safe and effective for treating or diagnosing the condition or sickness for which its use is proposed; or
  - Safe with promising efficacy:
    - For treating a life threatening dental disease or condition; and
    - In a clinically controlled research setting; and
    - Using a specific research protocol that meets standards equivalent to those defined by the National Institutes of Health

**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.

<table>
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<th>CDT Code</th>
<th>Description</th>
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<tr>
<td>D0600</td>
<td>Non-ionizing diagnostic procedure capable of quantifying, monitoring, and recording changes in structure of enamel, dentin, and cementum</td>
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*CDT® is a registered trademark of the American Dental Association*
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. 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. 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 been considered as 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.

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

- DIAGNodent®,
- CarieScan PRO
- Ti2200 Transillumination Cable,

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 CarlVu™,
- Ti2200 Transillumination Cable,
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/pmncfm.

**REFERENCES**


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

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<tr>
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<td>• Simplified content</td>
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<td>• Updated language to clarify non-ionizing diagnostic procedures are not indicated</td>
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<td>• Added list of coverage <em>Exclusions</em> to include:</td>
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<td>o Any Dental Procedure not directly associated with dental disease</td>
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INSTRUCTIONS FOR USE

This Dental Clinical Policy provides assistance in interpreting UnitedHealthcare standard dental benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard dental plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Dental Clinical Policy is provided for informational purposes. It does not constitute medical advice.