Non-Ionizing Diagnostic Procedures

Policy Number: DCP041.09
Effective Date: February 1, 2024

Instructions for Use

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Related Dental Policies
None

Coverage Rationale

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

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 Policies and 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 the use of devices 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. These include lasers that cause fluorescence of the mineral structure of the tooth, transillumination to see through the enamel, and near -infrared devices. These may be used as an adjunctive tool by the dental provider to identify high caries risk areas and develop prevention strategies, as well as create non-invasive treatment plans for remineralization before caries begins. Visual, tactile and radiographic examinations remain the standard diagnostic methods for diagnosing active caries.

Clinical Evidence

Shaalan, (2023) conducted a study to compare the diagnostic accuracy of the DIAGNOdent laser fluorescence device (KaVo USA) to the International Caries Detection and Assessment System-II (ICDAS-II) in the detection of facial, smooth surface

noncavitated carious lesions. Sixty patients with non cavitated, white spot lesions and 32 sound teeth were included. All areas were examined by 2 calibrated examiners separately. The results showed that the DIAGNOdent had an overall accuracy of 84.45% on teeth with an ICDAS score of 0. When the ICDAS score was 1 (first visual change in enamel) the DIAGNOdent had an accuracy of 74.15%, and accuracy was 100% when there were distinct visual changes in enamel. The authors concluded that DIAGNOdent shows overall equivalence to visual examination and could be used as an adjunct for caries detection.

In a 2021 systematic review and meta-analysis, Foros et al. appraised the evidence of 51 studies regarding the performance of various means of detection of incipient caries in permanent and primary teeth. For permanent teeth, when histologic examination was considered as the reference for occlusal surfaces, the sensitivity (Se) range appeared high for the DIAGNOdent Pen (DD Pen) at 0.81-0.89, followed by The International Caries Detection and Assessment System (ICDAS-II) at 0.62-1, DIAGNOdent (DD) at 0.48-1, and bitewing radiography (BW) at 0-0.29. The corresponding specificity (Sp) range was: DD Pen 0.71-0.8, ICDAS-II 0.5-0.84, DD 0.54-1, and BW 0.96-1. When operative intervention served as the reference for occlusal surfaces, again, the DD means valued the most promising results on Se: DD 0.7-0.96 and DD Pen 0.55-0.90, followed by ICDAS-II 0.25-0.93, and BW 0-0.83. The Sp range was: DD 0.54-1, DD Pen 0.71-1, ICDAS-II 0.44-1, and BW 0.6-1. For interproximal surfaces, the Se was: BW 0.75-0.83, DD Pen 0.6, and ICDAS-II 0.54; the Sp was: BW 0.6-0.9, DD Pen 0.2, and ICDAS-II 1. For primary teeth, under the reference of histologic assessment, the Se range for occlusal surfaces was: DD 0.55-1, DD Pen 0.63-1, ICDAS-II 0.42-1, and BW 0.31-0.96; the respective Sp was: DD 0.5-1, DD Pen 0.44-1, ICDAS-II 0.61-1, and BW 0.79-0.98. For approximal surfaces, the Se range was: DD Pen 0.58-0.63, ICDAS-II 0.42-0.55, and BW 0.14-0.71. The corresponding Sp range was: DD Pen 0.85-0.87, ICDAS-II 0.73-0.93, and BW 0.79-0.98. Se and Sp values varied, due to the heterogeneity regarding the setting of individual studies. The authors concluded that robust conclusions cannot be drawn, and different diagnostic means should be used as adjuncts to clinical examination. In permanent teeth, visual examination may be enhanced by DD on occlusal surfaces and BW on interproximal surfaces. In primary teeth, DD Pen may serve as a supplementary tool across all surfaces.

Jaafar et al. (2020) evaluated and compared the diagnostic performance of the DIAGNOdent Pen (DP) and The Canary System (CS) for the assessment and monitoring of occlusal enamel caries under fissure sealants placed on young permanent teeth. A total of 90 permanent teeth were examined using a visual examination method (ICDAS), a quantitative light-induced fluorescence (DP), and a photothermal radiometry (CS). Teeth were randomly divided into two groups based on the type of fissure sealants: a resin sealant and a glass-ionomer sealant. Sealants were placed over the study sites, and caries assessment was performed with each caries detection method at 3- and 6-month recall appointments. The results showed that the CS and DP were able to distinguish between sound and carious tissue beneath fully and partially retained sealants at 6-month follow-up with an accuracy of 46.7% and 33.4%, respectively. The authors concluded that the diagnostic performance of the CS and DP are acceptable and can be considered as useful adjunct tools in the clinical evaluation and monitoring the changes in enamel due to lesion progression under fissure sealants. However, in the clinical setting, sensitivity and specificity of these devices may be influenced by the sealant type, thickness, retention, and the differences in the lesion characteristics over time.

Makhija et al. (2018) evaluated whether using a device changed the percentage of suspicious occlusal carious lesions (SOCLs) that were opened surgically and, among those SOCLs that were opened, the proportion that had penetrated into dentin. Eighty-two dentists participated with a total of 1,500 SOCLs. Phase 1 of the study included dentists that obtained patient consent and recorded information about the lesion, treatment or treatments, and depth (if opened). The dentists were then randomly assigned to one of three groups: no device, DIAGNOdent (KaVo), and Spectra (Air Techniques). In phase 2 of the study, dentists enrolled approximately twenty additional patients and recorded the same phase 1 information while using the assigned device to help make their treatment decisions. After randomization, a mixed-model logistic regression was used to determine any differences in the proportion of lesions opened and, if opened, the proportion of lesions that penetrated into dentin. The authors concluded there was no statistically significant difference found in the change in proportion of lesions receiving invasive treatment from phase 1 to phase 2 across the 3 groups (P = .33) or in the change in proportion of percentage of opened lesions that extended into dentin (P = .31). It was determined the caries-detecting devices tested may not improve dentists' clinical decision making for SOCLs. Limitations included real world clinical practice and therefore no attempt was made to standardize or calibrate the diagnosis or treatment. Additional limitations were years since graduation for dentists and age of the patients.

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.

Bahrololoomi et al (2015) compared the efficacy of three diagnostic methods, 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.

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 radiolucency's. 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 radiolucency's, 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.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

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®
- 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
- DIAGNOcam 2170
- D-Carie

Information regarding non- ionizing diagnostic devices can can be found by searching by device name at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed October 2, 2023)

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Policy History/Revision Information

Date	Summary of Changes
02/01/2024	**Template Update** • Updated *Instructions for Use* to clarify this policy applies to both Commercial and Medicare Advantage plans **Coverage Rationale** • Replaced language indicating “non-ionizing diagnostic procedures are not indicated due to insufficient evidence of efficacy” with “non-ionizing diagnostic procedures *using any device* are not indicated due to insufficient evidence of efficacy” • Removed content addressing coverage exclusions **Definitions** • Removed definition of “Necessary” **Supporting Information** • Updated *Description of Services, Clinical Evidence, FDA,* and *References* sections to reflect the most current information • Archived previous policy version DCP041.08

Instructions for Use

This Dental Clinical Policy provides assistance in interpreting UnitedHealthcare standard and Medicare Advantage dental 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.