Non-Ionizing Diagnostic Procedures

Policy Number: DCP041.06
Effective Date: January 1, 2021

Instructions for Use

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Related Dental Policies
None

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 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. Some caries detection devices 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 develop prevention strategies as well as create non-invasive treatment plans for remineralization before caries begins. Visual and radiographic examinations remain the standard diagnostic methods for diagnosing active caries.

Clinical Evidence

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.

Abdelaziz et al. (2018) compared an infrared transillumination device, DIAGNOcam (DC) and bitewing radiography (BW) for the detection of proximal caries. The authors did a retrospective analysis of 18 students who had data from DC and BW images performed in 2013 for a check-up, and corresponding follow-up images performed in 2015. Two observers rated 376 proximal surfaces on a 4-level dentin lesion scale and reached a unanimous rating for each surface. Agreement between DC and BW was similar for dentin lesion detection, but was low for enamel caries detection; DC detected more enamel caries than BW. The authors concluded that DC is as reliable as BW to detect proximal dentin lesions as DC detects proximal enamel lesions at an earlier stage than BW. DC may reduce or even eliminate the need for X-ray monitoring in the future. Young patients with few or no restorations are more likely to benefit from regular DC monitoring, which drastically reduces their exposure to radiation. Limitations of the study included the low volume of participants and the number of missing images for DC.

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.

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.

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 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.

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.

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.

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®, 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. (Accessed October 21, 2020)

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Policy History/Revision Information

Date	Summary of Changes
03/15/2021	• Updated dental entity brand logo
01/01/2021	Template Update • Reformatted policy; transferred content to new template Supporting Information • Updated *Description of Services*, *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version DCP041.05

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.