Single Tooth Direct Restorations

Guideline Number: DCG023.11
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➲ Instructions for Use

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Related Dental Policies

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Coverage Rationale

Direct Restorations

Direct Restorations are indicated for the following:

- To replace tooth structure lost to caries or trauma
- To replace restorative material lost in the course of accessing pulp chamber for endodontic therapy
- To replace existing restorations that exhibit recurrent decay, fracture, or marginal defects

In addition to the above, Glass Ionomer restorations are indicated for the following:

- When teeth cannot be isolated properly to allow placement of resin restorations
- As an alternative to resin sealants when the teeth cannot be properly isolated (patient cooperation, partially erupted teeth)
- Class I, II, III, and V restorations on primary teeth
- Class III and V restorations on permanent teeth that cannot be isolated in high risk patients
- As a caries control plan for high risk patients using atraumatic techniques

Direct Restorations are not indicated for the following:

- Teeth with a hopeless prognosis (McGuire's Classification)
- Incipient enamel only lesions extending less than halfway to the dentinoenamel junction (DEJ)
- Primary teeth that are near exfoliation or less than 50% of the tooth root remains
- Composite resin restorations are not indicated for patients with heavy bruxism
- Composite resin restorations are not indicated for patients with extensive active caries, or high caries risk
- Amalgam restorations are not indicated for placement on teeth in which they will have contact with gold restorations

Protective Restoration

A protective restoration is indicated for the following:

- To relieve pain
- To promote healing
- To prevent further deterioration
- To retain tissue form

A protective restoration is not indicated for the following:

- As a liner or base for a definitive restoration
- Not for endodontic access closure

- Not for pulp capping
- As a definitive restoration

Interim Therapeutic Restoration - Primary Dentition

Interim Therapeutic restorations are indicated for the following:

- For very young, uncooperative, or special needs patients
- When traditional tooth preparation for an Amalgam or Composite restoration is not feasible or must be postponed
- As a caries control plan for high risk patients using atraumatic techniques

Resin Infiltration of Incipient Smooth Surface Lesions

Resin Infiltration of incipient smooth surface lesions is typically used for treating white spot, demineralized enamel resulting from orthodontic treatment, for aesthetic purposes. The code is used to describe a proprietary product (Icon Smooth Surface Caries Infiltration, DMG America Ridgefield park, New Jersey) and is not indicated due to insufficient evidence of efficacy.

Definitions

Amalgam: An alloy used in direct dental restorations. It is typically composed of mercury, silver, tin, and copper along with other metallic elements added to improve physical and mechanical properties. (ADA)

Composite: A dental restorative material made up of disparate or separate parts (e.g., resin and quartz particles). (ADA)

Direct Restoration: A restoration fabricated inside the mouth. (ADA)

Glass Ionomer: Polyelectrolyte cement in which the solid powder phase is a fluoride-containing aluminosilicate glass powder to be mixed with polymeric carboxylic acid. The cement can be used to restore teeth, fill pits and fissures, lute, and line cavities. It is also known as glass polyalkenoate cement, ionic polymer cement, polyelectrolyte cement. (ADA)

G.V. Black's Classification of Dental Caries and Restorations (Boushell, Roberson, Walter 2013):

- Class I: All pit-and-fissure preparations, these include preparations on occlusal surfaces of premolars and molars, occlusal two-thirds of the facial and lingual surfaces of molars, and the lingual surfaces of maxillary incisors.
- Class II: Preparations involving the proximal surfaces of posterior teeth.
- Class III: Preparations involving the proximal surfaces of anterior teeth that do not include the incisal angle.
- Class IV: Preparations involving the proximal surfaces of anterior teeth that include the incisal edge.
- Class V: Preparations on the gingival third of the facial or lingual surfaces of all teeth.
- Class VI: Preparations on the incisal edges of anterior teeth or the occlusal cusp tips of posterior teeth.

Interim: Belonging to, serving during, or taking place during an intermediate interval of time; temporary.

McGuire Classification of Tooth Prognosis (Levi 2016):

- Good: Teeth with adequate periodontal support where the etiologic factors can be controlled, including systemic factors.
- Fair: No more than 25% attachment loss with Grade 1 furcation invasion which can be maintained. Plaque control and systemic factors can be maintained.
- Poor: As much as 50% bone loss with Grade II furcation invasions, poor crown: root ratio; mobility greater than Miller Class I; systemic factors; poor patient participation in treatment.
- Questionable: Teeth with greater than 50% attachment loss; Grade II or III furcation involvements; the tooth is not easily maintained either with professional hygiene or by the patient.
- Hopeless: Inadequate attachment loss to support the tooth; Class III or IV furcation involvement; Miller Class III mobility; the tooth cannot be maintained with adequate plaque control by the clinician or by the patient.

Resin Infiltration: Application of a resin material engineered to penetrate and fill the sub-surface pore system of an incipient caries lesion to strengthen, stabilize, and limit the lesion's progression, as well as mask visible white spots. (ADA)

Therapeutic: Of or pertaining to therapy or treatment; beneficial. Therapy has as its goal the elimination or control of a disease or other abnormal state. (ADA)

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 guideline 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
D2140	Amalgam – one surface, primary or permanent
D2150	Amalgam – two surface, primary or permanent
D2160	Amalgam – three surface, primary or permanent
D2161	Amalgam – for or more surfaces, primary or permanent
D2330	Resin-based composite – one surface, anterior
D2331	Resin-based composite – two surface, anterior
D2332	Resin-based composite – three surface, anterior
D2335	Resin-based composite - four or more surfaces (anterior)
D2390	Resin-based composite crown, anterior
D2391	Resin-based composite – one surface, posterior
D2392	Resin-based composite – two surface, posterior
D2393	Resin-based composite – three surface, posterior
D2394	Resin-based composite – four or more surfaces, posterior
D2410	Gold foil – one surface
D2420	Gold foil – two surface
D2430	Gold foil – three surface
D2940	Protective restoration
D2941	Interim therapeutic restoration – primary dentition
D2990	Resin infiltration of incipient smooth surface lesions
D2999	Unspecified restorative procedure, by report

Description of Services

Direct Restoration procedures are the placement of restorative material directly into the defective, injured, or diseased tooth to re-establish normal form and function. Tooth preparation, all liners, or bases, etching and curing, as well as occlusal adjustments are inclusive. Preventive resin restorations are a conservative approach to restore a tooth that has active caries in pits and fissures that has not extended into the dentin. Protective restorations are placed to relieve pain, prevent further deterioration, and promote healing.

Pursuant to CA AB2585: While not common in dentistry, nonpharmacological pain management strategies should be encouraged if appropriate.

Clinical Evidence

In a 2020 systematic review, Bakdach et al. evaluated the current evidence on the management of orthodontically induced white spot lesions (OIWSLs). Thirteen articles were evaluated and reported interventions, and one included resin infiltration. Although this study indicated resin infiltration to be effective, there is a lack of available evidence to support this intervention for treating of OIWSLs and further research is needed.

Amin et al (2016). The purpose of this study was to assess the success rate of various treatments provided under general anesthesia for early childhood caries (ECC) over three-year follow-up period. ECC children no older than 72 months at the time of dental surgery, who had completed a three-year follow-up, were included. The success rate of every treatment was evaluated. The longevity of each treatment and significant factors associated with failures were assessed. A total of

818 children were included. Of these, 32.9 percent had restored teeth that required further treatment during the three-year follow-up. Amalgam restorations and stainless-steel crowns (SSCs) showed significantly longer survival than composite restorations in all types of restorations. The authors concluded that SSCs and amalgam restorations were clinically more successful and had better survival times than composite restorations.

Naghipur et al (2016). The purpose of this retrospective study was to determine the survival and reasons for failure of directly placed 2-surface composite resin restorations and directly placed 2-surface amalgam restorations on premolars placed by Canadian dental students. Using The University of Manitoba's dental management software and paper charts, all 2-surface composite resin and 2-surface amalgam restorations placed on premolars between January 1, 2002, and May 30, 2014, were included. Short-term failure (within 2 years), long-term failure, and reasons for failure were collected. A Kaplan-Meier survival estimate with an associated P value comparing composite resin to amalgam restoration curves was performed using SPSS statistical software. Over 12 years, 1695 composite resin and 1125 amalgam 2-surface premolar restorations were placed. Of these restorations, 134 composite resins (7.9%) and 66 amalgams (5.9%) failed. Short-term failures (2 years or less) consisted of 57 composite resin (4%) and 23 amalgam (2.3%) restorations. Long-term failures (greater than 2 years) consisted of 77 composite resin (4.5%) and 43 amalgam (3.8%) restorations. After 12 years of service, the survival probability of composite resin restorations was 86% and that of amalgam restorations 91.5%. The differences in composite resin and amalgam survival curves were also found to be statistically significant (P = .009 for Log-rank test). The main reasons for failure were recurrent caries and fracture of the tooth being restored. The authors concluded that within the limitations of this study, both composite resin and amalgam restorations had acceptable success rates and similar failure modes. Recurrent caries was still the most common reason for failure.

Moraschini et al (2015) conducted a systematic review and meta-analysis to test the hypothesis that there is no difference in failure rates between amalgam and composite resin posterior restorations. Randomized controlled trials, controlled clinical trials and prospective and retrospective cohort studies were included in this review. The eligibility criteria included clinical trials in humans with at least 12 months of follow-up comparing the failures rates between occlusal and occlusoproximal amalgam and composite resin restorations. A total of 8 studies published between 1992 and 2013 were included in this review, and according to the risk of bias evaluation, all were classified as high quality. The results showed that the mean survival of amalgam and composite resin varied from 76.320 to 100% and 56 to 100% with a mean annual failure of 1.71 and 3.17%, respectively. The authors concluded that based on the results of this systematic review and meta-analysis, composite resin restorations in posterior teeth still have less longevity and a higher number of secondary caries when compared to amalgam restorations. In relation to fractures, there was no statistically significant difference between the two restorative materials regarding the time of follow-up.

Kwang et al. (2014) conducted a study to investigate the time-lapse of endodontic intervention subsequent to various restorations and tooth surfaces and to assess and compare the associated risk factors. A comprehensive computerized analysis of all dental school patients at the Case Western Reserve University School of Dental Medicine who received restorations from 2008-2013 was obtained. Data collected included restoration type, restored tooth surfaces, tooth type, and the dates of restoration and subsequent endodontic treatment. The mean time between restoration placement and resultant endodontic intervention was 270 days, and further analysis revealed composite resin was 1.91 times more likely than amalgam and 5.69 times more likely than crowns to cause resultant endodontic intervention. Of the patients who required endodontic treatment after restoration placement, the critical time-lapse was 9 months, and composite restorations and teeth with 2 or more restorative surfaces were significantly associated with the need for endodontic treatment.

Rasines et al (2014) conducted a Cochrane database systemic review to examine the effects of direct composite resin fillings versus amalgam fillings for permanent posterior teeth, primarily on restoration failure. Of the 2205 retrieved references, seven trials (10 articles) were included in the systematic review. Two trials were parallel group studies involving 1645 composite restorations and 1365 amalgam restorations (921 children) in the analysis. The other five trials were split-mouth studies involving 1620 composite restorations and 570 amalgam restorations in an unclear number of children. (Due to major problems with the reporting of the data for the five split-mouth trials, the primary analysis is based on the two parallel group trials). All seven trials were judged to be at high risk of bias. There were 3265 composite restorations and 1935 amalgam restorations analyzed. The parallel group trials indicated that resin restorations had a significantly higher risk of failure and increased risk of secondary caries than amalgam restorations but no evidence of an increased risk of restoration fracture. The authors concluded that while there is low-quality evidence to suggest that resin composites lead to higher failure rates and risk of secondary caries than amalgam restorations, the benefits of amalgam restorations are particularly useful in parts of the world where amalgam is still the material of choice to restore posterior teeth with proximal caries.

Kovarik (2009) reviewed the current evidence regarding choosing amalgam versus composite material for posterior direct restorations. The review addresses the limitations of most of the current studies, most of which are non-randomized,

and/or university based rather than practice based. The restorative material decision is most often based on patient request or provider perception of composite over amalgam despite evidence to suggest higher failure rates. The author's goal was to find high level evidence to make evidence based decisions regarding restorative material choice. Only two studies met this criteria and both were conducted on children, with longevity a secondary outcome measured (the primary outcome measured was exposure to mercury from amalgams). In the New England Children's Amalgam Trial, 534 children randomly received composite or amalgam posterior restorations. Results showed a statistically insignificant survival rate between the two materials, however composites demonstrated more recurrent caries and required repair more frequently. The second study had the neurobehavioral effects of dental amalgam in children as the primary outcome measure, with survival of restorations secondary. This study randomly assigned 472 children (ages 8–12) to receive either amalgam or composite restorations in their posterior teeth. It was shown that recurrent caries is much more common in composite restorations compared to amalgam. The authors concluded that the two highest quality evidence studies show amalgam as superior to composite for posterior restorations with significantly less recurrent caries.

Resin Infiltration of Smooth Surface Incipient Lesions

In a 2020 systematic review and meta-analysis, Bakdach et. al reviewed the current evidence on the management of orthodontically induced white spot lesions (OIWSLs). Thirteen publications were included. The interventions reported in the management of OIWSLs were topical fluorides, casein phosphopeptide-amorphous calcium phosphate (CPP-ACP)-containing products, fluoride containing bonding materials, laser therapy, resin infiltration, and micro-abrasion. The methodological quality of the reviews ranged between moderate and critically low. The results showed that casein phosphopeptide-amorphous calcium phosphate (CPP-ACP)-containing products were effective in preventing and reversing these lesions, and there was a lack of reliable evidence for the efficacy of resin infiltration.

Gözetici et al. (2019) conducted a randomized controlled trial to compare the therapeutic effects of the resin infiltration technique, self-assembling peptide (P11-4), and fluoride varnish application on white spot lesions (WSLs) on buccal surfaces based on LF pen measurements and LAA-ICDAS scores. The lesions of 113 patients from a total of 319 patients with at least four visible WSL on buccal surfaces were assessed by LAA-ICDAS and laser fluorescence (LF pen). To be included in the study, participants were required to have at least 4 buccal WLSs, each in different quadrants, with an LF pen score ≥ 8. Twenty-one patients were included in the study based on the laser fluorescence values. The lesions were randomly assigned into 4 groups: IG (Icon), CRG (Curodont Repair), DG (Duraphat), and CG (control) groups. The treatment protocols were applied, but the control group received no treatment except regular brushing. Lesions were scored by LAA-ICDAS after 3 and 6 months and LF pen after 1 week, 3 and 6 months. The results showed a statistically significant decrease in LF pen measurements of the control and the intervention groups after 6 months when compared to baseline. The greatest lesion regression was observed with IG, which differed statistically significantly from CRG, DG and CG, followed by DG which differed statistically significantly from CG. Statistically significant differences were observed in the activity status of the lesions between baseline and 6 months, except for the control group. The authors concluded that in this study, the lesion regression rates shown by mean LF pen values in all groups after six months encourages the management of non-cavitated smooth surface caries lesions with non-operative treatment approaches. Regular brushing and professional tooth cleaning seem to be effective for the management of WSLs on buccal surfaces, and resin infiltration or fluoride varnish might enhance the improvement of these lesions in moderate- to high-caries-risk individuals.

Clinical Practice Guidelines

American Dental Association (ADA)

In 2023, an expert panel convened by the ADA Council on Scientific Affairs together with the ADA Science and Research Institute's program for Clinical and Translational Research conducted a systematic review and developed the following recommendations for the treatment of moderate and advanced cavitated caries lesions in patients with vital, nonendodontically treated primary and permanent teeth:

- Direct Restorative Materials for Primary Teeth
  - For moderate and advance caries lesions on vital anterior primary teeth requiring a Class III (approximal) restoration, the guideline panel suggests the use of either nanocomposite or hybrid resin composite (conditional recommendation, very low certainty)
  - For moderate and advance caries lesions on vital anterior primary teeth requiring a Class V (cervical third of facial or lingual) restoration, the guideline panel suggests the use of either conventional GIC, hybrid RC, or resin-modified GIC (conditional recommendation, very low certainty)
  - For moderate and advanced caries lesions on vital posterior primary teeth requiring a Class I (pit and fissure) restoration, the guideline panel suggests prioritizing the use of resin-modified GIC, RCs, conventional GIC, or preformed crowns over compomer or dental amalgam (conditional recommendation, very low certainty)
  - For moderate and advanced caries lesions on vital posterior primary teeth requiring a Class II (approximal) restoration, the guideline panel suggests prioritizing the use of resin-modified GIC, RCs, or preformed crowns over compomer, conventional GIC, or dental amalgam (conditional recommendation, very low certainty)

    - For moderate and advanced caries lesions on vital posterior primary teeth requiring a Class V (cervical third of facial or lingual) restoration, the guideline panel suggests the use of either conventional GIC, hybrid RC, or resin-modified GIC (conditional recommendation, very low certainty)
- Direct Restorative Materials for Permanent Teeth
    - For moderate and advanced caries lesions on vital anterior permanent teeth requiring a Class I (lingual pit and fissure) restoration, the guideline panel suggests the use of either conventional GIC, hybrid RC, or resin-modified GIC (conditional recommendation, very low certainty)
    - For moderate and advanced caries lesions on vital anterior permanent teeth requiring a Class III (approximal) restoration, the guideline panel suggests the use of either nanocomposite or hybrid RC (conditional recommendation, very low certainty)
    - For moderate and advanced caries lesions on vital posterior primary teeth requiring a Class I (pit and fissure) restoration, the guideline panel suggests prioritizing the use of resin-modified GIC, RCs, conventional GIC, or preformed crowns over compomer or dental amalgam (conditional recommendation, very low certainty)
    - For moderate and advanced caries lesions on vital posterior primary teeth requiring a Class II (approximal) restoration, the guideline panel suggests prioritizing the use of resin-modified GIC, RCs, or preformed crowns over compomer, conventional GIC, or dental amalgam (conditional recommendation, very low certainty)
    - For moderate and advanced caries lesions on vital posterior primary teeth requiring a Class V (cervical third of facial or lingual) restoration, the guideline panel suggests the use of either conventional GIC, hybrid RC, or resin-modified GIC (conditional recommendation, very low certainty) (Dahr et al., 2023)
- Definition of Certainty of Evidence
    - Very Low: Very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect
- Definition of Conditional Recommendations:
    - For Patients: Most patients in this situation would want the suggested course of action, but many would not
    - For Clinicians: Recognize that different choices will be appropriate for individual patients and that clinicians must help each patient arrive at a management decision consistent with values and preferences. Decision aids may be useful in helping patients making such decisions

Furthermore, the ADA supports the FDA recommendations regarding high risk groups for dental amalgam as good practice.

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.

On September 24, 2020 the FDA issued recommendations for certain high risk groups regarding dental amalgam. These groups may be at higher risk of potential harmful health effects from mercury vapor and should avoid amalgam when possible and appropriate. These higher risk groups include:

- Pregnant women and their developing fetuses
- Women who are planning to become pregnant
- Nursing women and their newborns and infants
- Children, especially those younger than six years of age
- People with pre-existing neurological disease such as multiple sclerosis, Alzheimer's disease, or Parkinson's disease
- People with impaired kidney function
- People with known heightened sensitivity (allergy) to mercury or other components of dental amalgam

Refer to the following website for further information: https://www.fda.gov/news-events/press-announcements/fda-issues-recommendations-certain-high-risk-groups-regarding-mercury-containing-dental-amalgam. Accessed March 26, 2024.

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Guideline History/Revision Information

Date	Summary of Changes
07/01/2024	**Supporting Information** • Updated *Description of Services, Clinical Evidence, FDA*, and *References* sections to reflect the most current information • Archived previous policy version DCG023.10

Instructions for Use

This Dental Coverage Guideline 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 guideline, 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 Coverage Guideline is provided for informational purposes. It does not constitute medical advice.