SINGLE TOOTH DIRECT RESTORATIONS

Guideline Number: DCG023.04  Effective Date: August 1, 2019

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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
- 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, and is not indicated due to insufficient evidence of efficacy.

**Coverage Limitations and Exclusions**

- Any dental procedure performed solely for cosmetic/aesthetic reasons (cosmetic procedures are those procedures that improve physical appearance)
- Any dental procedure not directly associated with dental disease
- Clinical situations that can be effectively treated by a less costly, dental appropriate alternative procedure will be assigned a benefit based on the least costly procedure
- Dental Services that are not Necessary

**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)

**Gold Foil:** Thin pure gold leaf that is self-adhering when condensed into a cavity. One of the oldest restorative techniques, it is compacted or condensed into a retentive cavity form. (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 I 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

**Necessary:** Dental 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 your basic dental needs; and
- Rendered in the most cost-efficient manner and type of setting appropriate for the delivery of the dental 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; and
- Consistent with the diagnosis of the condition; and
- Required for reasons other than the convenience of you or your 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

**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 Clinical Policies and Coverage Guidelines may apply.

<table>
<thead>
<tr>
<th>CDT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>D2140</td>
<td>Amalgam – one surface, primary or permanent</td>
</tr>
<tr>
<td>D2150</td>
<td>Amalgam – two surface, primary or permanent</td>
</tr>
<tr>
<td>D2160</td>
<td>Amalgam – three surface, primary or permanent</td>
</tr>
<tr>
<td>D2161</td>
<td>Amalgam – for or more surfaces, primary or permanent</td>
</tr>
<tr>
<td>D2330</td>
<td>Resin-based composite – one surface, anterior</td>
</tr>
<tr>
<td>D2331</td>
<td>Resin-based composite – two surface, anterior</td>
</tr>
<tr>
<td>D2332</td>
<td>Resin-based composite – three surface, anterior</td>
</tr>
<tr>
<td>D2335</td>
<td>Resin-based composite – four or more surfaces or involving incisal angle (anterior)</td>
</tr>
<tr>
<td>D2390</td>
<td>Resin-based composite crown, anterior</td>
</tr>
<tr>
<td>D2391</td>
<td>Resin-based composite – one surface, posterior</td>
</tr>
<tr>
<td>D2392</td>
<td>Resin-based composite – two surface, posterior</td>
</tr>
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<td>D2393</td>
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<td>Resin-based composite – four or more surfaces, posterior</td>
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<tr>
<td>D2410</td>
<td>Gold foil – one surface</td>
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<td>Gold foil – two surface</td>
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<td>D2430</td>
<td>Gold foil – three surface</td>
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<tr>
<td>D2940</td>
<td>Protective restoration</td>
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<tr>
<td>D2941</td>
<td>Interim therapeutic restoration – primary dentition</td>
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<tr>
<td>D2990</td>
<td>Resin infiltration of incipient smooth surface lesions</td>
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<tr>
<td>D2999</td>
<td>Unspecified restorative procedure, by report</td>
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## 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. For non-amalgam restorations, resin based composite is the material of choice. When conditions do not allow for complete isolation of the tooth, and salivary contamination is likely, a glass ionomer is considered an acceptable substitute. Preventive resin restorations are a conservative approach to restore a tooth that has active incipient caries in pits and fissures. Protective restorations are placed to relieve pain, prevent further deterioration and promote healing.
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.

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.

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.

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.

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.

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.

**Resin Infiltration of Smooth Surface Incipient Lesions**

Gözetici et al. (2019) conducted a study 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.

**REFERENCES**


**GUIDEINLE HISTORY/REVISION INFORMATION**

<table>
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<tr>
<th>Date</th>
<th>Action/Description</th>
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| 08/01/2019 | **Coverage Rationale**  
Simplified content  
Removed language indicating:  
o Direct restorations are not indicated when used as part of comprehensive or interceptive orthodontics to maintain an open bite  
o Glass ionomer restorations are not indicated as a definitive, long term restoration in permanent teeth when a sealant is indicated  
Replaced language indicating "resin infiltration of incipient smooth surface lesions is typically used for aesthetic purposes; it is used to describe a proprietary product, and there is a lack of established objective evidence to support its use" with "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, and is not indicated due to insufficient evidence of efficacy"  
Revised list of Coverage Limitations and Exclusions; added “dental services that are not Necessary”  
**Definitions**  
Added definition of "Necessary"  
**Supporting Information**  
Updated Description of Services, Clinical Evidence, and References sections to reflect the most current information  
Archived previous policy version DCG023.03 |

**INSTRUCTIONS FOR USE**

This Dental Coverage Guideline 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 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.