Sealants and Hydroxyapatite Enamel Regeneration

Policy Number: DCP026.12
Effective Date: February 1, 2026

Instructions for Use

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Related Dental Policies

- Prefabricated Crowns
- Single Tooth Direct Restorations
- Topical Medicaments for Caries Prevention or Remineralization

Coverage Rationale

Sealants

Sealants are indicated for the following:

- Caries prevention in pit and fissures on permanent molars
- Non-cavitated carious lesions
- Caries prevention in primary molars that are expected to have a reasonable period of retention

Sealants are not indicated for the following:

- In the presence of rampant caries and multiple interproximal lesions
- Extrinsic staining of pits and fissures
- For cavitated carious lesions

Hydroxyapatite Enamel Regeneration

Biomimetic products for the regeneration of tooth enamel are not indicated due to insufficient evidence of efficacy.

Definitions

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

Hydroxyapatite: A bioactive and non-toxic ceramic that is similar to the inorganic portion of human teeth and bone. Tooth enamel is composed of 97% inorganic component, and the dentin is composed of 70% inorganic component and are mainly made up of Hydroxyapatite. (Chen et al.)

Resin, Acrylic: Resinous material of the various esters of Acrylic acid, used as a denture base material, for trays or for other restorations. (ADA)

Sealant: A resinous material designed to be applied to the occlusal surfaces of posterior teeth to prevent occlusal caries. (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
D1351	Sealant – per tooth
D1353	Sealant repair – per tooth
D2991	Application of hydroxyapatite regeneration medicament – per tooth

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Description of Services

Dental Sealants are a thin protective coating that fills in the grooves of back teeth and prevents bacteria and food particles from being trapped and causing decay. Sealants can also prevent the progression of incipient carious lesions. Teeth are isolated from saliva contamination, cleaned, and prepared with a mild acid solution to aid in adherence. The tooth is then dried and the Sealant material is applied and either cured with a light, or self-cures. Preventive Resin restorations are fillings that also provide a protective barrier to the deep grooves when there is early decay present that has not extended into the dentin. A biomimetic self-assembling peptide P_{11}-4 has recently emerged as a promising biomaterial for the potential regeneration of tooth enamel. Unlike fluoride products that arrest caries progression, P_{11}-4 penetrates into the demineralized areas of enamel and facilitates Hydroxyapatite formation resulting in repair. This product has potential applications for managing early caries, white spot lesions and tooth sensitivity.

Clinical Evidence

While promising, the clinical evidence showing efficacy of self-assembling peptides for remineralizing tooth enamel in-vivo is limited at this time. Long term outcomes and superiority to standard caries arresting treatments cannot be established.

In a 2025 triple blinded randomized controlled trial, Khairy et al. (2025) compared the effects of intensive application of self assembling peptide P11-4 with fluoride, a casein phosphopeptide amorphous calcium phosphate fluoride (CPP-ACPF) varnish and 5% sodium fluoride varnish (NaF), on Streptococcus mutans (S. mutans) in the dental plaque of preschoolers in addition to assessing changes in plaque index. Sixty six preschoolers were randomly assigned to receive one of the three interventions, and S. mutans count in supragingival plaque samples was assessed at baseline (T0) and after the third application by 48 h (T1), one month (T2) and 3 months (T3). Dental prophylaxis was completed and products were applied according to manufacturer's directions. At baseline, P11-4 was applied after treatment with sodium hypochlorite to remove the pellicle and inorganic deposits. CPP-ACPF varnish and NaF varnish were applied after partial isolation on the affected dried areas. Two more applications of each material took place after two and four weeks using the same application methods. After all treatments, participants were asked to refrain from eating, drinking or rinsing for at least 30 minutes following P11-4, and for four hours after CPP-ACPF and NaF. For culturing S. mutans, all samples were examined in a microbiology laboratory and identified by characteristic appearance. Confirmatory testing was also done with film morphology, and Catalase and bile tests. There results showed S. mutans count found in supragingival plaque at all intervals. The results showed that there were no statistically significant reductions in bacterial count among the three study groups at T1 and T2. However, at T3, the group treated with CPP-ACPF showed a statistically significant reduction. Plaque index scores were also significantly reduced in all study groups at T2 and T3, with CPP-ACPF showing the most significant reduction. There was a significant reduction in bacterial count in the NaF group at T1, with significant reductions in the CPP-ACPF group at T3, and the antibacterial effect of P 11-4 increased over time. The authors concluded that all treatment groups showed reduced S mutans counts and plaque index scores, with the P11-4 showing potential for antimicrobial activity. Further research in larger numbers of patients with longer follow up is needed to validate these findings.

Shaalan et al. (2024) conducted a randomized controlled trial to compare the remineralization potential of self-assembling peptide P11-4 combined with fluoride (Curodont Repair Fluoride Plus™) to that of sodium fluoride varnish. Twenty- eight participants with fifty- eight incipient carious lesions were randomly divided into two groups with fourteen participants and twenty- nine lesions in each group. Products were applied according to manufacturer's directions and lesions were assessed by laser fluorescence (DIAGNOdent) at one, three and six months by blinded assesors. The results showed that DIAGNOdent scores improved significantly in both groups at one month, however at three and six months, the group treated with Curodont Repair Fluoride Plus showed statistically significant lower readings. This resulted in a decrease in caries progression of 60%. The authors concluded that P11-4 with fluoride may offer a new option for managing incipient carious lesions. Further research in larger numbers of patients with longer follow up is needed to validate these findings.

In a 2023 systematic review and meta-analysis of six randomized clinical trials, Keeper et al. assessed the efficacy of the self-assembling peptide P_{11}-4 [Curodont Repair (CR) and Curodont Repair Fluoride Plus (CRP)] on the arrest, cavitation, and progress of initial caries lesions. Primary outcomes were lesion progression, caries arrest, and cavitation at 24 months, however all included trials were only 6-12 months. Secondary outcomes included changes in combined International Caries Detection and Assessment System score categories, quantitative light-induced fluorescence (QLF; Inspektor Research System), esthetic appearance, and lesion size. All included trials showed a moderate to high risk of bias. The overall results showed CR likely results in caries arrest with 45% of all treated lesions arrested. CR likely shrinks caries lesions, but the overall effect of merged ICDA scores is very uncertain. The authors concluded that CR and CRP both have an effect on caries arrest with a synergistic effect apparent when fluoride is included. Further research with blinding, larger numbers of caries lesions, and longer term follow up to evaluate the effect on caries progression are needed to validate these findings. This study is limited by a small number of participants and short follow up time. Additional high quality independent research is needed to validate these findings.

Doberdoli et al. (2020, included in Keeper study above) conducted a randomized clinical trial to assess the effectiveness of monomeric self-assembling peptide P_{11}-4 (SAP P_{11}-4) in combination with fluoride varnish or polymeric self-assembling peptide matrix (SAPM) at home for treating non-cavitated occlusal caries. Ninety children and adolescents were included and equally randomized. Group 1 received SAP P_{11}-4 and fluoride varnish twice at baseline and at 6 months, group 2 received SAP P_{11}-4 at baseline and twice weekly SAPM (home-application), and the control group received fluoride varnish at baseline and 6 months. Caries progression was measured by laser fluorescence, Nyvad Caries Activity, ICDAS-II-codes, and investigator assessments. The results showed increase in laser fluorescence values for groups 1 and 2 and group 3 showed no statistically significant changes. For ICDAS and lesions requiring restoration, none of the control treatment group regressed, however at Day 360, there were 7 increased lesion size and 2 required restoration. No lesions in groups 1 and 2 progressed and one required restoration after 6 months. There were no statistically significant differences between groups 1 and 2.The authors concluded that treatment of initial caries lesions with self-assembling peptides is superior to fluoride varnish alone in arresting initial caries in occlusal surfaces. Additional research with larger numbers of participants and longer follow up times is needed to validate these findings.

Alkilzy et al. (2018, included in Keeper et al. study above) conducted a randomized controlled single-blinded study to assess the clinical efficacy and safety of a self-assembling peptide P_{11}-4 (Curodont™ Repair) for the treatment of visible active early caries on erupting permanent molars in children with a mean age of 10 years. Seventy participants were equally randomized to either the test group (P_{11}-4 + fluoride varnish) or control group (fluoride varnish alone). Caries were assessed at 3 -and 6- month post treatment primarily via laser fluorescence, and also visually and using the International Caries Detection and Assessment System, and Nyvad caries activity criteria. Six participants missed the 3- month follow up and 3 missed the 6 month follow up visits. The results showed that the test group had statistically and clinically superior results in all assessment outcomes in comparison with the control group. The test lesions treated with P_{11}-4 and fluoride varnish exhibited significantly greater remineralization and inactivation of carious lesions than the control. The authors concluded that the P_{11}-4 and fluoride varnish combination is clinically superior to the current gold standard of fluoride varnish. This study is limited by the small number of participants, and high-quality studies with larger numbers of participants and longer follow-up are needed to validate these findings.

Clinical Practice Guidelines

In a 2016 joint evidence based clinical practice guideline, the American Dental Association (ADA) and the American Academy of Pediatric Dentistry (AAPD) recommend the use of Sealants compared with nonuse or fluoride varnish in permanent and primary molars. Additionally, Sealants could minimize the progression of non cavitated lesions. (Wright et al., 2016).

In a 2018 evidence based clinical practice guideline on non-restorative treatments for carious lesions, the ADA recommended Sealants as an effective intervention to arrest or reverse noncavitated carious lesions on occlusal surfaces of primary and permanent teeth. The expert panel recommends clinicians prioritize the use of Sealants plus 5% NaF varnish (application every 3-6 months) or Sealants alone over 5% NaF varnish alone (Slayton et al., 2018).

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Policy History/Revision Information

Date	Summary of Changes
02/01/2026	**Title Change** • Previously titled *Sealants and Preventive Resin Restorations* **Coverage Rationale** • Removed content/language pertaining to preventive resin restoration (PRR) **Applicable Codes** • Removed CDT code D1352 **Supporting Information** • Archived previous policy version DCP026.11

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, 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.