

United Dental Benefit Healthcare Providers

UnitedHealthcare® Dental Dental Clinical Policy

Sealants and Preventive Resin Restorations

Guideline Number: DCP026.09 Effective Date: August 1, 2024

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

Preventive Resin Restoration (PRR)

Preventive Resin restorations may be indicated for the restoration of pit and fissures carious lesions contained to enamel in moderate to high caries risk individuals.

Preventive Resin restorations are not indicated for the following:

- When no caries is evident in pits and fissures
- When a Sealant is clinically indicated
- For carious lesions that extend into dentin

Hydroxyapatite Enamel Regeneration

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

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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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 |
| D1352 | Preventive resin restoration in a moderate to high caries risk patient – permanent 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 P₁₁-4 has recently emerged as a promising biomaterial for the potential regeneration of tooth enamel. Unlike fluoride products that arrest caries progression, P₁₁-4 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 2023 systematic review and meta-analysis of six randomized clinical trials, Keeper et al. assessed the efficacy of the self-assembling peptide P₁₁-4 (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 P₁₁-4 (SAP P₁₁-4) 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 P₁₁-4 and fluoride varnish twice at baseline and at 6 months, group 2 received SAP P₁₁-4 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 P₁₁-4 (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 (P₁₁-4 + 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 P₁₁-4 and fluoride varnish exhibited significantly greater remineralization and inactivation of carious lesions than the control. The authors concluded that the P₁₁-4 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.

References

Alkilzy M, Tarabaih A, Santamaria RM, et al. Self-assembling peptide P11-4 and fluoride for regenerating enamel. J Dent Res. 2018 Feb;97(2):148-154.

American Dental Association (ADA) CDT Codebook 2024.

American Dental Association (ADA). Glossary of Dental Clinical and Administrative Terms.

Azarpazhooh A, Main PA. Pit and fissure Sealants in the prevention of dental caries in children and adolescents: a systematic review. J Can Dent Assoc. 2008 Mar;74(2):171-7.

Chen L, Al-Bayatee S, Khurshid Z, et al. Hydroxyapatite in oral care products- a review. Materials (Basel). 2021 Aug 27;14(17):4865.

Deery C. Clinical Practice Guidelines Proposed the Use of Pit and Fissure Sealants to Prevent and Arrest Noncavitated Carious Lesions. J Evid Based Dent Pract. 2017 Mar;17(1):48-50.Keeper JH, Kibbe LJ, Thakkar-Samtani M, et al. Systematic review and meta-analysis on the effect of self-assembling peptide P11-4 on arrest, cavitation, and progression of initial caries lesions. J Am Dent Assoc. 2023 Jul;154(7):580-591.e11.

Ritter A, Walter R, Roberson T, Sturdevant's Art and Science of Operative Dentistry, 7th ed. St. Louis: Mosby c2019. Chapter 8, Clinical Technique for Direct Composite Resin and Glass Ionomer Restorations; p.219-263.

Sanders, Brian. McDonald and Avery's Dentistry for the Child and Adolescent. 11th edition. St. Louis: Elsevier. c2022. Chapter 11, Pit-and-Fissure Sealants and Preventive Resin Restorations; p.219-226.

Slayton RL, Urquhart O, Araujo MWB, et al. Evidence-based clinical practice guideline on nonrestorative treatments for carious lesions: A report from the American Dental Association. J Am Dent Assoc. 2018 Oct;149(10):837-849.

Wright JT, Crall JJ, Fontana M, et al. Evidence-based clinical practice guideline for the use of pit-and-fissure sealants: A report of the American Dental Association and the American Academy of Pediatric Dentistry. J Am Dent Assoc. 2016 Aug;147(8):672-682.e12.

Guideline History/Revision Information

| Summary of Changes |
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| Related Policies |
| Added reference link to the Dental Coverage Guideline titled <i>Topical Medicaments for Caries Prevention or Remineralization</i> |
| Coverage Rationale |
| Hydroxyapatite Enamel Regeneration |
| Added language stating biomimetic products for the regeneration of tooth enamel are not indicated due to insufficient evidence of efficacy |
| Definitions |
| Added definition of "Hydroxyapatite" |
| Applicable Codes |
| Added CDT code D2991 |
| Supporting Information |
| Updated Description of Services, Clinical Evidence, and References sections to reflect the most current information |
| Archived previous policy version DCG026.08 |
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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.