A.39	Resin-based composites – dental caries – EML and EMLc
Draft recommendation	☒ Recommended ☐ Not recommended Justification: There is a significant need for interventions that can prevent caries. There is evidence of efficacy with minimal adverse events (low to very low quality). Additionally it is a safe option (mercury free) recommended by multiple international institutions including WHO.
Does the proposed medicine address a relevant public health need?	☒ Yes ☐ No ☐ Not applicable Comments: WHO Global Oral Health Status Report estimates that oral diseases affect around 3.5 billion people worldwide, the most common disease group of all diseases and conditions studied. Dental caries is the most widespread oral disease with more than 2.5 billion cases of untreated disease. According to this report caries are more prevalent in deprived and disadvantaged populations. Additionally, cases have been increasing beyond the population growth during the same period. In children high prevalence and severity of untreated dental caries is associated with low BMI and poor growth.
Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication? (this may be evidence included in the application, and/or additional evidence identified during the review process)	☒ Yes ☐ No ☐ Not applicable Comments: - Sealants (including resin-based) seem to decrease he incidence of development of new caries lesions in primary teeth (low or very low certainty) [1.] - Compared with fluoride varnish, resin-based sealants prevented more caries in first permanent molars at two-year follow-up. The caries-preventive benefit for sealants was maintained at longer follow-up (low quality evidence). [2] - Fillings have a high effectiveness of around 80% [3.] - When compared with amalgam in posterior teeth, resin-based composites showed some shortcomings of the material (higher failure rate, higher risk of secondary caries development, clinical differences in procedures and requirements, higher cost). Unfortunately, this is based on older studies developed prior to improvements in the material [4.] Other considerations - Resin-based composites are a viable mercury-free alternative to dental amalgam and allow for less invasive treatment of dental caries. - There is currently no alternative material for fillings in anterior teeth with both high functional and aesthetic requirements.

Does adequate evidence exist for the safety/harms associated with the proposed medicine? (this may be evidence included in the application, and/or additional evidence identified during the review process)	☒ Yes ☐ No ☐ Not applicable Comments: - Trials evaluating resin-based composites did not report any adverse events [4] - Allergic reactions are possible but rare [5]. The main potential allergen is the metacrylate compound but reports of allergic reactions to resin-based composite fillings or dental sealants are rare. If symptoms occur, they are generally local (such as erythema of the surrounding gum) and subside after removal of the material.
Are there any adverse effects of concern, or that may require special monitoring?	☐ Yes ☒ No ☐ Not applicable Comments: Potential for allergic reaction should be considered
Are there any special requirements for the safe, effective and appropriate use of the medicines? (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)	☒ Yes ☐ No ☐ Not applicable Comments: Application requires trained personnel (this training is common for dental professionals).
Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?	☒ Yes ☐ No ☐ Not applicable Comments: Cost is widely variable depending on the setting. As a sealant cost-effectiveness has not been well studied. On the other hand, amalgam is more cost effective as a filling.
Are there any issues regarding the registration of the medicine by national regulatory authorities? (e.g. accelerated approval, lack of regulatory approval, off-label indication)	☐ Yes ☒ No ☐ Not applicable Comments: No concerns

Is the proposed medicine recommended for use in a current WHO guideline? (refer to: https://www.who.int/publications/who-guidelines)	☐ Yes ☒ No ☐ Not applicable Comments: It is not part of guidelines, but it is recommended as a treatment option in WHO publications [6,7] Additionally, it is recommended by guidelines developed by the following public health and professional organizations: - American Dental Association - Public Health England - Chinese Stomatological Association

References:

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4. Worthington HV, Khangura S, Seal K et al. Direct composite resin fillings versus amalgam fillings for permanent posterior teeth. Cochrane Database Syst Rev. 2021;8:CD005620.
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