

<b>A.16</b>	<b>Glass ionomer cement – dental caries</b>
Does the application adequately address the issue of the public health need for the medicine?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable  Comments:
Briefly summarize the role of the proposed medicine(s) relative to other therapeutic agents currently included in the Model List, or available in the market.	GIC has caries-preventive properties due to continued capture and release of fluoride ions that remineralise carious tooth structures and have a bacteriostatic effect. GIC results in lower rates of recurring caries compared to composite resin or amalgam fillings; and reduces incidence of new cavities on other teeth. The simplicity of application makes GIC suitable for primary health care and field settings, including for people with special needs.
Have all important studies and all relevant evidence been included in the application?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable  If no, please provide brief comments on any relevant studies or evidence that have not been included:
Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed indication?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable  Briefly summarize the reported benefits (e.g. hard clinical versus surrogate outcomes) and comment, where possible on the actual magnitude and clinical relevance of benefit associated with use of the medicine(s). <b>Dental sealants using high viscosity Glass Ionomer Cement (HV-GIC), a technique called Atraumatic Restorative Treatment (ART), prevent carious lesions in approximately 71% of treated surfaces regardless of initial lesion presence 1, with immediate outcomes for treated surfaces similar for conventional resin or HV-GIC, but better longer term results for HVGIC.21. In addition, HV-GIC reduces new caries incidence by 335 on untreated teeth adjacent to teeth with HV-GIC sealant, no other material shows similar effects. HVGIC fillings placed with the ART technique have a success rate of 87% after 3 years for single surface carious lesions and 77% after 5 years for multiple surface carious lesions.</b>  Is there evidence of efficacy in diverse settings (e.g. low-resource settings) and/or populations (e.g. children, the elderly, pregnant patients)? <b>Yes</b>

2021 Expert Committee on Selection and Use of Essential Medicines  
Application review

Does the application provide adequate evidence of the safety and adverse effects associated with the medicine?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: <b>Evidence is provided in the form of a recent Cochrane review that concluded that included studies analysing HV-GIC used for dental sealants did not report any adverse effects of the material. Various in-vitro and in-vivo studies did not find any significant negative effects on pulp, dentine or gingival tissues and cells.</b>
Are there any adverse effects of concern, or that may require special monitoring?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable Comments:
Briefly summarize your assessment of the overall benefit to risk ratio of the medicine (e.g. favourable, uncertain, etc.)	<b>The benefit to risk ration is favourable.</b>
Briefly summarize your assessment of the overall quality of the evidence for the medicine(s) (e.g. high, moderate, low etc.)	The overall quality of the evidence is favourable
Are there any special requirements for the safe, effective and appropriate use of the medicine(s)? (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable Comments:
Are you aware of any issues regarding the registration of the medicine by national regulatory authorities? (e.g. accelerated approval, lack of regulatory approval, off-label indication)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable Comments:
Is the proposed medicine recommended for use in a current WHO Guideline approved by the Guidelines Review Committee? (refer to: <a href="https://www.who.int/publications/who-guidelines">https://www.who.int/publications/who-guidelines</a> )	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable Comments:
Briefly summarize your assessment of any issues regarding access, cost and affordability of the medicine in different settings.	<b>A cost-benefit analysis provided quotes the author of the paper as concluding that “ease of application, minimal technical and infrastructure requirements, and cost-effectiveness make glass-ionomers a practicable option for governments making decisions under economic constraints.”</b>

2021 Expert Committee on Selection and Use of Essential Medicines  
Application review

Any additional comments	None
Based on your assessment of the application, and any additional evidence / relevant information identified during the review process, briefly summarize your proposed recommendation to the Expert Committee, including the supporting rationale for your conclusions, and any doubts/concerns in relation to the listing proposal.	The listing for glass ionomer cement (GIC) on both the core EMLc and core EML is being sought. The application request is that the entry should be part of the new category "30. Dental medicines" and a subgroup "30.1. Medicines for dental caries". Based on the evidence provided, I recommend that the committee accepts this application
References (if required)	