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| <b>A.18</b>   | <b>Glucagon-like peptide-1 receptor agonists – weight loss in obesity – EML</b>  |
| <b>Draft recommendation</b>   | <input type="checkbox"/> Recommended<br><input checked="" type="checkbox"/> Not recommended<br><br>Justification:<br>Although the proposed medication demonstrated significant weight reduction with a reasonable safety profile for patients with overweight or obesity, however the evidences are mostly from small size studies with high heterogeneity, also the cost of the treatment might still unaffordable in resource limited countries.   |
| Does the proposed medicine address a relevant public health need?   | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> Not applicable<br><br>Comments:<br>Obesity is an increasing global public health burden.  |
| Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication?<br><br>(this may be evidence included in the application, and/or additional evidence identified during the review process) | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> Not applicable<br><br>Comments:<br>Pharmacotherapy for obesity has been recommended in several guidelines as an adjunct to lifestyle modification. <sup>1</sup><br>Several systematic reviews already evaluated its' effectiveness on weight reduction among non-diabetic obese population, with a clinically important effect (>5% of weight loss). However the studies included in the SR are mostly in small size with high heterogeneity. |
| Does adequate evidence exist for the safety/harms associated with the proposed medicine?<br><br>(this may be evidence included in the application, and/or additional evidence identified during the review process)                 | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> Not applicable<br><br>Comments:<br>Increased in AEs (such as nausea) and Treatment Discontinuations due to AEs (TDAEs) but not SAEs<br>Common AEs: Nausea, constipation, diarrhea, vomiting.<br>Rare: Cholelithiasis and Pancreatitis.<br>However the risks are seemed to be balanced with the benefit.   |

<sup>1</sup> Pedersen SD, Manjoo P, Wharton S. Canadian Adult Obesity Clinical Practice Guidelines: Pharmacotherapy for Obesity Management. Available from: <https://obesitycanada.ca/guidelines/pharmacotherapy>.

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| <p>Are there any adverse effects of concern, or that may require special monitoring?</p>  | <p><input type="checkbox"/> Yes<br/> <input checked="" type="checkbox"/> No<br/> <input type="checkbox"/> Not applicable<br/> Comments:</p>  |
| <p>Are there any special requirements for the safe, effective and appropriate use of the medicines?</p> <p>(e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)</p> | <p><input type="checkbox"/> Yes<br/> <input checked="" type="checkbox"/> No<br/> <input type="checkbox"/> Not applicable<br/> Comments:<br/> SMC restriction: BMI <math>\geq 35\text{kg/m}^2</math>* (obesity class II and above) with:<br/> <input checked="" type="checkbox"/> Non-diabetic hyperglycaemia (prediabetes) at high risk of type 2 diabetes which is defined as having either:<br/> o Fasting plasma glucose level of 5.5 to 6.9mmol/L or<br/> o HbA1c of 6.0 to 6.4% (42 to 47mmol/mol), and<br/> <input checked="" type="checkbox"/> High risk of cardiovascular disease (CVD):<br/> o Total cholesterol <math>&gt;5\text{mmol/L}</math>, or<br/> o High-density lipoprotein (HDL) <math>&lt;1.0\text{mmol/L}</math> for men and <math>&lt;1.3\text{mmol/L}</math> for women, or<br/> o Systolic blood pressure (SBP) <math>&gt;140\text{mmHg}</math>.<br/> Patients should be treated in a specialist weight management service.<sup>2</sup></p> |
| <p>Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?</p>   | <p><input checked="" type="checkbox"/> Yes<br/> <input type="checkbox"/> No<br/> <input type="checkbox"/> Not applicable<br/> Comments:<br/> The cost is still high, and the cost effectiveness analyses are only from high income country.</p>  |
| <p>Are there any issues regarding the registration of the medicine by national regulatory authorities?</p> <p>(e.g. accelerated approval, lack of regulatory approval, off-label indication)</p>                    | <p><input type="checkbox"/> Yes<br/> <input checked="" type="checkbox"/> No<br/> <input type="checkbox"/> Not applicable<br/> Comments:<br/> Has been approved by FDA. It has also been launched in Germany, Italy, Denmark, the Netherlands, Sweden, Japan, Canada, the United States, France, Indonesia, Malaysia and Singapore. However, only 7 countries included it in their EML.<sup>3</sup></p>   |

<sup>2</sup> Scottish Medicines Consortium (SMC). SMC 2455. 2022. Available from <https://www.scottishmedicines.org.uk/media/6863/liraglutide-saxenda-resubmission-final-april-2022-for-website.pdf>

<sup>3</sup> <https://global.essentialmeds.org/dashboard/medicines/1071>

24<sup>th</sup> WHO Expert Committee on Selection and Use of Essential Medicines  
Expert review

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| <p>Is the proposed medicine recommended for use in a current WHO guideline?</p> <p>(refer to:<br/><a href="https://www.who.int/publications/who-guidelines">https://www.who.int/publications/who-guidelines</a>)</p> | <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input checked="" type="checkbox"/> Not applicable</p> <p>Comments: No current WHO guideline on obesity management.</p> |
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