

## A.28 Toripalimab – EML

<b>Reviewer summary</b>	<input type="checkbox"/> Supportive of the proposal <input checked="" type="checkbox"/> Not supportive of the proposal <p>Justification (based on considerations of the dimensions described below):</p> <p>Nasopharyngeal- While the data are encouraging, I think the OS data are still modest and immature. Other immunotherapy trials are also ongoing in this space. I think we need to wait for more mature data, and data from other ongoing trials of other immunotherapies, to make a final decision on this application. In addition, MCBS score of 3 is not very encouraging.</p> <p>Esophageal- MCBS score of 4, and OS gains of 6 months, seems decent. However, this is not as impressive as seen for other cancer drugs in other settings, listed on the EML list. Also noteworthy that the OS is interim and not final. In addition, there is no good biomarker to separate patients who are more likely to benefit. Also, there are other immunotherapies in the same setting, and the benefit across these trials have been consistent and of similar magnitude.</p>
<p>Does the EML and/or EMLc currently recommend alternative medicines for the proposed indication that can be considered therapeutic alternatives?</p> <p>(<a href="https://list.essentialmeds.org/">https://list.essentialmeds.org/</a> )</p>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable <p>Yes, chemotherapy, but not immunotherapy</p>
<p>Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication?</p> <p>(e.g., evidence originating from multiple high-quality studies with sufficient follow up. This may be evidence included in the application, and/or additional evidence identified during the review process;)</p>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
<p>Does adequate evidence exist for the safety/harms associated with the proposed medicine?</p> <p>(e.g., evidence originating from multiple high-quality studies with sufficient follow up. This may be evidence included in the application, and/or additional evidence identified during the review process;)</p>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
<p>Overall, does the proposed medicine have a favourable and meaningful balance of benefits to harms?</p>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
<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>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
<p>Are there any issues regarding price, cost-effectiveness and budget implications in different settings?</p>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable <p>Actually, this one is the most cost-effective among all immunotherapies available for this indication.</p>
<p>Is the medicine available and accessible across countries?</p> <p>(e.g. shortages, generics and biosimilars, pooled procurement programmes, access programmes)</p>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable
<p>Does the medicine have wide regulatory approval?</p> <p><i>Don't know how to define "wide" but this is approved by EMA and some other jurisdictions.</i></p>	<input checked="" type="checkbox"/> Yes, for the proposed indication <input type="checkbox"/> Yes, but only for other indications (off-label for proposed indication) <input type="checkbox"/> No <input type="checkbox"/> Not applicable