

## I.8 Prednisolone – adrenal insufficiency – EML and EMLc

<b>Reviewer summary</b>	<input checked="" type="checkbox"/> Supportive of the proposal <input type="checkbox"/> Not supportive of the proposal  Justification (based on considerations of the dimensions described below):  This feels like a no-brainer, obvious inclusion in the EML. Prednisolone is cheaper and more effective, thus more cost-effective, than currently included hydrocortisone. Plus, a lower dose formulation is sufficient and would be even more cost-effective. I can't think of a good reason not to support the proposal.
Does the EML and/or EMLc currently recommend alternative medicines for the proposed indication that can be considered therapeutic alternatives?  ( <a href="https://list.essentialmeds.org/">https://list.essentialmeds.org/</a> )	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable  Hydrocortisone. But prednisolone, specially lower dose as proposed, is more cost-effective.
Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication?  (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;)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
Does adequate evidence exist for the safety/harms associated with the proposed medicine?  (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;)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
Overall, does the proposed medicine have a favourable and meaningful balance of benefits to harms?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
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)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
Are there any issues regarding price, cost-effectiveness and budget implications in different settings?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable  This is better, cheaper, and more cost-effective.
Is the medicine available and accessible across countries?  (e.g. shortages, generics and biosimilars, pooled procurement programmes, access programmes)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable  Medicine is available, but lower dose formulation not so. Hence, the hope is that by including in EML, it will be more widely available and accessible.
Does the medicine have wide regulatory approval?	<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