| A.51 | Ustekinumab – severe psoriasis – EML |
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| **Draft recommendation** | ☐ Recommended<br>☒ Not recommended<br>Justification: The body of evidence from systematic reviews and network meta-analyses suggests that among the options for treating patients with psoriasis, ustekinumab is better than the less effective drugs (and placebo), but inferior to the other (more effective) half of groups of drugs. Overall, the safety profile of ustekinumab is similar to the other drugs. Data on cost-effectiveness suggest that using ustekinumab might be cost effective, but more data is needed to assess the effects in terms of how its cost-effectiveness compares to the rest of the drugs. Ustekinumab might be preferable to use in some countries where other more efficacious agents are not yet available. |
| Does the proposed medicine address a relevant public health need? | ☒ Yes<br>☐ No<br>☐ Not applicable<br>Comments: Psoriasis is a chronic skin disease affecting roughly 2% of the population worldwide, although with some differences in the rates among regions (e.g., high rates in island populations and lower among native Americans). Incidence varies between 2.3 to 30 per 100,00 persons per year in different countries. It is estimated that at least 60 million people worldwide are affected. The mean age of onset for the first presentation of psoriasis ranges from 15 to 20 years of age, with a second peak occurring at 55–60 years. Psoriasis affects the quality of life of patients with stigmatisation, depression, and even suicidal thoughts. Co-morbidities include psoriatic arthritis, obesity, cardiovascular disease, and raised serum lipids, among others. |
| 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) | ☒ Yes<br>☐ No<br>☐ Not applicable<br>Comments: IL-17 and IL-23 inhibitors have a higher efficacy when compared head-to-head with ustekinumab. In the most recent Cochrane systematic review and network meta-analysis, ustekinumab is superior to the minimal interventions (i.e., placebo and some other drugs close in efficacy estimates such as etanercept, ciclosporin, methotrexate) but with minimal to no benefit when compared to the interventions with best efficacy estimates (infliximab, ixekizumab, risankizumab, etc.). This effect estimates are seen in different outcomes of clinical relevance such as the PASI 90, PASI 75, and PAG, and are of low to moderate certainty. |
| 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) | ☒ Yes<br>☐ No<br>☐ Not applicable<br>Comments: Based on the same NMA from Cochrane, ustekinumab has a similar profile in terms of harms than the rest of the drugs when compared to placebo (moderate certainty). For SAEs, ustekinumab also presents a similar but favorable profile. Ustekinumab had a better profile than approximately half of the comparisons. |

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| Are there any adverse effects of concern, or that may require special monitoring? | ☒ Yes<br>☐ No<br>☐ Not applicable<br>Comments: Most common adverse events of special interest and to monitor include infections and malignancy. Although both are relatively rare and without a well-established causal association. |
| Are there any special requirements for the safe, effective and appropriate use of the medicines?<br><br>(e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc) | ☒ Yes<br>☐ No<br>☐ Not applicable<br>Comments: Health professionals using ustekinumab must have the appropriate knowledge and clinical skills to be aware of the diagnostic and treatment criteria. Also, monitoring for new infections is required. |
| Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings? | ☒ Yes<br>☐ No<br>☐ Not applicable<br>Comments: For patients under 100 kg, ustekinumab 45 mg is one of the most cost-effective biologic agents when considering its direct and indirect costs. Although it is more expensive per dose, it is cost-effective over the long term, as there is more adherence and less expenses due to side effects. |
| Are there any issues regarding the registration of the medicine by national regulatory authorities?<br><br>(e.g. accelerated approval, lack of regulatory approval, off-label indication) | ☐ Yes<br>☒ No<br>☐ Not applicable<br>Comments: |
| Is the proposed medicine recommended for use in a current WHO guideline?<br><br>(refer to: https://www.who.int/publications/who-guidelines) | ☐ Yes<br>☒ No<br>☐ Not applicable<br>Comments: No WHO guidelines are available for this condition. |