A.28	Ocrelizumab – multiple sclerosis – EML
Draft recommendation	☐ Recommended ☒ Not recommended Justification: MS has a global burden of disease that has been largely neglected especially with considerations for the WHO EML which is a first step to increasing government engagement in subsidizing cost of medication especially for global south where health insurance is limited. However, considering a previous application considering listings it will be more cost effecting to include a combination of therapies as proposed MS DMT submission than a single product.
Does the proposed medicine address a relevant public health need?	☒ Yes ☐ No ☐ Not applicable Comments: There is a significant global disease burden of multiple sclerosis (MS), which affects approximately 2.8 million people worldwide (1). MS primarily affects young adults, with patients usually being diagnosed between the ages of 20 and 40, and a mean age of diagnosis of approximately 30 years. MS is at least two to three times more frequent in women than in men, except in PPMS, where men and women are equally affected. In all forms of MS, there is a clear unmet need for a disease-modifying therapy (DMT) that has a benefit–risk profile which supports initiation at any time during the disease course and preserves neurological function, inhibits the accumulation of irreversible disability and improves health-related quality of life (HRQoL).
Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication? (this may be evidence included in the application, and/or additional evidence identified during the review process)	☒ Yes ☐ No ☐ Not applicable Comments:
Does adequate evidence exist for the safety/harms associated with the proposed medicine? (this may be evidence included in the application, and/or additional evidence identified during the review process)	☒ Yes ☐ No ☐ Not applicable Comments:

Are there any adverse effects of concern, or that may require special monitoring?	☐ Yes ☒ No ☐ Not applicable Comments:
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)	☒ Yes ☐ No ☐ Not applicable Comments: Diagnosis requires health technologies that will not be available in low resource settings.
Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?	☐ Yes ☒ No ☐ Not applicable Comments:
Are there any issues regarding the registration of the medicine by national regulatory authorities? (e.g. accelerated approval, lack of regulatory approval, off-label indication)	☐ Yes ☒ No ☐ Not applicable Comments:
Is the proposed medicine recommended for use in a current WHO guideline? (refer to: https://www.who.int/publications/who-guidelines)	☐ Yes ☒ No ☐ Not applicable Comments: