A.2 Aripiprazole – EML

Reviewer summary	☒ Supportive of the proposal ☐ Not supportive of the proposal Justification (based on considerations of the dimensions described below): Improved benefits with comparable harm. More alternatives in schizophrenia treatment is needed due to the heterogeneity of treatment response.
Does the EML and/or EMLc currently recommend alternative medicines for the proposed indication that can be considered therapeutic alternatives? (**https://list.essentialmeds.org/**) For injection: risperidone LAI	☒ Yes ☐ No ☐ Not applicable Several alternatives, both oral and injection.
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;) Evidence from several RCTs and real-world studies, as well as systematic review.	☒ Yes ☐ No ☐ 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;) Safety is comparable or even better than current available treatment in EML.	☒ Yes ☐ No ☐ Not applicable
Overall, does the proposed medicine have a favourable and meaningful balance of benefits to harms? Better benefits with comparable harms.	☒ Yes ☐ No ☐ 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) **A**lthough as injection it must be administered by an HCP, yet the frequency is only once a month. There are no requirements for diagnostic tests, specialised treatment facilities, or skill level of health care providers for the use of AOM. There are no requirements for post-dose monitoring with AOM.	☐ Yes ☒ No ☐ Not applicable
Are there any issues regarding price, cost-effectiveness and budget implications in different settings? Although treatment with AOM increased schizophrenia-related drug costs (oral SOC and AOM) per patient in the prospective period, this increment was offset by a reduction in psychiatric hospitalisation-related charged amounts in the retrospective period. Patent expiration is in October 2024	☐ Yes ☒ No ☐ Not applicable

Is the medicine available and accessible across countries? (e.g. shortages, generics and biosimilars, pooled procurement programmes, access programmes) Available in Asia Pacific, Europe, Middle East and Africa, and North America.	☒ Yes ☐ No ☐ Not applicable
Does the medicine have wide regulatory approval? Approved in 62 countries/ territories globally	☒ Yes, for the proposed indication ☐ Yes, but only for other indications (off-label for proposed indication) ☐ No ☐ Not applicable