A.30	Osimertinib – non-small cell lung cancer – EML
Draft recommendation	☐ Recommended ☒ Not recommended Treatment for advanced *EGFR*-mutant NSCLC, with first- and second-generation TKIs, has significantly improved progression-free survival. OS has not shown improvement due to a significant cross-over of patients being given chemotherapy in all trials. These drugs are already approved and on the EML list with widely available generics.
Does the proposed medicine address a relevant public health need?	☒ Yes ☐ No ☐ Not applicable Comments:
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: Like the first and second line TKIs for lung cancer. EGFR mutation analysis needs to be performed prior to administering the drug.
Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?	☐ Yes ☐ No ☐ Not applicable Comments: Osimertinib is more effective in EGFR mutated patients with brain metastasis and in patients with T790M. The incremental cost of the drug does not justify its inclusion in the EML list. Availability of generics is very limited.
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: It will be good to re-evaluate Osimertinib once generics are more widely available making it more cost effective for the public.