

<b>Title</b>	TAGRISSO – A Health Technology Assessment
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<b>Reference</b>	link to full report in French <a href="https://www.has-sante.fr/jcms/pprd_2983526/fr/tagrisso">https://www.has-sante.fr/jcms/pprd_2983526/fr/tagrisso</a>

## Aim

Assessment of TAGRISSO (osimertinib) with a view to funding by the French national health insurance system, and of its clinical contribution compared to other strategies, in the indication for first-line monotherapy treatment of adult patients with locally-advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) activating mutations.

## Conclusions of Transparency Committee

### Clinical Benefit

- Non-small cell lung cancer (NSCLC) is a life-threatening disease.
- TAGRISSO (osimertinib) is a specific curative treatment for NSCLC.
- The efficacy/adverse effects ratio is significant
- There are therapeutic alternatives.
- TAGRISSO (osimertinib) is a first-line treatment.
- TAGRISSO (osimertinib) is not likely to have an additional impact on public health.

Considering all of the above, the Committee deems that the clinical benefit of TAGRISSO (osimertinib) is substantial in the MA indication extension.

### Clinical Added Value

Considering:

- osimertinib's superiority over the anti-EGFR TKIs erlotinib or gefitinib in terms of:
    - progression-free survival assessed by the investigator (18.9 months median survival in the osimertinib group vs. 10.2 months in the comparator group; HR=0.46; 95%CI [0.37; 0.57];  $p < 0.0001$ ) and,
    - overall survival (38.6 months median survival in the osimertinib group vs. 31.8 months in the comparator group; HR=0.799; 95.05%CI [0.64; 0.99];  $p=0.0462$ ),
  - osimertinib's acceptable safety compared to the anti-EGFR TKIs erlotinib or gefitinib,
  - the absence of any formal conclusion that can be drawn based on the quality-of-life results,
- TAGRISSO (osimertinib) provides moderate clinical added value (CAV III) compared to the anti-EGFR TKIs TARCEVA (erlotinib) and IRESSA (gefitinib), in the first-line treatment

of locally advanced or metastatic non-small cell lung cancer with EGFR activating mutations.

## Recommendations

The Transparency Committee issued its approval for the funding of TAGRISSO (osimertinib) by the French national health insurance system (retail and hospital), in the indication for the first-line monotherapy treatment of adult patients with locally-advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) activating mutations.

## Methods

The assessment of TAGRISSO (osimertinib) was founded on evidence-based medicine with a critical analysis of the clinical data.

## Written by

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