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Minister of Medical Care and Sports
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2020038636

Date 21 September 2020
Subject Advice reassessment osimertinib (Tagrisso®)

**National Health Care
Institute**
Care II
Cardiovascular & Pulmonary

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Our reference
2020038636

Dear Ms van Ark,

In response to your request of 15 May 2020 (1688112-205176-GMT), Zorginstituut Nederland is advising you on the use of osimertinib (Tagrisso®) for the treatment of locally advanced or metastatic non-small cell lung carcinoma (NSCLC) with an epidermal growth factor receptor (EGFR) mutation. The basis of your request is the availability of additional evidence from the FLAURA study, the study on which the assessment of 2018 was based.

The Zorginstituut advises you to continue the inclusion of osimertinib in the package following successful price negotiations where the price of osimertinib should drop by about 35% to be cost effective at a reference value of €80,000/QALY.

Background

In the package advice of 7 November 2018, the Zorginstituut advised you not to include osimertinib in the health insurance package, unless a cost-effective use of osimertinib can be achieved through price negotiation.

At the time, the Zorginstituut gave you a number of reasons for price negotiations:

- Osimertinib meets the legal criterion of 'established medical science and medical practice' in the primary care treatment of patients with a locally advanced or metastatic lung adenocarcinoma and an ex(19)del or L858R activating EGFR mutation.
- The cost-effectiveness analysis provided by the marketing authorisation holder is of sufficient methodological quality, but the model used for this is highly dependent on the survival gain of osimertinib.
- The evidence available for the survival rate is uncertain, so the Zorginstituut presents a range for the ICER, instead of a point estimate.

The Zorginstituut advised you to base your price negotiations on the upper limit of the ICER range. The Zorginstituut also advised you to have a new assessment carried out if more evidence becomes available.

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Reassessment

In the advice from 2018, the Zorginstituut concluded that osimertinib meets the legal criterion of 'established medical science and medical practice' in the primary care treatment of patients with a locally advanced or metastatic lung adenocarcinoma and an ex(19)del or L858R activating EGFR mutation. The Oncological Medicines Assessment Committee (BOM) at the time gave a positive advice on the basis of progressive survival gains and has not adjusted its advice. Osimertinib is still considered the preferred treatment option, despite the fact that some new treatment options have become available for the mentioned indication. On this basis, the Zorginstituut sees no reason for a reassessment of the therapeutic value of osimertinib. The Zorginstituut confirms the conclusion that osimertinib complies with the legal criterion 'established medical science and medical practice' for the above indication.

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The August 2018 report shows that the Zorginstituut had one important point of criticism about the pharmaco-economic analysis, namely the immature data on overall survival (OS). In the new dossier of the marketing authorisation holder, these data have been adapted following the final OS analysis. This final analysis was planned for the moment 318 patients from the study had died, which corresponds to a 58% maturity of the OS data. In addition, additional data has been made available during the interim period, which has also been included in the model.

The Zorginstituut concludes that this analysis is of sufficient quality. Since there is now less uncertainty about the effects on the overall survival, the Zorginstituut believes that there is no longer a cost-effectiveness ratio (ICER) range to be used, but that the point estimation can be used.

The Zorginstituut concludes that the ICER is €134,757/QALY. The probability that osimertinib is cost-effective at a reference value of €80,000/QALY is about 2.8%. The price of osimertinib should drop by about 35% to fall below the reference value of €80,000/QALY.

Yours sincerely,

Peter Siebers
Member of the Board of Directors