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National Health Care Institute
Care
Medicinal Products

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Our reference
2021038253

Date 26 October 2021
Subject Package advice cemiplimab (Libtayo®)

Dear Mr Blokhuis,

The National Health Care Institute advises you on cemiplimab (Libtayo®) for the primary care treatment of stage IIIBC-IV non-small cell lung carcinoma (NSCLC) in adult patients with PD-L1 expression ≥50% without EGFR/ALK/ROS1 aberrations. The reason for this advice was that the said medicinal product was being placed in the so-called lock procedure for expensive medicinal products.

The National Health Care Institute has concluded that cemiplimab meets the statutory criterion of 'established medical science and medical practice' for the indication mentioned. The National Health Care Institute has determined that the therapeutic value of this combination is comparable to the value of pembrolizumab. Both treatment options have a clinically relevant effect on the survival rate. However, the use of cemiplimab is associated with additional costs. The National Health Care Institute is unable to determine the amount of these additional costs because the actual price of pembrolizumab is not known. We advise you to include the new treatment in the package, provided the price negotiations with the marketing authorisation holder (MAH) successfully deliver a net price that does not exceed that of the existing treatment. We would like to point out that the Insured Package Advisory Committee has recommended that the price for a treatment should be reduced when more resources are available.

General

At your request, the National Health Care Institute assesses whether new care should be part of the health insurance package, and makes a decision based on the health insurance package paid from joint premiums. We take into consideration the degree of certainty that this will be achieved, both in the scientific sense, as well as in terms of public support, and we consider the efficiency and transparency aspects. The National Health Care Institute has assessed Libtayo® on the basis of the four package criteria[1] of effectiveness[2], cost-effectiveness[3], necessity and feasibility.

[1] Real-world package management 3 (2013). National Health Care Institute, Diemen. Via www.zorginstituutnederland.nl

[2] Established medical science and medical practice assessment: updated version (2015). National Health Care Institute, Diemen. Via www.zorginstituutnederland.nl

[3] Cost-effectiveness report (2015). National Health Care Institute, Diemen. Via www.zorginstituutnederland.nl

Integral weighting of package criteria

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Established medical science and medical practice
The efficacy of cemiplimab in the treatment of stage IIIBC-IV NSCLC in adult patients with PD-L1 expression ≥50% without EGFR/ALK/ROS1 aberrations has been examined in one open label, randomized, controlled study (EMPOWER-Lung 1). The Median OS was 22.1 months in the cemiplimab group (95% BI: 17.7-not reached) and 14.3 months in the control group (95% BI: 11.7-19.2), which creates a hazard ratio (HR) of 0.68 (95% BI: 0.53-0.87). These results meet the PASKWIL criteria. The study control group consisted of 4-6 cycles of chemotherapy, which was the standard treatment at the time of commencement of the study. Nowadays, however, the standard treatment consists of pembrolizumab monotherapy. This is why an indirect comparison was made between cemiplimab and pembrolizumab in the assessment.

Making an indirect comparison between cemiplimab and pembrolizumab is difficult due to differences in study design (cross-over allowed/not allowed, patient characteristics (persons who have never smoked included yes/no) and follow-up duration (13 months vs. 43 months). This makes it unclear, based on the results from the GRADE Assessment, whether there are clinically relevant differences between the treatment options with regards to overall survival. The point estimations of the HRs/RRs of the indirect comparison show no (large) differences in overall survival and the incidence of severe adverse effects. Quality of life was not included in the study on pembrolizumab, and for this reason no comparison could be made here.

The effects of cemiplimab appear to be in the same range as that of pembrolizumab. It is also evident that cemiplimab has a clinically relevant effect on overall survival compared to chemotherapy alone, as is the case for pembrolizumab.

Budget impact
1,772 patients are expected to be eligible for treatment with cemiplimab. The National Health Care Institute assumes 20% market penetration in year 3 after inclusion. The National Health Care Institute therefore expects that in year 3 after inclusion, 354 patients will use cemiplimab. The treatment costs an average of €40,688 per patient per year. This is slightly more expensive than the list price of pembrolizumab (€40,153). The National Health Care Institute assumes the average number of claimed administrations per year for this indication.

Based on a market penetration of 20%, the budget impact, by substituting pembrolizumab, is expected to be €189,727. These calculations are based on the list price for both medicinal products. For pembrolizumab, a confidential price arrangement has been concluded; due to this, the actual budget impact is unknown. However, it will be higher than the budget impact calculated by the National Health Care Institute due to the lower (negotiated) price of pembrolizumab.

Cost-effectiveness
Because of the similarities in effectiveness (equal therapeutic value) of cemiplimab and pembrolizumab, the National Health Care Institute has not carried out any cost-effectiveness analysis.

Final conclusion
The National Health Care Institute advises you to include Libtayo® in the health insurance package, provided the price negotiations with the marketing authorisation holder (MAH) successfully deliver a net price that does not exceed that of the existing treatment. Since there is an equal value compared to a product already being reimbursed and there is no indication that one product is preferable to another, we advise you to take into account during the price negotiation the existing discount on the medicinal products already being reimbursed.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board

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