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National Health Care Institute
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Contact
Ms A. van der Waal
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Our reference
2026008997

Date: 28 April 2026
Re: Reimbursement advice lock procedure medicinal product serplulimab (Hetronifly®) for small cell lung cancer

Dear Ms Hermans,

The National Health Care Institute advises you on the assessment of serplulimab (Hetronifly®) for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC). This advice was prompted by the placement of serplulimab in the package lock for expensive medicinal products. The National Health Care Institute advises you not to include serplulimab for ES- SCLC in the basic health insurance package, unless the net price is reduced by at least 33% after successful price negotiations.

Small cell lung cancer is an aggressive form of lung cancer often caused by smoking. The disease can be divided into limited-stage (LS) and extensive-stage (ES) SCLC. In ES-SCLC, the tumour can no longer be treated with radiotherapy and the cancer has often metastasised to other organs. Annually, approximately 1,125 patients in the Netherlands are diagnosed with ES- SCLC. These patients are on average 68 years old. The median survival of patients with ES- SCLC is less than 1 year. These patients are currently being treated with chemotherapy (carboplatin or cisplatin in combination with etoposide) in the Netherlands. Serplulimab is a PD-1 inhibitor that can be added to chemotherapy.

Registered indication
Serplulimab (Hetronifly®) in combination with carboplatin and etoposide is indicated for the first-line treatment of adult patients with ES-SCLC.

Claim by the marketing authorisation holder (MAH)
Serplulimab in combination with carboplatin plus etoposide as first-line treatment of ES-SCLC in adults with an Eastern Cooperative Oncology Group performance status (ECOG PS)[1] score of 0-1 has an added value compared to standard treatment with carboplatin plus etoposide.

The claim is therefore narrower than the registered indication and relates to a subset of relatively fit patients with ES-SCLC.

[1] Scale measuring the level of performance and fitness of patients with cancer. ECOG PS 0-1 means patients are in relatively good condition.

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Reimbursement advice

The National Health Care Institute advises you not to include serplulimab as first-line treatment for adult patients with ES- SCLC and an ECOG PS score 0-1 in the basic health insurance package, unless the price is reduced by at least 33% after successful price negotiations. The National Health Care Institute has determined that serplulimab meets the legal criterion of 'established medical science and medical practice' for the indication mentioned above, and that it offers added value compared to standard treatment with chemotherapy. However, based on the available data, the cost-effectiveness is considered unfavourable.

The National Health Care Institute recommends that theprice negotiations of serplulimab should also take into account the underlying principles guiding the advice on financial arrangements for the other PD-1 and PD-L1 inhibitors. In addition, consideration should be given to the potential entry of competition, as durvalumab (Imfinzi®) is currently being assessed by the National Health Care Institute for the same indication.

We explain the preparation of this package advice below.

General

At your request, the National Health Care Institute assesses whether care should be part of the standard health insurance package from the perspective of the basic healthcare package paid from joint premiums.

The National Health Care Institute assesses on the basis of the four package criteria[2]: effectiveness[3], cost-effectiveness[4], necessity[5] and feasibility[6]. The Scientific Advisory Board (WAR) advises the National Health Care Institute on the (scientific) support and the conclusion of the assessment. If there are risks regarding the accessibility and affordability, the assessment of the package criterion of effectiveness (established medical science and medical practice) will be placed in the wider social context of the four package criteria. The Insured Package Advisory Committee (hereinafter also "ACP") advises the Executive Board of the National Health Care Institute in this regard. This social weighting results in the package advice. Stakeholders are consulted during the process.

[2] Real-world package management 4 (2023). National Health Care Institute, Diemen. Via www.zorginstituutnederland.nl.

[3] Assessment of the established medical science and medical practice (2023). National Health Care Institute. Via www.zorginstituutnederland.nl.

[4] Healthcare cost-effectiveness report (2024) National Health Care Institute, Diemen. Via www.zorginstituutnederland.nl.

[5] Necessity is related to both the medical need due to the severity of a disease for the patient (burden of disease) and the need to insure something. See the report on real-world package management 4 (2023).

[6] The package criterion of feasibility deals with whether it is feasible or sustainable to include a specific type of care in the basic health insurance package. It is therefore mainly a test of a number of implementation aspects, such as the healthcare organisation, the support base, ethical and legal aspects, budget impact, etc. See the report on real-world package management 4 (2023).

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Comprehensive weighting of package criteria

Effectiveness

Established medical science and medical practice

The randomised study (RCT) ASTRUM-005 compared serplulimab in combination with chemotherapy directly with chemotherapy in patients with ES-SCLC and ECOG PS 0-1. The study shows that adding serplulimab to chemotherapy results in a clinically relevant extension of median survival of 4.7 months.

The addition of serplulimab to chemotherapy does not result in a clinically relevant increase in severe adverse effects nor discontinuations due to adverse effects. There is also no evidence that the quality of life is affected by serplulimab. The adverse reactions of serplulimab are primarily immune-related and are considered acceptable by the physicians' associations.

The National Health Care Institute, advised by the Scientific Advisory Board (WAR), has concluded that serplulimab in combination with chemotherapy for this indication is in line with the established medical science and medical practice and that it has added value when compared to the standard treatment consisting of chemotherapy.

Cost-effectiveness

The cost-effectiveness analysis by the marketing authorisation holder is of sufficient quality and can be used for decision-making. The ICER is €102,213 per QALY gained. The cost-effectiveness estimate is higher than the reference value of €80,000 per QALY gained that is deemed relevant for this condition; serplulimab is therefore not considered to be a cost-effective intervention. The price of serplulimab would have to be reduced by at least 33% to become cost-effective.

Feasibility

Budget impact analysis

The National Health Care Institute estimates that 394 patients will be treated with serplulimab for the above indication in year 3 after inclusion in the package. The total cost per patient is €64,803 for an average treatment duration of 8.6 months. This results in macro costs of €25.5 million in the third year. There is no substitution as serplulimab is added to the standard treatment with chemotherapy.

Price arrangements for PD-1 and PD-L1 inhibitors

PD-1 and PD-L1 inhibitors have been registered and are reimbursed for several indications. Given the current expenditure and the expected increase in the macro-cost for these products, the National Health Care Institute recommended[7] in 2023 that a centrally negotiated financial (follow-up) arrangement is concluded for each product. Further indication expansions for serplulimab are expected to follow. Building on the previous advice for PD-1 and PD-L1 inhibitors, the National Health Care Institute recommends that this be taken into account when concluding the financial arrangement.

[7] Advice PD-1 and PD-L1 inhibitors for the treatment of cancer | National Health Care Institute

Should you need any further information, please do not hesitate to contact us.

Yours sincerely,

M.J. Janssen
Chairperson of the Executive Board

Annexes:
- -Pharmacotherapeutic report
- -Budget impact analysis
- -Pharmaco-economic report

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