National Health Care Institute

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Contact

2024026955

Date 10 July 2024
Re: Package advice reassessment of sacituzumab govitecan (Trodelvy®)

Our reference
2024026955

Dear Ms Agema,

The National Health Care Institute hereby advises you about the outcome of the reassessment of the pharmaco-economic dossier on sacituzumab govitecan (Trodelvy®) for the treatment of adult patients with inoperable or metastatic triple-negative breast cancer (mTNBC)[1] who have previously received two or more systemic therapies, including one line of taxane-containing therapy and at least one for advanced disease. This advice follows on from the previous positive reimbursement advice dated 15 July 2022. The National Health Care Institute informed you that sacituzumab govitecan for the aforementioned indication did meet the established medical science and medical practice, and could be included in the health insurance package if a discount of at least 75% was agreed in price negotiations.
After the price negotiations with the marketing authorisation holder had not yielded a satisfactory result, your predecessor at the time (Mr. Kuipers) decided in March 2023 that this medicine would not be included in the health insurance package, and he informed the Lower House of the Dutch Parliament accordingly.[2] The placement of sacituzumab govitecan in the lock procedure was not discontinued.

On 18 April this year, the marketing authorisation holder, with the support of the professional association NVMO[3] and the Dutch Breast Cancer Association OVN, requested the National Health Care Institute to reassess the pharmaco-economic dossier of sacituzumab govitecan on the basis of new and longer follow-up data from the registration study. This data would provide more certainty about the long-term outcomes on overall survival and also provide 'an up-to-date and representative picture of the cost-effectiveness'. The National Health Care Institute, advised by the Scientific Advisory Board (WAR), has now completed this cost-effectiveness reassessment.

Cost-effectiveness

[1] Triple-negative means that the growth of this type of breast cancer is not influenced by the hormones oestrogen and progesterone, and is not HER2-positive. As a result, this type of breast cancer cannot be successfully treated with targeted therapy (e.g. hormone therapy).

[2] *Parliamentary Papers II* 2022/23, 29477, no. 811

[3] Dutch Society for Medical Oncology

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The National Health Care Institute determined that the changes made by the marketing authorisation holder in the initial pharmaco-economic analysis (2022) are indeed based on new data and that these changes are valid. The marketing authorisation holder has fully and satisfactorily answered the essential and content-specific questions of the National Health Care Institute regarding critical aspects of the base case analysis. The criticisms from the initial pharmaco-economic assessment (2022) have not been addressed and are therefore still valid.

The National Health Care Institute concludes that the pharmaco-economic analysis is of sufficient quality. Its results can be used in the decision-making. The ICER is €154,502 per QALY gained. Taking into account the possible impact of the criticisms in its initial pharmaco-economic assessment, this ICER requires a price reduction of at least 55% to remain below the €80,000 reference value.

Final conclusion
Sacituzumab govitecan complies with the established medical science and medical practice for the treatment of adult patients with inoperable or metastasized triple-negative breast cancer who have previously received two or more systemic therapies, including one line of taxane-containing therapy and at least one for advanced disease. The National Health Care Institute advises you to include sacituzumab govitecan in the health insurance package for this indication. The National Health Care Institute considers a discount of at least 55% appropriate. As advised by the National Health Care Institute in 2022, the negotiations should take into account that indication expansions for sacituzumab govitecan are to be expected.

Should you need any further information, please do not hesitate to contact us. Our new pharmaco-economic assessment report has been added as an annex.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board