



> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health, Welfare and Sport
P.O. Box 20350
2500 EJ THE HAGUE

2025012190

Date 19 May 2025
Concerning Package advice for lock procedure medicinal product idecabtagene vicleucel (Abecma®) for multiple myeloma

Dear Ms Agema,

The National Health Care Institute advises you on the assessment of idecabtagene vicleucel (ide-cel, Abecma®) for treating patients with relapsed and refractory multiple myeloma (RRMM) from the third line of treatment. The reason for this advice was ide-cel being placed in the lock procedure for expensive medicinal products.

The National Health Care Institute advises you not to include ide-cel in the basic healthcare package for the said indication.

Condition

Multiple myeloma (MM) is an incurable form of bone marrow cancer, also known as Kahler's disease, in which plasma cells grow uncontrollably in the bone marrow. The cause is unknown. In the Netherlands, it is estimated that approximately 1400 patients are diagnosed each year. A small proportion of these could be eligible for treatment with ide-cel. Most patients are aged 65 or older, but there are also younger patients. The median survival is about 2-9 years after diagnosis. How long a patient survives depends on the patient's fitness and treatment options. Patients can undergo autologous stem cell transplantation and several new drugs are already available and in development. Two other reviews of medicines for MM are currently ongoing at the National Health Care Institute.

Registered indication

Ide-cel is indicated for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies, including an immunomodulatory agent (IMiD), a proteasome inhibitor and an anti-CD38 antibody, and have demonstrated disease progression on the last therapy.

Claim by the marketing authorisation holder

Ide-cel has added value over the standard treatment for the registered indication.

National Health Care Institute

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Package advice

The National Health Care Institute advises you not to include ide-cel in the basic healthcare package for the registered indication. The National Health Care Institute has determined that ide-cel does not meet the legal criterion of 'established medical science and medical practice' for the indication stated.

We have explained 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 criteria¹: effectiveness², cost-effectiveness³, necessity⁴ and feasibility⁵. The Scientific Advisory Board (WAR) advises the National Health Care Institute about the scientific basis and the conclusion of the assessment. Stakeholders are consulted during the process.

As ide-cel does not meet the legal criterion of 'established medical science and medical practice' for the stated indication, an integral weighting of the four package criteria and advice by the Package Advisory Committee (ACP) is not applicable.

Assessment of the content

Effectiveness

Established medical science and medical practice

In the KarMMA-3 randomised controlled trial (RCT), ide-cel was compared against the standard treatment in patients with RRMM who had undergone 2 to 4 previous treatments. The standard treatment in the study consisted of various drug combinations. Ide-cel shows a positive effect on progression-free survival compared to the standard treatment. However, the results show that ide-cel probably does not have a clinically relevant effect on patient (overall) survival. There is also evidence that ide-cel improves the quality of life to at least some extent, but the clinical relevance of this improvement is unclear. In addition, ide-cel may well cause more severe unfavourable effects than the standard treatment.

Because approximately half the patients in the control arm of the study were treated further with ide-cel after progression, the outcomes in terms of the

¹ Real-world package management 4 (2023). National Health Care Institute, Diemen. Via www.zorginstituutnederland.nl.

² Assessment of the established medical science and medical practice (2023). National Health Care Institute. Via www.zorginstituutnederland.nl.

³ Healthcare cost-effectiveness report (2024) National Health Care Institute, Diemen. Via www.zorginstituutnederland.nl.

⁴ 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).

⁵ The package criterion of feasibility deals with whether it is feasible or sustainable to include a specific form of care in the basic healthcare 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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survival may be biased. Additional analyses were therefore carried out that corrected for this. No clinically relevant survival benefit for ide-cel was demonstrated in these analyses either.

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Another CAR-T treatment that can be used in these patients in a later treatment line did show a convincing clinically relevant improvement in survival, in the study setting.

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The National Health Care Institute, advised by the Scientific Advisory Board (WAR), concluded that ide-cel does not meet the criterion of 'established medical science and medical practice' for the registered indication.

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We trust that this letter will have provided you with the information you need. The pharmacotherapeutic report is attached.

Yours sincerely,

M.J. Janssen
Chair of the Executive Board