NCPE Assessment

Plain English Summary

September 2023

Drug name: Ciltacabtagene autoleucel (pronounced: SIL-tuh-KAB-tuh-jeen AW-toh-LOO-sel) for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and have demonstrated disease progression on the last therapy

Brand name: Carvykti®

HTA ID: 22021

NCPE
National Centre for Pharmacoeconomics, Ireland

What is the NCPE?

The National Centre for Pharmacoeconomics (NCPE) is a team of experts who look at the health benefits and costs of medicines. The HSE asks us to advise on whether or not a new medicine is good value for money. We give unbiased advice to help the HSE provide the most effective, safe and cost-effective (value for money) treatments for patients.

How do we make our recommendations?

Our main focus is on the health benefits and cost effectiveness of a medicine. We look at the wider costs and health benefits associated with a new medicine, for example:

- Does the new medicine work better than other treatments available in Ireland?
- Is the new medicine easier to give or easier to take compared with other treatments available in Ireland?
- Does the new medicine reduce the need for patients to be hospitalised?
- Does the new medicine improve the quality of a patient's life over other treatments available in Ireland?
- Will the new medicine save resources elsewhere within the health system?

We review the information from clinical trials along with the cost and value for money data presented by the pharmaceutical company. We ask doctors and other healthcare professionals for advice about any health benefits of the new medicine compared with current treatments. We also ask patient organisations to send us their views on how the new drug may improve patients' day-to-day experience of living with a disease.

What is ciltacabtagene autoleucel used for?

Ciltacabtagene autoleucel, also called cilta-cel, is a medicine used to treat adults with multiple myeloma (a cancer of the bone marrow) when the cancer has come back (relapsed) and has not responded to treatment (refractory). It is used in adults who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and whose disease has worsened since the last treatment. Cilta-cel treatment uses the patient's own white blood cells which are extracted from the blood,

genetically modified in the laboratory and then given back to the patient as a single infusion (drip) into a vein. Cilta-cel must only be given to the patient whose cells were used to make the medicine.

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider not funding cilta-cel unless its cost effectiveness (value for money) can be improved. The HSE will consider our recommendation and make the final decision about reimbursement (funding). When making the funding decision, the HSE will also consider the additional criteria outlined in the Health (Pricing and Supply of Medical Goods) Act 2013.

We have received a Patient Organisation Submission from Multiple Myeloma Ireland about cilta-cel and shared it with the HSE. This submission will form part of the data that the HSE considers.

Why did we make this recommendation?

After reviewing the data presented by the pharmaceutical company, we concluded that cilta-cel may work as well or better than other ways to manage this condition. However, the price of the medicine is too high compared with other ways to manage this condition, and we believe that the medicine is very poor value for money. We recommend that the HSE consider not providing this medicine unless the HSE can agree a suitable price reduction with the pharmaceutical company.

The HSE considers a number of factors along with our recommendation when deciding whether to provide this medicine. These factors are listed in the Health (Pricing and Supply of Medical Goods) Act 2013.

Next steps

When the HSE receives our recommendation, it will look at all the relevant data about cilta-cel. The HSE makes the final decision on reimbursement.

Where can I get more information?

You can get more information about cilta-cel from the following online options:

- the NCPE Technical Summary Document
- Carvykti European Public Assessment Report (EPAR) – Summary for the public , or
- searching for ciltacabtagene autoleucel on our website (www.ncpe.ie);
- searching for ciltacabtagene autoleucel on the European Medicines Agency (EMA) website (www.ema.europa.eu).

Please refer to the NCPE website for updated information on the reimbursement status of this medicine