



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Tecvayli (teclistamab)

An overview of Tecvayli and why it is authorised in the EU

What is Tecvayli and what is it used for?

Tecvayli is a cancer medicine used to treat adults with multiple myeloma (a cancer of the bone marrow). It can be used in patients who have received at least three previous treatments for their cancer, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody, and whose cancer has worsened since receiving the last treatment.

Tecvayli contains the active substance teclistamab.

How is Tecvayli used?

The medicine can only be obtained with a prescription and treatment must be started and monitored by a doctor experienced in the management of multiple myeloma, in a location with appropriate medical support to manage severe side effects such as cytokine release syndrome (a potentially life-threatening condition that causes fever, vomiting, shortness of breath, headache and low blood-pressure; see risks section below).

Tecvayli is given as an injection under the skin. The recommended dose is based on the patient's body weight. Treatment starts with injections on days 1, 3 and 5 at increasing doses (so-called step-up dosing). One to three hours before receiving these injections, patients are given medicines to reduce the risk of developing cytokine release syndrome. After step-up dosing, patients are given maintenance doses once a week. Treatment can continue until the disease gets worse or the patient experiences unacceptable side effects.

For more information about using Tecvayli, see the package leaflet or contact your doctor or pharmacist.

How does Tecvayli work?

The active substance in Tecvayli is teclistamab, an antibody (a type of protein) that is designed to recognise and attach to two targets simultaneously: the B cell maturation antigen (BCMA) on myeloma cells and CD3 on the surface of T cells (cells in the immune system). By attaching to these target proteins, this medicine brings the cancer cells and T cells together. This activates the T cells, which then kill the multiple myeloma cells.

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What benefits of Tecvayli have been shown in studies?

The benefits of Tecvayli have been investigated in an ongoing study involving 165 patients with multiple myeloma who had received at least three prior treatments (including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody) and whose disease had not improved (refractory) or had come back (relapsed) after the last treatment. The study did not compare Tecvayli with other medicines or placebo (a dummy treatment). In this study, 63% (104 out of 165) of patients responded to treatment with Tecvayli and they lived for an average of 18 months without their disease getting worse.

What are the risks associated with Tecvayli?

The most common side effects with Tecvayli (which may affect more than 1 in 10 people) are hypogammaglobulinaemia (low immunoglobulin or antibody levels in the blood, which increases the risk of infection), cytokine release syndrome, neutropenia (low levels of neutrophils, a type of white blood cell that fights infection), anaemia (low levels of red blood cells or haemoglobin), pain in the muscles and bones, tiredness, thrombocytopenia (low levels of blood platelets, components that help the blood to clot), injection site reactions, upper respiratory tract (nose and throat) infection, lymphopenia (low levels of lymphocytes, a type of white blood cell), diarrhoea, pneumonia (infection of the lungs), nausea (feeling sick), fever, headache, cough, constipation and pain.

The most common serious side effects are pneumonia, COVID-19, cytokine release syndrome, sepsis (blood poisoning; when bacteria and their toxins circulate in the blood, leading to organ damage), fever, pain in the muscles and bones, acute kidney injury, diarrhoea, cellulitis (inflammation of deep skin tissue), hypoxia (lack of oxygen in body tissues), febrile neutropenia (low levels of neutrophils with fever), and encephalopathy (a brain disorder).

For the full list of side effects and restrictions of Tecvayli, see the package leaflet.

Why is Tecvayli authorised in the EU?

At the time of approval, treatment options were limited for patients with multiple myeloma once they no longer respond to an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody. Tecvayli addressed a medical need in these patients and showed a clinically relevant treatment effect, although the lack of a comparator, the short duration of the follow-up of patients within the main study and the small number of patients involved in this study limited the evaluation of the benefits and risks associated with its use.

Tecvayli has therefore been given 'conditional authorisation'. This means that the European Medicines Agency decided that the benefits of Tecvayli are greater than its risks, but the company will have to provide additional evidence after authorisation.

Conditional authorisation is granted on the basis of less comprehensive data than are normally required. It is granted for medicines that fulfil an unmet medical need to treat serious diseases and when the benefits of having them available earlier outweigh any risks associated with using the medicines while waiting for further evidence. Every year, the European Medicines Agency will review any new information that becomes available until data become comprehensive and this overview will be updated as necessary.

What information is still awaited for Tecvayli?

Since Tecvayli has been given conditional authorisation, the company that markets this medicine is required to submit the final results of the ongoing study in patients with multiple myeloma who were

treated with Tecvayli. In addition, they will have to provide data from a study that compares the effectiveness of Tecvayli in combination with daratumumab (another cancer medicine) with that of other treatments currently authorised for use in adults with relapsed or refractory multiple myeloma.

What measures are being taken to ensure the safe and effective use of Tecvayli?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Tecvayli have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Tecvayli are continuously monitored. Suspected side effects reported with Tecvayli are carefully evaluated and any necessary action taken to protect patients.

Other information about Tecvayli

Tecvayli received a conditional marketing authorisation valid throughout the EU on 23 August 2022.

Further information on Tecvayli can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/Tecvayli

This overview was last updated in 08-2022.