独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Ciltacabtagene autoleucel

January 13, 2026

Non-proprietary name

Ciltacabtagene autoleucel

Brand name (marketing authorization holder)

Carvykti Suspension for Intravenous Infusion (Janssen Pharmaceutical K.K.)

Japanese market launch

Before market launch

Indications or performance

Relapsed or refractory multiple myeloma. Carvykti must be used only in patients meeting both of the following criteria:

- Patients with no history of BCMA-targeted chimeric antigen receptor-expressing T cell infusion therapy
- Patients who have received at least 3 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody and who have failed to respond to or have relapsed after the last therapy

Summary of revisions

A precautionary statement concerning "enterocolitis" should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases involving enterocolitis were evaluated. Cases in which a causal relationship between ciltacabtagene autoleucel and enterocolitis was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases

and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases[*1] and patient mortalities involving enterocolitis reported in Japan and overseas

No cases have been reported in Japan to date.

A total of 31 cases have been reported overseas to date (including 22 cases in which a causal relationship between the regenerative medical product and the event was reasonably possible).

A total of 6 patient mortalities have been reported overseas to date. (A causal relationship between the regenerative medical product and the death following the event could not be established for any of these cases.)

*1: Cases collected in the PMDA's safety database for regenerative medical products

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).