

# TAK-620-4007: Retrospective Chart Review of Safety Outcomes Associated With Use of Maribavir in Patients With Post-transplant Refractory Cytomegalovirus (CMV) Infection and Comorbid Severe Chronic Kidney Disease (CKD) or Comorbid End-stage Renal Disease (ESRD), Including Patients on Peritoneal Dialysis or Hemodialysis

**First published:** 01/03/2024

**Last updated:** 01/07/2025

Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000006

### Study ID

1000000006

### DARWIN EU® study

No

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### **Study countries**

- Austria
- Belgium
- Denmark
- Estonia
- France
- Germany
- Italy
- Spain
- United Kingdom

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### **Study description**

The main aim of this study is to assess the safety of maribavir in adults with severe CKD or comorbid ESRD including participants on artificial filtering of the kidney (dialysis) or the blood (hemodialysis).

In this study, already existing data will be collected from the participant's medical records. The study will only review data collected as part of the normal clinical routine and will not impact the standard medical care and treatment of participants.

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### **Study status**

Planned

## Research institutions and networks

### Institutions

Takeda

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

### **Study institution contact**

Study Contact Takeda TrialDisclosures@takeda.com

Study contact

[TrialDisclosures@takeda.com](mailto:TrialDisclosures@takeda.com)

### **Primary lead investigator**

Study Contact Takeda

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 30/05/2025

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### **Study start date**

Planned: 30/11/2025

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### **Data analysis start date**

Planned: 01/01/2026

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#### **Date of interim report, if expected**

Planned: 28/02/2026

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#### **Date of final study report**

Planned: 31/01/2028

### Sources of funding

- Pharmaceutical company and other private sector

### More details on funding

Takeda

### Study protocol

[TAK-620-4007 PASS Protocol 02Jun2023 SR\\_Redacted.pdf](#) (682.19 KB)

### Regulatory

#### **Was the study required by a regulatory body?**

Yes

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#### **Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

### Methodological aspects

#### Study type

#### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study design:**

This is an observational, multi country, retrospective, post-authorization safety study (PASS)

based on the review of secondary data collected from medical records of transplant recipients.

**Main study objective:**

To characterize the safety of maribavir as prescribed in routine clinical practice in terms of occurrence of adverse events (AE) in patients with post-transplant refractory CMV infection and comorbid severe CKD or comorbid ESRD, including participants on peritoneal dialysis or hemodialysis.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

LIVTENCY

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**Study drug International non-proprietary name (INN) or common name**

MARIBAVIR

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**Anatomical Therapeutic Chemical (ATC) code**

(J05AX) Other antivirals

Other antivirals

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**Additional medical condition(s)**

Kidney failure

## Population studied

**Short description of the study population**

Participants treated with maribavir for a refractory (with or without resistance) CMV infection and who have severe CKD or comorbid ESRD including participants on peritoneal dialysis or hemodialysis.

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**Age groups**

- **Adult and elderly population (≥18 years)**

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**Special population of interest**

Frail population

Immunocompromised

Renal impaired

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**Estimated number of subjects**

## Study design details

### **Setting**

This proposed retrospective study will be conducted among eligible patients aged 18 years or older on maribavir treatment with comorbid severe CKD or ESRD within routine clinical practice settings. The source population will comprise of eligible patients across nine European nations. Included patients will contribute data from the start of eligible maribavir treatment to completion, discontinuation, end of study or death, whichever comes first. Data accrual will vary between countries, depending on their respective launch dates for maribavir.

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### **Comparators**

None

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### **Outcomes**

The primary outcome is to assess the number of participants with adverse events (AEs). The secondary outcomes will assess the number of participants with adverse events of special interest (AESIs).

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### **Data analysis plan**

The statistical analysis of the data will be primarily descriptive. Continuous variables will be described by the number of eligible participants, mean, standard deviation or standard error, median, first quartile, third quartile, and minimum and maximum values. Categorical variables will be described by the total number of participants and relative proportion per category.

## Data management

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### **Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

[Non-interventional study](#)

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

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## Data characterisation

## **Data characterisation conducted**

Unknown