Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Letermovir (new therapeutic indication: CMV disease, prophylaxis after kidney transplant, < 18 years, ≥ 40 kg)

of 6 November 2025

At their session on 6 November 2025, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. **In Annex XII, the following information shall be added after No. 5 to the information on the benefit assessment of Letermovir in the version of the resolution of 6 November 2025 on the therapeutic indication "CMV reactivation/ disease, prophylaxis after stem cell transplantation, < 18 years, ≥ 5 kg":**

Letermovir

Resolution of: 6 November 2025
Entry into force on: 6 November 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 25 April 2025):

PREVYMIS is indicated for prophylaxis of CMV disease in CMV-seronegative adult and paediatric patients weighing at least 40 kg who have received a kidney transplant from a CMV-seropositive donor [D+/R-].

Therapeutic indication of the resolution (resolution of 6 November 2025):

PREVYMIS is indicated for prophylaxis of CMV disease in CMV-seronegative paediatric patients weighing at least 40 kg who have received a kidney transplant from a CMV-seropositive donor [D+/R-].

1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy

CMV-seronegative recipients [R-] of a kidney transplant from CMV-seropositive donors [D+] aged 0 to < 18 years weighing at least 40 kg for whom prophylaxis of cytomegalovirus (CMV) disease is indicated

Appropriate comparator therapy:

– Ganciclovir or valganciclovir

Extent and probability of the additional benefit of letermovir compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

CMV-seronegative recipients [R-] of a kidney transplant from CMV-seropositive donors [D+] aged 0 to < 18 years weighing at least 40 kg for whom prophylaxis of cytomegalovirus (CMV) disease is indicated

No data available.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (25-68), unless otherwise indicated.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No data available.

Explanations:
↑: statistically significant and relevant positive effect with low/unclear reliability of data
↓: statistically significant and relevant negative effect with low/unclear reliability of data
↑↑: statistically significant and relevant positive effect with high reliability of data
↓↓: statistically significant and relevant negative effect with high reliability of data
↔: no statistically significant or relevant difference
∅: No data available.
n.a.: not assessable

2. Number of patients or demarcation of patient groups eligible for treatment

CMV-seronegative recipients [R-] of a kidney transplant from CMV-seropositive donors [D+] aged 0 to < 18 years weighing at least 40 kg for whom prophylaxis of cytomegalovirus (CMV) disease is indicated

Approx. 13 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Prevymis (active ingredient: letermovir) at the following publicly accessible link (last access: 22 September 2025):

https://www.ema.europa.eu/en/documents/product-information/prevymis-epar-product-information_en.pdf

Treatment with letermovir should only be initiated and monitored by doctors experienced in treating patients who have received an allogeneic haematopoietic stem cell transplant or kidney transplant.

4. Treatment costs

Annual treatment costs:

CMV-seronegative recipients [R-] of a kidney transplant from CMV-seropositive donors [D+] aged 0 to < 18 years weighing at least 40 kg for whom prophylaxis of cytomegalovirus (CMV) disease is indicated

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Letermovir	€ 33,602.17 - € 76,358.00
Appropriate comparator therapy:	
Ganciclovir	€ 8,107.40 - € 11,871.55
Valganciclovir	€ 3,378.68 - € 3,438.89

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 September 2025)

Costs for additionally required SHI services: not applicable

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Ganciclovir	Preparation of infusion solutions containing antibiotics and virustatics	€ 39.00	1	137 - 201	€ 5,343 - € 7,839

5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

CMV-seronegative recipients [R-] of a kidney transplant from CMV-seropositive donors [D+] aged 0 to < 18 years weighing at least 40 kg for whom prophylaxis of cytomegalovirus (CMV) disease is indicated

- No medicinal product with new active ingredients that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 6 November 2025.

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 6 November 2025

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken