Letermovir (prophylaxis of CMV disease after kidney transplantation, > 18 years)

Benefit assessment according to §35a SGB V[1]

EXTRACT

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[1] Translation of Sections I 1 to I 6 of the dossier assessment *Letermovir (CMV-Prophylaxe nach Nierentransplantation, < 18 Jahre) – Nutzenbewertung gemäß § 35a SGB V*. Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

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Medical and scientific advice

No advisor on medical and scientific questions was involved in the present dossier assessment.

Patient and family involvement

No patients or families were involved in the present dossier assessment.

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Part I: Benefit assessment

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[2] Table numbers start with “2” as numbering follows that of the full dossier assessment.

I List of abbreviations

Abbreviation	Meaning
ACT	appropriate comparator therapy
CMV	cytomegalovirus
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
RCT	randomized controlled trial
SGB	Sozialgesetzbuch (Social Code Book)

I 1 Executive summary of the benefit assessment

Background

In accordance with §35a Social Code Book V, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the benefit of the drug letermovir. The assessment is based on a dossier compiled by the pharmaceutical company (hereinafter referred to as the 'company'). The dossier was sent to IQWiG on 15 May 2025.

Research question

The aim of this report is to assess the added benefit of letermovir compared with ganciclovir or valganciclovir as the appropriate comparator therapy (ACT) for prophylaxis of cytomegalovirus (CMV) disease in CMV-seronegative paediatric patients with a body weight of at least 40 kg who have received a kidney transplant from a CMV-seropositive donor.

The research question shown in Table 2 was defined in accordance with the ACT specified by the G-BA.

Table 2: Research question for the benefit assessment of letermovir

Therapeutic indication	**ACT**[a]
Prophylaxis of CMV disease in CMV-seronegative paediatric patients with a body weight of at least 40 kg who have received a kidney transplant from a CMV-seropositive donor	ganciclovir or valganciclovir
a. Presented is the ACT specified by the G-BA. ACT: appropriate comparator therapy; CMV: cytomegalovirus; G-BA: Federal Joint Committee	

The company followed the specification of the ACT.

The assessment was conducted by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier. Randomized controlled trials (RCTs) were used for the derivation of the added benefit.

Results

Concurring with the company, the review of the completeness of the study pool did not identify any studies for the comparison of letermovir with the ACT in the given therapeutic indication. No data were therefore available for this assessment.

Results on added benefit

No data were available for the assessment of the added benefit of letermovir compared with the ACT for prophylaxis of CMV disease in CMV-seronegative paediatric patients with a body weight of at least 40 kg who have received a kidney transplant from a CMV-seropositive donor.

There is no hint of an added benefit of letermovir in comparison with the ACT; an added benefit is therefore not proven.

Probability and extent of added benefit, patient groups with therapeutically important added benefit[3]

Table 3 shows a summary of probability and extent of the added benefit of letermovir.

Table 3: Letermovir – probability and extent of added benefit

Therapeutic indication	**ACT[a]**	**Probability and extent of added benefit**
Prophylaxis of CMV disease in CMV-seronegative paediatric patients with a body weight of at least 40 kg who have received a kidney transplant from a CMV-seropositive donor	ganciclovir or valganciclovir	Added benefit not proven
a. Presented is the respective ACT specified by the G-BA. ACT: appropriate comparator therapy; CMV: cytomegalovirus; G-BA: Federal Joint Committee		

The G-BA decides on the added benefit.

[3] On the basis of the scientific data analysed, IQWiG draws conclusions on the (added) benefit or harm of an intervention for each patient-relevant outcome. Depending on the number of studies analysed, the certainty of their results, and the direction and statistical significance of treatment effects, conclusions on the probability of (added) benefit or harm are graded into 4 categories: (1) “proof”, (2) “indication”, (3) “hint”, or (4) none of the first 3 categories applies (i.e., no data available or conclusions 1 to 3 cannot be drawn from the available data). The extent of added benefit or harm is graded into 3 categories: (1) major, (2) considerable, (3) minor (in addition, 3 further categories may apply: non-quantifiable extent of added benefit, added benefit not proven, or less benefit). For further details see [1,2].

I 2 Research question

The aim of this report is to assess the added benefit of letermovir compared with ganciclovir or valganciclovir as the ACT for prophylaxis of CMV disease in CMV-seronegative paediatric patients with a body weight of at least 40 kg who have received a kidney transplant from a CMV-seropositive donor.

The research question shown in Table 4 was defined in accordance with the ACT specified by the G-BA.

Table 4: Research question for the benefit assessment of letermovir

Therapeutic indication	**ACT[a]**
Prophylaxis of CMV disease in CMV-seronegative paediatric patients with a body weight of at least 40 kg who have received a kidney transplant from a CMV-seropositive donor	ganciclovir or valganciclovir
a. Presented is the respective ACT specified by the G-BA. ACT: appropriate comparator therapy; CMV: cytomegalovirus; G-BA: Federal Joint Committee	

The company followed the specification of the ACT.

The assessment was conducted by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier. RCTs were used for the derivation of the added benefit. This concurred with the company's inclusion criteria.

I 3 Information retrieval and study pool

The study pool for the assessment was compiled on the basis of the following information:

Sources used by the company in the dossier:

- Study list on letermovir (status: 20 February 2025)
- Bibliographical literature search on letermovir (last search on 17 February 2025)
- Search of trial registries/trial results databases for studies on letermovir (last search on 17 February 2025)
- Search on the G-BA website for letermovir (last search on 17 February 2025)

To check the completeness of the study pool:

- Search of trial registries for studies on letermovir (last search on 26 May 2025); for search strategies, see I Appendix A of the full dossier assessment

Concurring with the company, the review of the completeness of the study pool did not identify any studies for the comparison of letermovir with the ACT in the given therapeutic indication. No data were therefore available for this assessment.

I 4 Results on added benefit

No data were available for the assessment of the added benefit of letermovir compared with the ACT for prophylaxis of CMV disease in CMV-seronegative paediatric patients with a body weight of at least 40 kg who have received a kidney transplant from a CMV-seropositive donor. There is no hint of an added benefit of letermovir in comparison with the ACT; an added benefit is therefore not proven.

I 5 Probability and extent of added benefit

Table 5 summarizes the result of the assessment of added benefit of letermovir in comparison with the ACT.

Table 5: Letermovir – probability and extent of added benefit

Therapeutic indication	**ACT[a]**	**Probability and extent of added benefit**
Prophylaxis of CMV disease in CMV-seronegative paediatric patients with a body weight of at least 40 kg who have received a kidney transplant from a CMV-seropositive donor	ganciclovir or valganciclovir	Added benefit not proven
a. Presented is the respective ACT specified by the G-BA. ACT: appropriate comparator therapy; CMV: cytomegalovirus; G-BA: Federal Joint Committee		

The assessment described above concurs with that by the company.

The G-BA decides on the added benefit.

I 6 References for English extract

Please see full dossier assessment for full reference list.

1. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Allgemeine Methoden; Version 7.0 [online]. 2023 [Accessed: 02.09.2024]. URL: https://www.iqwig.de/methoden/allgemeine-methoden_version-7-0.pdf.

2. Skipka G, Wieseler B, Kaiser T et al. Methodological approach to determine minor, considerable, and major treatment effects in the early benefit assessment of new drugs. Biom J 2016; 58(1): 43-58. https://doi.org/10.1002/bimj.201300274.

The full report (German version) is published under https://www.iqwig.de/en/projects/a25-68.html.