

ORIGINAL ARTICLE

Letemovir Prophylaxis in Pediatric Allogeneic Hematopoietic Stem Cell Transplantation: Clinical Effectiveness and Economic Implications

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ABSTRACT

Background: Cytomegalovirus (CMV) reactivation is a major infectious complication following pediatric allogeneic hematopoietic stem cell transplantation (HSCT), particularly in low- and middle-income countries (LMICs) with high CMV seroprevalence. Data on the clinical and economic impact of letermovir prophylaxis in pediatric HSCT recipients from resource-constrained settings remain limited.

Methods: We conducted a retrospective cost-effectiveness analysis of pediatric allogeneic HSCT recipients at a university-affiliated tertiary-care transplant center in India. Clinical outcomes and direct medical costs were compared between patients who received letermovir prophylaxis and those managed with a standard pre-emptive CMV strategy. The primary outcome was CMV reactivation by Day +100 post-transplant. Cost-effectiveness was evaluated using the incremental cost-effectiveness ratio (ICER).

Results: Fifty patients were included, of whom 15 received letermovir prophylaxis and 35 received standard pre-emptive management. By Day +100 post-transplant, CMV reactivation occurred in 26.7% of patients receiving letermovir compared with 91.4% in the non-letemovir group ($p < 0.001$). Median time to CMV reactivation was longer in the letermovir group at 28.5 days versus 18.0 days. No patient in the letermovir group required additional CMV-related hospitalization, whereas 50% of patients in the non-letemovir group required prolonged hospitalization. Mean total treatment costs were higher in the letermovir group at \$1868.5 compared with \$1698.6 in the non-letemovir group; however, the incremental cost-effectiveness ratio was \$262.6 per additional patient without CMV reactivation.

Conclusions: Despite higher upfront costs, letermovir demonstrated favorable cost-effectiveness in pediatric allogeneic HSCT recipients in resource-limited settings, while providing significant clinical benefits through reduced CMV reactivation, delayed breakthrough infection, and decreased CMV-related hospitalization.

Abbreviations: ATG, anti-thymocyte globulin; CMV, cytomegalovirus; DNA, deoxyribonucleic acid; GVHD, graft-versus-host disease; HSCT, hematopoietic stem cell transplantation; ICER, incremental cost-effectiveness ratio; IgG, immunoglobulin G; IQR, interquartile range; IU, international units; IVIg, intravenous immunoglobulin; LMICs, low- and middle-income countries; PCR, polymerase chain reaction; USD, United States Dollar.

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1 | Introduction

Cytomegalovirus (CMV) infection remains a major infectious complication following allogeneic hematopoietic stem cell transplantation (HSCT), contributing to increased morbidity, non-relapse mortality, and healthcare utilization. CMV reactivation occurs in 25%–40% of pediatric HSCT recipients, particularly among high-risk groups such as haploidentical and matched unrelated donor transplants [1–3]. The conventional pre-emptive strategy, based on serial viral load monitoring and treatment after detection of viremia, reduces overt CMV disease but requires intensive laboratory support and close surveillance. In resource-limited settings, delays in diagnosis and therapy may increase CMV-related complications and healthcare burden.

Letermovir, a CMV DNA terminase complex inhibitor, has emerged as an effective prophylactic agent, shifting CMV management from pre-emptive to preventive strategies. Randomized trials and pediatric real-world studies have demonstrated that letermovir significantly reduces clinically significant CMV infection with improved survival and lower toxicity compared to conventional antivirals [4–7]. However, its high acquisition cost limits widespread adoption, especially in low- and middle-income countries (LMICs). Although studies from high-income countries suggest that letermovir prophylaxis is cost-effective through reduced CMV complications, hospitalizations, and downstream healthcare utilization, evidence from LMICs remains scarce [8].

The need for effective CMV prevention is particularly relevant in India, where CMV seroprevalence among donors and recipients reaches 95%–97%, placing most pediatric HSCT recipients at risk of reactivation [1]. Indian studies report an overall CMV reactivation rate of approximately 25% following HSCT, with substantially higher rates among haploidentical HSCT recipients (54.5%). CMV reactivation has also been associated with increased all-cause mortality (39.9% vs. 19.6%) and a higher incidence of graft-versus-host disease (GVHD) [1]. Limited access to timely viral monitoring and second-line antivirals further amplifies the clinical and economic burden in LMIC settings. Additionally, letermovir became available in India only in February 2025, further limiting prior real-world and economic data in this setting. Given the high burden of CMV reactivation and limited real-world economic data from LMIC settings, this study aimed to evaluate the clinical efficacy and cost-effectiveness of letermovir prophylaxis compared with a conventional pre-emptive approach in pediatric allogeneic HSCT recipients in India.

2 | Patients and Methods

2.1 | Study Design

A retrospective cost-effectiveness analysis was conducted among pediatric patients (ages 0–18 years) undergoing allogeneic HSCT at a university-affiliated private academic tertiary-care teaching hospital in India.

2.2 | Study Population and Group Definitions

Patients were categorized into two groups based on letermovir use. The no-letermovir group included pediatric patients who underwent allogeneic HSCT between December 2021 and December 2025 and received acyclovir prophylaxis with routine CMV real-time Polymerase chain reaction (PCR) monitoring and pre-emptive antiviral therapy upon detection of viremia. The letermovir group included pediatric patients undergoing allogeneic HSCT from February 2025 onwards who received letermovir prophylaxis according to standard dosing recommendations [9].

2.3 | CMV Monitoring and Treatment Strategy

In both groups, CMV surveillance was performed using quantitative CMV real-time PCR at regular post-transplant intervals. In the no-letermovir group, a pre-emptive strategy was followed, with antiviral therapy (ganciclovir, valganciclovir, or cidofovir) initiated upon CMV viremia exceeding institutional thresholds. In the letermovir group, patients received letermovir prophylaxis during the high-risk period, while pre-emptive therapy was reserved for breakthrough CMV reactivation.

2.4 | Letermovir Prophylaxis Protocol

Letermovir was administered according to standard prescribing guidelines, including weight-based dosing in Pediatric patients and dose adjustments in the presence of concomitant cyclosporine [9]. Prophylaxis was initiated on Day +1 post-transplant period and continued through the period of highest risk for CMV reactivation (Day +100).

2.5 | Clinical Outcomes

The primary outcome of the study was CMV reactivation by Day +100 post-HSCT. As per institutional protocol, CMV viral loads <500 IU/mL were considered transient “blips” and were repeated within 7 days without initiation of therapy. CMV viral loads >500 IU/mL were considered clinically significant reactivation and were treated according to institutional CMV management protocols. Secondary outcomes included duration of hospital stay, requirements for antiviral therapy, and CMV-related complications.

2.6 | Costing Methodology

A micro-costing approach was employed to estimate direct medical costs from the institutional perspective, utilizing standardized, center-specific pricing (Table S1). Costs included antiviral therapy, letermovir prophylaxis, intravenous immunoglobulin (IVIg), administration consumables, CMV PCR monitoring, and hospitalization. Drug costs were based on institutional procurement prices, while hospitalization costs included general ward charges, nursing care, and physician consultation. To reflect real-world pediatric practice and minimize wastage, ganciclovir vials were shared for two doses in children weighing <25 kg,

and a single vial of cidofovir was utilized for two doses. The total cost per patient was calculated as the sum of drug, administration, laboratory, and hospitalization costs incurred during CMV prevention and management in the post-transplant period.

2.7 | Adverse Events

Treatment of CMV reactivation was associated with known drug toxicities, including cytopenia related to ganciclovir and valganciclovir, and nephrotoxicity associated with cidofovir. However, due to the retrospective nature of the study, costs related to the management of these adverse events could not be reliably quantified and were therefore not included in the cost analysis.

2.8 | Cost-Effectiveness Analysis

Effectiveness was defined as the proportion of patients without CMV reactivation, calculated as one minus the CMV reactivation rate. The incremental cost-effectiveness ratio (ICER) was calculated as the difference in mean cost between the letermovir and standard care groups divided by the difference in effectiveness between the two groups. All costs were converted to United States Dollars (USD) using an exchange rate of approximately ₹94.5 = 1 USD for international comparability.

3 | Results

3.1 | Study Population and Baseline Characteristics

A total of 50 pediatric patients undergoing allogeneic HSCT between December 2021 and December 2025 were included in the study, of whom 15 received letermovir prophylaxis and 35 were managed with a pre-emptive strategy prior to its availability. Baseline demographic, transplant, and CMV-related characteristics are summarized in Table 1. The mean age at transplant was comparable between groups (7.44 vs. 8.19 years), with a male predominance overall (62%). Hemoglobinopathies and acute leukemia were the most common indications for HSCT. Haploidentical transplantation was the predominant transplant type, particularly in the letermovir group (73.3% vs. 51.4%), indicating a relatively higher-risk transplant profile. Conditioning regimens and ATG use were similar across groups. Both donor and recipient CMV seropositivity rates were high (> 90%), consistent with the high CMV seroprevalence in the study population. Pre-transplant CMV viremia was infrequent (8%), and the median number of CMV real-time PCR tests was comparable between groups, suggesting similar surveillance intensity.

3.2 | Clinical Outcomes

3.2.1 | Primary Outcome: CMV Reactivation

By Day +100 post-transplant, CMV reactivation occurred in 36 of 50 patients (72%) and was significantly lower in the letermovir group compared with the non-letermovir group (26.7% vs. 91.4%;

$p < 0.001$). Among patients with reactivation, the median time to CMV reactivation was longer in the letermovir group (28.5 days [IQR 23.3–31.3] vs. 18.0 days [IQR 13.0–26.0]), suggesting delayed onset with prophylaxis (Figure 1).

Breakthrough CMV reactivation occurred in 4 of 15 patients receiving letermovir prophylaxis. These patients had additional high-risk features, including pre-transplant CMV viremia, graft-versus-host disease (GVHD), and intensified immunosuppression with corticosteroids and ruxolitinib (Table S2). Peak CMV viral load among patients with reactivation was comparable between groups (median 3.55 vs. 2.85×10^3 IU/mL), indicating that letermovir primarily reduced the incidence rather than the severity of breakthrough viremia.

3.2.2 | Secondary Outcomes: Hospitalization, Survival, and Adverse Events

Among patients with CMV reactivation, 50% of those in the non-letermovir group required hospitalization, with a median hospital stay of 15 days, whereas none in the letermovir group required additional CMV-related hospitalization. Overall Day +100 survival was 86%, with comparable survival between the letermovir and non-letermovir groups (86.7% vs. 85.7%). Among patients treated with ganciclovir and/or valganciclovir for CMV reactivation, 47.2% developed cytopenias and 16.6% experienced nephrotoxicity requiring modification of concomitant medications, including calcineurin inhibitors.

3.3 | Cost and Cost-Effectiveness Analysis

The median total cost of CMV management was higher in the letermovir group than in the non-letermovir group, \$1647.2 vs. \$1290.4, with corresponding mean costs of \$1868.5 and \$1698.6, respectively. Cost differences varied according to transplant type. Among haploidentical transplant recipients, overall costs were comparable between groups, whereas in matched unrelated donor transplants, costs were higher in the non-letermovir group (\$2738.0). In contrast, matched related donor transplant recipients had lower overall costs with the pre-emptive strategy (\$966.6).

Effectiveness, defined as the proportion of patients without CMV reactivation, was markedly higher with letermovir prophylaxis compared with the pre-emptive approach (73.3% vs. 8.6%), corresponding to an absolute risk reduction of 64.7%. The incremental cost-effectiveness ratio (ICER) was \$262.6 per additional patient without CMV reactivation, indicating a modest incremental cost for substantial clinical benefit. Detailed clinical outcomes, cost analysis, and cost-effectiveness measures are summarized in Table 2.

4 | Discussion

CMV remains a major complication after allogeneic HSCT, especially in India and other LMICs where CMV seroprevalence among donors and recipients is extremely high. In this retrospective cost-effectiveness analysis of pediatric allogeneic HSCT

TABLE 1 | Baseline characteristics and transplant details.

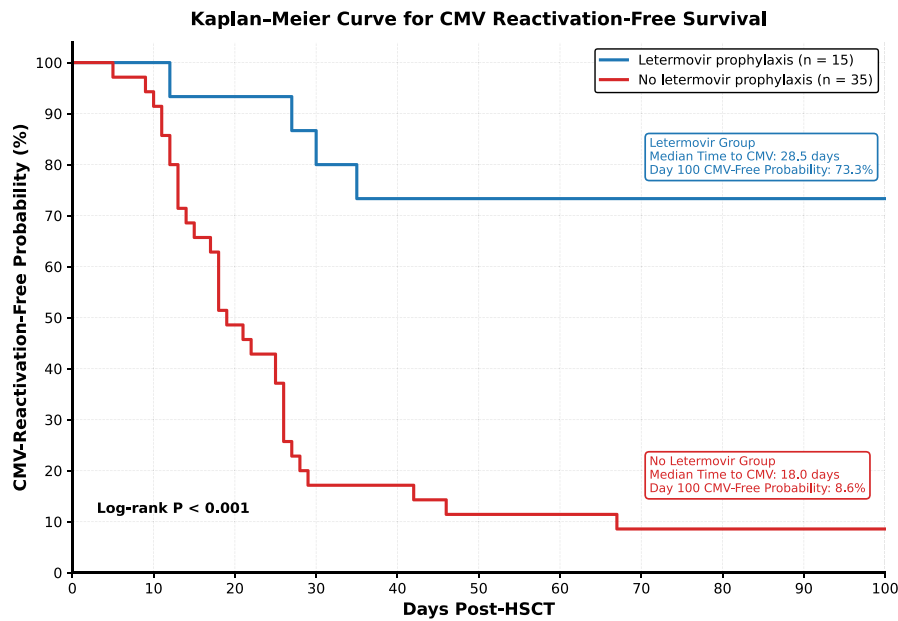
	Overall	Letermovir (<i>n</i> = 15)	No letermovir (<i>n</i> = 35)	<i>p</i>
Variable				
Age (years), mean $\pm$ SD	7.97 $\pm$ 4.63	7.44 $\pm$ 4.47	8.19 $\pm$ 4.74	0.604
Sex				
Male	31 (62%)	11 (73.3%)	20 (57.1%)	0.351
Female	19 (38%)	4 (26.7%)	15 (42.9%)	
Diagnosis				
Hemoglobinopathies	17 (34%)	4 (26.7%)	13 (37.1%)	0.507
Acute leukemia	15 (30%)	6 (40%)	9 (25.7%)	
Bone marrow failure	12 (24%)	4 (26.7%)	8 (22.9%)	
Primary immunodeficiency	4 (8%)	0	4 (11.4%)	
Other	2 (4%)	1 (6.7%)	1 (2.9%)	
Transplant type				
Haploidentical	29 (58%)	11 (73.3%)	18 (51.4%)	0.017
MRD/MSD	16 (32%)	1 (6.7%)	15 (42.9%)	
MUD	5 (10%)	3 (20%)	2 (5.7%)	
Conditioning regimen				
MAC	29 (58%)	8 (53.3%)	21 (60%)	0.319
RTC	16 (32%)	4 (26.7%)	12 (34.3%)	
RIC	5 (10%)	3 (20%)	2 (5.7%)	
Other clinical variables				
ATG use (yes/no)				
Yes	45 (90%)	14 (93.3%)	31 (88.6%)	1.000
No	5 (10%)	1 (6.7%)	4 (11.4%)	
Donor CMV IgG positivity (yes/no)				
Yes	47 (94%)	12 (80%)	35 (100%)	0.023
No	3 (6%)	3 (20%)	0 (0)	
Recipient CMV IgG positivity (yes/no)				
Yes	48 (96%)	13 (86.7%)	35 (100%)	0.086
No	2 (4%)	2 (13.3%)	0 (0)	
Pre-HSCT CMV (yes/no)				
Yes	4 (8%)	1 (6.7%)	3 (8.6%)	1.000
No	46 (92%)	14 (93.3%)	32 (91.4%)	
CMV tests, median (IQR)	11 (9–12)	11 (9–11)	10 (8–11.5)	0.516

Abbreviations: ATG, anti-thymocyte globulin; CMV, cytomegalovirus; HSCT, hematopoietic stem cell transplantation; IgG, immunoglobulin G; IQR, interquartile range; MAC, myeloablative conditioning; MRD, matched related donor; MSD, matched sibling donor; MUD, matched unrelated donor; RIC, reduced intensity conditioning; RTC, reduced toxicity conditioning; SD, standard deviation.

recipients from a resource-constrained setting, letermovir prophylaxis was associated with significantly lower CMV reactivation, delayed breakthrough infection, and reduced CMV-related hospitalization compared with a conventional pre-emptive strategy. Despite higher upfront drug costs, the reduction in CMV

burden resulted in favorable cost-effectiveness, particularly among higher-risk transplant recipients.

Consistent with previous Indian studies, donor and recipient CMV IgG positivity in our cohort exceeded 90%, reflecting



Kaplan Meier estimates of CMV-reactivation-free survival through Day +100 following HSCT.

FIGURE 1 | Kaplan–Meier curve for CMV reactivation-free survival. Kaplan–Meier analysis demonstrated significantly higher CMV reactivation-free survival in the letemovir group throughout the first 100 days post-HSCT. The estimated Day +100 CMV reactivation-free probability was 73.3% in the letemovir group compared to 8.6% in the non-letemovir group, indicating delayed and reduced CMV reactivation with prophylaxis. Survival distributions were compared using the log-rank test ($p < 0.001$).

TABLE 2 | Clinical outcomes, cost analysis, and cost-effectiveness (USD conversion calculated at an exchange rate of approximately ₹94.5 = 1 USD).

Variable	Letermovir (n = 15)	No letermovir (n = 35)	Overall	p
Primary outcome				
CMV reactivation, n (%)	4 (26.7%)	32 (91.4%)	36 (72%)	< 0.001
Time to CMV (days), median (IQR) ^a	28.5 (23.3–31.3)	18.0 (13.0–26.0)	20 (13–27)	0.190
Peak CMV viral load, median (IU/mL) (IQR) ^a	3.55 × 10 ³ (1.75–5.48)	2.85 × 10 ³ (0.98–10.5)	2.85 × 10 ³ (0.98–9.25)	0.790
Secondary outcomes				
Additional CMV hospitalization ^a				
Yes	0 (0)	16 (50%)	16 (55.6%)	0.113
No	4 (100%)	16 (50%)	20 (44.4%)	
Day + 100 survival				
Alive	13 (86.7%)	30 (85.7%)	43 (86%)	1.000
Dead	2 (13.3%)	5 (14.3%)	7 (14%)	
Cost analysis				
Median cost	\$1647.2 (₹155 660)	\$1290.4 (₹121 939)	—	0.122
Mean cost	\$1868.5 ± 648.0 (₹176 572 ± 61 232)	\$1698.6 ± 1426.9 (₹160 515 ± 134 750)	—	
Cost by transplant type (median cost)				
Haploidentical	\$1647.2 (₹155 660)	\$1700.6 (₹160 706)	—	—
MRD/MSD	\$1647.2 (₹155 660)	\$966.6 (₹91 341)	—	—
MUD	\$1886.6 (₹178 288)	\$2738.0 (₹258 744)	—	—

Note: Prices are presented in US Dollars (\$) and Indian Rupees (₹).

Abbreviations: CMV, cytomegalovirus; IQR, interquartile range; MRD, matched related donor; MSD, matched sibling donor; MUD, matched unrelated donor.

^aRestricted to patients with CMV reactivation (n = 36).

the substantial baseline risk for CMV reactivation in pediatric HSCT recipients [1, 3]. The high CMV reactivation rate in the non-letermovir group (91.4%) likely reflects our predominantly high-risk haploidentical HSCT cohort, intensive CMV surveillance, and lower treatment threshold compared with previous Indian studies [1]. In contrast, letermovir prophylaxis reduced CMV reactivation to 26.7%, corresponding to an absolute risk reduction of 64.7%. These findings align with the pivotal randomized trial by Marty et al. [6] and subsequent pediatric real-world studies demonstrating reduced clinically significant CMV infection with letermovir prophylaxis [2, 4, 5, 7, 10]. Previous studies have also reported breakthrough CMV reactivation rates ranging from approximately 10%–30% despite letermovir prophylaxis, particularly among patients with severe GVHD and intensified immunosuppression [4, 5, 7, 10, 11]. Consistent with these observations, breakthrough CMV reactivation in our cohort occurred predominantly in patients with additional high-risk features and augmented immunosuppression [10, 11].

Letermovir prophylaxis not only reduced CMV reactivation but also delayed breakthrough infection compared with the non-letermovir group, suggesting effective viral suppression during the highest-risk post-transplant period. Additionally, none of the patients receiving letermovir required CMV-related hospitalization, whereas half of the patients in the standard prophylaxis group required prolonged hospitalization, highlighting its potential to reduce the financial and logistical burden on families and healthcare systems in LMIC settings.

Despite superior clinical efficacy, letermovir prophylaxis was associated with higher overall direct medical costs. However, the incremental increase in cost was relatively modest compared with the substantial reduction in CMV reactivation. The ICER of \$262.6 per additional patient without CMV reactivation suggests that letermovir may represent a clinically valuable and economically reasonable intervention in high-risk pediatric HSCT populations. Importantly, stratified analysis demonstrated that in matched unrelated donor transplants, overall costs were substantially higher in the non-letermovir group, indicating that prophylaxis may offer greater economic benefit in higher-risk transplant settings.

Our findings are broadly consistent with prior pharmaco-economic studies from high-income countries, which demonstrated that letermovir prophylaxis reduces downstream healthcare utilization and may be cost-effective despite higher upfront drug costs [8, 12, 13]. However, economic data from LMICs remain scarce, and cost structures differ substantially from those in high-income settings. In India, where healthcare expenditure is frequently out-of-pocket and access to intensive monitoring or second-line antivirals may be limited, prevention of CMV reactivation may have even greater clinical and economic relevance.

This study has several limitations, including its retrospective single-center design and relatively small sample size, which may limit generalizability. The letermovir cohort also included a higher proportion of high-risk transplants, potentially biasing against the prophylaxis group despite lower CMV reactivation rates. In addition, the economic analysis likely underestimated the true financial burden of CMV reactivation, as hospitalization

costs were based on the minimum general ward charges at our teaching hospital, which are considerably lower than those reported in many high-income countries and do not reflect the isolation or private-room care often required for pediatric HSCT recipients and did not include costs related to the management of drug-related toxicities. Nevertheless, this study represents one of the earliest real-world pediatric cost-effectiveness analyses of letermovir prophylaxis from an LMIC setting following its recent introduction in India.

In conclusion, letermovir prophylaxis significantly reduced CMV reactivation and CMV-related hospitalization in pediatric allogeneic HSCT recipients in a high-seroprevalence LMIC setting. Despite higher upfront costs, it demonstrated favorable cost-effectiveness by reducing CMV-related morbidity and healthcare utilization, particularly in higher-risk transplants. These findings support letermovir as a promising preventive CMV strategy in resource-constrained settings such as India. Larger prospective multicenter studies with longer follow-up are needed to evaluate long-term clinical and economic outcomes and to assess whether CMV surveillance intensity can be safely reduced in selected low-risk patients receiving letermovir prophylaxis.

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Ethics Statement

This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and its later amendments. The study protocol was reviewed and approved by the Institutional Ethics Committee/Institutional Review Board of Kasturba Medical College and Kasturba Hospital Institutional Ethics Committee, Manipal, India (Approval No.: IEC1:108/2026).

Consent

Given the retrospective nature of the study, the requirement for informed consent was waived by the Ethics Committee. Patient confidentiality was strictly maintained, and all data were anonymized prior to analysis.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support this study are available from the corresponding author upon reasonable request.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Table S1:** Unit costs included in the micro-costing analysis. **Table S2:** Characteristics of patients with CMV reactivation in letermovir prophylaxis group.