LETERMOVIR PO

Generic	Brand	HICL	GCN	Exception/Other
LETERMOVIR	PREVYMIS		44049 44061	

GUIDELINES FOR USE

1. Is the patient undergoing an allogeneic hematopoietic stem cell transplant (HSCT) and meet **ALL** of the following criteria?
   - The patient is at least 18 years of age or older
   - The patient is CMV-seropositive [R+]
   - Prevymis will be used for prophylaxis of cytomegalovirus (CMV) infection and disease
   - Prevymis will be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment)
   - Patient is not receiving the medication beyond 100 days post-transplantation

   If yes, **approve for 98 days (14 weeks) by GPID for all daily dosage strengths with the following quantity limits:**
   - **240mg tablets (GPID 44049): #1 tablet per day. AND**
   - **480mg tablets (GPID 44061): #1 tablet per day.**

   If no, do not approve.
   DENIAL TEXT: The guideline named **LETERMOVIR PO (Prevymis)** requires the patient to be undergoing an allogeneic hematopoietic stem cell transplant (HSCT). In addition, the following criteria must also be met:
   - The patient is at least 18 years of age or older
   - The patient is CMV-seropositive [R+]
   - Prevymis will be used for prophylaxis of cytomegalovirus (CMV) infection and disease
   - Prevymis will be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment)
   - Patient is not receiving the medication beyond 100 days post-transplantation

RATIONALE
Promote appropriate utilization of **LETERMOVIR** based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS
Prevymis is indicated for prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).

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FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

The recommended dosage of Prevymis is 480 mg administered orally or intravenously once daily. Prevymis is recommended to be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment), and continue through Day 100 post-transplantation. Dosage of Prevymis should be decreased to 240mg once daily when co-administered with cyclosporine.

- If cyclosporine is initiated after starting Prevymis, the next dose of Prevymis should be decreased to 240mg once daily.
- If cyclosporine is discontinued after starting Prevymis, the next dose of Prevymis should be increased to 480mg once daily.
- If cyclosporine dosing is interrupted due to high cyclosporine levels, no dose adjustment of Prevymis is needed.

Prevymis injection, which contains hydroxypropyl betadex, should be used only in patients unable to take oral therapy. Patients should be switched to oral Prevymis as soon as they are able to take oral medications. Prevymis tablet and injection may be used interchangeably at the discretion of the physician, and no dosage adjustment is necessary when switching formulations.

AVAILABLE STRENGTHS

Tablet: 240mg, 480mg tablets; Injection: 240mg/12 mL (20mg/mL), 480mg/24mL (20mg/mL) single dose vials

REFERENCES

- Prevymis [Prescribing Information]. Merck & Co, Inc.; Whitehouse Station, NJ. November 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/18
Created: 02/18
Client Approval: 03/18
P&T Approval: 01/18