Geisinger

# POLICIES AND PROCEDURE MANUAL

**Policy: MBP 177.0**

**Section: Medical Benefit Pharmaceutical Policy**

**Subject: Prevymis IV (letermovir)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | X |
| Medicare | X | ACA | X |
| CHIP | X | | |

**I. Policy:**
Prevymis IV (letermovir)

**II. Purpose/Objective:**
To provide a policy of coverage regarding Prevymis IV (letermovir)

**III. Responsibility:**
A. Medical Directors
B. Medical Management
C. Pharmacy Department

**IV. Required Definitions**
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

**V. Additional Definitions**
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

**Medicaid Business Segment**
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

**DESCRIPTION:**
Prevymis IV (letermovir) is an antiviral agent that inhibits cytomegalovirus (CMV) replication by targeting the CMV DNA terminase complex (pUL51, pUL56, pUL89), which is required for viral DNA processing and packaging. Letermovir affects production of genome unit lengths and alters virion maturation.

**CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee**

**GRANDFATHER PROVISION** – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Prevymis IV (letermovir) will be considered medically necessary for Commercial, Exchange, CHIP, and Medicaid lines of business when ALL of the following criteria are met:

**Stem Cell Transplant**
- Prescription written by or in consultation with a hematologist/oncologist, infectious disease, or transplant specialist **AND**
- Medical record documentation of age greater than or equal to 6 months of age and older and weighing at least 6 kg **AND**
- Medical record documentation that the member is a recipient of an allogeneic hematopoietic stem cell transplant **AND**
- Medical record documentation that the member is a confirmed CMV seropositive recipient (R+) **AND**
- Medical record documentation that Prevymis is being used for CMV prophylaxis **AND**
- Medical record documentation that Prevymis is being initiated between Day 0 and Day 28 post-transplantation **AND**
- Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine) **AND**
- Medical record documentation of intolerance to or contraindication to Prevymis tablets or pellet pak based on age and weight.

**OR**

**Kidney Transplant**
- Medical record documentation that Prevymis is prescribed by or in consultation with a transplant or infectious disease specialist **AND**
- Medical record documentation of age greater than or equal to 12 years of age and older AND weighing at least 40 kg **AND**
- Medical record documentation that member is a recipient of a kidney transplant **AND**
- Medical record documentation that member is at high risk of CMV [defined as CMV seropositive donor and CMV seronegative recipient (D+/R-)] **AND**
- Medical record documentation that Prevymis is being used for cytomegalovirus (CMV) prophylaxis **AND**
- Medical record documentation that Prevymis is being initiated between Day 0 and Day 7 post-transplantation **AND**
- Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine) **AND**
- Medical record documentation of intolerance to or contraindication to Prevymis tablets or pellet pak based on age and weight

**AUTHORIZATION DURATION:**

- **Stem Cell Transplant:** If approved, a one-time authorization for 100 days with a maximum of 100 doses will apply.
- **Kidney Transplant:** If approved, a one-time authorization for 200 days with a maximum of 200 doses will apply.

**QUANTITY LIMIT**:

- **Stem Cell Transplant:** 100 doses per 100 days
- **Kidney Transplant:** 200 doses per 200 days

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

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Prevymis IV (letermovir) will be considered medically necessary for the Medicare line of business when ALL of the following criteria are met:

**Stem Cell Transplant**

- Prescription written by or in consultation with a hematologist/oncologist, infectious disease, or transplant specialist **AND**
- Medical record documentation of age greater than or equal to 6 months of age and older and weighing at least 6 kg **AND**
- Medical record documentation that the member is a recipient of an allogeneic hematopoietic stem cell transplant **AND**
- Medical record documentation that the member is a confirmed CMV seropositive recipient (R+) **AND**
- Medical record documentation that Prevymis is being used for CMV prophylaxis **AND**
- Medical record documentation that Prevymis is being initiated between Day 0 and Day 28 post-transplantation **AND**
- Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine)

**OR**

**Kidney Transplant**

- Medical record documentation that Prevymis is prescribed by or in consultation with a transplant or infectious disease specialist **AND**
- Medical record documentation of age greater than or equal to 12 years of age and older AND weighing at least 40 kg **AND**
- Medical record documentation that member is a recipient of a kidney transplant **AND**
- Medical record documentation that member is at high risk of CMV [defined as CMV seropositive donor and CMV seronegative recipient (D+/R-)] **AND**
- Medical record documentation that Prevymis is being used for cytomegalovirus (CMV) prophylaxis **AND**
- Medical record documentation that Prevymis is being initiated between Day 0 and Day 7 post-transplantation **AND**
- Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine).

**AUTHORIZATION DURATION:**

- **Stem Cell Transplant:** If approved, a one-time authorization for 100 days with a maximum of 100 doses will apply.
- **Kidney Transplant:** If approved, a one-time authorization for 200 days with a maximum of 200 doses will apply.

**QUANTITY LIMIT**:

- **Stem Cell Transplant:** 100 doses per 100 days
- **Kidney Transplant:** 200 doses per 200 days

**LINE OF BUSINESS:**
**Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.**

**REFERENCES**


1. Prevymis [prescribing information]. Rahway, NJ: Merck Sharp & Dohme LLC; January 2025.


This policy will be revised as necessary and reviewed no less than annually**.**

**Devised:** 5/15/18

**Revised:** 12/17/22 (LOB carve out, Medicaid PARP statement), 11/21/23 (added kidney transplant Medicaid business segment), 5/15/24 (ID specialist for kidney transplant per PARP, references), 2/19/25 (updated age, pellet pak, LOB table, taglines)

**Reviewed:** 4/22/19, 1/1/20, 1/1/21, 12/17/21

**MA UM Committee Approval:** 12/31/23, 12/31/24, 4/29/25

**DHS PARP approval**: 4/24/25