CMV Oral Quantity Limit Program Summary

This program applies to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
12/1/2023	7/1/2022

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
LIVTENCITY® (maribavir) Tablets	Treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet		2
PREVYMIS® (letermovir) Tablets	Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients (R+) of an allogeneic hematopoietic stem cell transplant (HSCT) Prophylaxis of CMV disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

REFERENCES

Number	Reference
1	PREVYMIS prescribing information. Merck Sharp & Dohme LLC. August 2023.
2	LIVTENCITY prescribing information. Takeda Pharmaceuticals America, Inc. April 2023.

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Livtencity	Maribavir Tab	200 MG	120	Tablets	30	DAYS			
Prevymis	letermovir tab	240 MG ; 480 MG	200	Tablets	365	DAYS	Quantity limit is cumulative at GPI 12		

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Livtencity	Maribavir Tab	200 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Prevymis	letermovir tab	240 MG ; 480 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Livtencity	**Quantity limit for Livtencity** will be approved for an increased quantity when **ALL** of the following are met: 1. The patient has a post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet **AND** 2. The patient will NOT be using the requested agent in combination with ganciclovir and/or valganciclovir for the requested indication **AND** 3. The prescriber has provided information in support of therapy with a higher dose and/or and increased quantity for the requested indication **Length of Approval:** 12 months
Prevymis	**Quantity limit for Prevymis** will be approved for an increased quantity and/or an extended duration when **BOTH** of the following are met: 1. ONE of the following: A. The patient has had an additional allogeneic hematopoietic stem cell transplant (HSCT) and requires initiation of PREVYMIS **OR** B. The patient has had an additional kidney transplant and is at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]) and requires initiation of PREVYMIS **OR** C. The prescriber has provided information in support of therapy with a higher dose and/or a longer duration for the requested indication **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** Additional transplant: 200 tablets/365 days Higher quantity/longer duration: Approve quantity requested/365 days