DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Infectious Disease – Livtencity Drug Quantity Management Policy – Per Days
- Livtencity™ (maribavir tablets – Takeda)

REVIEW DATE: 11/12/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Livtencity, an antiviral, is indicated for the treatment of adult and pediatric patients (≥ 12 years of age and weighing ≥ 35 kg) with **post-transplant cytomegalovirus (CMV) infection/disease** that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir, or foscarnet.[1]

Dosing

The recommended dose of Livtencity is 400 mg (two 200 mg tablets) taken twice daily (BID) with or without food.[1] The dose of Livtencity should be increased to 800 mg BID in patients who are also taking carbamazepine; and to 1,200 mg BID in patients who are also taking phenytoin or phenobarbital. In the pivotal study (SOLSTICE), patients were treated with Livtencity (or another medication) for up to 8 weeks. However, in clinical practice, CMV treatment does not follow a fixed duration and is usually continued until resolution of CMV DNAemia on 1 or 2

consecutive weekly CMV polymerase chain reactions (PCRs).[2] Furthermore, resistant and refractory CMV infections can occur; resistant CMV infection is defined as detection of a known viral genetic mutation(s) that decrease susceptibility to one or more anti-CMV medications, whereas refractory CMV is characterized by persistent signs and symptoms of CMV disease or persistent CMV DNAemia.[3] Finally, some patients may experience disease relapse. Refractory or relapsed CMV disease may all warrant treatment past 8 weeks. Monitoring CMV viral load is important for identifying cure or the emergence of possible resistance. CMV viral loads are often drawn at weekly intervals.

Availability

Livtencity is available as 200 mg tablets, in bottles of 28 or 56 tablets.[1]

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Livtencity. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year, unless otherwise noted below.

Drug Quantity Limit

Product	Strength	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity per 84 Days
Livtencity™ (maribavir tablets)	200 mg tablets	112 tablets*	336 tablets*

* This is enough drug to allow for two 200 mg tablets twice daily for 28 days at retail or 84 days at home delivery.

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

1. If a patient is taking carbamazepine concomitantly with Livtencity, approve 224 tablets per 28 days at retail or 672 tablets per 84 days at home delivery.

2. If a patient is taking phenytoin or phenobarbital concomitantly with Livtencity, approve 336 tablets per 28 days at retail or 1,008 tablets per 84 days at home delivery.

REFERENCES

1. Livtencity™ tablets [prescribing information]. Lexington, MA: Takeda: March 2024.
2. Kotton CN, Kumar D, Manuel O, et al. The fourth international consensus guidelines on the management of cytomegalovirus in solid organ transplantation. *Transplantation* 2025; 1-45.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/13/2023
Annual Revision	No criteria changes.	12/13/2024
Annual Revision	Policy statement was modified to "All approvals are provided for 1 year, unless otherwise noted below." Previously, All approvals are provided for 8 weeks, unless otherwise noted below. **Livtencity 200 mg tablets:** • Quantity limits was changed from 224 tablets per 56 days at home delivery to 336 tablets per 84 days at home delivery. • Override criteria was changed to approve 224 tablets per 28 days at retail or 672 tablets per 84 days at home delivery, if a patient is taking carbamazepine concomitantly with Livtencity. Previously, the criteria approved 224 tablets per 28 days for up to 8 weeks (56 days) at retail or a one-time override for 448 tablets as a 56-day supply at home delivery. • Override criteria was changed to approve 336 tablets per 28 days at retail or 1,008 tablets per 84 days at home delivery, if a patient is taking phenytoin or phenobarbital concomitantly with Livtencity. Previously, the criteria approved 336 tablets per 28 days for up to 8 weeks (56 days) at retail or a one-time override for 672 tablets as a 56-day supply at home delivery.	11/12/2025