DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Somatostatin Analogs – Mycapssa Drug Quantity Management Policy – Per Days
- Mycapssa® (octreotide delayed-release capsules – Chiasma)

REVIEW DATE: 02/06/2025

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

Mycapssa, a somatostatin analog, is indicated for long-term maintenance treatment in **acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide**.[1]

Dosing

The initial recommended dose of Mycapssa is 20 mg administered twice daily (BID).[1] The dose of Mycapssa is then titrated based on insulin-like growth factor 1 (IGF-1) levels and the patient's signs and symptoms of acromegaly. The dose can then be increased in increments of 20 mg daily. For doses of 60 mg daily, Mycapssa should be administered as 40 mg in the morning and 20 mg in the evening. For doses of 80 mg daily, administer Mycapssa as 40 mg BID. The maximum recommended dose of Mycapssa is 80 mg per day.

Availability
Mycapssa is supplied as 20 mg delayed release capsules in wallets containing 28 capsules each.[1]

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

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity per 84 days
Mycapssa® (octreotide delayed-release capsules)	20 mg capsules (28 capsules per wallet)	56 capsules (2 wallets)	168 capsules (6 wallets)

***Somatostatin Analogs – Mycapssa Drug Quantity Management Policy – Per Days* product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.**

CRITERIA
1. If the patient requires a dose of 60 mg per day, approve 84 capsules per 28 days at retail or 252 capsules per 84 days at home delivery.

2. If the patient requires a dose of 80 mg per day, approve 112 capsules per 28 days at retail or 336 capsules per 84 days at home delivery.

REFERENCES
1. Mycapssa® delayed-release capsules [prescribing information]. Needham, MA: Chiasma; July 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	01/18/2023
Annual Revision	No criteria changes.	01/24/2024
Annual Revision	Override criteria were updated to remove the language to "approve the requested quantity, not to exceed". Criteria now approves the amount needed for the dose outlined in the criteria for 28-day supply at retail and an 84-day supply at home delivery.	02/06/2025