Drug Quantity Management – Per Days
Multiple Sclerosis – Kesimpta® (ofatumumab subcutaneous injection)

Table of Contents

Product Identifier(s)

Effective 1/1/23 to 4/11/23: 110155

Effective 4/12/23: 94453

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. 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.

National Formulary Medical Necessity

This Drug Quantity Management program has been developed to manage potential premature dose escalation of Kesimpta. 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 the duration noted below.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per 28 Days
Kesimpta® (ofatumumab subcutaneous injection)	20 mg/0.4 mL Sensoready pen	1 pen*

* This is a quantity sufficient for a 28-day supply at a dose of 20 mg once every 4 weeks.

Cigna covers quantities as medically necessary when the following criteria are met:

1. If the individual is initiating treatment or requires additional induction dosing, approve a one-time override of four 20 mg Sensoready pens.
   Note: This would provide for Week 0, 1, 2, and 4 induction doses.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview
Kesimpta, a CD20-directed cytolytic antibody, is indicated for the treatment of relapsing forms of **multiple sclerosis** (MS) to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive MS in adults.[1]

Dosing
The recommended dose of Kesimpta is an initial dose of 20 mg by subcutaneous (SC) injection at Week 0, 1, and 2, followed by subsequent doses of 20 mg SC once monthly starting at Week 4.[1]

Availability
Kesimpta is available as a 20 mg/0.4 mL single-dose prefilled Sensoready pen and a 20 mg/0.4 mL single-dose prefilled syringe.[1] The prefilled syringe is not on the market and therefore, is not currently targeted in this policy.

References

1. Kesimpta® subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis; August 2020.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	Kesimpta 20 mg/0.4 mL prefilled syringes removed from the policy as they are not on the market.	06/02/2022