DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Multiple Sclerosis – Kesimpta Drug Quantity Management Policy – Per Days
- Kesimpta® (ofatumumab subcutaneous injection – Novartis)

REVIEW DATE: 06/02/2022

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.

POLICY STATEMENT
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.

Automation: None.

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.

CRITERIA

1. If the patient 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.

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