

DRUG QUANTITY MANAGEMENT POLICY - PER DAYS

POLICY:	Apomorphine Duration Limit
DRUGS AFFECTED:	Kynmobi™ (apomorphine sublingual film – Sunovion Pharmaceuticals, Inc.) Apokyn® (apomorphine subcutaneous injection – US WorldMeds, LLC)
DATE REVIEWED:	08/26/2020
Apokyn 30 mg/3 ml pen injector	Maximum quantity per 30 days = 30 pen injectors
Kynmobi 10, 15, 20, 25, 30 mg sublingual film	Maximum quantity per 30 days = 150 films
Kynmobi Titration Kit	Maximum quantity per 365 days = 1 kit (10 films)

OVERVIEW

Apokyn and Kynmobi are non-ergoline dopamine agonists indicated for the acute, intermittent treatment of "off" episodes associated with Parkinson's disease.¹⁻²

DOSING

Because of the high incidence of nausea and vomiting with Apokyn and Kynmobi when administered at recommended doses, an antiemetic (e.g., trimethobenzamide 300 mg three times a day), beginning 3 days prior to the initial dose of either medication, is recommended. Dose initiation should be supervised by a healthcare provider and titrated on the basis of effectiveness and tolerance, up to a maximum recommended dose. Treatment with the antiemetic should only be continued as long as necessary to control nausea and vomiting, and generally no longer than two months after initiation of treatment.

The dose range for Kynmobi is 10 mg to 30 mg per dose, administered sublingually. Doses should be separated by at least 2 hours. If a single dose is ineffective for a particular "off" episode, a second dose should not be given for that "off" episode. The efficacy or safety of administering a second dose for a single "off" episode has not been studied. Do not administer more than 5 doses per day. The maximum single dose of is 30 mg.

The recommended starting dose of Apokyn is 0.2 mL (2 mg). There is no evidence from controlled trials that doses greater than 0.6 mL (6 mg) gave an increased effect and therefore, individual doses above 0.6 mL (6 mg) are not recommended. There is limited experience with single doses greater than 0.6 mL (6 mg), dosing more than 5 times per day.

A quantity of 30 Apokyn pen injectors per 30 days will be covered without prior authorization. This is enough drug for 30 days of therapy at maximum approved doses. A quantity of 150 Kynmobi 10, 15, 20, 25, 25 or 30 mg films per 30 days will be covered without prior authorization. This is enough drug for 30 days of therapy at maximum approved doses. For coverage of additional quantities of Kynmobi Titration Kits, a coverage review is required. The objective of this program is to prevent stockpiling, misuse and/or overuse while providing a sufficient quantity for the approved indication.

CRITERIA

Kynmobi Titration Pack

1. For patients who need to undergo additional titration in a 365-day period, a one-time override of 1 kit (10 films) maybe approved.

Apokyn 30 mg/3 ml pen injector, Kynmobi 10, 15, 20, 25, 30 mg sublingual films

Additional quantities are not recommended.

REFERENCES

1. Apokyn® [prescribing information]. Louisville, KY: US WorldMeds, LLC; April 2020.
2. Kynmobi™ [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; May 2020.

HISTORY

Type of Revision	Summary of Changes	Date
New policy	Reviewed and approved at TAC	08/26/2020