

DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

- POLICY:** Gonadotropin-Releasing Hormone Antagonists – Orilissa Drug Quantity Management Policy – Per Days
- Orilissa™ (elagolix tablets – AbbVie)

REVIEW DATE: 05/25/2022

OVERVIEW

Orilissa, an oral gonadotropin-releasing hormone (GnRH) receptor antagonist, is indicated for the management of moderate to severe pain associated with **endometriosis**.¹ Orilissa is contraindicated in patients with severe hepatic impairment. Duration of therapy is limited due to the anti-estrogenic effects of the medication which include a decrease in bone mineral density.

Dosing

In patients with normal liver function, the recommended dosage is 150 mg once daily (QD) for up to 24 months (no coexisting conditions) or 200 mg twice daily (BID) for up to 6 months (dyspareunia).¹ In patients with moderate hepatic impairment (Child-Pugh Class B), the recommended dosage is 150 mg QD for up to 6 months and the use of 200 mg BID dosing is not recommended.

Availability

Orilissa is available as 150 mg and 200 mg tablets in blister packs of 28 tablets and 56 tablets, respectively.¹

POLICY STATEMENT

This Drug Quantity Management program has been developed to prevent stockpiling, misuse and/or overuse while providing a sufficient quantity of Orilissa. 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 in duration.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per 365 Days*
Orilissa™ (elagolix tablets)	150 mg tablets	180 tablets [†]
	200 mg tablets	360 tablets [‡]

*This is enough drug for patients to complete six months of therapy; [†] 30 tablets per dispensing; [‡] 60 tablets per dispensing.

CRITERIA

Orilissa 150 mg tablets

1. If the patient meets the following criteria (A and B), approve 30 tablets per dispensing to complete a total of 24 months of therapy:
 - A) Patient meets ONE of the following (i or ii):
 - i. Patient has normal liver function; OR
 - ii. Patient has mild hepatic impairment (Child-Pugh A); AND
 - B) The request is for continuation of therapy.

Orilissa 200 mg tablets

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No overrides recommended.

REFERENCES

1. Orilissa™ [prescribing information]. North Chicago, IL: AbbVie Inc.; February 2021.