Drug Quantity Management – Per Days
Gonadotropin-Releasing Hormone Antagonists – Orilissa™ (elagolix tablets)

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Product Identifier(s)

Effective 1/1/23 to 4/11/23: 110154

Effective 4/12/23: 66354

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 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.

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 individuals to complete six months of therapy; † 30 tablets per dispensing; ‡ 60 tablets per dispensing.

Criteria

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

Orilissa 150 mg tablets

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

Orilissa 200 mg tablets

No overrides recommended.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

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]

References

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

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	**Orilissa 150 mg tablets:** Override criteria were revised for patients with mild hepatic impairment to specify "Child-Pugh A". Override criteria for patients with moderate or worse hepatic impairment (Child-Pugh B or C) was removed from the policy. No additional quantities were approved; criteria are not needed.	05/25/2022