DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

REVIEW DATE: 05/29/2024; selected revision 09/04/2024

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Orilissa, an oral gonadotropin-releasing hormone (GnRH) receptor antagonist, is indicated for the management of moderate to severe pain associated with **endometriosis**.[1] Limitations of Use: Limit the duration of use based on the dose and coexisting condition (see additional information below).

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 the duration noted below.

Drug Quantity Limits

Product	Strength and Form	Retail or Home Delivery Maximum Quantity
Orilissa® (elagolix tablets)	150 mg tablets	180 tablets per 365 days* (30 tablets per Rx at retail and 90 tablets per Rx at home delivery)
	200 mg tablets	360 tablets per 365 days* (60 tablets per Rx at retail and 180 tablets per Rx at home delivery)

* This is enough drug for patients to complete six months of therapy.

Gonadotropin-Releasing Hormone Antagonists – Orilissa Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Orilissa 150 mg tablets

1. If the patient meets BOTH of the following (A and B), approve 365 tablets per 365 days for a total of 24 months of therapy (2 year approval):
   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.
   Note: The limit of 30 tablets per dispensing at retail and 90 tablets per dispensing at home delivery continues to apply.

Orilissa 200 mg tablets

No overrides recommended.

REFERENCES

1. Orilissa® [prescribing information]. North Chicago, IL: AbbVie; June 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.	05/25/2023

	No criteria changes.	
Annual Revision	No criteria changes.	05/29/2024
Selected Revision	**Orilissa 150 mg tablets**: The override criteria were updated to approve 365 tablets per 365 days for a total of 24 months of therapy at retail and home delivery if the patient meets the existing criteria. Previously, these criteria approved 30 tablets per dispensing at retail or 90 tablets per dispensing at home delivery for a total of 24 months.	09/04/2024

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