DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Wakefulness-Promoting Agents – Wakix Drug Quantity Management Policy – Per Rx
- Wakix® (pitolisant tablets – Harmony)

REVIEW DATE: 08/27/2024

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

Indication

Wakix, an antagonist/inverse agonist of the histamine-3 receptor, is indicated for the following:[1]
- **Excessive daytime sleepiness or cataplexy in adults with narcolepsy**.
- **Excessive daytime sleepiness in patients ≥ 6 years of age with narcolepsy**.

Dosing

The recommended dosage range for Wakix in adults is 17.8 mg to 35.6 mg administered orally once daily (QD) in the morning upon wakening.[1] Titrate dosage as follows:
- Week 1: Initiate with a dosage of 8.9 mg (two 4.45 mg tablets) QD;
- Week 2: Increase dosage to 17.8 mg (one 17.8 mg tablet) QD;
- Week 3: May increase to the maximum recommended dose of 35.6 mg (two 17.8 mg tablets) QD.

The recommended dose for Wakix in patients ≥ 6 years of age varies based on the patient's weight and is administered orally QD in the morning upon wakening. Titrate dosage as follows:

- Week 1: Initiate with a dosage of 4.45 mg (one 4.45 mg tablet) QD;
- Week 2: Increase dosage to 8.9 mg (two 4.45 mg tablets) QD;
- Week 3: Increase dosage to 17.8 mg (one 17.8 mg tablet) QD (maximum recommended dosage for patients who weigh < 40 kg);
- Week 4: For patients who weigh ≥ 40 kg, may increase to the maximum recommended dosage of 35.6 mg (two 17.8 mg tablets) QD.

Dose may be adjusted based on tolerability. If a dose is missed, patients should take the next dose the following day in the morning upon waking. It may take up to 8 weeks for some patients to achieve a clinical response. For patients with moderate hepatic impairment or with moderate-to-severe renal impairment, the maximum daily dose should not exceed 17.8 mg. Wakix is contraindicated in patients with severe hepatic disease and is not recommended in patients with end stage renal disease.

Availability

Wakix is available as 4.45 mg and 17.8 mg tablets supplied in bottles containing 30 tablets.[1]

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Wakix. 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, unless otherwise noted.

Drug Quantity Limit

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Wakix® (pitolisant tablets)	4.45 mg tablets	30 tablets	90 tablets
	17.8 mg tablets	60 tablets	180 tablets

Wakefulness-Promoting Agents – Wakix Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Wakix 4.45 mg tablets

1. If the patient requires a daily dose of 8.9 mg, approve 60 tablets per dispensing at retail and 180 tablets per dispensing at home delivery.

Wakix 17.8 mg tablets
No overrides recommended.

REFERENCES

1. Wakix® tablets [prescribing information]. Plymouth Meeting, PA: Harmony; June 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/23/2023
Annual Revision	No criteria changes.	08/27/2024