

Commercial/Healthcare Exchange PA Criteria

Effective: January 1, 2021

Prior Authorization: Qdolo

Products Affected: Qdolo (tramadol hydrochloride)5mg/ml oral solution

<u>Medication Description</u>: Tramadol and its active metabolite (M1) binds to μ -opiate receptors in the CNS causing inhibition of ascending pain pathways, altering the perception of and response to pain; also inhibits the reuptake of norepinephrine and serotonin, which are neurotransmitters involved in the descending inhibitory pain pathway responsible for pain relief

<u>Covered Uses</u>: Indicated in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Exclusion Criteria:

- 1. Significant respiratory depression
- 2. Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
- 3. Known or suspected gastrointestinal obstruction, including paralytic ileus
- 4. Hypersensitivity to tramadol, any other component of this product or opioids
- 5. Concurrent use of monoamine oxidase inhibitors (MAOIs) or use within the last 14 days

Required Medical Information:

- 1. Diagnosis
- 2. Previous therapies tried/failed

Age Restriction: 18 years of age and older

Prescriber Restriction: N/A

Coverage Duration: 12 months

Other Criteria:

Approval may be granted for patients who meet one of the following criteria:

- A. The patient has a cancer or sickle-cell disease diagnosis; **OR**
- B. The patient is in hospice program, end-of-life care, or palliative care; **OR**
- C. For patients who do not have a cancer diagnosis, approve if the patient meets the following criteria (i, ii, and iii):
 - i. Non-opioid therapies (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs], acetaminophen) have provided an inadequate response or are inappropriate according to the prescribing physician; **AND**
 - ii. The patient's history of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP), unless unavailable in the state (see note below), according to the prescribing physician; **AND**

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- iii. Risks (e.g., addiction, overdose) and realistic benefits of opioid therapy have been discussed with the patient according to the prescribing physician; **AND**
- D. Patient has a documented intolerance to, contraindication, or treatment failure to tramadol tablets

References:

1. Qdolo (tramadol) [prescribing information]. Athens, GA: Athena Bioscience LLC; September 2020.

Policy Revision history

Rev#	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	1/1/2021

