Select Tramadol Products

Policy # 00738
Original Effective Date: 04/12/2021
Current Effective Date: 04/12/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider select tramadol products, such as the branded Tramadol 100 mg tablets and Qdolo™‡ oral solution, to be **eligible for coverage**** when the patient selection criteria for the requested drug are met.

Patient Selection Criteria

Coverage eligibility will be considered for branded Tramadol 100 mg tablets and Qdolo oral solution when their respective criteria are met:

- For branded Tramadol 100 mg tablet requests:
    - Patient is experiencing pain; AND
    - Patient's pain is severe enough to require an opioid analgesic and alternative treatments are inadequate; AND
    - Patient is 18 years of age or older; AND
    - Patient has tried and failed (e.g. intolerance or inadequate response) TWO of the following GENERIC products: tramadol immediate release 50 mg tablets, tramadol extended release tablets, tramadol/acetaminophen tablets unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
      *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- For Qdolo oral solution requests:
    - Patient is experiencing pain; AND

- Patient's pain is severe enough to require an opioid analgesic and alternative treatments are inadequate; AND
- Patient is 18 years of age or older; AND
- Patient has a gastrostomy tube (G-tube) OR is otherwise unable to swallow tablets and/or capsules (for example, has dysphagia or difficulty swallowing tablets and/or capsules); AND
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient is NOT taking other medications in tablet and/or capsule form.
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of branded Tramadol 100 mg tablets when the patient has not has tried and failed TWO of the following GENERIC products: tramadol immediate release 50 mg tablets, tramadol extended release tablets, tramadol/acetaminophen tablets to be **not medically necessary.****

Based on review of available data, the Company considers the use of Qdolo oral solution when the patient does NOT have a gastrostomy tube (G-tube) or is otherwise able to swallow tablets and/or capsules OR when the patient is taking any other medications in tablet and/or capsule form to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of branded Tramadol 100 mg tablets or Qdolo oral solution when the patient selection criteria are not met (except those denoted as **not medically necessary****) to be **investigational.***

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Background/Overview

Both branded Tramadol 100 mg tablets and Qdolo oral solution are indicated in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Qdolo is available in a 5 mg/mL oral solution. Neither of these products were studied in unique clinical trials to prove their efficacy but rather were proven equivalent to the tramadol tablets currently on the market.

There are more economical options when choosing a tramadol product to treat with, which include generic tramadol immediate release 50 mg tablets, generic tramadol extended release tablets, and generic tramadol/acetaminophen tablets. There is no generic tramadol 100 mg tablet available on the market, but using two 50 mg tablets is still a more economical option than taking a single branded Tramadol 100 mg tablet. Qdolo would be an option for therapy when members are unable to take other versions of tramadol as reflected in the patient selection criteria.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Branded Tramadol 100 mg tablets and Qdolo oral solution are both indicated in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Rationale/Source

The intent of this policy is to ensure that these products are being used per their FDA approved indications. Additionally, the most economical option for therapy should be used as there is no advantage in using branded Tramadol 100 mg tablets or Qdolo (except for the inability to use other tramadol formulations) over the available generic formulations of tramadol.

References

1. Tramadol 100 mg tablets [package insert]. Rubicon Research Private Limited. Thank, India. Updated April 2019.
2. Qdolo [package insert]. Athena Bioscience, LLC. Athens, Georgia. Updated September 2020.

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Policy History

Original Effective Date: 04/12/2021
Current Effective Date: 04/12/2021
03/04/2021 Medical Policy Committee review
03/10/2021 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 03/2022

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.