Nexiclon™ XR (clonidine extended release tablets)

Policy # 00793
Original Effective Date: 07/11/2022
Current Effective Date: 04/01/2025

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 Nexiclon™‡ XR (clonidine extended release tablets) and branded Clonidine extended release tablets to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Nexiclon XR (clonidine extended release tablets) and branded Clonidine extended release tablets will be considered when the following criteria are met:

- Patient has a diagnosis of hypertension; AND
- There is clinical evidence or patient history that suggests the use of GENERIC clonidine patches or GENERIC clonidine immediate release tablets will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient selection 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 Nexiclon XR (clonidine extended release tablets) and branded Clonidine extended release tablets when there is an absence of clinical evidence or patient history that suggests the use of GENERIC clonidine patches or GENERIC clonidine immediate release tablets will be ineffective or cause an adverse reaction to the patient to be **not medically necessary.****

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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 Nexiclon XR (clonidine extended release tablets) and branded Clonidine extended release tablets for non-FDA approved indications to be **investigational.***

Background/Overview

Nexiclon XR is a central alpha-adrenergic agonist indicated for the treatment of hypertension. Nexiclon XR is available in 0.17 mg and 0.26 mg extended release tablets. It also has a branded generic version available as 0.17 mg tablets. The initial recommended dose of Nexiclon XR is 0.17 mg once daily. Elderly patients may benefit from a lower initial dose. Further increments of 0.09 mg once daily may be made at weekly intervals as needed. The most common therapeutic doses used have ranged from 0.17 mg to 0.52 mg once daily. Nexiclon XR was not studied in clinical trials. It was only studied in kinetic studies versus the generic clonidine immediate release tablets. The generic immediate release clonidine tablets are available in 0.1 mg, 0.2 mg, and 0.3 mg strengths. Another option for therapy with clonidine includes the patch formulation. The generic clonidine patches are available in 0.1 mg/24 hours, 0.2 mg/24 hours, and 0.3 mg/24 hours strengths. There is no advantage of using Nexiclon XR over the available generic clonidine products approved for the treatment of hypertension, which offer a safe, efficacious, and economically advantageous option for therapy. It should be noted that the generic extended release version of clonidine 0.1 mg tablets are for the treatment of attention deficit hyperactivity disorder (ADHD).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Nexiclon XR is indicated for the treatment of hypertension.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The intent of this policy is to ensure that Nexiclon XR and its branded generic are being used per the FDA approved indication. Additionally, the most economical option for therapy should be used as there are no safety or efficacy advantages to using Nexiclon XR or its branded generic over generic clonidine patches or generic clonidine immediate release tablets.

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References

1. Nexiclon XR [package insert]. Athena Bioscience, LLC. Athens, Georgia. Updated August 2021.
2. Clonidine Extended-Release Tablets [package insert]. Palmetto Pharmaceuticals, Inc. Greenville, South Carolina. Updated March 2022.

Policy History

Original Effective Date: 07/11/2022
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06/02/2022	Medical Policy Committee review
06/08/2022	Medical Policy Implementation Committee approval. New policy.
03/02/2023	Medical Policy Committee review
03/08/2023	Medical Policy Implementation Committee approval. Branded Clonidine extended release tablets, the authorized generic of Nexiclon XR, have been added to this policy with the same criteria as parent drug.
03/07/2024	Medical Policy Committee review
03/13/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/06/2025	Medical Policy Committee review
03/12/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2026

*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 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.

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**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.

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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.