ivermectin tablets (Stromectol®, generics)

Policy # 00763
Original Effective Date: 01/01/2022
Current Effective Date: 11/11/2024

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 ivermectin tablets (Stromectol®, generics)‡ for the treatment of intestinal (i.e., non-disseminated) strongyloidiasis, onchocerciasis, and other accepted compendia indications to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for ivermectin tablets (Stromectol, generics) will be considered when the following criteria are met:

- Patient has a diagnosis of any of the following:
  - Intestinal (i.e., non-disseminated) strongyloidiasis due to the nematode parasite *Strongyloides stercoralis*; OR
  - Onchocerciasis due to the nematode parasite *Onchocerca volvulus*; OR
  - Ascariasis due to *Ascaris lumbricoides*; OR
  - Demodicosis due to *Demodex folliculorum* and *Demodex brevis*; OR
  - Enterobiasis (pinworm infection) due to *Enterobius vermicularis*; OR
  - Gnathostomiasis due to *Gnathostoma spinigerum*; OR
  - Hookworm-related cutaneous larva migrans; OR
  - Pediculosis caused by head (*pediculus humanus capitis*), body (*pediculus humanus corporis),* or pubic (*Phthirus pubis*) lice; OR
  - *Mansonella ozzardi* infection; OR
  - *Mansonella streptocerca* infection; OR

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  - Scabies due to *Sarcoptes scabiei*; OR
  - Trichuriasis (whipworm infection) due to *Trichuris trichiura*; OR
  - *Wucheria bancrofti* infection; AND
- If the request is for brand Stromectol: Patient has tried and failed (e.g., intolerance or inadequate response) the generic equivalent ivermectin tablets unless there is clinical evidence or patient history that suggests use of the generic equivalent 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)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand Stromectol when there is no clinical evidence or patient history that suggests the generic equivalent will be ineffective or cause an adverse reaction to the patient 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 ivermectin tablets (Stromectol, generics) for any indication not listed in the patient selection criteria to be **investigational.***

Background/Overview

Stromectol and its generic equivalent, ivermectin tablets, are indicated for the treatment of intestinal (i.e., non-disseminated) strongyloidiasis due to the nematode parasite *Strongyloides stercoralis*. They are also indicated for the treatment of onchocerciasis due to the nematode parasite *Onchocerca volvulus*. These products also have a large number of accepted compendia indications, as noted above in the patient selection criteria. Stromectol and its generic equivalent are available in 3 mg tablets, and dosing is typically based on body weight.

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Recently, the Centers for Disease Control (CDC) released an official Health Advisory noting a rapid increase in ivermectin prescriptions and reports of severe illness associated with the use of ivermectin to prevent or treat COVID-19. The National Institutes of Health's (NIH) COVID-19 Treatment Guidelines Panel has also determined that there are currently insufficient data to recommend ivermectin for the treatment of COVID-19 and that more adequately powered, well designed, and well conducted trials are needed to provide more specific, evidence-based guidance. The Infectious Diseases Society of America (IDSA) also suggests against ivermectin for the treatment of patients with COVID-19. ClinicalTrials.gov has a listing of ongoing clinical trials that may provide more data about ivermectin use in COVID-19 in the future.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Stromectol and its generic equivalent, ivermectin tablets, are indicated for the treatment of intestinal (i.e., non-disseminated) strongyloidiasis due to the nematode parasite *Strongyloides stercoralis*. They are also indicated for the treatment of onchocerciasis due to the nematode parasite *Onchocerca volvulus*.

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 rationale behind this policy is to ensure that ivermectin tablet products are being appropriately utilized based on FDA approved indications or accepted compendia indications. This policy also ensures that the generic product is utilized, where possible, prior to the brand product.

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Policy History

Original Effective Date: 01/01/2022
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10/07/2021	Medical Policy Committee review
10/13/2021	Medical Policy Implementation Committee approval. New policy.
10/06/2022	Medical Policy Committee review
10/11/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/05/2023	Medical Policy Committee review
10/11/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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10/03/2024 Medical Policy Committee review
10/08/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 10/2025

*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.

**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.

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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.

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.