

## **Clinical Policy: Moxidectin**

Reference Number: CP.PMN.162

Effective Date: 07.31.18

Last Review Date: 11.18

Line of Business: Commercial, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Moxidectin is an anthelmintic.

### **FDA Approved Indication(s)**

Moxidectin is indicated for the treatment of onchocerciasis due to *Onchocerca volvulus* in patients aged 12 years and older.

Limitation(s) of use:

- Moxidectin tablets do not kill adult *O. volvulus* parasites. Follow-up is advised.
- The safety and efficacy of repeat administration of moxidectin tablets in patients with *O. volvulus* has not been studied.

### **Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that moxidectin is **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

##### **A. Onchocerciasis** (must meet all):

1. Diagnosis of onchocerciasis;
2. Prescribed by or in consultation with an infectious disease specialist;
3. Age  $\geq$  12 years;
4. Dose does not exceed 8 mg (4 tablets) as a single dose.

**Approval duration: 12 months (4 tablets only)**

##### **B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

#### **II. Continued Therapy**

##### **A. Onchocerciasis** (must meet all):

1. Previously received medication via Centene benefit or member has previously met initial approval criteria;
2. Member has not received a dose of moxidectin in the previous 12 months;
3. Member is responding positively to therapy;

- If request is for a dose increase, new dose does not exceed 8 mg (4 tablets) as a single dose.

**Approval duration: 12 months (4 tablets only)**

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

Not applicable

*Appendix C: Contraindications/Boxed Warnings*

None reported

*Appendix D: General Information*

- Onchocerciasis, also known as river blindness, is a disease of the skin and eye caused by *Onchocerca volvulus*, a parasitic worm transmitted by black flies that breed in fast-flowing rivers and streams. The disease is rare in the United States and is endemic in sub-Saharan Africa, three countries in South America, and Yemen.
- To date the standard of care is ivermectin, which kills the microfilariae (larvae), but not the macrofilariae (adult worms). Evidence has shown that treatment with ivermectin every 3 to 6 months is beneficial.
- Treatment with a six week course of doxycycline has been shown to kill adult female worms and to sterilize the females 20 months after treatment. However, doxycycline does not kill the microfilariae; therefore treatment with ivermectin is needed.
- Similar to ivermectin, moxidectin is not effective in killing adult worms; however it inhibits the intra-uterine embryogenesis and release of microfilariae from the adult worms.
- A positive response to therapy can be considered as relief of significant symptoms or reduced microfilariae counts.

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Onchocerciasis	8 mg (4 tablets) as a single oral dose	8 mg

**VI. Product Availability**

Tablet: 2 mg

**VII. References**

- Moxidectin Prescribing Information. Melbourne, Victoria, Australia: Medicines Development for Global Health; June 2018. Available at

- [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/2108671bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/2108671bl.pdf). Accessed June 26, 2018.
2. Opoku NO, Bakajika DK, Kanza EM, et al. Single dose moxidectin versus ivermectin for *Onchocerca volvulus* infection in Ghana, Liberia, and the Democratic Republic of the Congo: a randomised, controlled, double-blind phase 3 trial. *Lancet* 2018; published online Jan 17. [http://dx.doi.org/10.1016/S0140-6736\(17\)32844-1](http://dx.doi.org/10.1016/S0140-6736(17)32844-1).
  3. Awadzi K, Opoku NO, Attah SK et al. A randomized, single-ascending-dose, ivermectin-controlled, double-blind study of moxidectin in onchocerca volvulus infection. *PLOS Neglected tropical Diseases*. 2014 June;8(6): e2953.
  4. Parasites - Onchocerciasis (also known as River Blindness). Centers for Disease Control and Prevention Website. [https://www.cdc.gov/parasites/onchocerciasis/health\\_professionals/index.html#tx](https://www.cdc.gov/parasites/onchocerciasis/health_professionals/index.html#tx). Published February 19, 2014. Updated February 19, 2014. Accessed June 26, 2018.
  5. World Health organization. Guidelines for stopping mass drug administration and verifying elimination of human onchocerciasis. Available at [http://apps.who.int/iris/bitstream/handle/10665/204180/9789241510011\\_eng.pdf;jsessionid=1D1E838481DC0616E38444D3177C66D9?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/204180/9789241510011_eng.pdf;jsessionid=1D1E838481DC0616E38444D3177C66D9?sequence=1). Accessed June 26, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	07.31.18	11.18

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a

discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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