Clinical Policy: Moxidectin

Reference Number: ERX.NPA.103
Effective Date: 07.31.18
Last Review Date: 11.18

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 Envolve Pharmacy Solutions™ 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 ≥ 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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Onchocerciasis (must meet all)**:**
1. Previously received medication via a health plan affiliated with Envolve Pharmacy Solutions 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;
4. 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)

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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

A. 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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ivermectin (Stromectol®)	150 mcg/kg orally in one dose every 3-6 months	150 mcg/kg

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

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

1. Moxidectin Prescribing Information. Melbourne, Vicoria, Australia: Medicines Development for Global Health; June 2018. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210867lbl.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.
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. 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. 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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.