RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	moxidectin
Policy Number:	RxA.211
Drug(s) Applied:	Moxidectin
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Moxidectin is an anthelmintic. It 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.

Dosing Information

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

Dosage Forms

- Tablet: 2 mg

Clinical Policy

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

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

Commercial: 12 months (4 tablets only)
Medicaid: 12 months (4 tablets only)

II. Continued Therapy Approval

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

1. Previously receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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
Commercial: 12 months (4 tablets only)
Medicaid: 12 months (4 tablets only)

III. Appendices

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

APPENDIX B: Therapeutic Alternatives
Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported
- Boxed Warning(s):
  - 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.

References

1. Moxidectin Prescribing Information. Melbourne, Victoria, Australia: Medicines Development for Global Health; January 2019. Available at

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210867lbl.pdf. Accessed June 23, 2020.
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 23, 2020.
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 23, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy title table was updated. **2.** Initial and Continued approval duration was updated to specify Commercial and Medicaid plans. **3.** Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 4. References were updated.	07/10/2020	09/14/2020