

## Tindamax (tinidazole) Policy Number: C15431-C

**CRITERIA EFFECTIVE DATES:**

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
4/1/2013	12/4/2019	12/4/2020
J CODE	TYPE OF CRITERIA	LAST P&T APPROVAL/VERSION
NA	RxPA	Q1 2020 20200122C15431-C

**PRODUCTS AFFECTED:**

Tindamax (tinidazole)

**DRUG CLASS:**

Anti-Infective Agents, Misc.

**ROUTE OF ADMINISTRATION:**

Oral

**PLACE OF SERVICE:**

Retail Pharmacy

**AVAILABLE DOSAGE FORMS:**

Tindamax 250mg tab, 500mg tab, tinidazole 250mg tab, tinidazole 500mg tab

**FDA-APPROVED USES:**

Amebic liver abscess - Infection due to Entamoeba histolytica, Bacterial vaginosis, Helicobacter pylori gastrointestinal tract infection, Infection by Giardia lamblia, Infection due to Entamoeba histolytica - Intestinal infectious disease, Nongonococcal urethritis, Trichomoniasis

**COMPENDIAL APPROVED OFF-LABELED USES:**

Helicobacter pylori eradication; Prophylaxis against sexually transmitted diseases following sexual assault; Urethritis, nongonococcal (persistent and recurrent)

**COVERAGE CRITERIA: INITIAL AUTHORIZATION**

**DIAGNOSIS:**

Amebic liver abscess - Infection due to Entamoeba histolytica, Bacterial vaginosis, Helicobacter pylori gastrointestinal tract infection, Infection by Giardia lamblia, Infection due to Entamoeba histolytica - Intestinal infectious disease, Nongonococcal urethritis, Trichomoniasis

**REQUIRED MEDICAL INFORMATION:**

**A. TRICHOMONIASIS OR GIARDIASIS:**

1. Documented diagnosis of infection  
AND
2. Documentation of trial/failure or contraindication of metronidazole

**B. ALL OTHER INDICATIONS:**

1. Documented diagnosis of susceptible infection

**DURATION OF APPROVAL:**

One time- 3 months

**QUANTITY:**

20 tablets

**PRESCRIBER REQUIREMENTS:**

None

**AGE RESTRICTIONS:**

3 years of age and older

**CONTINUATION OF THERAPY:**

NA

**CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:**

All other uses of Tindamax (tinidazole) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy

**OTHER SPECIAL CONSIDERATIONS:**

None

**BACKGROUND:**

None

**APPENDIX:**

None

***Documentation Requirements:***

*Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.*

---

**REFERENCES:**

1. Product Information: tinidazole oral tablets, tinidazole oral tablets. Roxane Laboratories, Inc. (per manufacturer), Columbus, Ohio, 2011.
2. Chey WD, Leontiadis GI, Howden CW, et al: ACG clinical guideline: treatment of Helicobacter pylori infection. Am J Gastroenterol 2017; 112(2):212-239.

3. Centers for Disease Control and Prevention (CDC): Sexually transmitted diseases (STDs): prevention. Centers for Disease Control and Prevention (CDC). Atlanta, GA. 2015. Available from URL: <https://www.cdc.gov/std/prevention/default.htm>
4. Francavilla R, Lionetti E, Castellaneta SP, et al: Improved efficacy of 10-Day sequential treatment for Helicobacter pylori eradication in children: a randomized trial. Gastroenterology 2005; 129(5):1414-1419.
5. Jokipii AMM & Jokipii L: Treatment of giardiasis: comparative evaluation of ornidazole and tinidazole as a single oral dose. Gastroenterology 1982; 83:399-404.
6. Simjee AE, Gathiram V, Jackson TFGH, et al: A comparative trial of metronidazole v. tinidazole in the treatment of amoebic liver abscess. S Afr Med J 1985; 68:923-924.
7. Carmona O, Silva H, & Acosta H: Vaginitis due to Gardnerella vaginalis treatment with tinidazole. Curr Ther Res 1983; 33:898-904.
8. Lossick J & Kent HL: Trichomoniasis: Trends in diagnosis and management. Am J Obstet Gynecol 1991; 165:1217-1222.
9. Thijs JC, van Zwet AA, Thijs WJ, et al: One-week triple therapy with omeprazole, amoxicillin and tinidazole for Helicobacter pylori infection: the significance of imidazole resistance. Aliment Pharmacol Ther 1997; 11:305-309.
10. Batagol R (Ed): Australian Drug Evaluation Committee: Medicines in Pregnancy-An Australian categorisation of risk of drug use in pregnancy, 4th. Australian Government Publishing Service, Canberra, Australia, 1999