



Indiana Medicaid Therapeutics Committee Therapeutic Class Review Summary

Therapeutic Class:

Vaginal Antimicrobials

Overview:

Vaginal antimicrobial agents are a group of medications used to treat vaginal infections caused by various microorganisms in the vagina. Bacterial vaginosis (BV) is the most common vaginal infection in women of childbearing age. The development of BV occurs when there is a change in the environment of the vagina that causes an increase in harmful bacteria including *Gardnerella vaginalis*, *Bacteroides*, *Mobiluncus*, and *Mycoplasma hominis*. Changes in vaginal pH also accompany this disease state. More than 50% of women with BV have no symptoms. Another common vaginal infection is a vaginal yeast infection caused by *Candida albicans* fungus. Approximately 75% of all women will have at least one yeast infection in their lifetime.

Currently, several therapeutic treatment options approved for BV and vaginal yeast infections are available in the United States. Agents approved to treat BV in this therapeutic class review include clindamycin and metronidazole. Both products inhibit bacterial protein synthesis and cause cell death in susceptible organisms. Clinical trial data have shown that these two medications have either cured or improved signs and symptoms of BV. Vaginal yeast infections have been successfully treated with butoconazole, clotrimazole, miconazole, terconazole, and tioconazole. These medications are antifungal agents that alter cellular membranes, while increasing membrane permeability, therefore resulting in loss of essential intracellular nutrients. Treatment regimens range from 1 to 7 days. Clinical data suggest that all medications have been effective in the treatment and relief of signs and symptoms of vaginal yeast.

GENERIC NAME	TRADE NAME	MANUFACTURER	GENERIC	OTC
Butoconazole	Gynazole [®] 1 Mycelex-3 [®]	Ther Rx Corp	N	N
Clindamycin	Cleocin [®] 2% Vaginal Cream, suppository ClindaMax [®] 2% Vaginal Cream Clindesse [™] 2% Vaginal Cream	Upjohn, Pharmaderm, Ther-RX, various	Y (vaginal cream) N	N



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Clotrimazole	Gyne-Lotrimin [®]	Various	Y	Y
Metronidazole	Metrogel [®] Vaginal	3M, various	Y	N
Miconazole	Monistat [®]	Various	Y	Y
Terconazole	Terazol [®]	Ortho-McNeil, various	Y	N
Tioconazole	Vagistat-1 [®]	Bristol-Myers Squibb	Y	Y

Summary:

Available data suggest that all agents used to treat vulvovaginal candidiasis and bacterial vaginosis are effective in eradicating symptoms. No one agent has proven to be significantly better than another. Selection of vaginal antimicrobial agents for the preferred drug list should be based on indications, generic availability, and cost.