Antifungal Medications

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for antifungal medications when they are determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Sporanox (itraconazole) for the treatment of onychomycosis of the fingernails and toenails may be considered medically necessary for patients with the following co-morbidities:

- diabetes mellitus
- immunocompromised condition (i.e., HIV/AIDS, organ transplant)
- peripheral vascular disease, with or without claudication
- impaired ambulation or severe pain due to pain/inflammation from the infection
- soft tissue involvement around nail bed

If the drug is not being used to treat onychomycosis, the diagnosis and duration of therapy must be indicated.

Diflucan (fluconazole) 150mg is considered medically necessary for the treatment of vaginal candidiasis. The quantity is limited to 3 tablets per month.

Vfend will be approved for patients who meet one of the following criteria:

- diagnosis of invasive aspergillosis
- diagnosis of serious fungal infection caused by Scedosporium apiospermum and Fusarium species that are resistant to other systemic antifungals
- patients who were started on and stabilized on IV voriconazole and oral voriconazole is being used as a continuation of therapy.

When Policy Topic is not covered
Antifungal medications are considered not medically necessary if the criteria above are not met.

For onychomycosis, failure on other antifungals, either OTC or Rx, does not qualify for coverage.

Considerations
Prior authorization through the pharmacy services area is required.

Approval for the treatment of onychomycosis will be granted for up to 12 weeks. Continuation of therapy will require additional review for medical necessity.

Pharmacy Services and/or the Medical Director will review requests outside of the above criteria on an individual consideration basis.
This Blue Cross and Blue Shield of Kansas City policy was developed using available resources such as, but not limited to: Food and Drug Administrative (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

Description of Procedure or Service

Sporanox (itraconazole) is an antifungal agents that may be used in the treatment of Onychomycosis (mycotic nail) a fungal infection of the nail plate, usually caused by species of Epidermophyton, Microsporum, and Trichophyton, and producing nails that are opaque, white, thickened, friable, and brittle.

Diflucan (fluconazole) is an antifungal agent used in the treatment of various candidal infections, as well as some forms of meningitis.

Vfend (voriconazole) is indicated for use in the treatment of invasive aspergillosis. It is also indicated for use in the treatment of serious fungal infections caused by Scedosporium apiospermum and Fusarium species in patients intolerant of, or refractory to, other therapies.

Rationale

Sporanox® (itraconazole):

Onychomycosis is not life-threatening, but can cause discomfort, pain, and disfigurement and may create physical and occupational limitations which may require medical attention. A clinical benefit may exist from treatment, especially when co-morbidities (see above), serious pathology, or a functional impairment are involved.

After treatment with normal courses of terbinafine with 12-32 weeks of continuous or pulse dose therapy, a disease-free nail (defined as clinically normal nail plus negative results of KOH microscopy and culture) was achieved in approximately 35%-50% of patients. Continuous or pulse dose therapy with 12-16 weeks of itraconazole produced approximately 25%-40% disease-free nail. Greater effectiveness has been seen with terbinafine than itraconazole in onychomycosis treatment in most comparative trials. Also, some data suggests that pulse therapy (daily therapy 1 week a month) may be as effective and more cost efficient than daily therapy. The use of systemic itraconazole and terbinafine is limited by their risk for potential side effects and needs to be weighed against the risk/benefit ratio.

A black box warning for itraconazole was issued in 2001, regarding its use in patients with congestive heart failure as well as major drug interactions: “itraconazole capsules should not be administered for the treatment of onychomycosis in patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF… Coadministration of cisapride, pimozide, quinidine, or dofetilide with itraconazole is contraindicated. Itraconazole, a potent cytochrome P450 3A4 isoenzyme system (CYP3A4) inhibitor, may increase plasma concentrations of drugs metabolized by this pathway…”

Diflucan® (fluconazole)

Fluconazole is indicated for vaginal candidiasis, oropharyngeal and esophageal candidiasis, and cryptococcal meningitis. After long-term treatment, azole-resistant Candida strains may develop. Fluconazole is not effective in C.krusei candidiasis or aspergillosis. C. galbrata requires higher dosing.

Prophylaxis for fungal infections is currently not recommended, despite evidence that fluconazole can lower the incidence of oral and esophageal candidiasis. Current therapies for treating these diseases are highly effective, while prophylaxis carries the risk of fluconazole resistance.

Vfend® (voriconazole):
Initial therapy with voriconazole may provide a better response, improved survival and result in fewer adverse events than initial therapy with non-liposomal formulations of amphotericin B in the treatment of invasive aspergillosis. [8] Co-administration of voriconazole is contraindicated with rifampin, rifabutin, ritonavir, carbamazepine, long-acting barbiturates, sirolimus, terfenadine, astemizole, cisapride, pimozide, quinidine, ergot alkaloids, and efavirenz. [11]

Voriconazole therapy has variable success rates for treating invasive fungal infections (e.g., aspergillosis, scedosporiosis, candidiasis, and others) in pediatric patients with hematological or chronic granulomatous disease, who are intolerant of, or refractory to conventional antifungal therapy. [9]

Voriconazole has modest efficacy for treating fungal infections in adult patients who have failed to respond to other antifungal drug(s), or have infections for which there are no approved antifungal therapies. Voriconazole has shown good in-vitro activity against Scedosporium apeospermum and Fusarium species; and therefore may provide salvage therapy for these serious fungal infections, in patients intolerant of, or refractory to other therapy. [10]

References


Billing Coding/Physician Documentation Information
N/A Antifungal medications are a pharmacy benefit

Additional Policy Key Words
5.01.510

Policy Implementation/Update Information
10/99 Origination date
10/00 Reviewed – no changes made
10/01 Reviewed – no changes made
05/02 Revised – policy criteria modified to eliminate severe pain and debilitating extensive toenail involvement, and failure on other antifungals
10/02 Reviewed – no changes made
10/03 Reviewed – no changes made
07/04 Revised – title changed from Pharmacologic Treatment of Onychomycosis to Antifungal Medications; policy updated to include statements on Diflucan (fluconazole) and Vfend (voriconazole)
10/04 Reviewed – no changes made
10/05 Reviewed – no changes made
10/06 Reviewed – no changes made
10/07 Reviewed – no changes made
10/08 Reviewed – no changes made
10/09 Reviewed – no changes made
10/10 Reviewed – deleted qty limits for Diflucan doses other than 150mg.
10/11 Reviewed – no changes made
10/12 Reviewed – no changes made
10/13 Revised – Lamisil removed from policy
10/14 Reviewed – no changes made
10/15 Reviewed – no changes made
10/16 Reviewed – no changes made
10/17 Reviewed – no changes made

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