Proposed Preferred Drug List

with

Clinical Criteria

Proposal for TennCare

August 29, 2006
LENGTH OF AUTHORIZATIONS: Duration of therapy (unless otherwise specified)

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?
   Acceptable reasons include:
   - **Allergy** to medications not requiring prior approval
   - **Contraindication** to or drug-to-drug interaction with medications not requiring prior approval
   - **History** of unacceptable/toxic side effects to medications not requiring prior approval

2. The requested medication may be approved if both of the following are true:
   - If there has been a therapeutic failure of at least one medication within the same class not requiring prior approval
   - The requested medications corresponding generic (if a generic is available and preferred by the State) has been attempted and failed or is contraindicated

3. The requested medication may be approved if the following is true:
   - An indication which is unique to a non-preferred agent and is supported by peer-reviewed literature or an FDA approved indication exists.
NEW: ANTI-INFECTIVE AGENTS: Oral Tetracyclines

RECOMMENDATION
Three chemical entities (doxycycline, minocycline and tetracycline) in this class have a demonstrated safety and efficacy profile that allow them to be considered therapeutic alternatives to one another. Demeclocycline has demonstrated efficacy, but its side-effect profile (induction of diabetes insipidus syndrome in some patients) may limit its use as an anti-infective, but allows it to have a unique place in the treatment of the syndrome of inappropriate antidiuretic hormone (SIADH).

COMMITTEE VOTE
APPROVED   DISAPPROVED   APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

<table>
<thead>
<tr>
<th>NEW: ANTI-INFECTIVE AGENTS: Oral Tetracyclines</th>
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<tbody>
<tr>
<td>PREFERRED</td>
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<tr>
<td>DEMECLOYCYCLINE (compares to Declomycin®)</td>
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<tr>
<td>DOXYCYCLINE (compares to Vibra®-tabs and Vibramycin® and equivalent to Adoxa® was recently approved on 6.2.06)</td>
</tr>
<tr>
<td>MINOCYCLINE (compares to Dynacin®, Minocin®)</td>
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<td>TETRACYCLINE (compares to Sumycin®)</td>
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References

NEW: ANTI-INFECTIVE AGENTS: Oral Tetracyclines Indicated for Non-Systemic Infections

RECOMMENDATION

Subantimicrobial doses of tetracyclines have been used for non-systemic infections (ie periodontal disease, acne and rosacea) predominantly for their anti-inflammatory effects (not anti-bacterial effects) and theoretical decreased ability to induce resistance. This class of tetracyclines has demonstrated safety and efficacy and may be considered as therapeutic alternatives to existing agents. It is recommended that the agents in this class be subject to clinical criteria as alternatives exist and also so as to ensure that these agents are not used inappropriately for systemic infections.

COMMITTEE VOTE

APPROVED    DISAPPROVED    APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<thead>
<tr>
<th>PREFERRED</th>
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<tbody>
<tr>
<td>ARESTIN® CC, (minocycline sustained release microspheres, 1mg)</td>
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<tr>
<td>ORACEA® CC, QL, (doxycycline 40mg (30mg IR and 10mg DR beads))</td>
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<tr>
<td>PERIOSTAT® CC, QL, (doxycycline hyclate) 20mg tab</td>
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</tr>
<tr>
<td>SOLODYN® CC, QL, (minocycline 45mg, 90mg, 135mg)</td>
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</table>
### PROPOSED CRITERIA

#### Recommended Criteria for Arestin® (minocycline sustained release microspheres)

Arestin® (minocycline sustained release microspheres) will be approved when both of the following conditions are met:

- It is indicated as an adjunct to scaling and root planing procedures for reduction of pocket depth in patients with adult periodontitis or when used as part of a periodontal maintenance program which includes good oral hygiene, and scaling and root planing.
- In patients with any of the following:
  1. Multiple sites unresponsive to mechanical debridement
  2. Acute infections
  3. Medically compromised patients
  4. Presence of tissue-invasive organisms and ongoing disease progression

**Length of Authorization:** One year

**References**

Arestin® (minocycline hydrochloride). Package insert. OraPharma. 2.16.01.


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### COMMITTEE VOTE

**APPROVED** **DISAPPROVED** **APPROVED with MODIFICATION**

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#### Recommended Criteria for Periostat® (doxycycline 20mg tab)

Periostat® (doxycycline 20mg capsules) will be approved when both of the following conditions are met:

- When used as an adjunct to scaling and root planing to promote attachment level gain and to reduce pocket depth in patients with adult periodontitis.
- In patients with any of the following:
  1. Multiple sites unresponsive to mechanical debridement
  2. Acute infections
  3. Medically compromised patients
  4. Presence of tissue-invasive organisms and ongoing disease progression

**References**


**Length of Authorization:** One year

**COMMITTEE VOTE**

**APPROVED** **DISAPPROVED** **APPROVED with MODIFICATION**
Recommended Criteria for Oracea® (doxycycline 40mg (30mg IR and 10mg DR beads)

Oracea® (doxycycline 40mg capsules) will be approved for the treatment of inflammatory lesions (papules and pustules) of rosacea in adult patients who have attempted, failed, or have a contra-indication to at least one of the following:

- Topical antibiotics (any of the following)
  1. Metronidazole (Metrogel®)
  2. Azelaic acid (Azelex®, Finacea®)
  3. Erythromycin (A/T/S® solution, gel), OR
- The recipient requires long–term therapy with an oral antibiotic

Length of Authorization: One year

References

COMMITTEE VOTE
APPROVED DISAPPROVED APPROVED with MODIFICATION

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Recommended Criteria for Solodyn® (minocycline 45mg, 90mg, 135mg extended release tab)

Solodyn® (minocycline extended release) will be approved if all of the following are true:
1. Diagnosis is the treatment of non-nodular moderate to severe acne vulgaris with inflammatory lesions.
2. Recipient has failed, has an intolerance, contraindication or adverse reaction to at least two of the following agents:
   - Topical antibiotics (such as the following examples below)
     1. Metronidazole (Metrogel®)
     2. Azelaic acid (Azelex®, Finacea®)
     3. Erythromycin (A/T/S® solution, gel)
     4. Clindamycin (Cleocin T®)
   - Topical keratolytic agent/Antibacterial agents (such as benzoyl peroxide, salicylic acid preparations)
   OR
3. The recipient requires long –term therapy with an oral antibiotic

Length of Authorization: One year

References

COMMITTEE VOTE
APPROVED DISAPPROVED APPROVED with MODIFICATION
NEW: ANTI-INFECTIVE AGENTS: Oral Glycopeptides

RECOMMENDATION

Currently the only oral glycopeptide available is oral vancomycin. The only FDA labeled indication for oral vancomycin is that of the treatment of Clostridium difficile-associated diarrhea. Oral vancomycin is considered a product whose safety and efficacy demonstrate that it is a therapeutic alternative to the only other alternative therapy (metronidazole) for C. difficile. Routine use of oral vancomycin may contribute to the emergence of vancomycin-resistant Enterococcus species such that all oral vancomycin products should be reserved and subject to criteria in order to preserve its long term usefulness and decrease emergent resistance.

COMMITTEE VOTE

APPROVED   DISAPPROVED   APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

NEW: ANTI-INFECTIVE AGENTS: Oral Glycopeptides

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<tr>
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<tr>
<td></td>
<td>VANCOCIN® (vancomycin 125mg, 250mg pulvules)</td>
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PROPOSED CRITERIA

Recommended Criteria for oral Vancocin® (vancomycin)
1. The recipient must have a diagnosis of C. difficile colitis
2. Before authorization of oral vancomycin the recipient will need to have tried and failed oral metronidazole unless there is a contra-indication, adverse reaction or drug to drug interaction that would preclude the recipient using metronidazole. (Note that the following is a common list (not all inclusive) of reasons why metronidazole may not be appropriate and oral vancomycin may be approved)
   • The recipient is either pregnant or a child under the age of 10 years of age
   • The recipient is severely ill
   • The recipient is receiving an alcohol related compound (interaction with metronidazole)
   • The recipient is allergic to metronidazole
   • The organism if resistant to metronidazole
   • There is evidence to suggesting the diarrhea is caused by Staphylococcus aureus
   • The recipient failed metronidazole in the past
   • The diarrhea is a suspected recurrent C.difficile colitis

Length of Authorization: One year

References

COMMITTEE VOTE

APPROVED   DISAPPROVED   APPROVED with MODIFICATION
NEW: ANTI-INFECTIVE AGENTS: Oral Aminoglycosides

RECOMMENDATION
Both neomycin and paromomycin are classified as oral aminoglycosides and both agents have similar antibacterial spectrums. Paromomycin has additional spectrum of activity against protozoa and cestodes which differentiates the drug from neomycin. With the difference in spectrum, the two drugs although in the same pharmacologic class, are not considered equivalent.

COMMITTEE VOTE
APPROVED   DISAPPROVED   APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<tr>
<td>NEOMYCIN Sulfate tablets (500mg)</td>
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<tr>
<td>NEO-FRADIN® (neomycin 125mg/5ml oral solution)</td>
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<tr>
<td>HUMATIN® (paromomycin sulfate)</td>
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NOTE: Kantrex® (Kanamycin is no longer made)

References
RECOMMENDATIONS

This class contains various agents of different pharmacologic properties used in the treatment of parasitic infections. The drugs in this class are not considered clinically equivalent to each other as no one agent is the drug of choice for all parasitic infections. Nitazoxamide (Alinia®) although considered the drug of choice for the treatment of Cryptosporidium parvum has been shown to be a safe and effective therapeutic alternative to other therapies in the treatment of Giardia lamblia.

COMMITTEE VOTE

APPROVED    DISAPPROVED    APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<td>BILTRICIDE® (praziquantel)</td>
<td>ALINIA® (nitazoxanide)</td>
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<td>CHLOROQUINE Phosphate (Tablets:250 mg (equiv. to 150 mg base))</td>
<td>ARALEN® Phosphate (chloroquine phosphate - Tablets:500 mg (equiv. to 300 mg base))</td>
</tr>
<tr>
<td>DARAPRIM® (pyrimethamine)</td>
<td>LARIAM® (mefloquinine)</td>
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<tr>
<td>DAPSONE</td>
<td>Benzimidazoles</td>
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<tr>
<td>FANSIDAR® (sulfadoxine and pyrimethamine)</td>
<td>VERMOX® (mebendazole)</td>
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<td>HUMATIN® (paromomycin sulfate)</td>
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<td>MALARONE® (atovaquone and proguanil)</td>
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<tr>
<td>MEFLOQUINE (compares to Lariam®)</td>
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<td>MEPRON® (atovaquone)</td>
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<td>QUININE</td>
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<td>PENTAMIDINE</td>
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<td>PRIMAQUINE</td>
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<td>STROMECTOL® (ivermectin)</td>
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<td>YODOXIN® (iodoquinol)</td>
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**Benzimidazoles**

ALBENZA® (albendazole)
MEBENDAZOLE (compares to Vermox®)
MINTEZOL® (thiabendazole)

**Note:** Hetrazan® (diethylcarbamazine) is available on compassionate use
PROPOSED CRITERIA

**Recommended Criteria for Alinia® (nitazoxanide)**

Alinia® (nitazoxanide) will be authorized for:

1. The treatment of diarrhea caused by *Cryptosporidium parvum* (or suspected *Cryptosporidium parvum* in immunocompromised recipients)

2. The treatment of diarrhea caused by *Giardia lamblia* if the recipient has:
   - Failed metronidazole
   - Has a contra-indication, intolerance, adverse drug reaction or other reason not to use metronidazole

**Length of Authorization:** One year

**References**


**COMMITTEE VOTE**

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<th>APPROVED</th>
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</table>
NEW: ANTI-INFECTIVE AGENTS: Oral Anti-Tuberculosis Agents

RECOMMENDATIONS
The drugs in this class are not considered clinically equivalent to each other as no one agent or combination of agents is considered the drug of choice in all situations. The antitubercular drugs can be divided into three classes: those that are bacteriocidal (ie INH and to a lesser degree rifampin), those that are sterilizing (ie rifampin and PZA) and those that eliminate all bacterial populations and help to decrease the emergence of resistance. When used in combinations and at different times during the course of the disease, these agents can effectively treat TB. Within the rifamycin class each agent has a superior and inferior aspect in the varied types of TB recipients seen such that no one agent can be recommended to treat all recipients.

COMMITTEE VOTE
APPROVED  DISAPPROVED  APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<th>NEW: ANTI-INFECTIVE AGENTS: Oral Anti-tuberculosis Agents</th>
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<tr>
<td>ETHAMBUTOL (compares to Myambutol®)</td>
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<td>ISONIAZID</td>
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<td>PASER® (aminosalicylic acid)</td>
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<td>PYRAZINAMIDE</td>
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<td>SEROMYCIN® Pulvules (cycloserine)</td>
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<td>TRECATOR-SC® (ethionamide)</td>
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<tr>
<td><strong>Rifamycins for Systemic Infections</strong></td>
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<tr>
<td>ISONARIF® (300mg rifampin, 150mg isoniazid)</td>
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<tr>
<td>MYCOBUTIN® (rifabutin)</td>
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<td>PRIFTIN® (rifapentine)</td>
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<td>RIFAMATE® (rifampin/isoniazid)</td>
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<tr>
<td>RIFAMPIN (compares to Rifadin® and Rimactane®)</td>
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<tr>
<td>RIFATER® (120mg rifampin, 50mg isoniazid, 300mg pyrazinamide)</td>
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<tr>
<td>MYAMBUOTOL® (ethambutol)</td>
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<tr>
<td><strong>Rifamycins for Systemic Infections</strong></td>
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<td>RIFADIN® (rifampin)</td>
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<td>RIMACTANE® (rifampin)</td>
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References
NEW: ANTI-INFECTIVE AGENTS: Non-Absorbable Rifamycins

RECOMMENDATION
Rifaximin (Xifaxan®) is the only non-absorbable rifamycin available. Rifaximin (Xifaxan®) is approved for traveler’s diarrhea and the only FDA approved drug for hepatic encephalopathy; however, both lactulose and neomycin have been used off-label. Although efficacy of the product has been demonstrated, there are theoretical concerns surrounding the use of rifaximin (Xifaxan®). Concerns and questions regarding the use of rifamycins (the class) as monotherapy for other indications other than tuberculosis is whether their use will result in the development of rifampin-resistant tuberculosis and the development/induction of resistance in S. aureus. Rifaximin (Xifaxan®) is considered a product whose efficacy and safety demonstrates that it is a therapeutic alternative to currently available therapies and should be subject to the recommended criteria below.

COMMITTEE VOTE
APPROVED    DISAPPROVED    APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

NEW: ANTI-INFECTIVE AGENTS: Non-Absorbable Rifamycins

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<tbody>
<tr>
<td>XIFAXAN®</td>
<td>XIFAXAN®</td>
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PROPOSED CRITERIA

Criteria Xifaxan® (rifaximin)

Rifaxxin® (rifaximin) will be authorized if either #1 or #2 are true:

1. The treatment of traveler’s diarrhea caused by non-invasive strains of Escherichia coli that can not be treated with another agent such as:
   - A fluoroquinolone [ie Ciprofloxacin (Cipro®)] OR
   - Azithromycin (Zithromax®)

2. The treatment of hepatic encephalopathy

Length of Authorization: One year

References


Rifaximin (Xifaxan®) for Travelers’ Diarrhea. The Medical Letter on Drugs and Therapeutics. Vol 46(Iss 1191). September 13, 2004 :74-76.


COMMITTEE VOTE
APPROVED    DISAPPROVED    APPROVED with MODIFICATION
NEW: ANTI-INFECTIVE AGENTS: Oral Sulfonamides, Folate Antagonists and Combination Products

RECOMMENDATION
The sulfonamides, folate antagonists and combination products represent a group of agents whose coverage encompasses a range of gram positive and gram negative organisms and varying disease states. These agents still have a place in the treatment predominantly of urinary tract infections and some respiratory infections. All of the agents within this class show similar efficacy against E. coli, Klebsiella, Proteus mirabilis, and staphylococcus; and therefore, can be used for UTIs and other infections caused by susceptible bacteria. Trimethoprim/sulfamethoxazole has more FDA-approved indications than the other agents in this class, including use in treatment and prophylaxis of pneumocystis carinii (PCP), treatment of traveller’s diarrhea, and treatment of shigellosis enteritis. Therefore, all of these agents can be considered therapeutic alternatives, with the exception of trimethoprim/sulfamethoxazole.

COMMITTEE VOTE
APPROVED    DISAPPROVED  APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

NEW: ANTI-INFECTIVE AGENTS: Oral Sulfonamides, Folate Antagonists, and Combination Products

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<tr>
<td>GANTRISIN® Pediatric (sulfisoxazole oral suspension)</td>
<td>BACTRIM® (trimethoprim/sulfamethoxazole)</td>
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<tr>
<td>PRIMSMOL® (trimethoprim oral solution)</td>
<td>BACTRIM® DS (trimethoprim/sulfamethoxazole)</td>
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<tr>
<td>SULFADIAZINE (generic only)</td>
<td>PROLOPRIM® (trimethoprim)</td>
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<tr>
<td>SULFISOXAZOLE (generic only – compared to Gantrisin® tablets – to be discontinued – available until supplies last)</td>
<td>SEPTRA® (trimethoprim/sulfamethoxazole)</td>
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<tr>
<td>TRIMETHOPRIM (compares to Proloprim®)</td>
<td>SEPTRA DS® (trimethoprim/sulfamethoxazole)</td>
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<td>TRIMETHOPRIM/ SULFAMETHOXAZOLE (compares to Bactrin®,Bactrim® DS, Septra®, Septra DS®)</td>
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References
RE-REVIEW: ANTI-INFECTIVE AGENTS: Oral Penicillins and Related Compounds

RECOMMENDATION

The penicillins are bactericidal antibiotics that include natural and semisynthetic derivatives (aminopenicillins and the penicillinase resistant penicillins). There are differences in the agents in the subclasses in regards to: the resistance to gastric inactivation, inactivation by beta-lactamase and corresponding spectrum of activity (which is enhanced by the addition of a beta-lactamase compound such as clavulanic acid). Due to differences in the subclasses of penicillins at least one agent in each of the subclasses should be present in order to have full spectrum of coverage.

COMMITTEE VOTE

APPROVED    DISAPPROVED  APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<td>AUGMENTIN® (amoxicillin and clavulanate)</td>
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<td>TRIMOX® (amoxicillin)</td>
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<td>VEETIDS® (penicillin VK)</td>
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References

Augmentin XR The Medical Letter • Vol. 45 (Issue 1148) January 20, 2003
RE-REVIEW: ANTI-INFECTIVE AGENTS: Oral Cephalosporins

RECOMMENDATION

First Generation Cephalosporins
Within the First Generation Cephalosporins the three agents are products whose safety and efficacy demonstrate that they may be considered therapeutic alternatives to one another.

COMMITTEE VOTE
APPROVED  DISAPPROVED  APPROVED with MODIFICATION

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Second Generation Cephalosporins
Within the Second Generation Cephalosporins there are four chemical entities, cefprozil, cefuroxime, loracarbef and cefaclor. Cefprozil and cefuroxime are considered therapeutic alternatives to one another as they have similar antimicrobial activity and side-effect profiles. Cefprozil and cefuroxime are considered superior over cefaclor and loracarbef due to their in-vitro activity over S. pneumoniae and H. influenzae.

COMMITTEE VOTE
APPROVED  DISAPPROVED  APPROVED with MODIFICATION

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Third Generation Cephalosporins
Within the third generation cephalosporins there are five chemical entities that can be considered therapeutic alternatives to one another based on their antimicrobial spectrum and recent guidelines.

COMMITTEE VOTE
APPROVED  DISAPPROVED  APPROVED with MODIFICATION
## RE-REVIEW: ANTI-INFECTIVE AGENTS: Oral Cephalosporins

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<tr>
<td>CEFADROXIL (compares to Duricef®)</td>
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<td>KEFLEX® (cephalexin)</td>
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<tr>
<td>CEPHRADINE (compares to Velosef®)</td>
<td>KEFLEX® 333, 750mg (cephalexin)</td>
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<td>KEFTAB® (cephalexin)</td>
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<td>VELOSEF® (cephradine)</td>
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<tr>
<td><strong>Second Generation Cephalosporins</strong></td>
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<td>CEFPROZIL (compares to Cefzil® tabs and suspension)</td>
<td>CEFACLOR (compares to Ceclor®, Ceclor CD®)</td>
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<td>CEDAX® (ceftibuten)</td>
<td>SPECTRACEF® (cefditoren)</td>
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<tr>
<td>CEPPODOXIME (compares to Vantin® tabs)</td>
<td>VANTIN® (cefpodoxime suspension)</td>
</tr>
<tr>
<td>OMNICEF® (cefdinir caps and susp)</td>
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<tr>
<td>SUPRAX® (cefixime suspension and tabs)</td>
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</tbody>
</table>

## References


RE-REVIEW: ANTI-INFECTIVE AGENTS: Oral Herpetic Antivirals

RECOMMENDATION

Famciclovir (Famvir®) and Valacyclovir (Valtrex®) are products whose safety and efficacy demonstrate that they are therapeutic alternatives to one another. Acyclovir (Zovirax®) is the only agent that has been studied and approved for the treatment of varicella zoster virus (VZV); therefore, it along with at least one other long acting herpetic antiviral agent should be available.

COMMITTEE VOTE

APPROVED   DISAPPROVED   APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<thead>
<tr>
<th>PREFERRED</th>
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<tr>
<td>ACYCLOVIR (compares to Zovirax® tabs, caps, oral susp)</td>
<td>ZOVIRAX® (acyclovir) (tabs, caps, oral susp)</td>
</tr>
<tr>
<td>FAMVIR®QL (famciclovir)</td>
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</tr>
<tr>
<td>VALTREX®QL (valacyclovir)</td>
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</tbody>
</table>

References

RECOMMENDATION

All agents are products whose safety and efficacy demonstrate that they are therapeutic alternatives to one another when given within 48 hours after the onset of illness in the treatment of influenza A virus. Both agents have been shown to decrease the duration of illness by approximately one (1) day when given within 48 hours. Additionally, both products have demonstrated safety and efficacy when used as prophylaxis against influenza A. If resistance patterns change during the 2006-2007 flu season and/or CDC recommendations change, then action will be taken immediately to adjust agents as preferred or non-preferred.

COMMITTEE VOTE

APPROVED  DISAPPROVED  APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

<table>
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<tr>
<th>RE-REVIEW: ANTI-INFECTIVE AGENTS: Influenza A Antivirals</th>
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<tr>
<td>AMANTADINE (compares to Symmetrel®)</td>
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<tr>
<td>RIMANTADINE (compares to Flumadine®)</td>
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References


RE-REVIEW: ANTI-INFECTIVE AGENTS: Influenza A and B Antivirals – Neuraminidase Inhibitors

RECOMMENDATION

Both zanamivir (Relenza®) and oseltamivir (Tamiflu®) when used to treat influenza A or B have been shown to reduce clinical illness and viral shedding by one (1) day if started within 48 hours after the onset of symptoms. The neuraminidase inhibitors have both demonstrated efficacy; however, safety issues may vary as zanamivir (Relenza®) is not recommended for use in patients with underlying airway disease such as asthma or COPD. In terms of prophylaxis, both agents have shown efficacy; however, zanamivir (Relenza®) has not been proven effective for prophylaxis of influenza in the nursing home setting, and oseltamivir (Tamiflu®) is the only agent approved for prophylaxis in children one (1) to twelve (12) years of age for both influenza A and B. Due to the efficacy of these agents to decrease flu-like symptoms for approximately only one (1) day and the varied prevalence of influenza B it is recommended that these agents be subject to the following criteria.

If resistance patterns change during the 2006-2007 and CDC recommendations change, then action will be taken immediately to adjust agents as preferred or non-preferred.

COMMITTEE VOTE

APPROVED DISAPPROVED APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<tr>
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<tr>
<td>RELENZA® cc (zanamivir)</td>
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<tr>
<td>TAMIFLU® cc (oseltamivir)</td>
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</tr>
</tbody>
</table>
PROPOSED CRITERIA

**Recommended Criteria:**

Tamiflu® (oseltamivir) will be approved if any of the following are true:

- For all patients diagnosed with influenza B by a Rapid Type ID test or by culture, Tamiflu® can be authorized if started within 48 hours of onset of symptoms.
- For suspected cases of avian influenza species (optimal doses and duration of treatment are not known, but will be dealt with on a case by case basis if such cases occur)
- For prophylaxis of close contacts of a recipient with known influenza B

Length of authorization: Tamiflu® may be used for prevention of influenza A & B for the duration of peak influenza in communities or for outbreak control in high risk populations. Thus length of authorizations may vary.

Relenza® (zanamivir) will be approved if any of the following are true

- For all patients diagnosed with influenza B by a Rapid Type ID test or by culture, Relenza® can be authorized if started within 48 hours of onset of symptoms.
- For suspected cases of avian influenza species (optimal doses and duration of treatment are not known, but will be dealt with on a case by case basis if such cases occur)
- For prophylaxis of close contacts of a recipient with known influenza B

Length of authorization: For date of service only. In addition, only 1 course of therapy will be allowed each 6 months.

**References**


**COMMITTEE VOTE**

APPROVED   DISAPPROVED   APPROVED with MODIFICATION
**RE-REVIEW: ANTI-INFECTIVE AGENTS: Influenza Intranasal Vaccinations**

**RECOMMENDATION**

Influenza live virus (FluMist®) is considered a product whose efficacy and safety demonstrate that it is a therapeutic alternative to other currently available agents.

**COMMITTEE VOTE:**

APPROVED  DISAPPROVED  APPROVED with MODIFICATION

**PROPOSED CRITERIA**

<table>
<thead>
<tr>
<th>Criteria for FluMist® (influenza intranasal vaccine)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FluMist® will only be authorized if all of the following are true:</td>
</tr>
<tr>
<td>• The patient is unable to receive the intramuscular injection due to insufficient muscle mass or muscle wasting</td>
</tr>
<tr>
<td>• The patient must be a healthy adult or child between the ages of 5-49.</td>
</tr>
</tbody>
</table>

**References**

CDC Alert. [http://www.cdc.gov/flu/han011406.htm](http://www.cdc.gov/flu/han011406.htm)  

**COMMITTEE VOTE:**

APPROVED  DISAPPROVED  APPROVED with MODIFICATION
NEW: ANTI-INFECTIVE AGENTS: Cytomegalovirus (CMV) Oral Antivirals

RECOMMENDATION

Oral valganciclovir (Valcyte®) has largely replaced oral ganciclovir (Cytovene®) in clinical practice. Valganciclovir (Valcyte®) is an oral prodrug of ganciclovir (Cytovene®) with a high oral bioavailability that is able to achieve plasma concentrations similar to that of IV administered ganciclovir (Cytovene®). Valganciclovir (Valcyte®) has shown to be effective in the treatment of cytomegalovirus (CMV) retinitis and has been shown to be as effective as ganciclovir in the prevention of CMV disease in solid organ transplants (with the exception of liver transplant). Although a pro-drug of ganciclovir, valganciclovir (Valcyte®) has exhibited differing results in the prevention of CMV in liver transplant patients such that it has not yet gained FDA approval for use, nor has it consistently shown efficacy or superiority to ganciclovir (Cytovene®) in this group of patients. At this time it is recommended that both agents be preferred for their possible differentiating properties.

COMMITTEE VOTE

APPROVED    DISAPPROVED    APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

<table>
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<tr>
<th>NEW: ANTI-INFECTIVE AGENTS: Cytomegalovirus (CMV) Oral Antivirals</th>
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<tbody>
<tr>
<td>GANCICLOVIR (compares to Cytovene®)</td>
<td>VALCYTE® (valganciclovir)</td>
<td>CYTOVENE® (ganciclovir)</td>
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</tbody>
</table>

References

Drugs for Non-HIV Viral Infections. Treatment Guidelines from The Medical Letter • Vol. 3 (Issue 32) April 2005


RE-REVIEW: ANTI-INFECTIVE AGENTS: Hepatitis C Oral Antivirals

RECOMMENDATION

The use of ribavirin with peginterferon alpha has produced higher results than with the use of peginterferon alone and is considered the regimen of choice for chronic HCV. All agents are products whose safety and efficacy demonstrate that they are therapeutic alternatives to one another.

COMMITTEE VOTE

APPROVED  DISAPPROVED  APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<tr>
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<tbody>
<tr>
<td>RIBAVIRIN [200 mg tabs and caps (generic of COPEGUS® and REBETOL®)]</td>
<td>COPEGUS® [200 mg caps (ribavirin)]</td>
</tr>
<tr>
<td>RIBASPHERES [200 mg tab and caps, 400 mg tab, 600 mg tab (ribavirin)]</td>
<td>REBETOL® [200 mg tabs (ribavirin)]</td>
</tr>
<tr>
<td>RIBAPAK™ (ribavirin dose pack)</td>
<td>RIBATAB® [400 mg, 600 mg tabs (ribavirin)]</td>
</tr>
<tr>
<td>REBETOL® (ribavirin 40 mg/ml oral solution)</td>
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</tr>
</tbody>
</table>

References


Drugs for Non-HIV Viral Infections. Treatment Guidelines from The Medical Letter • Vol. 3 (Issue 32) April 2005


RE-REVIEW: ANTI-INFECTIVE AGENTS: Pegylated Interferons

RECOMMENDATION
All agents are products whose safety and efficacy demonstrate that they are therapeutic alternatives to one another in the treatment of Hepatitis C. Both agents have been studied in the treatment of Hepatitis B, albeit only pegylated interferon alpha 2a (Pegasys®) has the current FDA labeled indication.

COMMITTEE VOTE
APPROVED  DISAPPROVED  APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<th>PREFERRED</th>
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<tbody>
<tr>
<td>PEG-INTRON® QL (pegylated interferon alpha 2b)</td>
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<tr>
<td>PEGASYS® QL (pegylated interferon alpha 2a)</td>
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</tbody>
</table>

References

Drugs for Non-HIV Viral Infections. Treatment Guidelines from The Medical Letter • Vol. 3 (Issue 32) April 2005


NEW: ANTI-INFECTIVE AGENTS: Non-Pegylated Interferon Alphas

RECOMMENDATION

The non-pegylated alpha interferons share common biological activities such as antiviral activity, antiproliferative activity and immunomodulatory effects; however, the extent of the activity may vary amongst the subtype of the alpha interferon. The INF alfa-2a and INF alpha-2b subtypes share the closest activity and have exhibited similar results in the treatment of Hepatitis C; however they are still considered second line agents to their pegylated counterparts. The INF alfa-2a and INF alpha-2b products (Roferon-A®, Intron A®) have demonstrated efficacy and safety such that they may be considered therapeutic alternatives for one another. Rebetron ® (alfa-2b and 200mg ribavirin) differs only in that it is a combination product with ribavirin. Infergen® (interferon alpha-con-1) differs from other recombinant products (IFN alpha-2a and alpha-2b) by 20 amino acids. IFN alpha-con-1 (Infergen®) is indicated for chronic hepatitis C viral infections and is the only IFN proven to be effective in the treatment of nonresponders. Interferon alpha-n3 (Alferon N®) is only used in the treatment of cancer and includes the treatment of veneral and genital warts. There are differences in the activity of INF alpha-con-1 (Infergen®) and INF alpha-n3 (Alferon N®) such that neither agent can be deemed as a therapeutic alternative to one another.

COMMITTEE VOTE:

APPROVED   DISAPPROVED   APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS:

| NEW: ANTI-INFECTIVE AGENTS: Non-Pegylated Interferon Alphas |
|-------------------|-------------------|
| PREFERRED         | NON-PREFERRED     |
| ALFERON N® (interferon alfa-N3) |                   |
| INTRON A® (interferon alfa-2b)   |                   |
| INFERGEN® (interferon alpha-con-1) |                     |
| REBETRON® (interferon alfa-2b and 200mg ribavirin) | |
| ROFERON-A® (interferon alpha-2a) | |

References


Drugs for Non-HIV Viral Infections. Treatment Guidelines from The Medical Letter • Vol. 3 (Issue 32) April 2005


NEW: ANTI-INFECTIVE AGENTS: Oral Hepatitis B Antivirals

RECOMMENDATION
The agents in this class vary in resistance patterns, tolerance, side-effects and efficacy in recipients who have chronic HBV infection and concurrent co-infection with HIV/HBV such that at this time all they are not considered therapeutic alternatives to one another.

COMMITTEE VOTE
APPROVED   DISAPPROVED   APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

NEW: ANTI-INFECTIVE AGENTS: Oral Hepatitis B Antivirals

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<tr>
<td>BARA克莱® (entecavir)</td>
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<tr>
<td>EPIVIR-HB® (lamivudine)</td>
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<tr>
<td>HEPESERA® (adefovir)</td>
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</tbody>
</table>

References
Entecavir (Baraclude) for Chronic Hepatitis B: The Medical Letter. Vol 47: Issue 1210. June 6, 2005
Drugs for Non-HIV Viral Infections Treatment Guidelines from The Medical Letter. Vol. 3 (Issue 32); April 2005.

NEW: ANTI-INFECTIVE AGENTS: Monoclonal Antibodies for Prevention of Respiratory Syncitial Virus (RSV)

RECOMMENDATION
Guidelines from the American Academy of Pediatrics (AAP) recommend the use of palivizumab for prophylaxis of RSV in high risk infants, children younger than 24 months with chronic lung disease, and certain preterm infants. However, the guidelines state that due to the high cost of this drug, immunoprophylaxis should not be considered for infants who do not meet the established risk criteria. For this reason, it is recommended that Synagis be available only for infants meeting the criteria established by the AAP.

COMMITTEE VOTE
APPROVED   DISAPPROVED   APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

NEW: ANTI-INFECTIVE AGENTS: Oral Hepatitis B Antivirals

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<tr>
<td>SYNAGIS® (palivizumab)</td>
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</table>
PROPOSED CRITERIA

Criteria for Synagis (palivizumab)

Synagis® may be approved for patients under the age of 2 years meeting the following criteria.

For patients less than 6 months of age at the onset of the RSV season:

- If patient was born at 32 weeks’ gestation or earlier - May approve therapy beginning October 1st with a last date of therapy not after the end of the RSV season (April 30th).
- If the patient was born at 32-35 weeks’ gestation, the patient must have two or more of the following risk factors for severe RSV disease:
  - Exposure to environmental air pollutants, including tobacco smoke
  - Child care out of the home (>4 hours per week)
  - Siblings attending school or day-care
  - Congenital abnormalities of the airways
  - Severe neuromuscular disease
  - Long distance from hospital care, defined as 30 miles or 30 minutes distance
  - Low birth weight (<2500 Gm)

For patients less than 12 months of age at the onset of the RSV season:
- If the patient was born at 28 weeks’ gestation or earlier - May approve therapy beginning October 1st with a last date of therapy not after the end of the RSV season (April 30th).

For patients less than 24 months of age at the onset of the RSV season:
- If the patient has Chronic Lung Disease (formerly called bronchopulmonary dysplasia), that has required daily respiratory medications or treatments within the previous 6 months - May approve therapy beginning October 1st with a last date of therapy not after the end of the RSV season (April 30th).
- If the patient has a diagnosis of hemodynamically significant congenital heart disease (those receiving medication to control CHF, those with moderate to severe pulmonary hypertension, or those with cyanotic heart disease) - May approve therapy beginning October 1st with a last date of therapy not after the end of the RSV season (April 30th).

Diagnosis criteria must be established via a phone call/fax to the call center.

Claims will be denied for those infants and children with hemodynamically insignificant heart disease including:
- Secundum atrial septal defects
- Small ventricular septal defect
- Pulmonic stenosis
- Uncomplicated aortic stenosis
- Mild coarctation of the aorta
- Patent ductus arteriosus
- Mild cardiomyopathy in patients who are not receiving medical therapy
- Heart lesions adequately corrected by surgery unless the patient continues to require medication for CHF

References

Robinson R, Nahata M. Respiratory syncitial virus (RSV) immune globulin and palivizumab for prevention of RSV infections. AJHP. 2000; 57(3): 259-64.
Facts and Comparisions, www.factsandcomparison.com
USPDI, Micromedix, 2004
ANTI-INFECTIVE AGENTS

COMMITTEE VOTE
APPROVED   DISAPPROVED   APPROVED with MODIFICATION

RE-REVIEW: ANTI-INFECTIVE AGENTS: Oxazolidinones - Oral

RECOMMENDATION
Linezolid (Zyvox®) is currently the only agent in the class of oxazolidinones which serves to treat primarily resistant gram positive cocci. The arrival of this agent is important, when the emergence of resistance to last line drugs is rapidly spreading. However, careful use of this agents is important if long-term value is to be preserved such that the agent is recommended to have the criteria in place prior to approval to ensure its appropriate use.

COMMITTEE VOTE
APPROVED   DISAPPROVED   APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<th>RE-REVIEW: ANTI-INFECTIVE AGENTS: Oxazolidinones - Oral</th>
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<tbody>
<tr>
<td>ZYVOX®&lt;sup&gt;CC, QL&lt;/sup&gt; (linezolid)</td>
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</table>

PROPOSED CRITERIA

Criteria for Zyvox® (linezolid)

- For all requests for Zyvox® by mouth, the patient must have a diagnosis as listed below:
  - Vancomycin-resistant Enterococcus faecium infections
  - Vancomycin-resistant Enterococcus faecalis infections
  - Methicillin-resistant Staph aureus (MRSA) infections
- The patient must have culture documentation of the aforementioned diagnoses

Length of Authorization:
- Dependent upon diagnosis and length of therapy needed to treat.
- Maximum 14 days of therapy is recommended; however exceptions may exist.

References

COMMITTEE VOTE
APPROVED   DISAPPROVED   APPROVED with MODIFICATION
ANTI-INFECTIVE AGENTS

NEW: ANTI-INFECTIVE AGENTS: Nitrofurans - Oral

RECOMMENDATION

All agents are products whose safety and efficacy demonstrate that they are therapeutic alternatives to one another.

COMMITTEE VOTE

APPROVED   DISAPPROVED   APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<tr>
<td>NITROFURANTOIN MACROCRYSTALS (compares to Macrobid®)</td>
<td>FURADANTIN (nitrofurantoin oral susp)</td>
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<tr>
<td>NITROFURANTOIN monohydrate/macrocrystals (compares to Macrobid®)</td>
<td>MACRODANTIN® (nitrofurantoin macrocrystals)</td>
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<tr>
<td></td>
<td>MACROBID® (nitrofurantoin monohydrate/macrocrystals)</td>
</tr>
</tbody>
</table>

References


NEW: ANTI-INFECTIVE AGENTS: Methenamine and Combination Agents- Oral

RECOMMENDATION

All agents are products whose safety and efficacy demonstrate that they are therapeutic alternatives to one another.

COMMITTEE VOTE

APPROVED    DISAPPROVED    APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

<table>
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<th>NEW: ANTI-INFECTIVE AGENTS: Methenamine and Combination Agents- Oral</th>
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<tbody>
<tr>
<td><strong>PREFERRED</strong></td>
</tr>
<tr>
<td>METHENAMINE mandelate (Mandelamine®)</td>
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<tr>
<td>HIPREX® (methenamine hippurate)</td>
</tr>
<tr>
<td>Generic combinations of methenamine and phenylsalicylate, hyoscyamine, atropine and others</td>
</tr>
</tbody>
</table>

References


RECOMMENDATION

Fosfomycin (Monurol®) is considered a product whose safety and efficacy demonstrates that it is an alternative to other currently available therapies and that it is recommended to be subject to the criteria presented.

COMMITTEE VOTE:

APPROVED   DISAPPROVED   APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

NEW: ANTI-INFECTIVE AGENTS: Misc – Oral Agent for UTI

PREFERRED | NON-PREFERRED
---|---
MONUROL® (fosfomycin)

PROPOSED CRITERIA

Criteria for Monurol® (fosfomycin)

Monurol® (fosfomycin) will be authorized if any of the following are true:
1. The recipient is pregnant with a urinary tract infection (UTI)
2. The recipient has a contra-indication, intolerance, previous failure or is infected with an organism resistant to sulfamethoxazole/trimethoprim (Bactrim®, Septra®, Bactrim DS®, Septra DS®)

Length of Authorization: One year

References


COMMITTEE VOTE:

APPROVED   DISAPPROVED   APPROVED with MODIFICATION
NEW: ANTI-INFECTIVE AGENTS: NITROIMIDAZOLE ORAL AGENTS

RECOMMENDATION
Both metronidazole and tinidazole appear to be equally effective in the treatment of trichomoniasis, giardiasis and amebiasis such that they may be considered therapeutic alternatives to one another. Although both agents share *in vitro* activity against anaerobic bacteria and *H. pylori* only metronidazole carries an FDA labeled indication for both. There is conflicting evidence as to whether tinidazole is effective in metronidazole resistant strains of trichomoniasis; however, authorization will be allowed if treatment failure occurs with metronidazole 2 g single dose and reinfection is excluded.

COMMITTEE VOTE
APPROVED   DISAPPROVED   APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

<table>
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<tr>
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<tr>
<td>METRONIDAZOLE (compares to Flagyl®)</td>
<td>FLAGYL® (metronidazole)</td>
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<tr>
<td>METRONIDAZOLE ER (compares to Flagyl® ER)</td>
<td>FLAGYL® ER (metronidazole 750mg)</td>
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<td></td>
<td>TINDAMAX® (tinidazole)</td>
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</tbody>
</table>

References


RE-REVIEW: ANTI-INFECTIVE AGENTS: Oral Macrolides and Azalides

RECOMMENDATION

In the macrolide class consisting of brand and generic erythromycin products there are various formulations consisting of various salt forms and release properties that exist; however, the efficacy of erythromycin remains the same when used in equivalent dosages.

The advanced generation macrolides/azalides are separated from erythromycin as these agents confer greater activity against one of the major organisms (H. influenzae) in community acquired pneumonia, bronchitis and sinusitis over erythromycin. Although both agents have been studied in the treatment of H. pylori, only clarithromycin (Biaxin®) is FDA approved. In terms of respiratory infections, the two chemical entities and formulations are considered therapeutic alternatives to one another.

COMMITTEE VOTE

APPROVED   DISAPPROVED   APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<tr>
<td>ERYTHROMYCIN generic products</td>
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<tr>
<td>AZITHROMYCIN®QL (compares to Zithromax®)</td>
<td>BIAxin® (clarithromycin)</td>
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<tr>
<td>CLARITHROMYCIN (compares to Biaxin®)</td>
<td>BIAxin XL® (clarithromycin extended release)</td>
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<td>ZITHROMAX®QL (azithromycin)</td>
</tr>
<tr>
<td></td>
<td>ZMAX®QL (azithromycin)</td>
</tr>
</tbody>
</table>

References


RE-REVIEW: ANTI-INFECTIVE AGENTS: Oral Ketolides

RECOMMENDATION

Telithromycin (Ketek®) is considered a product whose efficacy demonstrates that it is a therapeutic alternative to currently available therapies and holds an advantage over macrolide resistant *S. pneumonia*. The arrival of this agent is important due to the emergence of resistant infections. Due to recent safety concerns (possible liver injury and failure) and the need to utilize these agents prudently so that long-term value is maintained it is recommended that the agent be subject to the following criteria.

COMMITTEE VOTE

APPROVED   DISAPPROVED   APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<tbody>
<tr>
<td>KETEK® (telithromycin)</td>
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</table>

PROPOSED CRITERIA

Criteria Ketek® (telithromycin)

For healthy recipients in the treatment of acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, or previously well ambulatory community-acquired pneumonia in recipients Ketek® will be authorized if there is a previous trial (within 28 days) of any of the following antibiotics:

- A penicillin, cephalosporin, sulfonamide, advanced macrolide, respiratory quinolone, doxycycline, amoxicillin/clavulanate, or ceftriaxone (note this is currently systematically in place)

For recipients with comorbidities (ie COPD, Diabetes, renal failure, CHF, asthma, recent hospitalization)

- A failure, trial, intolerance or suspected insusceptibility to one of the following: an advanced generation macrolide or respiratory fluoroquinolone will be required prior to authorization

Length of Authorization: One year

References


COMMITTEE VOTE

APPROVED   DISAPPROVED   APPROVED with MODIFICATION
ANTI-INFECTIVE AGENTS

NEW: ANTI-INFECTIVE AGENTS: Oral Lincosamides

RECOMMENDATION

Clindamycin is the only orally available lincosamide and is effective agent for anaerobes and some gram positive organisms. The safety and efficacy of clindamycin has shown that it is a valuable agent in the antimicrobial armamentarium.

COMMITTEE VOTE

APPROVED   DISAPPROVED   APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<tr>
<th>NEW: ANTI-INFECTIVE AGENTS: Oral Lincosamides</th>
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<tr>
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<tr>
<td>CLINDAMYCIN (compares to Cleocin® caps)</td>
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<tr>
<td>CLEOCIN® Pediatric granules for oral suspension</td>
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<tr>
<td><strong>NON-PREFERRED</strong></td>
</tr>
<tr>
<td>CLEOCIN® (clindamycin caps)</td>
</tr>
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</table>

References


**RE-REVIEW: ANTI-INFECTIVE AGENTS: Oral Quinolones**

**RECOMMENDATION**

In the second generation quinolone sub-class, ciprofloxacin (non-sustained release formulation) is considered to be superior in terms of gram negative activity. All other agents are products whose safety and efficacy demonstrate that they may be considered therapeutic alternatives to one another. Within the second generation urinary tract infections (UTI) agents, these agents have demonstrated efficacy and safety in the treatment of UTIs, but not that of systemic infections such that they may be considered alternatives to existing therapies for UTI treatment.

In the third generation quinolone sub-class, also known as the respiratory quinolones, Avelox® (moxifloxacin), Factive® (gemifloxacin) and Levaquin® (levofloxacin) may be considered therapeutic alternatives to one another in terms of the activity against organisms that cause most common respiratory illnesses. In terms of anaerobic activity, Avelox® (moxifloxacin) and Factive (gemifloxacin) share the same spectrum of activity whereas Levaquin® (levofloxacin) does not. It is recommended that at least one respiratory quinolone with adequate coverage against the organisms implicated in most respiratory infections be available.

**COMMITTEE VOTE**

APPROVED  DISAPPROVED  APPROVED with MODIFICATION

**PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS**

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<tr>
<td><strong>Second generation</strong></td>
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<tr>
<td>CIPROFLOXACIN (compares to Cipro®)</td>
<td>CIPRO® (ciprofloxacin)</td>
</tr>
<tr>
<td>OFLOXACIN (compares to Floxin®)</td>
<td>FLOXIN® (ofloxacin)</td>
</tr>
<tr>
<td></td>
<td>NOROXIN® (norfloxacin)</td>
</tr>
<tr>
<td><strong>Third generation</strong></td>
<td></td>
</tr>
<tr>
<td>AVELOX® (moxifloxacin)</td>
<td>FACTIVE® (gemifloxacin)</td>
</tr>
<tr>
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<td>LEVAQUIN® (levofloxacin)</td>
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</table>

**Note:** Tequin® (gatifloxacin) is no longer manufactured

**References**


RE-REVIEW: ANTI-INFECTIVE AGENTS: Oral Antifungals used for Onychomycosis

RECOMMENDATION

The treatment of onychomycosis will not be allowed for cosmetic use and will be approved when health would be compromised without care. The two oral agents currently FDA labeled for the treatment of onychomycosis are terbinafine (Lamisil®) and itraconazole (Sporanox®). Terbinafine (Lamisil®) is considered a product whose safety and efficacy demonstrate that it is superior to itraconazole in the treatment of onychomycosis.

COMMITTEE VOTE

APPROVED  DISAPPROVED  APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<tr>
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<tbody>
<tr>
<td>LAMISIL®&lt;sup&gt;cc,ql&lt;/sup&gt; (terbinafine)</td>
<td>ITRACONAZOLE&lt;sup&gt;cc,ql&lt;/sup&gt; (compares to Sporanox®)</td>
</tr>
<tr>
<td></td>
<td>SPORANOX®&lt;sup&gt;cc,ql&lt;/sup&gt; (itraconazole)</td>
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</table>

PROPOSED CRITERIA

Onychomycosis Class Criteria
Antifungals will be authorized for the diagnosis of nail fungal infections (onychomycosis) if the following are present:

- There is a positive lab culture
- If there is an underlying disease (ie diabetes, patients peripheral vascular disease, poor circulation, immunocompromised recipients etc)

Note:
For the diagnosis of onychomycosis – itraconazole (Sporanox®) should only be approved if the recipient has failed, has an intolerance or contra-indication to terbinafine (Lamisil®) and the clinical criteria for onychomycosis has been met. Approval will not be made for cosmetic reasons. For a non-onychomycosis diagnosis, Itraconazole (Sporanox®) is unrestricted.

Length of authorization: Up to 3 months. Max of 1 course per year for the diagnosis of onychomycosis.
References


COMMITTEE VOTE

APPROVED   DISAPPROVED   APPROVED with MODIFICATION
RE-REVIEW: ANTI-INFECTIVE AGENTS: Oral Antifungals Used for Systemic Infections

RECOMMENDATION

Fluconazole (Diflucan®), ketoconazole (Nizoral®), itraconazole (Sporanox®), voriconazole (Vfend®) and flucytosine (Ancobon®) are products whose safety and efficacy differ by virtue of their spectrum of activity, bioavailability, adverse effects and potential for drug interactions. Voriconazole (Vfend®) and Itraconazole (Sporanox®) share a spectrum of activity close to one another, although Voriconazole (Vfend®) appears to be more active against Aspergillus spp and some species of Candida. Careful use of Voriconazole (Vfend®) is important if long-term value is to be preserved. Itraconazole (Sporanox®) will be subject to the onychomycosis criteria, but use will be unrestricted for systemic infections. Flucytosine (Ancobon®) has both safety (potential for bone marrow depression) and efficacy (resistance emerges when used alone) issues such that it is considered an inferior product that should only be used in combination with other antifungal agents (typically IV amphotericin B).

COMMITTEE VOTE

APPROVED   DISAPPROVED  APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

RE-REVIEW: ANTI-INFECTIVE AGENTS: Oral Antifungals Used for Systemic Infections

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<tr>
<td>GRISEOFULVIN</td>
<td>ANCOBON (flucytosine)</td>
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<tr>
<td>GRIS-PEG® (griseofulvin)</td>
<td>DIFLUCAN® (fluconazole)</td>
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<tr>
<td>GRIFULVIN V® (griseofulvin)</td>
<td>ITRACONAZOLECC (compares to Sporanox®)</td>
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<td>FLUCONAZOLE (compares to Diflucan®)</td>
<td>NIZORAL® (ketoconazole)</td>
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<td>KETOCONAZOLE (compares to Nizoral®)</td>
<td>SPORANOX®CC (itraconazole)</td>
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<tr>
<td>VFEND®CC (voriconazole)</td>
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</table>

PROPOSED CRITERIA

Criteria for Sporanox® (itraconazole)

Onychomycosis Class Criteria

Antifungals will be authorized for the diagnosis of nail fungal infections (onychomycosis) if the following are present:
- There is a positive lab culture
- If there is an underlying disease (ie diabetes, patients peripheral vascular disease, poor circulation, immunocompromised recipients etc)

Note:
For the diagnosis of onychomycosis – itraconazole (Sporanox®) should only be approved if the recipient has failed, has an intolerance or contra-indication to terbinafine (Lamisil®) and the clinical criteria for onychomycosis has been met. Approval will not be made for cosmetic reasons. For a non-onychomycosis diagnosis, Itraconazole (Sporanox®) is unrestricted.

Length of authorization: Up to 3 months. Max of 1 course per year for the diagnosis of onychomycosis.

COMMITTEE VOTE

APPROVED   DISAPPROVED  APPROVED with MODIFICATION
PROPOSED CRITERIA

Criteria for Vfend® (voriconazole)

Vfend® will be approved for the following diagnoses:

- Treatment of invasive aspergillosis
- Serious fungal infections caused by S. apiospermum and Fusarium species including F. solani in patients intolerant of or refractory to other therapy
- Other serious fungal infections where other agents [ie Diflucan® (Fluconazole), Nizoral® (Ketoconazole), Sporanox® (Itraconazole)] are resistant or refractory to the fungal infection
- The treatment of candidemia or esophageal candidiasis in neutropenic or nonneutropenic patients (those without low white blood cell counts) and the following Candida infections: disseminated (deep tissue) infections in skin and infections in abdomen, kidney, bladder wall, and wounds if the Candida species is resistant or suspected to be resistant to other antifungals [ie Diflucan® (Fluconazole), Nizoral® (Ketoconazole), Sporanox® (Itraconazole)]
- As part of standard anti-fungal regimen in febrile neutropenic recipients

Note:
If started as an inpatient hospital regimen and this is a continuation of therapy via home health or in a nursing home, then the drug is approvable

Length of Authorization: variable dependent upon disease state

References


COMMITTEE VOTE

APPROVED   DISAPPROVED   APPROVED with MODIFICATION
NEW: ANTI-INFECTIVE AGENTS: Rx Vaginal Antifungals

RECOMMENDATION
All of the products in this category have been shown to be safe and effective for the local treatment of vulvovaginal candidiasis. The available clinical studies fail to show any significant differences in response rates or tolerability between the available vaginal antifungal products. Published reviews on these agents state that differences in formulation are not considered to be clinically relevant to therapeutic outcome and are more a function of patient preference.
Miconazole is active against susceptible strains of Trichophyton spp., Epidermophyton spp., Candida albicans, and Microsporum spp., whereas nystatin, terconazole, and butoconazole are active against Candida albicans. Nystatin is Pregnancy Category A and poorly absorbed; therefore this product should be available for pregnant or breast-feeding women. Based on this information, it is recommended that at least miconazole and nystatin be available within this category. The remaining vaginal antifungal products can be considered therapeutic alternatives to one another.

COMMITTEE VOTE
APPROVED        DISAPPROVED        APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<tr>
<td>MICONAZOLE 3 vaginal supp., 200 mg (compares to Monistat® 3)</td>
<td>GYNAZOLE-1® (butoconazole)</td>
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<tr>
<td>NYSTATIN vaginal tablets, 100,000 U</td>
<td>MONISTAT® 3 vaginal supp. (200 mg)</td>
</tr>
<tr>
<td>TERCONAZOLE 0.4%, 0.8% (compares to Terazol® 3, 7)</td>
<td>TERAZOL® 3, 7 (terconazole)</td>
</tr>
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<td>ZAZOLE® (terconazole)</td>
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</table>

References
Facts and Comparisons, www.factsandcomparison.com
USPDI, Micromedix, 2004
NEW: ANTI-INFECTIVE AGENTS: Antifungals for Oropharyngeal Candidiasis

RECOMMENDATION
All agents in this category are indicated for the treatment of oropharyngeal candidiasis. Clotrimazole troches are also indicated for prevention of oropharyngeal candidiasis. However, clotrimazole troches are not indicated for use in children less than 3 years of age, whereas nystatin oral suspension can be used even in infants. Based on this information, it is recommended that at least one oral clotrimazole product and at least one oral nystatin product be available.

COMMITTEE VOTE
APPROVED    DISAPPROVED    APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<th>RE-REVIEW: ANTI-INFECTIVE AGENTS: Rx Vaginal Antifungals</th>
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<tr>
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</tr>
<tr>
<td>CLOTRIMAZOLE troches (compares to Mycelex®)</td>
</tr>
<tr>
<td>NYSTATIN oral suspension, tablets, powder</td>
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</tbody>
</table>

References
Facts and Comparisons, www.factsandcomparison.com
USPDI, Micromedix, 2004
NEW: ANTI-INFECTIVE AGENTS: Vaginal Antibiotics

RECOMMENDATION
The products in this class all contain 0.9% acetic acid and 0.025% oxyquinoline sulfate, and are used to maintain a vaginal pH of around 4 in order to prevent growth of infectious bacteria or fungus. They are considered to have similar efficacy and tolerability, and can be considered therapeutic alternatives to one another.

COMMITTEE VOTE
APPROVED   DISAPPROVED   APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<tr>
<th>RE-REVIEW: ANTI-INFECTIVE AGENTS: Rx Vaginal Antifungals</th>
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<tbody>
<tr>
<td>ACID JELLY (oxyquinoline sulfate, ricinoleic acid, glacial acetic acid)</td>
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</tr>
<tr>
<td>ACIDIC VAGINAL (oxyquinoline sulfate, ricinoleic acid, glacial acetic acid)</td>
<td>NON-PREFERRED</td>
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<tr>
<td>FEM PH (0.9% glacial acetic acid, 0.025% oxyquinoline sulfate)</td>
<td>NON-PREFERRED</td>
</tr>
<tr>
<td>RELAGARD (0.9% glacial acetic acid, 0.025% oxyquinoline sulfate) – priced as brand, but more utilization</td>
<td>NON-PREFERRED</td>
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</table>

References
Facts and Comparisions, www.factsandcomparison.com
USPDI, Micromedix, 2004
HEMATOPOIETIC AGENTS

LENGTH OF AUTHORIZATIONS: ONE YEAR-IF MEDICALLY JUSTIFIED.

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?
   
   Acceptable reasons include:
   
   - **Allergy** to medications not requiring prior approval
   - **Contraindication** to or drug-to-drug interaction with medications not requiring prior approval
   - **History** of unacceptable/toxic side effects to medications not requiring prior approval
   - Recipient’s condition is **clinically unstable**—and changing to a medication not requiring prior approval might cause deterioration of the recipient’s condition
   - Document clinically compelling information

2. The requested medication may be approved if both of the following are true:
   
   - If there has been a therapeutic **failure to no less than a one-month trial** of at least **one medication within the same class** not requiring prior approval. Verify via the recipient’s medication history to assure medication compliance
   - The requested medications corresponding generic (if a generic is available and covered by the State) has been attempted and failed or is contraindicated

3. The requested medication may be approved if the following is true:
   
   - An indication which is unique to a non-preferred agent and is supported by peer-reviewed literature or an FDA approved indication exists.
NEW: HEMATOPOIETIC AGENTS: r-Erythropoietin

RECOMMENDATION
All agents are products whose safety and efficacy demonstrate that they are therapeutic alternatives to one another.

COMMITTEE VOTE
APPROVED  DISAPPROVED  APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

NEW: HEMATOPOIETIC AGENTS: r-Erythropoietin

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<tr>
<td>ARANESP®&lt;sup&gt;CC&lt;/sup&gt; (darbepoetin alfa)</td>
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<tr>
<td>EPOGEN®&lt;sup&gt;CC&lt;/sup&gt; (epoetin alfa)</td>
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<tr>
<td>PROCRIT®&lt;sup&gt;CC&lt;/sup&gt; (epoetin alfa)</td>
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PROPOSED CRITERIA

Approval Criteria
1. The patient must have one of the following diagnoses:
   - Anemia associated with chronic renal failure
   - Treatment of chemotherapy induced anemia for non-myeloid malignancies
   - Retrovir<sup>®</sup> or Combivir<sup>®</sup> induced anemia
   - Autologous blood donations by patients scheduled to undergo nonvascular surgery
   - Patients with autonomic disorders that have anemia but only if orthostatic or postural hypotension is secondary to autonomic disorder.

   Examples of autonomic disorders:
   - Primary autonomic system failure
   - Multisystem atrophy (Shy-Drager syndrome)
   - Pure autonomic dysautonomia
   - Secondary autonomic system failure
   - Brain and brainstem stroke
   - Multiple sclerosis
   - Spinal cord transverse myelitis; syringomyelia
   - Tumor
   - Tabes dorsalis
   - Peripheral nervous system
   - Diabetes mellitus
   - Guillain-Barre syndrome
   - Alcoholic polyneuropathy
   - Human immunodeficiency virus infection
   - Amyloidosis
   - Porphyria
   - Hepatitis C Treatment related anemia
   - Any indication not mentioned above will require the submission of a peer reviewed study to support the use of the hematopoietic agent

2. The patient must have a hematocrit of 33 or less
   Note: Infants to age 6 months with a diagnosis of Anemia of Prematurity will not require lab work

Length of Authorization: 6 months
COMMITTEE VOTE

APPROVED   DISAPPROVED   APPROVED with MODIFICATION

NEW: HEMATOPOIETIC AGENTS: Colony Stimulating Factors

RECOMMENDATION
Among the G-CSF agents (filgrastim and peg-filgrastim), both products safety and efficacy demonstrate that they are therapeutic alternatives to one another. Between the GM-CSF and G-CSF agents, the ASCO 2006 guidelines on the use of white blood cell growth factors state that no recommendation can be made regarding equivalency of the two.

COMMITTEE VOTE

APPROVED   DISAPPROVED   APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

NEW: HEMATOPOIETIC AGENTS: Colony stimulating factors

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<tr>
<td>LEUKINE® (sargramostim, GM-CSF)</td>
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<tr>
<td>NEUPOGEN® (filgrastim, G-CSF)</td>
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<tr>
<td>NEULASTA® (pegfilgrastim, G-CSF)</td>
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</table>

References
NEW: HEMATOPOIETIC AGENTS: Interleukins

RECOMMENDATION
Oprelvekin (Neumega®) is the only approved growth factor used for the enhancement of platelets. Oprelvekin (Neumega®) is an effective agent for the prevention of severe chemotherapy-induced thrombocytopenia and appears to be safer than transfusion therapy and just as effective. It has been studied, but not approved, for use in drug-induced thrombocytopenias as well. Oprelvekin (Neumega®) represents a unique agent with demonstrated safety and efficacy.

COMMITTEE VOTE
APPROVED     DISAPPROVED     APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<tr>
<td>NEUMEGA® (oprelvekin, interleukin 11; IL-11)</td>
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</table>

References
LENGTH OF AUTHORIZATIONS: 1 YEAR (unless otherwise specified)

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?
   Acceptable reasons include:
   - **Allergy** to medications not requiring prior approval
   - **Contraindication** to or drug-to-drug interaction with medications not requiring prior approval
   - **History** of unacceptable/toxic side effects to medications not requiring prior approval

2. The requested medication may be approved if both of the following are true:
   - There has been a therapeutic **failure to no less than a one-month trial** of at least two medication(s) within the same class not requiring prior approval.
   - The requested medication’s corresponding generic (if a generic is available and preferred by the State) has been attempted, failed, or is contraindicated.

3. The requested medication may be approved if the following is true:
   - An indication which is unique to a non-preferred agent and is supported by peer-reviewed literature or an FDA approved indication exists.
NEW: UROLOGICS: Urinary Alkalizing Agents

RECOMMENDATION
All products in this category are effective in increasing the urine pH and preventing/dissolving uric acid or cystine calculi in the urinary tract. Potassium citrate products and potassium citrate/citric acid products can prevent/dissolve calcium oxalate and calcium phosphate calculi, in addition to uric acid and cystine calculi. Differences in the amount of sodium and potassium among the various products in this category may play a role in product selection for patients who are sodium restricted, hyper- or hypo-kalemic, etc. Therefore, it is recommended that at least one tri-citrate product, at least one sodium citrate/citric acid product, at least one potassium citrate product (with or without citric acid) be made available.

COMMITTEE VOTE
APPROVED   DISAPPROVED   APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<tr>
<td>CITRIC ACID/SODIUM CITRATE (compares to</td>
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<td>Bicitra)</td>
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<tr>
<td>CYTRA-2® (citric acid/sodium citrate)</td>
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<td>CYTRA-3® (potassium citrate/sodium citrate)</td>
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<tr>
<td>CITRA-K® (citric acid/potassium citrate)</td>
</tr>
<tr>
<td>TRICITRATES® (potassium citrate/sodium citrate/citric acid)</td>
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<td><strong>PA REQUIRED</strong></td>
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<tr>
<td>BICITRA® (citric acid/sodium citrate)</td>
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<tr>
<td>ORACIT® (citric acid/sodium citrate)</td>
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<tr>
<td>POLYCITRA® (potassium citrate/sodium citrate/citric acid)</td>
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<tr>
<td>POLYCITRA-K® (citric acid/potassium citrate)</td>
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<tr>
<td>POLYCITRA-LC S/F® (potassium citrate/sodium citrate/citric acid)</td>
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<tr>
<td>CITROLITH® (potassium citrate/sodium citrate)</td>
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<tr>
<td>UROCIT-K® (potassium citrate)</td>
</tr>
</tbody>
</table>

References:
Facts & Comparisons. 4.0. http://www.factsandcomparisons.com/
Thomson MICROMEDEX. http://www.thomsonhc.com/home/dispatch

NEW: UROLOGICS: Urinary Acidifying Agents

RECOMMENDATION
All products in this category are effective at acidifying the urine, resulting in increased calcium solubility, and reduced odor, rash, and skin irritation from ammonia in the urine. Uroquid acid #2® contains methanamine (a urinary antibiotic) in addition to potassium phosphate (a urinary acidifier); however, the other urinary acidifying agents can be used with methanamine as well. Therefore, the available urinary acidifying products can be considered therapeutic alternatives to one another.

COMMITTEE VOTE
APPROVED   DISAPPROVED   APPROVED with MODIFICATION
## PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS:

### NEW: UROLOGICS: Urinary Acidifying Agents

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<td>K-PHOS ORIGINAL® (potassium acid phosphate)</td>
<td>UROQUID ACID #2® (methanamine mandelate/potassium phosphate)</td>
</tr>
<tr>
<td>K-PHOS #2® (potassium acid phosphate/sodium acid phosphate)</td>
<td>PEDAMETH® (racemethionine)</td>
</tr>
<tr>
<td>K-PHOS MF® (potassium acid phosphate/sodium acid phosphate)</td>
<td>RENACIDIN® (magnesium carbonate/citric acid/glucono-lactone)</td>
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<tr>
<td>K-PHOS NEUTRAL® (dibasic sodium phosphate/monobasic potassium phosphate/monobasic sodium phosphate)</td>
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<tr>
<td>PHOSPHA NEUTRAL® (dibasic sodium phosphate/monobasic potassium phosphate/monobasic sodium phosphate)</td>
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<tr>
<td>URO-KP-NEUTRAL® (dibasic sodium phosphate/monobasic potassium phosphate/monobasic sodium phosphate)</td>
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References:

### NEW: UROLOGICS: Urinary Analgesics

**RECOMMENDATION**

All products in this category contain phenazopyridine as an active ingredient. Phenazopyridine has been shown to exert an analgesic effect on the mucosa of the urinary tract, relieving pain, burning, urgency, and frequency associated with urinary tract infections. Phenazopyridine/hyoscyamine/butabarbital combination products have been shown to provide additional benefit compared to phenazopyridine alone in patients experiencing detrusor muscle spasm along with pain, burning, frequency, etc. All phenazopyridine products can be considered therapeutic alternatives to one another. Likewise, all phenazopyridine/hyoscyamine/butabarbital products can be considered therapeutic alternatives to one another. However, both a phenazopyridine and a phenazopyridine/hyoscyamine/butabarbital product should be made available.

**COMMITTEE VOTE**

- APPROVED
- DISAPPROVED
- APPROVED with MODIFICATION
NEW: UROLOGICS: Urinary Analgesics

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</thead>
<tbody>
<tr>
<td>PHENAZOPYRIDINE (Compares to Pyridium®)</td>
<td>PYRIDIUM® (phenazopyridine)</td>
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<tr>
<td>PHENAZOPYRIDINE PLUS (Compares to Pyridium Plus®)</td>
<td>PYRIDIUM PLUS® (phenazopyridine)</td>
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<tr>
<td>URELFIE PLUS® (phenazopyridine/hyoscyamine/butabarbital)</td>
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<tr>
<td>PYRELLE HB® (phenazopyridine/hyoscyamine/butabarbital)</td>
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<tr>
<td>TREFERL PLUS® (phenazopyridine/hyoscyamine/butabarbital)</td>
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<tr>
<td>URODOL® (phenazopyridine)</td>
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</table>

References:

NEW: UROLOGICS: Interstitial Cystitis Agents

RECOMMENDATION

Elmiron® (pentosan polysulfate sodium) is the first oral medication approved by the FDA specifically for interstitial cystitis (IC). It is thought to help replenish the bladder lining and can be used long-term in patients with IC to relieve pain, urgency, and frequency. In contrast, the urinary analgesics, while effective at relieving pain associated with IC, should not be used long-term due to risks of serious side effects, including jaundice and anemia. For this reason, it is important to have pentosan polysulfate sodium available.

COMMITTEE VOTE

APPROVED   DISAPPROVED   APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

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<tr>
<th>PREFERRED</th>
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<tbody>
<tr>
<td>ELMIRON® (pentosan polysulfate sodium)</td>
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</table>

References:
NEW: UROLOGICS: Kidney Stone Agents

**RECOMMENDATION**
Cystagon® (cysteamine bitartrate) and Thiola® (tiopronin) exhibit similar efficacy and safety in treating cystinuria and preventing kidney stone formation. Calcibind® (cellulose sodium phosphate) can cause severe metabolic abnormalities, including hypomagnesemia, hyperoxaluria, calcium malabsorption, and iron malabsorption. Due to this serious side-effect profile, Calcibind® has a limited role in treatment today. In addition, Stonex® (eucalyptus/bornyl/fenchone/pinene alpha-beta/camphene) has little to no clinical data to support its use. Therefore, Cystagon® and Thiola® should be considered reasonable choices for the prevention of cystine kidney stone formation, while the use of Calcibind® and Stonex® should not be encouraged at this time.

**COMMITTEE VOTE**
APPROVED  DISAPPROVED  APPROVED with MODIFICATION

**PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS**

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<th>NEW: UROLOGICS: Kidney Stone Agents</th>
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<tbody>
<tr>
<td><strong>PREFERRED</strong></td>
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<tr>
<td>CYSTAGON® (cysteamine bitartrate)</td>
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<tr>
<td>THIOLA® (tiopronin)</td>
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References:
Facts & Comparisons. 4.0. [http://www.factsandcomparisons.com/](http://www.factsandcomparisons.com/)

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RE-REVIEW: UROLOGICS: Urinary Tract Antispasmodics

**RECOMMENDATION**
Based on the results of several head to head clinical trials, the drugs in this class can be considered equivalent with regards to efficacy (improvements in incontinence, decreased urgency/frequency, etc.). Oxybutynin has been shown to be associated with a higher incidence of adverse effects (especially dry mouth) compared to the other agents in this class. Transdermal oxybutynin is also associated with higher rates of adverse events (mainly application site reactions) compared to tolteridine. Lastly, the long-acting formulations were found to be associated with fewer adverse events than the immediate-release formulations. Based on these clinical findings, it is recommended that at least one long-acting agent, and at least one non-oxybutynin product be made available to TennCare recipients.

**COMMITTEE VOTE**
APPROVED  DISAPPROVED  APPROVED with MODIFICATION
PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

RE-REVIEW: UROLOGICS: Urinary Tract Antispasmodics

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<tr>
<td>OXYBUTYNIN (Compares to Ditropan®)</td>
<td>DETROL® (tolterodine)</td>
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<tr>
<td>DETROL LA® (tolterodine)</td>
<td>OXYTROL® (oxybutynin)</td>
</tr>
<tr>
<td>ENABLEX® (darifenacin)</td>
<td>SANCTURA® (trospium)</td>
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<tr>
<td>FLAVOXATE (Compares to Urispas®)</td>
<td>DITROSPAN® (oxybutynin)</td>
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<tr>
<td>VESICARE® (solifenacin)</td>
<td>DITROSPAN XL® (oxybutynin)</td>
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<tr>
<td>DETROL® (tolterodine)</td>
<td>URISPAS® (flavoxate)</td>
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<td>OXYTROL® (oxybutynin)</td>
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<td>SANCTURA® (trospium)</td>
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<tr>
<td>DITROSPAN® (oxybutynin)</td>
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<tr>
<td>DITROSPAN XL® (oxybutynin)</td>
<td></td>
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<tr>
<td>URISPAS® (flavoxate)</td>
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</table>

References:
Facts & Comparisons. 4.0. http://www.factsandcomparisons.com/
Thomson MICROMEDEX. http://www.thomsonhc.com/home/dispatch

RE-REVIEW: UROLOGICS: Non-Selective Alpha-Blockers

RECOMMENDATION
All agents within this class have similar efficacy and safety profiles. While prazosin is not FDA-approved for treatment of BPH, it would be expected to provide similar benefits in BPH patients to the other non-selective alpha-blockers given its similar mechanism of action. All non-selective alpha-blockers are approved for the treatment of benign prostatic hyperplasia (BPH) and the treatment of hypertension, with the exception of Cardura XL®, which is indicated only for the treatment of BPH. Despite its extended-release formulation, Cardura XL® is associated with similar rates of hypotension as doxazosin. While Cardura XL® has lower rates of postural hypotension and dizziness than doxazosin, it does not have as favorable an adverse event profile as the selective alpha blockers. Based on this information, the non-selective alpha-blockers can be considered therapeutic alternatives for the treatment of BPH. In addition, all non-selective alpha blockers, with the exception of Cardura XL®, can be considered therapeutic alternatives for the treatment of hypertension.

COMMITTEE VOTE
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PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

RE-REVIEW: UROLOGICS: Non-Selective Alpha-Blockers

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<tr>
<td>DOXAZOSIN (Compares to Cardura®)</td>
<td>CARDURA® (doxazosin)</td>
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<tr>
<td>PRAZOSIN (Compares to MiniPress®)</td>
<td>CARDURA XL® (doxazosin extended-release)</td>
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<tr>
<td>TERAZOSIN (Compares to Hytrin®)</td>
<td>MINIPRESS® (prazosin)</td>
</tr>
<tr>
<td></td>
<td>HYTRIN® (terazosin)</td>
</tr>
</tbody>
</table>

References:
Facts & Comparisons. 4.0. http://www.factsandcomparisons.com/
Thomson MICROMEDEX. http://www.thomsonhc.com/home/dispatch
RE-REVIEW: UROLOGICS: Selective Alpha-Blockers

RECOMMENDATION
All agents within this class have similar efficacy in reducing the signs and symptoms of BPH. In addition, they have very similar adverse event profiles. Therefore, the products in this class can be considered therapeutic alternatives to one another for the treatment of BPH.

COMMITTEE VOTE
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<tr>
<td>UROXATRAL® (alfuzosin)</td>
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<tr>
<td>FLOMAX® (tamsulosin)</td>
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References:
Facts & Comparisons. 4.0. [http://www.factsandcomparisons.com/](http://www.factsandcomparisons.com/)
RE-REVIEW: UROLOGICS: 5-Alpha-Reductase Inhibitors

RECOMMENDATION
Based on the clinical literature, all agents within this class have similar efficacy in reducing the signs and symptoms of BPH. The adverse event profiles of these products are rather similar, as well. Therefore, the products in this class can be considered therapeutic alternatives to one another for the treatment of BPH.

COMMITTEE VOTE
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<tbody>
<tr>
<td>PROSCAR® (finasteride)</td>
<td>AVODART® (dutasteride)</td>
</tr>
<tr>
<td></td>
<td>FINASTERIDE (Compares to Proscar®)</td>
</tr>
</tbody>
</table>

References:
Facts & Comparisons. 4.0. http://www.factsandcomparisons.com/
Thomson MICROMEDEX. http://www.thomsonhc.com/home/dispatch
Proscar® (finasteride) product information. Merck & Co., Inc., July 2003
NEW: DERMATOLOGICS: Oral Retinoids, Acitretin
(follow-up item from May 4, 2006 PAC Meeting)

RECOMMENDATION
Acitretin has been shown to be effective in the treatment of severe psoriasis in adults; however, because its use can be associated with serious birth defects (Pregnancy Category X), it should be tightly controlled to ensure providers are closely monitoring patients receiving this medication.

COMMITTEE VOTE
APPROVED   DISAPPROVED  APPROVED with MODIFICATION

PDL ASSESSMENT BASED ON CLINICAL RECOMMENDATIONS

<table>
<thead>
<tr>
<th>Criteria for Soriatane® (acitretin)</th>
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<tbody>
<tr>
<td>Soriatane® will be approved only for patients meeting the following criteria:</td>
</tr>
<tr>
<td>• Recipient has a diagnosis of severe psoriasis (covering at least 10-20% of the body surface area).</td>
</tr>
<tr>
<td>• Recipient has tried and failed, of had an intolerance or contraindication to, ALL of the following:</td>
</tr>
<tr>
<td>o Topical corticosteroids</td>
</tr>
<tr>
<td>o Topical antipsoriatrics, including Dovonex® (calcipotriene), Tazorac® (tazarotene), anthralin, Psoriatec® (anthralin), or Taclonex® (calcipotriene/betamethasone).</td>
</tr>
<tr>
<td>o Phototherapy (UVB, PUVA, etc.)</td>
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<tr>
<td>• If the recipient is female:</td>
</tr>
<tr>
<td>o Must have had TWO negative urine or serum pregnancy tests (one performed during the first 5 days of the menstrual period immediately preceding the beginning of Soriatane® therapy).</td>
</tr>
<tr>
<td>o Must have committed to use 2 effective forms of contraception simultaneously, unless absolute abstinence is chosen or the patient has undergone a hysterectomy or is clearly postmenopausal. The 2 selected forms of contraception must be initiated at least 1 month prior to starting Soriatane® and continued for 3 years after discontinuing the drug.</td>
</tr>
<tr>
<td>o Must have read and signed a Patient Agreement/Informed Consent for Female Patients form.</td>
</tr>
<tr>
<td>• Recipient must NOT have impaired liver or kidney function, or abnormally elevated lipid levels.</td>
</tr>
<tr>
<td>• Recipient must NOT be receiving concomitant methotrexate (due to risk of hepatitis) or tetracyclines (due to risk of increased intracranial pressure).</td>
</tr>
</tbody>
</table>

Length of Authorization: 1 year

References

COMMITTEE VOTE
APPROVED   DISAPPROVED  APPROVED with MODIFICATION