MINUTES OF THE MAY 10, 2005
PHARMACY AND THERAPEUTICS (P&T) COMMITTEE MEETING

Members Attending: Larry Calvert, R.Ph., Chairman; Todd Barrett, R.Ph.; Gary Davis, M.D.; David Hudson, R.Ph.; Jeff Jones, R.Ph.; Michael O'Dell, M.D.; Pearl Wales, Pharm.D.

Members Absent: Craig Dawkins, M.D.; Jennifer Gholson, M.D.; Raymond Wynn, M.D.; Myrna Alexander, M.D.

Also Present: Sharon Barnett-Myers, Deputy Director of Health Services; Judith Clark, R.Ph, Warren A. Jones, M.D., FAAFP; Terri Kirby, R.Ph; Phillip Meredith, M.D., J.D.—DOM; Rob DiBenedetto; Sam Warman, R.Ph.; Dennis Smith, R.Ph.; Lew Anne Snow, R.N.; Pam DeRuiter, R.Ph.—HID.

Chairman Larry Calvert called the meeting to order at 1:00 p.m.

Introductions
Judith Clark welcomed all committee members and guests present, and thanked committee members for volunteering their time and service. Ms. Clark then introduced members present from the MS Division of Medicaid. Sharon Barnett-Myers, the Deputy Director of Health Services, also welcomed the members and explained that Dr. Warren Jones would be arriving later to address the committee.

Administrative Business
Judith Clark requested that guests in the audience sign in, turn off all cell phones and pagers, or to place them on silent as to not disrupt the meeting. Instructions were given regarding exit procedures from the building in the case of an emergency. She reminded everyone that the minutes of the meeting would be recorded, and the recording tapes would be destroyed upon completion of transcription of the minutes. To facilitate the recording of the minutes, Committee members were directed to use the microphones provided when speaking. Ms. Clark reminded members that their packets contained travel vouchers, the updated PDL, the public comment guidelines, the paper ballot and the list of maintenance medications that could be written for a 90-day supply. Ms. Clark drew their attention to the paper ballots and explained that the ballots now list each chemical entity accompanied by a numeric rating. She reminded everyone that the ballots would not be tallied at the meeting. She reminded all members that it is not a secret ballot and in accordance with the Mississippi Open Meetings Act, the minutes would reflect each person's vote. Each ballot should be signed, dated, placed in the manila envelope provided and a DOM staff member would collect the packets.

Larry Calvert informed the committee that Betsy Cummings, C.F.N.P. had submitted her resignation as a member of the P & T committee.

Approval of minutes from the last meeting (March 29, 2005):
Jeff Jones made a motion to accept the minutes of the March 29, 2005 P&T meeting as written. Dr. Michael O'Dell seconded the motion. All voted in favor of the approval.

Dr. Warren Jones arrived and thanked the committee members for their hard work and personal and professional sacrifice. Dr. Jones issued to them a challenge to let science and their clinical experience guide their judgment and recommendations, and to keep the healing arts foremost in their vision. Mr. Calvert responded by expressing for the committee their pleasure in working with Dr. Jones and their appreciation for his work and commitment.

Therapeutic Category Reviews
Pam DeRuiter of Health Information Designs (HID) moderated the therapeutic class reviews.

ANTI-INFLUENZA AGENTS
Tamiflu is effective in the treatment of both Influenza A and B and is indicated for prophylaxis when started within 48 hours of exposure. Consideration should be made to limit to one course of treatment per year, as indicated by the CDC recommendations. If needed, a second course of treatment may be made available by providing medical justification. Tamiflu is ranked a 1.
Relenza is effective in the treatment of both Influenza A and B, but it is not indicated as prophylaxis. Delays in initiating treatment could result in worsening of symptoms and may limit the effectiveness of this agent, as it is important that this product be initiated within 48 hours of the onset of symptoms. Consideration should be made to limit to one course of treatment per year, as indicated by the CDC recommendations. If needed, a second course of treatment may be made available by providing medical justification. Relenza is ranked a 1. Amantadine is effective in the treatment, as well as prophylaxis of Influenza A. Amantadine is available generically and is given a rank of 1.
Rimantadine is effective in the treatment, as well as prophylaxis of Influenza A. Rimantadine is available generically and appears effective when started within 48 hours of the onset of generically. Rimantadine is ranked a 1.

There was no public comment on this category.

HID recommended all agents with a ranking of 1 for inclusion on the PDL – Tamiflu, Relenza, amantadine and rimantadine.

Ms. Clark asked if the recommendation would include treatment be limited to one course annually. Ms. DeRuiter answered that as indicated by the CDC, the recommendation did include treatment be limited to one course annually (i.e. Tamiful and Relenza). Jeff Jones made a motion to accept the recommendation. Dr. O'Dell seconded the motion.

Drug	Barrett	Calvert	Davis	Hudson	Jones	O'Dell	Wales
Amantadine(generic)	x	x	x	x	x	x	x
Oseltamivir(Tamiflu)	x	x	x	x	x	x	x
Rimantadine(generic)	x		x	x	x	x	x
Zanamivir(Relenza)	x		x	x	x	x	x

Executive Director's Decision: Approve HID Recommendation

ANTIPROTOZOAL AGENTS
All formulations of Metronidazole have numerous indications for use, and have been widely used in Mississippi and nationally. Treatment guidelines refer to it as a drug of choice for

numerous indications and it appears to be used effectively for numerous unlabeled uses as well as endorsed by the American Academy of Pediatrics in children. Disadvantages of this agent are its potential for adverse effects. Metronidazole has a rank of 1.

Alinia is the first drug approved for the treatment of cryptosporidiosis in children ages one to eleven, and the first to become available as a liquid for treatment of giardiasis. Although cryptosporidiosis incidents in the Mississippi Medicaid community were minimal in the last two years, the agent is novel in its indication, efficacy, and safety. It has the advantage over Metronidazole in its liquid formulation for giardiasis and short duration of treatment. Alinia has a rank of 1.

Tindamax has been available outside the United States for many years and appears to be as effective as Metronidazole, though perhaps better tolerated. It also offers the advantage of shorter duration of treatment. Disadvantages include its smaller list of approved indications, as well as unlabeled uses. This agent is reserved for use in patients with Metronidazole-resistant trichomoniasis. Tindamax has a rank of 3.

Mepron is an oral agent, usually reserved per its own indications for PCP in patients intolerant to TMP-SMZ. It offers a relatively short duration of therapy—twenty-one days. Studies also indicate that it appears to be as effective as Pentamidine, but with fewer treatment-limiting effects. Additionally, Mepron shows promise for use in treating toxoplasmosis. Mepron has a rank of 4.

Pentamidine, with a rank of 5, is narrow in its approved indications and is as effective as previous agents; however, studies show that it may be associated with a higher incidence of treatment-limiting effects. As with other agents for PCP, this agent is reserved for patients intolerant to TMP-SMZ, as well as in definite at-risk populations. Pentamidine is used in more unlabeled uses, and its formulation as an inhalation aerosol for nebulization offers an additional advantage for decreased potential risks. However, due to its potential risks, administration guidelines limit its use for patients and healthcare providers, who should take certain precautionary steps when administering the inhaled formulation. Although this medicine is available in many formulations, only the IV administration is recommended. The parenteral formulation of Pentamidine should be exempt from consideration as a preferred or non-preferred agent.

Neutrexin is only indicated for PCP in immunosuppressed patients. It is associated with significant adverse effects and toxicities and must be given with leucovorin. In one listed study, it was associated with nearly twice the mortality rate as the comparator drug in treating PCP. Its use in the POS system is extremely limited. Neutrexin is only available in parenteral dosage form and should be exempt from preferred or non-preferred status.

HID recommended agents with rankings of 1 for PDL inclusion -Metronidazole and Alinia. HID also recommended the parenteral formulation of Pentamidine and Neutrexin should be exempt from consideration as a preferred or non-preferred agent.

There was no public comment on this category.

Mr. Jones made a motion to complete this page of the ballot. Mr. Barrett seconded the motion.

Drug	Barrett	Calvert	Davis	Hudson	Jones	O'Dell	Wales
Metronidazole(all-including brand only Flagyl formulations)	x	x	x	x	x	x	x
Nitazoxanide(Alinia)	x		x	x	x	x	x
Tinadazole(Tindamax)			x			x	
Atovaquone(Mepron)			x				x
Pentamidine(NebuPent)-exempt IV route from preferred/non-preferred status							
Trimetrexate(Neutrexin)(should be exempt from preferred/non-preferred status)							

Executive Director's Decision: Approve the recommendation of the committee contained in the motion.

ANTIVIRAL AGENTS

Generic acyclovir has a rank of 1. Acyclovir is standard therapy for herpes virus, and this drug is highly utilized and as effective as other agents. Brand acyclovir is not recommended as preferred because the generic is available.

Valacyclovir has a rank of 1. It offers the advantage of BID dosing for treatment and QD dosing for suppressive therapy. These dosing schedules may help improve outcomes by improving compliance. Valacyclovir is as effective as acyclovir.

Generic ganciclovir oral and valganciclovir are the only oral agents available for CMV retinitis. Brand name ganciclovir is not recommended for inclusion on the PDL since a generic is available. Ganciclovir and valganciclovir have a rank of 1.

Adefovir and generic ribavirin and the brand name ribavirin tablets are the only oral agents available for hepatitis B and hepatitis C. Brand ribavirin (Rebetol) is not recommended for inclusion on the PDL since a generic is available. These agents have a rank of 1. Famciclovir is as effective as other agents against the herpes virus. Famciclovir may offer an advantage in suppressive therapy since it can be given once daily. It has a rank of 2.

HID recommended all agents with a rank of 1-acyclovir generic, valacyclovir, ganciclovir, valganciclovir, adefovir, ribavirin generic capsules, and brand-name ribavirin tablets.

Public comments in the antiviral agent category were presented by the following:
Carol Collins, GSK, Valtrex.

Jeff Jones asked the physicians on the committee if they recalled reading that Famvir had a very positive impact on shingles in duration and pain. Dr. O'Dell recalled similar findings. Todd Barrett made a motion to complete the ballot. Jeff Jones seconded the motion.

Drug	Barrett	Calvert	Davis	Hudson	Jones	O'Dell	Wales
Acyclovir (Generic)	x	x	x	x	x	x	x
Valacyclovir(Valtrex)	x	x	x	x	x	x	x
Ganciclovir (Generic)	x	x	x	x	x	x	x
Valganciclovir(Valcyte)	x	x	x	x	x	x	x
Adefovir(Hepsera)	x	x	x	x	x	x	x
Ribavirin(generic caps &Brand Copegus tabs)	x	x	x	x	x	x	x
Famciclovir(Famvir)		x	x	x	x	x	

Executive Director's Decision: Approve HID recommendation

CEPHALOSPORINS

Mississippi utilization data suggest that oral cephalosporins are used more frequently than the available IM or IV preparations, which are usually reserved for use in institutionalized settings and appropriate situations. Nevertheless, restricting access to IM and IV preparations may not be beneficial to the Division of Medicaid and Medicare beneficiaries, so exemption from the PDL is recommended. These agents should be considered neither preferred nor non-preferred.
According to the July 2004 issue of The Journal of Family Practice, one additional child will benefit for every 13 children treated with a cephalosporin rather than penicillin. This conclusion was drawn from a meta-analysis of randomized controlled trials for the treatment of streptococcal infections in children. Therefore the following recommendations refer to the oral cephalosporins.

Cephalexin has a rank of 1. A 2002 article in The Medical Letter suggests that cephalexin, an effective and widely-used first-generation cephalosporin, is a better choice for skin and soft tissue infections. Cephalexin is available in many dosage forms and is currently approved for bone infections caused by staphylococci or P. mirabilis, and is indicated for GU tract infections including acute prostatitis.
Cefadroxil is suggested in one study to be as effective dosed once daily as the multi-day dosing of cephalexin in treating Group A beta-hemolytic strep. Cefadroxil is indicated for a variety of infections and is available in many preparations. It has a rank of 1.
Cephradine is another generically-available cephalosporin with multiple indications. It also has a rank of 1.
Cefaclor has a rank of 1. This generic cephalosporin is available in many formulations and possesses multiple indications. The July 2004 issue of the Journal of Family Practice comments on a meta-analysis of randomized controlled trials, concluding that cefaclor and loracarbef were the only cephalosporins not demonstrating an advantage over penicillin. In a study comparing cefaclor and amoxicillin/clavulanate, however, cefaclor was effective and possibly caused fewer GI adverse effects.

Cefuroxime has a rank of 1. This safe and effective second-generation cephalosporin has various indications particularly in children as young as three months. Cefuroxime is indicated for the treatment of Lyme disease. Two unlabeled uses also include CAP and meningitis in neonates. Cefuroxime has a rank of 1.
Cefdinir has a rank of 1 and is a possible second-line alternative to amoxicillin for children with AOM, especially those who may not be compliant with amoxicillin's more frequent dosing schedule. Cefdinir may also be indicated when there is a strong likelihood that the infection is due to amoxicillin-resistant organism. Safety, efficacy palatability and short duration of treatment may ensure better outcomes because of better compliance.
Cefprozil appears to be safe and effective. Studies indicate it may be as effective as cefdinir, but cefprozil's indications are limited and only one unlabeled use, for CAP, exists. Other second-generation cephalosporins are available for a wider array of indications. Cefprozil has a rank of 2.
Cefpodoxime is a third-generation cephalosporin offering reduced treatment time—five days—and a pleasant taste in suspension form. Although safe and effective, cefpodoxime does not have as many indications as cefdinir, such as for CAP. Cefpodoxime has a rank of 2.
Cefixime is a third-generation oral cephalosporin. The third-generation oral agents have demonstrated marginal benefits in treating mild to moderate respiratory infections, UTIs, skin, and skin structure infections. They do possess improved eradication rates. Cefixime offers a decreased dosing schedule, which may help with compliance, and is indicated for use in uncomplicated gonorrhea. There are other agents, however, that are also indicated for treatment of gonorrhea. Cefixime has a rank of 3.
Ceftibuten has a rank of 5. Ceftibuten is active against S. aureaus, as are cefdinir and cefpodoxime, and offers few advantages in its indications, safety, or efficacy over the recommended third-generation cephalosporins.
Loracarbef has a rank of 10. Loracarbef is a second-generation oral cephalosporin. It offers few advantages over other cephalosporins. The July 2004 issue of The Journal of Family Practice comments on a meta-analysis of randomized controlled trials, concluding that cefaclor and loracarbef were the only cephalosporins unable to show an advantage over penicillin.
Cefditoren is a third-generation agent. The authors of a 2002 review in the Medical letter concluded that this agent offers no clinical advantage over cefdinir or cefpodoxime. Additionally, older narrower-spectrum agents are just as effective as cefditoren for approved indications and less likely to promote emergence of resistance.

HID recommended all agents having a rank of 1—generic cephalexin, cefadroxil, cephradine, cefaclor, cefuroxime, and Omnicef (cefdinir). HID also recommended that the IM and IV formulations be exemption from the PDL; therefore, these agents should be considered neither preferred nor non-preferred.

Public comments in the cephalosporin category were presented by the following:
Dr. Martin, Abbott Labs- Omnicef.

Todd Barrett made a motion to complete the ballot. Dr. O'Dell seconded the motion.

Drug	Barrett	Calvert	Davis	Hudson	Jones	O'Dell	Wales
Cephalexin (generic)	x	x	x	x	x	x	x
Cefadroxil (generic)	x	x	x	x	x	x	x
Cephradine (generic)	x		x	x		x	x
Cefaclor (generic)	x	x	x	x	x	x	x
Cefuroxime (generic tabs & CeftinSusp)	x	x	x	x	x	x	x
Cefdinir(Omnicef)	x	x	x	x	x	x	x
Cefprozil (Cefzil)	x		x	x	x		x
Cefpodoxime (generic tabs & Vantin Susp)	x		x	x			x
Cefixime (Suprax)			x				
Ceftibuten (Cedax)							
Loracarbef (Lorabid)							
Cefditoren (Spectracef)							

Executive Director's Decision: Approved HD recommendation

MACROLIDES

Rankings of the Macrolides are based on the analysis of all the preceding data.

The first agent is erythromycin, all generic formulations, plus erythromycin and sulfisoxazole combinations. Erythromycin, in various salt forms and dosage forms, has numerous indications for use and has been widely utilized for many years. Erythromycin's value is well-accepted and understood by the provider community, and for most indications, it has been shown to be comparable in efficacy to the newer macrolide antibiotics and to antibiotics in other classes. Erythromycin has a rank of 1.

As noted earlier, azithromycin is the most commonly-prescribed macrolide antibiotic in Mississippi, with a wide range of approved and off-label indications for both children and adults. Zithromax (azithromycin) has proven to be comparable in efficacy to antibiotics in other classes, and its once-daily dosing and short treatment duration encourages compliance. Azithromycin holds an advantage among the macrolides in regard to drug interactions; it has a very low incidence of treatment–related adverse effects. Zithromax has a rank of 1. Clarithromycin, has a rank of 1 and is a distant second to azithromycin in terms of macrolide use in Mississippi Medicaid recipients in 2004. Clarithromycin is comparable in efficacy to other macrolides and antibiotics in the class. This agent generally has a slightly higher incidence of side effects than azithromycin and a less-convenient dosing schedule. Clarithromycin does hold the advantage of a label indication that's approved for the treatment of H. pylori and disseminated mycobacterium infections.

Ketek (telithromycin) is similar to azithromycin and clarithromycin in side effects and dosing, but with enhanced activity against S. pneumoniae. Thirty to forty percent of S. pneumoniae cases are thought to be resistant to penicillin and/or macrolides, but additional clinical trials are

needed to determine the clinical relevance of this enhanced activity. Trials to date show similar rates of clinical cure compared to other macrolides in common respiratory tract infections. Telithromycin should be reserved as an alternative to amoxicillin/clavulanate or fluoroquinolones for treatment of confirmed or suspected infections caused by resistant S. pneumoniae. Availability through prior authorization will help to limit use to appropriate cases. Ketek has a rank of 5.
Dynabac (dirithromycin) is not commonly used in the patient population as reflected in the 2004 Medicaid claims. This agent is not approved for pediatric use and has a rank of 5. It offers no unique advantage or compelling reason for inclusion as the preferred macrolide antibiotic.

HID recommended all agents that have a rank of 1, which are all generic erythromycin products, Zithromax (azithromycin), and clarithromycin.

Mr. Jones pointed out that Ketek is not a macrolide, but is in its own class, and asked why it was included in this category. Dennis Smith, R.Ph. with HID answered that because of its structural similarity to the macrolides, it was decided to include Ketek with the macrolides rather than have a separate category for it. Mr. Barrett asked if the recommendation included Biaxin XL formulation. Mr. Smith answered that it did. Ms. Clark pointed out that that was not on the recommendation, but instead the generic was recommended. Mr. Jones asked if it needed to be added on, and Mr. Calvert suggested that a notation be made on the ballot if voting to include XL.

Public comments in the macrolide category were presented by the following:
Keith Campagna; Sanofi-Aventis - Ketek.
Mark Forshag, M.D.; Pfizer - Zithromax.
Eddilisa Martin; Abbott Labs - Biaxin.

Todd Barrett moved to complete the ballot. Pearl Wales seconded the motion.

Drug	Barrett	Calvert	Davis	Hudson	Jones	O'Dell	Wales
Erythromycin- generics- including Eryth/Sulfisoxazole Combo	x	x	x	x	x	x	x
Azithromycin (Zithromax)	x	x	x	x	x	x	x
Clarithromycin (generic tabs, Biaxin Susp & BiaxinXL	x	X (no XL)	x	X (no XL)	x	x	x
Telithromycin (Ketek)		x	x		x		x
Dirithromycin (Dynabac)							

Executive Director's Decision: Approved for HID recommendation

MISCELLANEOUS ANTI-BACTERIAL AGENTS
The first agent is generic clindamycin oral capsules and Cleocin pediatric solution. Clindamycin has broad antibacterial applications and uses in outpatient clinical practice, especially in patients

who are allergic to penicillin. Brand Cleocin capsules are not recommended as preferred, since they are available in generic. These have a rank of 1.
Vancomycin in oral form is indicated only for treatment of pseudomembranous colitis, but generic metronadazole offers a more cost-effective approach to treatment. Oral vancomycin may be considered a second-line therapy after metronidazole failure. This has a rank of 2. Zyvox (linezolid) should not be considered first-line therapy for treatment of common bacterial infections in the outpatient setting and should be used only after very careful consideration of other agents. Zyvox has a rank of 3.
Lincomycin has a similar spectrum of activity compared to clindamycin, but is less completely absorbed when given orally. Lincomycin should be considered after failure of clindamycin in serious infections. This has a rank of 4.

HID recommended the agents with a rank of 1 which are generic clindamycin and the Cleocin pediatric solution. HID also recommended that the IM and IV formulations be exemption from the PDL; therefore, these agents should be considered neither preferred nor non-preferred.

Public comments on the miscellaneous anti-bacterial category were presented by the following: Mark Forshag, M.D., Pfizer - Zyvox.

Dr. O'Dell asked if there was a mechanism whereby someone with a nosocomial diagnosis could receive Zyvox on an outpatient basis. After some discussion, it was decided that Zyvox would be voted on separately. Jeff Jones made a motion to complete the ballot with the exception of Zyvox which would be discussed separately. Todd Barrett seconded the motion. Following more discussion, Dr. O'Dell moved that Zyvox be listed as a discharge medication with a coded diagnosis. The motion died from lack of a second. Dr. Davis moved that Zyvox be placed on neither a preferred nor non-preferred status so that it can be obtained without a PA. Pearl Wales seconded the motion. Voice vote, all in favor.

Drug	Barrett	Calvert	Davis	Hudson	Jones	O'Dell	Wales
Clindamycin (generic caps &Cleocin Ped Soln)	x	x	x	x	x	x	x
Vancomycin (caps & soln.)	x	x	x		x	x	x
Linezolide (Zyvox)*	-	-	-	-	-	-	-
Lincomycin (Lincocin)							
*Vote was on items 1,2 & 4 only.							

Executive Director's Decision: Approve HID recommendation and Zyvox as non preferred.

PENICILLINS
Amoxicillin is the recommended drug of choice for endocarditis prophylaxis and otitis media when antimicrobial therapy is appropriate. All generic forms are recommended as preferred. Amoxicillin has a rank of 1.

Ampicillin is also available in generic form and is recommended for complicated urinary tract infections acquired in institutional settings, such as long-term care centers. Ampicillin has a rank of 1.
Dicloxacillin, another penicillinase-resistant penicillin, is one of the two agents indicated for osteomyelitis. A 1982 study found dicloxacillin effective for osteomeylitis, but the study is dated and current studies are needed to confirm or dispute these twenty-three-year-old findings. Until then, however, oral dicloxacillin should be available without restriction for this indication. This has a rank of 1.
Penicillin V is available generically and is widely used and available for many indications. It also has a rank of 1.
Geocillin (carbenicillin) is the only oral extended-spectrum penicillin indicated for use in UTIs and prostatitis. Other more cost-effective agents are available, however, such as co-trimoxazole, doxycycline, and ciprofloxacin. This has a rank of 2.
Oxacillin is a penicillinase-resistant penicillin that has been a reasonable first choice for empiric therapy of skin infections caused by penicillinase-producing staphylococci. Although the increasing prevalence of MRSA has limited its use, oxacillin may still offer benefits. This has a rank of 2.
Nafcillin has a rank of 2 and has also seen limited use because of the increasing prevalence of MRSA. Available only in parenteral form, nafcillin is more useful in the institutional setting. The extended-spectrum antibiotics are usually reserved for serious infections, usually requiring hospitalization.

HID recommended that these parenteral formulations of penicillin should be exempt from the preferred drug list. These parenteral agents should not be given preferred or non-preferred status. HID recommends all agents with a rank of 1 in the penicillin category which include amoxicillin, ampicillin and dicloxacillin.

There was no public comment on this category.

Mr. Jones moved to complete the ballot. Dr. Davis seconded.

Drug	Barrett	Calvert	Davis	Hudson	Jones	O'Dell	Wales
Amoxicillin (generic)	x	x	x	x	x	x	x
Ampicillin (generic)	x	x	x	x	x	x	x
Dicloxacillin (generic)	x	x	x	x	x	x	x
Penicillin V (generic)	x		x	x	x	x	x
Carbenicillin (Geocillin)			x			x	x
Oxacillin (generic)			x			x	x
Nafcillin (generic)			x			x	x

Executive Director's Decision: Approve HID recommendation.

PENICILLIN COMBINATIONS

The only combination product approved by Mississippi Medicaid for use in the general population is amoxicillin/clavulanate, and the only currently approved indications are CAP and acute maxillary sinusitis. The only formulation of this product not available generically is the XR formulation, which is not indicated in children and is only available in a tablet. The other versions are available generically in oral suspension, chewable tablet, and tablet formulations. Studies show that the 875/125 strength is as effective as the XR formulation for treating community-acquired pneumonia. The other agents are reserved for treatment of more serious infections, these agents being Unasyn, Zosyn, and Timentin, and normally are used in institutional and hospital settings. These agents should be exempt from the PDL and would not be considered preferred or non-preferred.

Amoxicillin/clavulanate has a rank of 1. This combination is available generically and offers various dosage forms with indications for use in both adults and children. Studies show that it is as effective as agents from other classes and successfully treats conditions for which it is indicated, such as otitis media and sinusitis. The XR preparation shows promise for effectively treating sinusitis and is listed as the drug of choice in treating this condition developed by the Sinus and Allergy Health Partnership for acute bacterial rhinosinusitis.

Therefore, HID recommended that all preparations should be considered preferred, generic and brand.

Public comment on penicillin combinations were presented by the following:
Spencer Moody, M.D. - Augmentin XR.

Pearl Wales moved to complete the ballot, and David Hudson seconded the motion.

Drug	Barrett	Calvert	Davis	Hudson	Jones	O'Dell	Wales
Amoxicillin/Clavulanate (all-including Augmentin XR)	x	x (no XR)	x	x	x	x	x

Executive Director's Decision: Approved

QUINOLONES

Rankings are based on analysis of all the preceding data as well as other factors. Ciprofloxacin has a rank of 1. It is the oldest of the fluoroquinolones, has numerous indications, and has been widely used for many years. This agent is available generically, and its value is well-accepted and understood by the provider community. As it offers no significant clinical advantage over the generic formulation, Cipro XR is not included in this recommendation.

Levofloxacin was the most commonly prescribed fluoroquinolone in the Mississippi Medicaid population in 2004. It has been on the market for almost ten years, and its value is established and understood by providers. It has a rank of 1.

Ofloxacin has a rank of 1. It is another well established fluoroquinolone, available in generic form, with relatively wide use among the Medicaid providers.

Tequin (gatifloxacin), yet another fluoroquinolone with relatively wide use in this population, does not offer any compelling clinical advantages and has a rank of 5. This agent has a place in therapy, however, and is specifically recommended along with other fluoroquinolones in some of the guidelines above.
Avelox has a rank of 6. In 2004, this agent was the third most commonly used fluoroquinolone in the Mississippi Medicaid population. Approved for several respiratory indications and skin infections, moxifloxacin is also approved for use in CAP patients with multiple drug resistant S. pneumonia. Although it may offer some advantages, moxifloxacin should not be considered a first-line agent.
Maxiquin, has a rank of 10 and has shown no established clinical advantage and is not relevant to this patient population. Based on usage data, there were no prescriptions for this agent in 2004.
Norfloxacin shows no established clinical advantage and is not relevant to this patient population based on usage data. It has a rank of 10.
NegGram has a very limited antibacterial spectrum and is only indicated for UTI caused by limited gram-negative species. Based on usage data, this agent is not relevant in this population. It has a rank of 10.
Gemifloxacin has the advantage of being approved for multiple drug-resistant strains of S. pneumonia. The clinical importance of this indication is not yet known, however, so the agent should be reserved for confirmed cases involving resistant pathogens. This drug has a rank of 10.
Zagam (sparfloxacin) has a limited number of approved indications, and when compared to other fluoroquinolones, has a higher number of possible drug interactions and an inferior safety profile. Zagam has a rank of 10.These concerns are reflected by the lack of use by Medicaid providers in 2004—there were no prescriptions.

HID recommended all agents with a rank of 1 in this category - ciprofloxicin, Levaquin, and ofloxacin.

Public comments on quinolones were presented by the following:
Dr. William Webster; Schering-Plough; -Avelox.
David Williamson, Ph.D.; Jansen Medical Affairs - Levaquin.

Mr. Jones suggested that Avelox be considered in addition to the recommendations made by HID because it does not have a labeling warning about use in diabetic patients as do all the other quinolones. Mr. Jones also stated that it does not require dosage adjustments for patients with mild to moderate renal or hepatic impairment. Following these comments, Jeff Jones made a motion to complete the ballot, and Dr. O'Dell seconded the motion.

Drug	Barrett	Calvert	Davis	Hudson	Jones	O'Dell	Wales
Ciprofloxacin(generics-exclude Cipro XR)	x	x	x	x	x	x	x
Levofloxacin(generic750mg tabs, other strengths Levaquin)	x	x	x	x	x	x	x
Ofloxacin (generics)	x	x	x	x	x	x	x
Gatifloxacin(Tequin)			x				x
Moxifloxacin(Avelox)		x	x	x	x		x
Lomefloxacin(Maxiquin)							x
Norfloxacin(Noroxin)							
Nalidixic Acid(generic)							
Gemifloxacin(Factive)							
Sparfloxacin(Zagam)							

Executive Director's Decision: Approve HID recommendation

SULFONAMIDES

Co-trimoxazole is a generically available agent used for many indications, and is considered the drug of choice or an effective alternative in numerous unlabeled uses. Co-trimoxazole is effective, and experience with the agent is wide-spread. This is available in many formulations and can be used effectively in pediatric patients two months old and older. Brand preparations are not recommended. Co-trimoxazole has a rank of 1.

Sulfisoxazole is available generically in tablet form and a single-source brand name oral suspension. Sulfisoxazole's relative solubility in alkaline and slightly acidic urine makes this drug useful in treating UTIs, and additional indications exist. Sulfisoxazole has a rank of 1.

Sulfasalazine, with a rank of 1, is the only unique agent in this review because of its indications for use in ulcerative colitis, rheumatoid arthritis, and juvenile rheumatoid arthritis. Studies indicate this agent is effective and has its place in therapy. Evidence for use in Crohn's disease show it may be more useful in patients with ilocolonic or colonic involvement and particularly helpful in patients with left-sided disease. All formulations are recommended.

Sulfasalazine has a rank of 1. Sulfadiazine and pyrimethamine are the treatments of choice for toxoplasmosis in both adults and children, as well as in immunocompromised individuals. Sulfadiazine is also recommended by the Prevention of Opportunistic Infections Working Group of the US Public Health Service and the Infectious Diseases Society of America for the prevention of toxoplasmosis. This agent has a rank of 1.

Sulfamethizole is currently available in fixed combination with 250 milligrams of oxytetracycline and 50 milligrams of phenazopyridine. Based on a review of this drug by the National Academy of Sciences' National Research Council, the FDA has classified the combination as lacking substantial evidence of effectiveness as a fixed combination. This has a rank of 5.

The vaginal sulfonamide combination products have a rank of 5. The FDA announced in 1979 that the Anti-Infective and Topical Drug Advisory Committee and the Fertility and Maternal Health Advisory Committee had concluded no sufficient evidence existed that the then-available vaginal sulfonamide formulations were effective. A 2001 study showed that 2 percent

clindamycin vaginal cream is more effective that triple sulfonamide vaginal cream in the treatment of bacterial vaginosis.

HID recommended all agents with a rank of 1 in this category – co-trimoxazole, sulfisoxazole, sulfasalazine, and sulfadiazine.

There was no public comment on this category.

Jeff Jones made a motion to complete the ballot. The motion was seconded by David Hudson.

Drug	Barrett	Calvert	Davis	Hudson	Jones	O'Dell	Wales
Co-trimoxazole(SMX-TMP)-generics	x	x	x	x	x	x	x
Sulfisoxazole-generic tabs & Gantrisin Oral Susp	x		x	x	x	x	x
Sulfasalazine-generics	x	x	x	x	x	x	x
Sulfadiazine-generics	x		x	x	x	x	x
Sulfamethizole (Urobiotic)							
Vaginal sulfonamide combos (Gyne-Sulf,Trysul,Sultrin,TripleSulfa Vag.Cr.							

Executive Director's Decision: Approve HID recommendation.

TETRACYCLINES

HID recommended that all parenteral tetracycline formulations be exempt from the preferred drug list, so that they will not be considered preferred or non-preferred. The remaining oral tetracyclines were then discussed.

Demeclocycline is a generically available tetracycline used as an antibacterial agent. It also appears to be effective for the treatment of Syndrome of Inappropriate Anti-diuretic Hormone Secretion as an unlabeled use. It has a rank of 1.

Doxycycline, also with a rank of 1, is indicated for use in many conditions. It is important in treating sexually–transmitted diseases and anthrax, as recommended by the CDC. Doxycycline is effective, relatively safe, and available generically. One study suggested that fewer GI side effects are associated with the enteric-coated pellets than with the capsules containing doxycycline hyclate powder, but more studies are needed. Only the generic formulation should be considered preferred. The brand-name suspension formulation may be useful, but tetracyclines are used rarely in children too young to swallow tablets or capsules. Minocycline has a rank of 1. It is another generically available tetracycline agent, which appears to be as effective as doxycycline and is relatively safe, although adverse vestibular effects may occur frequently. Minocycline is used as an adjunctive agent for acne. No studies suggest that the brand formulation has an advantage over the generic preparations, so only generic preparations are to be considered preferred.

Tetracycline has a rank of 1. There are many indications for tetracycline. It is available generically, and no studies have been found indicating that the brand formulations are more effective than their generic counterparts; therefore, only generics are recommended.

HID recommended all tetracyclines for inclusion on the PDL. HID recommended that all parenteral tetracycline formulations be exempt from the preferred drug list, so that they would not be considered preferred or non-preferred.

There were no public comments presented in this category.

Todd Barrett moved to complete the ballot. Jeff Jones seconded the motion.

Drug	Barrett	Calvert	Davis	Hudson	Jones	O'Dell	Wales
Demeclocycline-generics	x	x	x	x	x	x	x
Doxycycline-generics	x	x	x	x	x	x	x
Minocycline-generics	x	x	x	x	x	x	x
Tetracycline-generics	x	x	x	x	x	x	x

Executive Director's Decision: Approve HID recommendation.

Other Business

Judith Clark requested that committee members place their ballots and travel vouchers in their envelope to be picked up by a DOM staff member. She explained that the 90-day maintenance drug list provided in the committee members' packets would be published in the July Medicaid Provider Bulletin, which would deal with changes pursuant to House Bill 1104. Ms. Clark then reviewed the current PDL list and the implementation dates for the therapeutic classes.

Ms. Clark presented a pharmacy program update stating that in March of 2005, there were approximately 942,000 pharmacy claims. 42.3 percent were brand, with an average price of $112.87, which represented 75 percent of total costs. 50.4 percent were generic, with an average price of $27.79, or approximately 21 percent of total costs. In April of 2005, there were approximately 900,000 pharmacy claims. 41 percent were for brand-name, with an average of $113 .14 per claim, which represented 73.6 percent of total costs. 51.9 percent were for generic products, at an average price of $27.79, representing 22.8 percent of total costs.

Ms. Clark then pointed out that ophthalmic products were removed from today's agenda due to time limitations, and would be rescheduled. She also called attention to a change in the email address for DOM employees. She explained that there would be some changes in the make-up of the committee before the next meeting, as Dr. Davis and David Hudson terms on the committee would expire, and that those changes would be posted on the DOM website. She also pointed out that the changes pursuant to House Bill 1104 would go into effect on July 1 for the pharmacy program. Mr. Jones asked why Lanoxin was not on the maintenance list of

medications to which Ms. Clark responded that the two brand limit made it difficult and the decision was postponed until better direction was received.

Sharon Barnett-Myers then explained other changes pursuant to House Bill 1104 taking effect July 1. These include the elimination of the category of hospice care; and changes in the pre-certification for maternity stays from three days for vaginal deliveries to two days and from five days for cesarean to four days for cesarean. She also stated that DOM would send beneficiary notices around the 23rd of May. Ms. Myers stated that DOM would be providing provider education regarding these changes beginning with hospitals in June, followed by physician and other provider workshops in June and July.

Mr. Clark said that according to legislation, only long-term care will be exempt from the two-brand/five-maximum prescription limit, but that if something is medically necessary for a child, that service would have to be provided according to federal regulations. Therefore, there would soon be a new medical necessity prior authorization form for children. Jeff Jones asked if DOM was following through with re-evaluating every patient on the Medicaid rolls. Ms. Myers answered that all thirty regional offices have been opened up and the Division is re-determining every Medicaid beneficiary recipient.

Larry Calvert stated that the next meeting was scheduled for July 12. Dr. O'Dell explained that date was in conflict with the Mississippi Family Physicians meeting. Ms. Clark suggested moving it back a week, and Jeff Jones made a motion the next meeting be re-scheduled for July 19th. Todd Barrett seconded the motion. The motion carried.

There being no further business, Mr. Calvert adjourned the meeting at 3:18 p.m.