

Preferred Drug List Committee Meeting
Meeting Minutes, Open Session
June 4, 2008

<p>Preferred Drug List Committee Meeting Minutes, Open Session EDS / White Lakes Mall Wichita / Kansas City Room Topeka, KS June 4, 2008</p>	<p>Members Present: Michael Burke, M.D, Ph.D., Chair; Matthew Schlotterback, M.D. Brenda Schewe, M.D. Donna Sweet, M.D. Dennis D. Tietze, M.D. Glenn Harte, Pharm.D. Kenneth Mishler, Pharm.D. KHPA Staff Present: Wayne Wallace, M.D. Susan Wood. R.N. Dennise Weichert EDS Staff Present: Lisa Todd, R.Ph. Karen Kluczykowski, R.Ph.</p>	<p>Representatives: Charles Dahm, Amgen Scott Sabrowsa, Amgen Dave Walters, Centocor Ortho Biotech Jim Baumann, Pfizer Kate Kwlesner, Wyeth Matthew Stafford, Merck Alex Bennett, Forest Laboratories Michael Jones, GlaxoSmithKline Matthew Wieman, Endo Pharmaceuticals Rick Barbarash, AstraZeneca</p>
TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>I. Call to Order</p>	<p>Dr. Michael Burke called the Meeting of the Preferred Drug List (PDL) Advisory Committee to order at 10:04 am with eight members present.</p>	
<p>II. Announcements</p>	<p>Lisa Todd thanked the committee members for taking time to assist with this Advisory Committee. She reminded the public attending to sign in and complete a disclosure sheet if they are intending to speak. She asked those participating in public comment to limit their discussions to new information from studies of the drugs.</p> <p>Reminder that EDS will be moving in the fall to Forbes Field. The dates will be posted and information sent when plans are complete.</p>	
<p>III. Review and Approval of Mach 12, 2008 Minutes</p>	<p>There were a few changes to the March 2007 draft minutes. These changes involved misspelling of</p>	<p>Dr. Sweet moved to approve the minutes with the minor revisions discussed.</p>

	names and incorrect numbering.	Dr. Schlotterback seconded the motion and it carried by a unanimous vote.
<p>IV. Non-Sedating Antihistamines Xyzal®</p> <ul style="list-style-type: none"> a. Public Comment b. Committee Discussion c. Committee Recommendation / Action 	<p>Dr. Burke stated the last review of this class was in August 2006. The committee position was that they were clinically equivalent. Since that date a new agent Xyzal® has been marketed.</p> <p><u>Public Comment</u></p> <p>Ms. Schrader stated consumers have had availability of levocetirzine in Europe since 2005. The tablet form and oral liquid is now available here in the United States. She stated there were head to head studies with other antihistamines when the drug was introduced in Europe.</p> <p><u>Committee Discussion</u></p> <p>Dr. Haneke asked if there are any contraindications or renal precautions regarding Xyzal®. Ms. Schrader stated it was contraindicated in renal failure.</p> <p>Dr. Haneke stated he would consider it clinically equivalent to other non-sedating antihistamines. Dr. Sweet agreed.</p> <p>Dr. Tietze asked all speakers to have data to back-up for claims of superiority of their product over another.</p>	<p>Dr. Sweet moved that the drugs in this class including Xyzal® are clinically equivalent.</p> <p>Dr. Tietze seconded and it carried by a unanimous vote.</p>

<p>V. Triptans</p> <ul style="list-style-type: none">a. Public Commentb. Committee Discussionc. Committee Recommendation/Action	<p>The Triptan class were last reviewed in August 2006. At that time the committee's position was that drugs in this class were clinically equivalent. It was recommended at that time that all routes of delivery be available in the preferred category.</p> <p>The committee was provided with the most recent report from the Oregon Evidence-based Practice Center report dated March 2008.</p> <p>Treximet® is a new medication in the Triptan class. It is the combination of sumatriptan and naproxen.</p> <p><u>Public Comment</u></p> <p>Dr. Michael Jones, GlaxoSmithKline, spoke about Treximet®. He stated that this drug is competitively priced. He stated Treximet® would prevent the use of step therapy. There is data showing that using step therapy the patient will not get the delayed peak in naproxen or the earlier peak with Imitrex®.</p> <p>Matthew Wieman, Endo Pharmaceuticals, spoke about Frovatriptan. He stated it is important to consider Frovatriptan as a drug for the formulary because of its efficacy, safety, and a few unique aspects that may be helpful in patients that have comorbidities and other issues.</p> <p><u>Committee Discussion</u></p> <p>Dr. Sweet stressed that Treximet® cannot be considered clinically equivalent to the other Triptans. She stated that she would not want that as the preferred drug in the Triptan class because she has</p>	
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patients that she wouldn't put on naproxen at the same time that they are having headaches and vomiting. She stated that the sumatriptan is equivalent to the other Triptans. She found nothing in either report that did anything but reiterate the problems with Treximet®. She stated that she would stand on the previous recommendation that Triptans are clinically equivalent.

Dr. Burke stated that Treximet® would not clinically equivalent to the other agents which are only Triptan monotherapy. He stated that there is no evidence that the Treximet® formulation is superior to the co-use of sumatriptan and naproxen.

Karen Kluczykowski stated that Treximet® does fall within the other Triptan limitations because it doesn't contain the sumitriptan 18 units per 30 days. There are limitations on it, but prior authorization is not required. In this regard Dr. Burke recommended the DUR Board look specifically at Treximet® and whether or not it should require a PA.

Dr. Sweet stated her concern of the possibility of Treximet® being the only preferred medication in the Triptan class, because many patients cannot take naproxen.

Dr. Sweet moved that we continue our current recommendation that the Triptans are clinically equivalent with the exception of Treximet® by virtue of being a combination agent and there is no evidence that the combo formulation is superior to co-use of individual agents.

		Seconded by Dr. Schewe and it carried by a unanimous vote.
<p>VI. Intranasal Corticosteroids</p> <ul style="list-style-type: none"> a. Omnaris b. Public Comment c. Committee Discussion d. Committee Recommendation/Action 	<p>Dr. Burke stated that this class was last reviewed in 2005. At that time the committee’s position was that Intranasal Corticosteroids were clinically equivalent.</p> <p>The committee was provided with updates from Facts and Comparisons and information on a new Intranasal Corticosteroid, Omnaris® (ciclesonide).</p> <p><u>Public Comment</u></p> <p>Dr. Rick Barbarash, AstraZeneca, stated Rhinocort Aqua® has no perfume or benzenecarbonyl chloride. A benefit for the patients is no after taste. It is the only Intranasal Corticosteroid that has a pregnancy B category rating from the FDA.</p> <p>Dr. Burke stated that Rhinocort Aqua® is currently a preferred drug on our PDL.</p> <p><u>Committee Discussion</u></p> <p>Dr. Burke stated that Omnaris® is approved down to age 6 for seasonal allergies and down to age 12 for year round allergies and is somewhat unique due to hypotonic solution.</p>	<p>Dr. Haneke moved that all intranasal corticosteroids are clinically equivalent.</p> <p>Seconded by Dr. Sweet and it carried with a unanimous vote.</p>
<p>VII. Beta blockers</p> <ul style="list-style-type: none"> a. Bystolic®-new medication to class 	<p>This class was last reviewed in March 2007. At that time the committee reiterated their prior position that</p>	

<p>b. Public Comment*</p> <p>c. Committee Discussion</p> <p>d. Committee Recommendation/Action</p>	<p>the oral beta blockers are clinically equivalent with the exception that carvedilol and metoprolol are preferred agents for congestive heart failure.</p> <p>The committee had been providedr with the most recent report from Oregon Evidence-based Practice Center dated September 2007.</p> <p>There is a new beta blocker, Bystolic[®] (nebivolol), in this class . Lisa Todd stated that Bystolic is a 3rd generation beta blocker. The other two agents that are 3rd generation beta blockers are Coreg[®] (carvedilol) and Trandate[®] (labetalol).</p> <p><u>Public Comment</u></p> <p>Dr. Alex Bennett, Forest Laboratories, stated that nebivolol is the only cardioselective and vasodilating beta blocker using epithelial and nitric oxide mechanisms. Nebivolol is hemodynamically and clinically different from other beta blockers. Other beta blockers lower heart rate and cardiac output and raise peripheral vascular resistance. In a trial vs. metoprolol, nebivolol decreased peripheral vascular resistance, raised stroke volume, and maintained cardiac output. Data shows that nebivolol, when used with typically harder to treat patients, such as African Americans, obese patients, and the elderly is similar to other populations in lowering blood pressure. It's demonstrated a neutral impact on plasma glucose. Compared to metoprolol, nebivolol raises insulin sensitivity. The side effect profile is similar to placebo in regards to: cold extremities, fatigue, and erectile dysfunction.</p> <p>Dr. Tietze asked if there have been any head to head</p>	
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studies with other beta blockers. Dr. Bennett stated that in addition to the trials that she mentioned there have been head to head trials looking at metoprolol and atenolol in terms of efficacy and tolerability.

Dr. Tietze asked if there are outcomes trials for nebivolol since it has been in Europe for 10 years. Dr. Bennett stated that there is a large outcome trial for seniors in heart failure. It was the basis for the approval in Europe.

Committee Discussion

Dr. Burke asked Dr. Bennett when nebivolol was approved for use in the U.S. She stated that it was approved in December 2007 and launched in January 2008.

Dr. Harte stated he considers nebivolol as effective as Toprol XL[®] and Coreg CR[®] and superior to atenolol or metoprolol.

Dr. Haneke stated nebivolol may turn out to be superior to other beta blockers in the future, but there is no basis for that determination today.

Dr. Mishler stated that nebivolol has the ability to be used in many settings and may have particular application with erectile dysfunction.

Dr. Sweet stated that she has not seen a great deal of difference between nebivolol and the other beta blockers. She suggested that it be considered clinically equivalent to the other beta blockers for use in hypertension. When more data is available on

	<p>nebevilol it can be reevaluated by the PDL committee.</p> <p>Dr. Bennett asked if a new indication comes out for a drug does that automatically put that drug back up for review.</p> <p>Karen Kluczykowski stated that a new indication can be a basis for a re-review.</p>	<p>Dr. Harte moved that the beta blockers reviewed are clinically equivalent including Bystolic®. Bystolic® will be re-reviewed when new indications come out. And he maintained the decision carvedilol and metoprolol are preferred agents for congestive heart failure.</p> <p>Seconded by Dr. Haneke and it carried with a unanimous vote.</p>
<p>VIII. Hepatitis C</p> <ul style="list-style-type: none"> a. Public Comment b. Committee Discussion c. Committee Recommendation/Action 	<p>Dr. Burke noted the considerable amount of information including the May 2007 Oregon Health Science Center report on Pegylated Interferons, which was reviewed by the PDL committee. Lisa Todd provided a table showing usage pattern in 2007 for Interferon, Peginterferon, and Ribavirin.</p> <p>Dr. Burke stated the discussion will be limited to the peginterferons, because they're clearly clinically different than interferon and ribavirin.</p> <p>This class has not been reviewed by the PDL committee before.</p> <p>Public Comment</p>	

Dr. Eli Corner, Roche, states Hepatitis C is the leading indication for liver transplantation in the state of Kansas. Since FDA approval in 2002, pegasys when given concomitantly with ribavirin has become the most prescribed treatment for HCV in the US. Pegasys along with ribavirin has achieved the highest overall sustained response rate.

Dr. Todd Midler, Schering Plough, reviewed the efficacy of peg inron and cited the IDEAL trial.

Committee Discussion

Dr. Sweet stated she does not believe there is evidence that one peg interferon is superior to the other. States she uses pegasys almost exclusively due to HIV. She noted that both companies have excellent indigent pop programs

Dr. Burke reiterated that ribavirin is not part of today's discussion and is a different drug than the interferons.

Lisa Todd mentioned ribavirin was included on the chart prepared for today's meeting to indicate that the majority of patients on peg interferon are on ribavirin also.

Dr. Haneke stated there is not enough data yet to make determination of superiority of one of the peg interferons.

Dr. Burke concurred that there is not enough data to indicate the superior efficacy and tolerability of either pegylated interferon alpha 2a or alpha 2b. Dr. Burke

	<p>reviewed the contents of eight letters he had received by practitioners requesting the availability of both peg-interferons.</p>	<p>Dr. Sweet made the motion that there is not enough data available to declare pegylated interferon alpha 2a and alpha 2b clinically equivalent at this time.</p> <p>Seconded by Dr. Mishler and it carried with a unanimous vote.</p>
<p>IX. Glaucoma Medications</p> <ul style="list-style-type: none"> a. Travatan Z® –new medication to class b. Public Comment* c. Committee Discussion d. Committee Recommendation/Action 	<p>Dr. Burke stated the glaucoma medication class was last reviewed in May 2005. The committee found the agents in this class to be clinically equivalent with the exception of Rescula which was felt to be less efficacious. Dr. Burke stated Travatan Z and Combigan are two new additions to this drug class since the last PDL review.</p> <p>Dr. Burke pointed out that the only difference between Travatan and Travatan Z is the preservative. He also noted that Combigan is a combination product containing Xalatan and timolol.</p> <p>No public comment.</p> <p>Dr. Haneke stated that the only difference is the removal of the benzalconium and the insertion of the buffer. He stated there may be some patients who benefit from this change and others for whom this is not a meaningful difference. He reminded those present that “non-preferred” products are available by prior authorization and added the he saw no difference in the clinically efficacy in these agents.</p>	

	<p>Dr. Burke noted that on previous review the committee had felt that Rescula stood out as not being as efficacious as the other agents and in the newer studies Rescula is no longer included.</p> <p>Dr, Haneke stated he stated he has not dispensed Rescula in his pharmacy for the last 10 years.</p> <p>Dr. Sweet stated Combigan, the combination of Xalatan and timolol, like other combination products, shouldn't be considered as clinically equivalent to other things in the class since it is a combination product.</p>	<p>Dr. Sweet made a motion to consider all drugs in the class clinically equivalent with the exception of Rescula, and that there is no compelling data that a combination formulation of a prostaglandin analogue with a beta blocker is superior to the individual agents used together.</p> <p>Seconded by Dr. Haenake and it carried with a unanimous vote.</p>
X. Adjournment	Dr. Burke called for a motion to adjournment.	<p>Dr. Sweet moved to adjourn.</p> <p>Seconded by Dr. Harte and it carried with a unanimous vote.</p>