



Kansas Medical Assistance Program

Preferred Drug List Committee

Meeting Minutes

February 28, 2006

<p>Preferred Drug List Committee Meeting Minutes Capitol Plaza Hotel President's Room, February 28, 2006 10:00 A.M.-3:30 P.M.</p>	<p>Members Present: Michael Burke, M.D., Ph.D., Chair; Robert Haneke, PharmD; Kenneth Mishler, PharmD; Glenn Harte, PharmD; Brenda Schewe, M.D.; Donna Sweet, M.D.; Dennis D. Tietze, M.D.</p> <p>DHPF Staff Present: Mary Obley, R.Ph.; Anne Ferguson, R.Ph.; Dennise Weichert</p> <p>EDS Staff Present: Karen Kluczykowski, R.Ph</p>	<p>Public: Todd Houldsworth (Ortho-McNeir-Janssen); Susan Zalenski (Johnson & Johnson); Brian Navman (Cephzylon); Bill Giltner (Pfizer); Ann Gustafson (GlaxoSmithKline); Nick Ybarra (King); Mike Manacle (King); David Hammett (Novo-Nordisk); Nikki Goff (Novo Nordisk); Jadraulea Popovic, M.D. (Pediatric Endocrinologist); Ron Godsey (TAP); Joe Summers (TAP) Dave Chapman (UCB); Monica Fay (UCB); Arnie Basemore (Sepracor); Amy Evans (AstraZeneca); Jim Williams, Ph.D. (Reliant); Jacqueline Marinac (Pfizer); Marcia Wright (Pfizer); Perry Johnson (3M Pharmaceuticals); Bruce Kirby (Genentech); Tammara Capps (SP); Jim Backes (KU Lipid Clinic); Kent Pearson (Abbott); Emily McGTinnis (Abbott); Patrick Maloney (Takeda); Mike Vogel (Takeda); Chris Torrey (Takeda); Dale Roof (Takeda); Dan Stansel (Pfizer); Sharon Kelsew (Pfizer); Mark Juhn, D.O. (Pfizer); Jim Bauman, R.Ph. (Pfizer); Martin Earley (Schering-Plough); Krishna Patel, PharmD (Schering-Plough); Colleen Stack, Carol Vaughn, Eric Swanson, Matthew Fullerton</p>
TOPIC	DISCUSSION	DECISION/ACTION
<p>I. Call to Order</p>	<ul style="list-style-type: none"> Dr. Michael Burke, Chair, called the Meeting of the Preferred Drug List (PDL) Advisory Committee to order at 10:15a.m. with a quorum of five present. 	
<p>II. Announcements</p>	<ul style="list-style-type: none"> Dr. Burke announced that Dr. Sweet and Dr. Schewe are on their way. Dr. Fink will not be attending today. Dr. Mills has resigned from the PDL Committee due to his new responsibilities with the Health Care Authority Board. He will be contributing to the State in that and other ways. Dr. Mills continues to support the process and efforts of the PDL Advisory Committee. Mary Lesperance stated that anyone intending to speak during the public comment period will need to please fill out a Conflict of Interest Disclosure form. 	

TOPIC	DISCUSSION	DECISION/ACTION
<p data-bbox="58 110 499 175">III. Review Approval of October 07, 2004, Meeting Minutes</p> <p data-bbox="58 207 552 329">IV. Growth Hormones for indication for growth hormone deficiency (Excluding Zorbitive®; Serostim®; Serostim LQ®)</p> <p data-bbox="58 483 300 508">1. Public Comment</p> <p data-bbox="58 727 390 751">2. Committee Discussion</p>	<ul data-bbox="583 110 1392 1287" style="list-style-type: none"> • There were no additions or corrections to the June 8, 2005 meeting minutes. • Mary Lesperance stated that all of the Growth Hormones under review today are somatropin, the same chemical entity with varying strengths, indications and brand names. The intention is to look at these through the established PDL process in order for them to appear on the PDL list. • Dr. Burke reiterated that these are the same compound and this is a formality. • Dr. Jadranka Popovic , presented information on Norditropin®. • Bruce Kirby (Genetech) discussed Neutropin® and Neutropin AQ® regarding the BX rating among growth hormone products. • Drs. Schewe and Sweet arrived at the PDL Committee meeting during the public comment period. • Dr. Mishler stated that an FDA rating of BX is considered inequivalent until proven to be equivalent. This is due to a lack of data. Dosage is adjusted based on the response to the drug which would compensate for any inequivalencies that may exist. • Dr. Sweet asked if Serostim® was being reviewed for HIV patients. Mary stated that Serostim® is not being reviewed today. • Dr. Tietze stated we are focused on clinical use. • Dr. Kristen Fink sent her written comments recommending clinical equivalence for the listed growth hormones for growth hormone deficiency. 	<ul data-bbox="1423 110 2032 232" style="list-style-type: none"> • A motion to approve the minutes as written was made by Dr. Haneke and seconded by Dr.Harte. The motion carried unanimously by roll call of members present.

- Dr. Kore Liow, Epileptologist at Via Christi, provided the PDL Committee with information regarding his medical practice at the Epilepsy Center at Via Christi.
- Dr. Tietze stated that the State is not asking neurologists to do anything that other specialists have been asked to do. Dr. Sweet said that epilepsy is a chronic disease as is diabetes, HIV, and cardiovascular disease. Physicians treating these and other chronic conditions work with the prior authorization process for non-preferred drugs every day. Dr. Sweet stated that the PDL Committee does not stop any patient from receiving a non-preferred drug when appropriate.
- There was a discussion among the Committee members in regard to the different mechanisms of action of the drugs under review.
- Dr. Burke said that these drugs all have different mechanisms of action and it is difficult to predict which drug will work for each individual patient.
- Dr. Tietze said that there is no data to support that these drugs are interchangeable, but physicians use them all for the same conditions.
- Dr. Sweet said that the drugs are not “clinically equivalent” as with other classes but if you look at clinical medicine, the mechanism of action of a drug is probably not considered when a physician chooses medication for a patient, because physicians choose medications for patients based on the individual. Dr. Sweet stated that the drugs are not pharmacologically equivalent, but from a clinical use standpoint, they are equivalent. The non-preferred drugs are still available through the prior authorization process. She would support these drugs being on the PDL and suggests monitoring for any problems.
- Dr. Mishler clarified that physicians are not prohibited from prescribing non-preferred drugs. The non-preferred drugs are still available.
- Dr. Haneke stated that he would like to see more appropriate use of these drugs.
- Dr. Kristen Fink sent written comments recommending clinical equivalence of the adjunct antiepileptics when compared by approved indication. The selection of an effective agent is going

- A motion was made by Dr. Sweet that the five adjunct antiepileptics can be used clinically interchangeably, despite pharmacological differences. The motion was seconded by Dr. Schewe. Recommendations to the DUR Board

<p>3. Committee Recommendation/ Action</p>	<p>to vary by individual, and in any case, the prior authorization process allows for access to any of the drugs with documentation.</p> <ul style="list-style-type: none"> • Dr. Burke asked that a report on Drug Utilization Review Board (DURB) activities be given to the PDL Committee at each meeting, since the DUR Board is responsible for making recommendations on prior authorization criteria. 	<p>will include allowances for patients with co-morbidities or pre-existing conditions that would contraindicate use of a preferred drug. The motion carried unanimously by roll call.</p>
<p>VI Fibric Acid Derivatives (gemfibrozil; fenofibrate)</p> <p>1. Public Comment</p> <p>2. Committee Discussion</p> <p>3. Committee Recommendation/ Action</p>	<ul style="list-style-type: none"> • Jim Backes, representing Abbott, gave information to the PDL Committee regarding Tricor® • Dr. Kristen Fink sent written comments recommending clinical equivalence of the fibric acid derivatives • Dr. Tietze stated that when statins are being used in combination with fibric acid derivatives, fenofibrate is safer than gemfibrozil. • Dr. Sweet agreed that gemfibrozil is not as good when being used in combination therapy. 	<p>A motion was made by Dr. Sweet that all formulations of fenofibrate are clinically equivalent. Dr. Mishler seconded the motion. The motion passed unanimously by roll call.</p>
<p>VII. New Inhaled Corticosteroid Mometasone (Asmanex Twisthaler®)</p>	<ul style="list-style-type: none"> • Mary stated that this class of drugs was reviewed by the PDL Committee in February 2005 and the drugs in the class were evaluated to be clinically equivalent. Mometasone (Asmanex Twisthaler®) is a new drug to this class. This is a review of mometasone to determine if it is clinically equivalent to the other drugs in this PDL class. 	

<p>2. Committee Discussion</p> <p>3. Committee Recommendation/Action</p>	<ul style="list-style-type: none"> • Dr. Sweet said that Ramelteon is a very different drug because it is non-scheduled, accumulates over time (takes 7 to 8 days to work), but appears to improve sleep habits. There is a group of people who do not want any controlled drugs with addictive potential. The only thing Ramelteon has in common with Ambien®, Sonata®, and Lunesta® is that they are all non-benzodiazepines. Dr. Sweet would like 	
	<ul style="list-style-type: none"> • to have this drug in a stand alone class separate from the sedative/hypnotic class. • Dr. Schewe concurred that Ramelteon is not really a hypnotic. • Dr. Harte said that Ramelteon should be considered in its own class. • Dr. Haneke stated that the drug is pharmacologically different but clinically interchangeable. • Dr. Kristen Fink recommended clinical equivalence of Ramelteon to the other previously reviewed sedative/hypnotics. 	<ul style="list-style-type: none"> • Dr. Sweet made a motion that Ramelteon is not clinically equivalent to the other sedative/hypnotics. Dr. Harte seconded the motion. The motion passed with all in favor except that Dr. Haneke voted no.
<p>IX. Meeting Adjournment</p>	<ul style="list-style-type: none"> • With no further discussion, a motion to adjourn was placed before the Committee. 	<ul style="list-style-type: none"> • A motion was made by Dr. Burke to adjourn the meeting. This was seconded by Dr. Schewe. The motion carried unanimously by roll call. The meeting was adjourned at 1:35 pm.