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Governor

STATE OF NEVADA
DEPARTMENT OF HUMAN RESOURCES
DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID

MICHAEL J. WILLDEN
Director

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Administrator

PHARMACY & THERAPEUTICS COMMITTEE

Legislative Building
Room 2134
401 S. Carson St.
Carson City, NV

Meeting Minutes
January 26, 2006
Time: 1:00 p.m.

Committee Members Present:
Steven Phillips, MD, Chairman
Judy Britt, Pharm.D.
Carl Heard, MD
Larry Pinson, Pharm.D.
Susan Pintar, MD
Diana Bond, R.Ph. (called-in)
Linda Flynn, R.Ph. (called-in)
Robert Horne, MD (called-in)

Others Present:
Darrell Faircloth DAG, Vickie Langdon DHCFP, Jeff Monaghan FHSC, Shirley Hunting FHSC, Dawn Daly FHSC, Dana Hurley Amgen, Roland Baldwin Wyeth, Bert Jones Glaxo SmithKline, David Case Astellas Pharma, Mark Ellison Glaxo SmithKline, Joe Schwab Novartis, Jerome Catalino Novartis, Kara Smith Cephalon, Robert Broersma Astra Zeneca, Steve Schaerrer Astra Zeneca, Kirk Huffaker Schering-Plough, Alan Sloan Purdue, Joann Phillips, Bill Ferguson Amgen, Nancy Fairchild Sepracor, Sandy Sierawski Pfizer, Edward Lewis Pfizer, Eric Rouse Lilly.

I. Call to Order and Roll Call

Chairman Steven Phillips called the meeting to order at 1:02 p.m.

II. Review and Approval of October 26th Meeting Minutes

MOTION: Larry Pinson motioned to accept the minutes as written.
SECOND: Carl Heard
VOTES: Unanimous
MOTION CARRIED

III. Public Comment

No comment.

IV. Central Nervous System: ADHD/Stimulants/Non-Stimulants - Consideration of New Agent - Focalin XR® (Dexmethylphenidate Extended Release)

Public Comment

Joe Schwab, Novartis, presented a handout and spoke in support of Focalin XR®**.** He stated that Focalin XR® has been formulated into a once a day preparation which provides rapid onset. In addition to being effective in children and adolescents, it has been shown to be effective in adults and is the only methylphenidate preparation approved for adults. It's easy to dose and well tolerated.

Dr. Heard asked if there is any information on the abuse potential. Mr. Schwab replied that there is no indication that it has anymore than existing preparations. In the QD preparation, there is a lot less likelihood that it's going to be diverted and subsequently abused.

Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that this category was reviewed in October 2005, and because there was no new information at that time to present, no changes were recommended. He stated that there is now a new drug to be considered.

There are currently three groups of drugs represented on the Nevada PDL to treat the symptoms of ADHD, the methylphenidate products, amphetamines, and atomoxetine. Focalin® (dexmethylphenidate) is currently on the PDL. He asked the Committee to consider adding the extended release version of this drug which is Focalin XR®**.**

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in this Class and Identify Exclusions/Exceptions for Certain Patient Groups

Dr. Horne asked when modafinil will be going generic. Dr. Monaghan replied this year but was not certain which month.

MOTION: Larry Pinson motioned that the agents in this class be considered therapeutically equivalent.
SECOND: Judy Britt
VOTES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Dr. Monaghan stated that it is the recommendation of DHCFP and First Health to add Focalin XR® to the Preferred Drug List.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Judy Britt motioned to add Focalin XR® to the PDL.
SECOND: Larry Pinson
VOTES: Unanimous
MOTION CARRIED

V. Inhaled Corticosteroids - Consideration of New Agent - Asmanex Twisthaler® (mometasone furoate)

Public Comment

Kirk Huffaker, Schering-Plough Pharmaceuticals, spoke in support of Asmanex Twisthaler®. He stated that Asmanex Twisthaler® has been FDA approved for once daily p.m. dosing providing around-the-clock coverage for mild, persistent asthma. It has been shown to reduce night time awakenings as well as reducing the need for short-acting, rescue medications.

Bob Broersma, Astra-Zeneca, spoke in support of inhaled budesonide (Pulmicort®), both the respules, a suspension of budesonide nebulized and Pulmicort® Turbuhaler, the dry powder. He stated that Pulmicort® Respules improves both night and daytime symptoms both in a once and twice a day dose. It reduces the need for daily bronchodilator treatment, improves lung function, reduces the incidence of exacerbations and is approved for use in children twelve months to eight years of age. Pulmicort Turbuhaler® is effective for controlling mild to severe asthma, is also once a day dosing and clinically approved for six years of age through adulthood. He asked that consideration be given to having these products more accessible.

Dr. Heard stated that Pulmicort® Respules is currently on the PDL with no prior authorization (PA) required for < 4 years of age and asked Mr. Broersma if he is advocating it be available for all ages without a PA. Mr. Broersma replied that the respules are FDA approved for up to age eight and the turbuhaler approved for six years and over. Dr. Heard asked if his product is the only one approved for nebulizer use and Mr. Broersma replied, yes, the respules which are approved for twelve months to eight years old.

Drug Class Review Presentation – First Health Services

Jeff Monaghan reminded the Committee that at the October 2005, meeting, this class was placed in the category where no changes were recommended and that was the action taken by the Committee at that time. Since then, a new agent, Asmanex® Twisthaler, has been released. Including Asmanex® Twisthaler, there are now six inhaled corticosteroids available with four currently on the PDL in some form (Azmacort®, Flovent®, QVAR®, Pulmicort Respules® [no PA required <4 years old]). Fluticasone (Flovent®) is also available in combination with a long-acting beta-agonist, salmeterol, but the Committee has not formally added it to the PDL; i.e., there currently are no restrictions on the drug. Asmanex® (mometasone) is considered a high potency agent with low systemic bioavailablity and available as a dry powdered inhaler. Memetasone is also available as a topical corticosteroid in a cream form, Elocon®, and also as an intranasal spray, Nasonex® and currently on the PDL. Asmanex® initial dosing is once daily in the evening; maximum dosing can go up to two puffs, twice a day. Pharmacology, contraindications, major adverse events and warnings are similar to the other inhaled corticosteroids and considered class effects. In the updated report on inhaled corticosteroids, dated January, 2006, the Evidence-Based Practice Center included mometasone (Asmanex®) and took the position when given in equal potent doses, the drugs within this class are therapeutically equivalent.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in this Class and Identify Exclusions/Exceptions for Certain Patient Groups
Dr. Heard asked for clarification regarding Advair®. Dr. Phillips stated that since Advair® is a dual agent, it could not be place under the inhaled corticosteroids or under the beta-agonists. The Committee decided not to address it as PDL or non-PDL; i.e., it is covered by Medicaid with no restrictions.

Dr. Heard asked when considering a motion for equivalency, will Advair® be left out again and Dr. Phillips replied that is correct.

MOTION: Carl Heard motioned that the agents in this class be considered therapeutically equivalent carving out Advair® as previously stated.
SECOND: Robert Horne
VOTES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Dr. Monaghan stated that it is the recommendation of DHCFP and First Health to add Asmanex® to the Preferred Drug List.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Judy Britt motioned to add Asmanex® to the PDL.
SECOND: Larry Pinson
VOTES: Unanimous
MOTION CARRIED

VI. Ophthalmic Quinolones - New Drug Class to be Considered

Public Comment
No Comment.

Drug Class Review Presentation – First Health Services
Dawn Daly informed the Committee that within the meeting packet are letters of written public testimony for various drugs being reviewed today.

Ms. Daly stated that there are currently five ophthalmic fluoroquinolones available. Two of the agents are available generically. In general, the quinolones have a wide spectrum of antimicrobial activity but individual differences exist. The ophthalmic quinolones differ in dosage, administration, spectrum of activity and FDA approved indications. All are indicated for bacterial conjunctivitis; ciprofloxacin, ofloxacin and levofloxacin are also indicated for corneal ulcers. The organism affecting the eye is rarely, if ever, identified in clinical practice therefore providing any fluoroquinolone would effectively treat the infection in the majority of patients. Pre- or post-surgical treatment protocols often include fluoroquinolones to prevent endo-opthalmitis and kerititis. Fourth generation quinolones, moxifloxacin and gatifloxacin have become the choice due to the growing bacterial resistance to second generation. Selection of one agent over another is often based on physician preference and on treatment centers' specific protocols.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in this Class and Identify Exclusions/Exceptions for Certain Patient Groups
Dr. Heard stated that given the spectrum of antibiotic resistant susceptibility, it raises the question about equivalency. Ms. Daly stated that fluoroquinolones have been used rather freely in treating conjunctivitis when sulfacetamide or gentamicin would have been effective thereby developing resistance. The fourth generations take two mutations before they develop resistance thus the request that a fourth generation be available.

Dr. Britt asked with the availability of a fourth generation for post-surgicals, would the DUR Board establish prior authorization criteria or is the request to add it to the PDL without a prior authorization requirement. Ms. Daly responded without a prior authorization requirement because in most instances, the prescriptions will be written by an ophthalmologist. Dr. Britt asked if there is a mechanism to have the system look for ophthalmology specialization in the Rx process. Ms. Daly stated that she would look into that.

Dr. Phillips asked with the fourth generation, is it when there's already established endophthalmitis or kerititis? Ms. Daly responded it's used prophylactically because it can occur within eight hours and destroy sight. Dr. Phillips said that an ICD-9 could not be attached then as it could be used because of suspicion rather than actual presence and Ms. Daly stated that it correct.

Dr. Pintar stated that because these don't generally have pediatric indications, they are not supposed to be prescribed, but ophthalmic preparations are prescribed for a different use. Is there a way to monitor that or is there a need to in terms of who prescribes it? Ms. Daly responded that from a claims standpoint, there is no way to determine how the drug is being administered.

Dr. Heard stated that his company has recently researched this issue as well and he was under the impression that there are certain agents that slow healing of a corneal ulcer and asked if Ms. Daly was stating that there is no difference between them? Ms. Daly replied that only ciprofloxacin, ofloxacin and levofloxacin have the indication for corneal ulcer.

MOTION: Larry Pinson motioned that as a class, the agents be considered therapeutically equivalent and to include a fourth generation.
SECOND: Judy Britt
VOTES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Ms. Daly stated that it is the recommendation of DHCFP and First Health to add ciprofloxacin (Ciloxan®) and moxifloxacin (Vigamox®), the fourth generation quinolone, to the PDL.

Committee Discussion and Approval of Drugs for Inclusion in the PDL
Judy Britt felt that a fourth generation should be included in the PDL but recommended DUR Board involvement otherwise primary care physicians will be using a fourth generation fluoroquinolone quite readily. Although appropriate for surgical procedures, she expressed concern it would be used for uncomplicated conjunctivitis.

Dr. Heard suggested approval of the recommended additions to the PDL with the requirement that a report of injudicious use of the medication be presented at the next meeting.

Dr. Pintar stated that a number of optometrists are the follow-up physicians for ophthalmologists and felt that usage by the optometrists should be included as well.

MOTION: Carl Heard motioned to approve the addition of ciprofloxacin (Ciloxan®) and moxifloxacin (Vigamox®) to the PDL with a request that specific management recommendations are presented at the next meeting.
SECOND: Larry Pinson
VOTES: Unanimous
MOTION CARRIED

VII. Ophthalmic Antihistamines-New Drug Class to be Considered

Public Comment
Jerome Catalino, Novartis, spoke in support of Zaditor®. He stated that Zaditor® is a selective, H1-receptor blocker, mast cell stabilizer which decreases the activation of eosinophils, has a rapid onset of action and long duration of effect. He presented a handout which includes a list of articles speaking to its efficacy and safety, use in the pediatric population and tolerability and adherence.

Dr. Pintar asked if there is a pediatric indication. Mr. Catalino said that the package states for three years and above.

Dr. Heard stated that when looking for therapeutic equivalency, consideration is given as to whether the drug has exceptional therapeutic value or has exceptional risks that outweigh its' benefit and asked Mr. Catalino what makes this drug exceptional in either direction. Mr. Catalino replied that all are efficacious but this drug (Zaditor®) has the longest duration in the class.

Drug Class Review Presentation – First Health Services
Jeff Monaghan stated that there are five available ophthalmic antihistamines. None are available in a generic formulation. All are indicated for allergic conjunctivitis. Livostin® was a QID product which was discontinued by Novartis in October, 2004, and is no longer on the market. All these agents have mast cell stabilizing properties in addition to their antihistaminic effects. Although the clinical significance of this is yet to be clearly established, the theory is that this additional effect confers an additional benefit when treating chronic symptoms; i.e., the effect lasts longer with the dual action. Contraindications, warnings and precautions are comparable with the exception of Emadine® which has a pregnancy category B warning versus C as with the other agents. A systematic review and meta-analysis by Owen of the effectiveness of these medications found that overall there was a benefit when compared to placebo. The study also concluded that there was insufficient evidence to recommend the use of one over another. For most patients, any of these available ocular antihistamines will provide similar efficacy with comparable side effects. There are no studies available that look at specific sub-populations. It is the recommendation of DHCFP and First Health that the agents in this class be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in this Class and Identify Exclusions/Exceptions for Certain Patient Groups

MOTION: Ms. Bond motioned that the ophthalmic antihistamines as presented by First Health be considered therapeutically equivalent.
SECOND: Linda Flynn
VOTES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Dr. Monaghan stated that it is the recommendation of DHCFP and First Health that epinastine (Elestat®) and ketotifen (Zaditor®) be added to the PDL.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Judy Britt motioned that Elestat® and Zaditor® be added to the PDL.
SECOND: Diana Bond
VOTES: Unanimous
MOTION CARRIED

VIII. Nasal Calcitonins- New Drug Class to be Considered

Public Comment
No comment.

Drug Class Review Presentation – First Health Services
Ms. Daly stated that there are two calcitonins available, Miacalcin® and Fortical®. Both have the indication for post-menopausal osteoporosis in women greater than five years post-menopause but they are not considered first line agents in the treatment or prevention of osteoporosis. Miacalcin® is derived from synthetic origin and Fortical® uses recombinant DNA. Both agents are administered once per day alternating nostrils. Contraindications, adverse effects, drug interactions, precautions and warnings are similar and should be considered a class effect. It is the recommendation of DHCFP and First Health that these agents be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Groups

MOTION: Larry Pinson motioned that these agents (Miacalcin® and Fortical®) be considered therapeutic alternatives.
SECOND: Carl Heard
VOTES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Ms. Daly stated that it is the recommendation of DHCFP and First Health to add Miacalcin® to the PDL.

Committee Discussion and Approval of Drugs for Inclusion in the PDL
Dr. Phillips asked if any type of limitation for use will be applied; i.e., failure of another bisphosphonate. He stated that in general, from a geriatric perspective, most of the osteoporosis is seen with patients on oral corticosteroids or some of the congenital problems. The nasal is used for acute vertebral compression fractures for approximately four weeks. There seems to be an analgesic property with Miacalcin®. The literature supports the bisphosponates and Evista® which are more effective in the treatment of osteoporosis. Dr. Phillips felt that if it can be tolerated, it is his recommendation a bisphosponate be used over Miacalcin®.

Ms. Daly responded that criteria for use would have to be referred to the DUR Board if this Committee is requesting limitations be applied.

MOTION: Susan Pintar motioned that Miacalcin® be added to the Preferred Drug List.
SECOND: Larry Pinson
VOTES: Unanimous
MOTION CARRIED

IX. Injectable Immunomodulators-New Drug Class to be Considered

Public Comment
Dana Hurley, Amgen, spoke in support of etanercept (Enbrel®). She stated that etanercept is known to only produce non-neutralizing antibodies in approximately 6% of patients; has the broadest coverage of indications including both rheumatology and determatology; is safe, noting the rate of infection and adverse effects has remained low over the past seven years; has been shown to have sustained rheumatoid arthritis efficacy over seven years; dosing is a once weekly 50mg injection for rheumatoid arthritis; offers unique advantages such as the indication for juvenile rheumatoid arthritis and predictable dosing.

Dr. Heard asked if TNF blockers have been used in cachexia or chronic wasting states because TNF has been implicated in people with cancer as a main mode of weight or appetite loss. Ms. Hurley replied that she was not aware of any studies in that area.

Drug Class Review Presentation – First Health Services
Dawn Daly stated that the three agents in this class all have the indication for rheumatoid arthritis RA). Enbrel® and Humira® both have the indication for psoriatic arthritis. Enbrel® is also indicated in the treatment of polyarticular-course juvenile rheumatoid arthritis (JRA), ankylosing spondylitis and plaque psoriasis. All agents are administered subcutaneously. Enbrel® and Humira® are tumor necrosis blockers; Kineret® is a genetically engineered interleukin-1 receptor antagonist. Enbrel® is dosed weekly with two separate injections; Humira® is dosed every other week but may be administered weekly in patients who are not receiving methotrexate concurrently; Kineret® is administered daily and all agents can be administered with methotrexate. Adverse event profiles are similar among these agents. Humira® carries a black box warning stating a risk of infection has been observed, specifically, tuberculosis; Enbrel® has warnings regarding the risk of tuberculosis infection. All three agents can be associated with increased incidence or serious infections and administration should be discontinued or not initiated in patients with active infections. There are no head-to-head clinical trials comparing these agents. It is the recommendation of DHCFP and First Health that in the

treatment of rheumatoid arthritis and psoriatic arthritis that Enbrel® and Humira® are therapeutic alternatives and that Kineret® does not fit within this role.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in this Class and Identify Exclusions/Exceptions for Certain Patient Groups
Judy Britt stated that, although it is an IV, there are rheumatologists in the community that are sending their patients to the drug store to pick up Remicade and asked if that will eventually be considered to be added to the Medicaid PDL.

Ms. Daly stated that at their next meeting, the DUR Board will be considering treatment criteria for rheumatoid arthritis to include these agents as well as Remicade. Remicaid may not be considered for PDL inclusion, but if obtained at a pharmacy, prior authorization criteria may apply.

Dr. Phillips clarified that consideration is specifically for equivalency for rheumatoid arthritis and psoriatic arthritis with Enbrel® and Humira® only and Ms. Daly replied that is correct. Dr. Phillips asked for clarification regarding the indication for Kineret®.

Jeff Monaghan stated that Kineret® is not a good therapeutic alternative within this class. Though somewhat indication driven, Enbrel® and Humira® can be considered therapeutic alternatives with the assumption use will be for the correct indication. Dr. Phillips asked if this would be accomplished through education and asked Dr. Pintar, as a pediatrician who has seen JRA, is this something within the discipline of pediatrics. Dr. Pintar felt that a pediatric rheumatologist, not the general pediatrician, would be prescribing these. Dr. Monaghan added that this item had been agendized for the December DUR Board meeting but was bumped due to other issues. This will be on the DUR Board agenda for consideration of clinical criteria at the March, 2006, meeting.

Dr. Heard asked for clarification from First Health. He stated that it seems Kineret® may benefit JRA but the requested recommendation is an indication specifically for RA not JRA and that Enbrel® and Humira® are therapeutic alternatives and exclude Kineret®. Dr. Monaghan stated that is correct and added that for most indications, Enbrel® and Humira® can be considered therapeutic alternatives knowing the DUR Board is going to be addressing criteria for the approved indications.

Dr. Phillips clarified that Enbrel® and Humira® can be considered therapeutic alternatives, but not Kineret® without a diagnosis qualification, and with the understanding that this will be going to the DUR Board.

MOTION: Judy Britt motioned to accept Enbrel® and Humira® as therapeutically equivalent.
SECOND: Robert Horne
Dr. Heard felt that Kineret® should be listed as PDL, non-PDL or not listed. Dr. Monaghan stated that Kineret® is a part of this drug class. If it's not listed as preferred on the PDL, it will require a prior authorization.
AYES: Horne, Flynn, Bond, Britt, Phillips, Heard, Pinson
ABSTAIN: Pintar
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Ms. Daly stated that it is the recommendation of DHCFP and First Health to add Enbrel® and Humira® to the PDL.

Committee Discussion and Approval of Drugs for Inclusion in the PDL
Diana Bond expressed concern that if action is not taken on Kineret®, it will be open to use with nothing to preclude it. Dr. Monaghan replied that because it is part of the class, it will be considered non-preferred within the class.

Dr. Phillips asked how this can be better clarified and Dr. Horne suggested stating that Kineret® is on the non-preferred list. Dr. Monaghan responded that there is not a non-preferred list only a preferred list and drugs not considered preferred within the drug category automatically are deemed non-preferred.

Mr. Faircloth suggested asking for DUR Board review and/or request it be PA'd independently. From his perspective, he expected it would be a drug that is therapeutically equivalent and included in this review and from these three drugs, two preferred agents would be selected.

Dr. Phillips reminded the Committee that when the H2-blockers were reviewed, it was specifically stated that cimetadine could not be prescribed due to the side-effect profile. The Committee felt that it was not a therapeutic equivalent and as part of the motion, it was felt that cimetadine should not be prescribed and was considered non-preferred. Dr. Monaghan also reminded the Committee that in order to obtain a non-preferred drug, the patient must have failed or had adverse reactions to the preferred drugs.

Ms. Bond said that it should be indicated that Kineret® is part of the class but not equal and felt that distinction should be made.

Dr. Britt suggested that if the motion is made specifically that Kineret® not be added to the Preferred Drug List since it was not considered equivalent, it can have its own motion.

MOTION: Diana Bond motioned to accept First Health's recommendation for inclusion of Humira® and Enbrel® to the PDL.
SECOND: Robert Horne
Dr. Heard asked for clarification of the motion. He stated that it sounds as if this is being broken down into two different motions; Kineret® will be a separate motion and Humira® and Enbrel® will be added to the PDL. Dr. Phillips stated that is correct.
VOTES: Unanimous
MOTION CARRIED

MOTION: Judy Britt motioned that Kineret® not be added to the PDL.
SECOND: No second was offered.
Dr. Heard asked First Health for further clarification. Kineret® does not seem to be extraordinarily beneficial or extraordinarily dangerous therefore we do not seem to be in the same picture as cimetadine. Why is there special consideration of this drug?

Dr. Monaghan stated that what is brought forth to the Committee is a category of drugs that can reasonably be expected to be therapeutic alternatives which is up to discussion

and debate by this group. By definition, if they are considered therapeutic alternatives and recommendations are made to add one or two agents, the agents not added, will automatically become non-preferred, will not appear on the list, will require prior authorization and will require failure of the preferred agents before a non-preferred agent is authorized. Hopefully, what is brought forth to this Committee can be considered as therapeutic alternatives and it's reasonable to say that Kineret® is a therapeutic alternative within this group.

Dr. Heard suggested changing the motion to state that this is a therapeutic class, and that the three agents are alternatives. The second motion would be to consider what agents are to be included on the PDL.

Dr. Britt stated that she was agreeable to the suggestion and commented that one of the reasons that she personally felt there is not therapeutic equivalence is that they are not the same class of drug; only two are TNF blockers. She did not view Kineret® as being therapeutic equivalent when the mechanism of action is different.

Dr. Monaghan agreed that they have a different mechanism of action and said according to the AMA definition of therapeutic alternative, they can be chemically different and what you look for is comparable therapeutic outcomes.

Dr. Phillips stated that a motion was passed to accept First Health's recommendation to add Enbrel® and Humira® to the PDL. Dr. Phillips deferred to Darrell Faircloth, DAG, asking if a new motion can be entered to consider all three agents as equivalent superseding the previous motion of equivalency. Mr. Faircloth said that is acceptable.

MOTION: Carl Heard motioned to consider the three agents in this class as therapeutic alternatives.
SECOND: Larry Pinson
AYES: Pintar, Pinson, Heard, Phillips, Bond, Flynn
ABSTAIN: Britt, Horne
MOTION CARRIED

Dr. Phillips requested that since the new motion is to accept all three agents as therapeutic equivalents, Dr. Monaghan state the recommendation by DHCFP and First Health for PDL inclusion.

Dr. Monaghan stated that it is the recommendation of DHCFP and First Health to add Enbrel® and Humira® to the PDL in this class.

MOTION: Diana Bond motioned to accept First Health's recommendation for inclusion of Humira® and Enbrel® to the PDL.
SECOND: Larry Pinson
VOTES: Unanimous
MOTION CARRIED

X. Removal of Erectile Dysfunction Drugs from Preferred Drug List due to Congressional Action to Discontinue Federal Funding for these Agents Presentation by DHCFP/First Health Services

Darrell Faircloth stated that in October, 2005, House of Representatives Bill 3971 was signed into law which removed Medicaid coverage at the Federal level of erectile

dysfunction (ED) drugs when used for the treatment of sexual or erectile dysfunction. To the extent those agents are used to treat those conditions, the state Medicaid agency will no longer cover these agents. What is being agendized is the removal of this class of drugs from the Preferred Drug List.

Dr. Heard stated that this seems to be a political decision which has echoed through the medical system. He said it was concerning to him because a payer class has chosen not to support a medication that has been widely known and recognized as taking an organ that is not functioning properly and aiding it in functioning properly. To a certain extent, it has social implications and he asked what the Committee's options are. Does the State have the option to continue with this class of drugs and to not eliminate this class of drugs? If the Committee has no other choice, can the Committee protest if they chose to do so?

Dr. Phillips said the other alternative is to not rule on this because it is not within the Committee's domain as cost is not to be a consideration. The State can do what it chooses to do without Committee permission.

Dr. Heard stated that if the Committee chose not to act or eliminate this class, the onus is on the State to continue supplying these drugs with or without Federal support, because the Committee does not consider dollar support or financial ramifications. If the Committee chose to not approve this as recommended, there are two basic options. One is to leave the class on the PDL unless someone can come forth and show there is a medical contraindication to this, it's a class that works, and we recommend our patients have access to that. Secondly, if this class is going to be eliminated regardless of Committee action, what is the limit of the Committee's ability to protest or to add clinical insight into an administrative and financial decision?

Mr. Faircloth said this came about as a result of controversy regarding the provision by some state Medicaid programs of ED drugs to sex offenders. There has been much on the national level and Congress' reaction was to withdraw financial support for all ED drugs when used for those purposes. Understanding the way the Medicaid program is structured, at the Federal level, there is an arching umbrella of law that dictates what items must be covered by the Medicaid program and then a group of optional services that may be provided by the states' Medicaid programs. The Federal government has dictated that this may not be covered with Medicaid dollars. Therefore, the state Medicaid program, which is the program that this Committee serves by setting up a Medicaid preferred drug list, cannot override the federal authority that states this may not be covered by your Medicaid program. There other avenues in the State system where drugs are covered that might not be covered by the Medicaid program. For example, the Senior Rx program can cover drugs that are beyond the scope of the Medicaid program. There's a different source of funding there and that may be an alternative. There are other programs as well. We don't have the authority as a Committee to tell Medicaid they must cover this. Medicaid at the federal level, the Centers for Medicaid and Medicare Services, has dictated that this is not a part of Medicaid coverage.

Dr. Heard referenced the procedure memo included in the packet which states that "First Health Services Corporation to change the following in Point of Sale (POS) on-line claims processing…" and the second paragraph states "The Federal Government has passed legislation which will no longer provide Federal Financial Participation (FFP) to Medicaid programs…" He said that it does not state nor has he ever heard that the

Federal Government has stated that you can not or will not include these in your Medicaid program. What they are saying is that they will not pay for it and this Committee is prohibited from considering finance. What we are trying to do is bring clinical light to an unfortunate and exaggerated response to what was inappropriate prescribing of this medication. If there is a diagnosis that contraindicates the drug, we simply say don't prescribe the drug for that indication. If there is a history of pedophilia or sexual aggression, that's a contraindication for this drug's use.

Dr. Phillips asked that if this is a State decision, why it is being brought to the P&T Committee. Dr. Heard said if the Committee's only clinical input is considering therapeutic alternative and whether to include a drug on the PDL or not, why consider deletion of a class that has clear clinical value.

Jeff Monaghan said that this item was placed on the agenda to inform the Committee of the Federal mandate and to have the Committee act to remove this drug class from the PDL.

Public Comment

Bert Jones, Glaxo SmithKline, stated that in 1990 when the Omnibus Budget Reconciliation Act (OBRA) was passed is when the Pharma companies agreed to pay rebates on Medicaid. The Feds set up optional categories which were not covered; e.g, smoking cessation and obesity. They didn't think in terms of how technology would evolve. Those categories are now optional. Every state has a matching funds system with the Feds. A state could decide in the optional category to cover a category, but that would come out of the general revenue with no Federal money. In reading the procedure document, federal appropriations will not be received but the document does not state that is has been moved to the optional category.

Committee Discussion and Action

Diana Bond suggested that Nevada Medicaid and the Attorney General's office present at the next meeting the legal parameters of the Committee. She said that this is not just a PDL question but a policy question because there has been a Federal mandate stating what Medicaid funds can be used for. Her concern is that the class remains published on the list and it's misleading. If Nevada Medicaid is not going to pay for this medication, it still has the potential to be published on the PDL, misunderstood by the prescribing community and the patient and creating a traumatic situation at the pharmacies when the patient is told they are responsible for paying for the drug.

Dr. Heard stated that he disagreed with removing it from the PDL during the interim. No one has supplied the Committee with a medical reason to remove these drugs from the PDL.

Vickie Langdon said that the procedure memo was written prior to receiving the CMS guidance letter which stated that Medicaid was no longer to issue medications for impotence or erectile dysfunction. Since that time, CMS issued a new state guidance letter. Mr. Faircloth said that the content of the letter was that they would not be providing any Federal Financial Participation and also stated that coverage of those drugs could lead to sanctions of this Medicaid program. He stated that the state Medicaid program is not going to be covering these drugs for the treatment sexual dysfunction or erectile dysfunction. The question is what this Committee is going to do in response.

Dr. Phillips asked whether the State can remove drugs from the PDL without Committee action and added that he is not in favor of taking an action.

Ms. Langdon stated that on a public hearing was conducted on December 20, 2006. Revisions to Chapter 1200, which is related to pharmacy benefit, were presented and included that medications for erectile dysfunction or impotence will no longer be covered. Coverage of these medications will continue for the diagnoses of primary pulmonary hypertension or pulmonary arterial hypertension.

Dr. Heard asked that if any or all aspects of the PDL are at the administrative discretion of the health division, what the Committee's role is. He said that he wants information about what a committee such as this can do to reverse administrative decisions which do not take into account the clinical consequences. He suggested the Committee not take action and this be addressed at the next meeting.

Dr. Monaghan stated that this is something that needs to be referred to the Division and/or the Deputy Attorney General. First Health, as a contractor for the State of Nevada, administers the Preferred Drug List. State policy and the Committee's clinical decisions determine how the PDL is administered. He suggested Mr. Faircloth review AB384 as well as the federal directive.

Larry Pinson asked if the PDL can reflect that sildenafil is only indicated for PPH and PAH. Dr. Monaghan stated that modifying the PDL will require a formal motion by this Committee. It may be simpler to delete the category entirely from the PDL.

MOTION: Dr. Heard motioned that action not be taken today on this item and clarification/direction of the P&T Committee's role and the Committee's ability to react be presented at the next meeting by DHCFP and First Health.
SECOND: Larry Pinson
Dr. Britt stated that there will be confusion not just for the pharmacies and patients but also the physicians who will have the PDL that includes the ED drugs. If action is not taken today, will the drugs be removed from the list? Dr. Monaghan replied that based on the direction given by the State, notification has been sent to pharmacies and prescribers that effective 1/1/06, the drug would no longer be covered by Medicaid, however, the ICD-9 codes pertaining to primary pulmonary hypertension or pulmonary arterial hypertension would allow the claims to pass through.
AYES: Pintar, Pinson, Heard, Phillips, Britt, Flynn, Horne
NAYES: Bond
MOTION CARRIED

XI. Adjournment

The next meeting is scheduled for April 27, 2006 in Las Vegas (site to be announced).

MOTION: Larry Pinson motioned for adjournment.
SECOND: Susan Pintar
VOTES: Unanimous
MOTION CARRIED
Meeting adjourned at 3:04 p.m.