

**ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE**

**Location of Meeting
Frontier Building, 3601 C Street, Room 890/896**

**DRAFT - MINUTES OF MEETING
January 20, 2012
8:00 a.m.**

Committee Members Present:

Marvin Bergeson, MD
Amber L. Briggs, Pharm.D.
Robert H. Carlson, MD (telephonic)
Jeffrey G. Demain, MD
Mary Elizabeth Gardner, ANP
Vincent Greear, R.Ph.
Daniel P. Kiley, DDS MPH (telephonic)
Diane Liljegren, MD (telephonic)
William McCormick, Pharm.D.
Paul Michaud, Pharm.D.
Claudia Phillips, MD
John Riley, PA

Committee Members Absent:

Dharma Begich, Pharm.D.
Richard Brodsky, MD
John Pappenheim, MD
Jill Reid, R.Ph.
Trish White, R.Ph.

Others Present:

Chad Hope, Pharm.D.
Julie A. Pritchard, Pharm.D.
CJ Kim, R.Ph.

1. Call to Order – Chair

Dr. Demain called the meeting to order at 8:02 a.m.

2. Roll Call

A quorum was present. Dr. Liljegren, who was present for the roll call telephonically, disconnected.

3. Public Comments - Local Public/Health Practitioners

There were no public comments.

4. Review of Smoking Cessation Agents (Red Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Smoking Cessation Agents. There are two types of agents in this class: nicotine replacement products that include inhalers, nasal sprays and lozenges in Buccal and transdermal formulations; and non-nicotine replacement products, which include Bupropion and Chantix. Most nicotine replacement therapies are available over the counter, whereas Bupropion and Chantix require a prescription. Polls show the majority of smokers wish to quit, but there are withdrawal symptoms associated with smoking cessation that tend to lead to relapse. The 2008 guidelines from the Agency for Health Care Research and Quality state that all smokers trying to quit should be offered medication, except where contraindicated. All seven FDA approved therapies are considered first-line. Combining the nicotine patch with other therapies increases long-term abstinence rates, whereas combining Chantix with nicotine replacement therapy seems to result in higher rates of adverse effects. In December, there were 190 claims: 45% for Chantix, 47% for Bupropion, 5% for nicotine patches, and the rest were less than 2%. This is a new class so there was no previous discussion and no significant changes.

Dr. Hope noted that Chantix accounted for 85 claims on the market shift report, which is 44.7% of the total claims in December.

Dr. Briggs felt that each of the therapies in the class were different and questioned how they should be classified. Dr. Demain said the therapies were alternate approaches. Some could be used together while others could not. Dr. Hope said the over-the-counter nicotine products could be covered by the PDL.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

5. Re-review of Angiotensin Modulators: Angiotensin II Receptor Blockers (Red Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Angiotensin Modulators: Angiotensin II Receptor Blockers. These agents can be used as first-line antihypertensive treatments. The ARBs block the vasoconstrictive and aldosterone-secreting effects of Angiotensin II by selectively blocking the binding of Angiotensin II to the AT1 receptors in certain tissues. All ARBs reduce blood pressure to a similar degree. In December, there were 641 claims. For the Angiotensin receptor blockers: 37% for Diovan and 31% for Losartan. For the Angiotensin receptor blockers and the diuretic combinations: 55% for Diovan HCT, and 17% each for Benicar HCT and Losartan HCTZ. At the previous discussion, a motion for class effect passed unanimously. Significant changes include Edarbi (Azilsartan) became available, but there were no claims for that product. The sole indication for Edarbi is hypertension. It is available in 40- and 80-milligram tablets. Initial trials indicate this agent may have a greater systolic lowering effect than other agents, but no long-term outcomes are yet available. Valsartan and Candesartan earned an indication for treatment of CHF. ACE inhibitors are first-line, but ARBs are an acceptable alternative. The FDA is reviewing two trials involving Benicar (Olmesartan) and a possible increased rate of death from cardiovascular causes. In June 2011, the FDA concluded a review on the relationship between ARBs and cancer. They found there was no increased cancer risk associated with the use of ARBs. At the last review, a motion for class effect passed unanimously.

DR. (NOT STATED ON RECORD) MOVED A CLASS EFFECT. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

6. Re-Review of Hypoglycemics, Incretin Enhancers/Mimetics (Red Category)

DOUG GELOWITZ: A representative of Bristol-Myers Squibb discussed four major changes in Onglyza's prescribing information. Onglyza has been approved for use with type 2 diabetics with renal impairment, all the way down to end-stage renal disease, and in combination with insulin. It is the only DPP-4 inhibitor to have a labeled indication for patients with renal impairments, and it has been found to be both safe and effective. This is important, because diabetes is the leading cause of chronic kidney disease in the U.S. Another label update deals with the inclusion of non-inferiority data to FU. Fifty-two weeks of combination therapy of Onglyza and Metformin resulted in similar A1C reduction to that of Glipizide and Metformin, but with a slight reduction in weight and a much lower proportion of hypoglycemia. The final label update was in the warnings and precautions with regard to pancreatitis. The FDA asked that we include the statement that there has been post-marketing reports of acute pancreatitis associated with Onglyza. This brings our label in line with the first DPP-4 inhibitor to the market, and the FDA may require this statement in the future for all drugs in this class. Pancreatitis should be considered with this class when treating type 2 diabetics, but the global incidence rates are extremely low. We request that Onglyza be added to the PDL to provide patients with another tool to use against the progressive disease of diabetes, which is seldom treated with a single agent.

STEVEN HALL: A representative of Boehringer Ingellheim discussed Tradjenta. It is a DPP-4 inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Tradjenta should not be used in patients with type I diabetes or for the treatment of diabetic ketoacidosis. It has not been studied in combination with insulin. The recommended dose was reviewed. It can be taken with or without food. It is the only FDA approved DPP-4 inhibitor that has no dose adjustment recommended in patients with renal impairment. Several studies and their outcomes were reviewed. Tradjenta is contraindicated in patients with a history of hypersensitivity reaction to linagliptin such as urticaria, angioedema, or bronchial hyperactivity. There have been no clinical studies establishing conclusive evidence of macular risk reduction with Tradjenta tablets or any other anti-diabetic drug. The adverse reactions were reviewed. The efficacy of Tradjenta may be reduced when administered in combination with a strong P-glycoprotein/CYP3A4 inducer such as Rafampin, so alternative treatments are strongly recommended in that case. For additional information, please see the full prescribing information, including patient information for Tradjenta.

TODD PAULSEN: A representative of Novo Nordisk said that a presentation had previously been done on Victoza and asked if there were any questions. There were no questions.

Dr. Demain noted that all submitted letters or documents not included in the binder were printed out and available for the committee, as discussed at the last meeting.

Dr. Pritchard gave the Magellen presentation on Hypoglycemics, Incretin Enhancers/Mimetics. Last year, the GLP-1 receptor agonists, DPP-4 inhibitors and amylin analogs were voted on separately. This year, they have been combined. The GLP receptor agonists include Byetta and Victoza. They are used as an adjunct to diet and exercise in adults with type 2 diabetes. The Incretin hormone GLP-1 is part of the system involved in the regulation of glucose homeostasis. GLP-1 receptor agonists were associated with a .5 to a 1.1 reduction in HBA1C levels and a decrease in weight of up to two kilograms from

baseline, as opposed to weight gain in patients taking placebo. In December, there were 28 claims: 86% for Victoza and 14.3% for Byetta. At the last review, a motion for therapeutic alternatives passed unanimously. Significant changes include Byetta has an added indication of add-on therapy to insulin glargine with or without Metformin and/or a TZD, in conjunction with diet and exercise for adults with type 2 diabetes who are not yet achieving adequate glycemic control with insulin glargine alone. Some patients may develop anti-exenatide antibodies; therefore, continuation of glycemic response could occur.

For the DPP-4 inhibitors, the 2011 guidelines state that these drugs can be used as monotherapy or in combination with other antihyperglycemics. For patients with type 2 diabetes, the mechanism of action of the DPP-4 enzyme inhibitors is to slow inactivation of GLP-1 and GIP, and extend the secretion of the incretins. Since insulin secretion is increased and glucagon secretion reduced, the result is lower glucose levels. In December, there were 151 claims: 73% for Januvia, 21% for Janumet, and the rest were less than 5%. At the last review, a motion for class effect passed unanimously. Significant changes include Juvisync and Tradjenta became available. Juvisync is the combination of Sitagliptin and Simvastatin. Bioequivalence studies show the components are bioequivalent to the single agents taken together. Juvisync, taken with strong CYP3A4 inhibitors can result in an increased risk of myopathy and it is a pregnancy category X. Tradjenta's generic name is Linagliptin. Its T-1/2 is 12 hours. There are no active metabolites. It is excreted 80 percent in feces and 5 percent in urine. Headache and hypoglycemia were the reported adverse effects. It is a pregnancy category B. In 2011, the REMS for Byetta, Januvia, and Janumet were all removed.

The amylin analogs is the Symlin pen. In December, there were 5 claims and no significant changes. At the last review, a motion for class effect passed unanimously.

Dr. Hope reiterated that several categories were combined into a single class. Motions can pertain to all of the products or the agents can be addressed separately.

In response to Dr. Bergeson, Dr. Hope discussed the combination products. If both of the individual products are on the PDL, the combination products will be included as well.

Dr. Demain noted that Dr. Maciejewski requested that Tradjenta be added to the PDL. The currently preferred agents are Victoza, Byetta, Januvia, Janumet, and the Symlin pen.

Dr. Briggs referred to Dr. Maciejewski's letter. Although Tradjenta is the only agent that is not renally eliminated, there are significant drug-drug interactions through the P-glycoprotein and 3A4. Therefore, it has a benefit in one area and a disadvantage in another.

**MR. GREAR MOVED TO SEPARATE THE CLASS INTO GLP-1s AND DPP-4s.
SECONDED BY DR. CARLSON. THE MOTION PASSED.**

Dr. Demain noted that the Symlin pens would be included with the GLP-1s.

**DR. BERGESON MOVED THAT THE DRUGS IN THE GLP-1 CATEGORY WERE
THERAPEUTIC ALTERNATIVES. THE MOTION FAILED DUE TO LACK OF A SECOND.**

DR. BRIGGS MOVED THE GLP-1 CATEGORY WERE A CLASS EFFECT. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

DR. BERGESON MOVED THE DPP-4 CATEGORY WERE A CLASS EFFECT. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

7. Re-review of Immunosuppressants, Oral (Red Category)

TANIA SIMON: A representative of Astellas discussed Prograf (Tacrolimus). Prograf is an immunosuppressive agent indicated for prophylaxis of organ rejection in patients receiving allogeneic liver, kidney, and heart transplants. It is widely used and falls into the category of narrow therapeutic index drugs. Several studies and their outcomes were reviewed. In a citizen's petition, Astellas requested that the FDA institute labeling changes requiring physician and patient notification and consultation before a switch is made between formulations of Tacrolimus, but the FDA declined to do so when it approved the first generic formulation. Health outcomes data was reviewed. Please refer to full prescribing information for black box warnings and safety information. As with other immunosuppressant agents, Prograf has a black box warning that includes increased risk of malignancies and infections. Warnings have also been included for cases of pure red cell aplasia. Only physicians experienced in immunosuppressant therapy should prescribe Prograf.

Dr. Pritchard gave the Magellen presentation on Immunosuppressants, Oral. Although there are no public guidelines in the U.S. and the drugs and dosing varies, there is a general schedule for use. Induction therapy is started at time of surgery and then combinations of anti-proliferative agents such as Azathioprine and Mycophenolate and calcineurin inhibitors such as Cyclosporine and Tacrolimus are added. Sirolimus and Everolimus are proliferation inhibitors, but with a different mechanism of action than Mycophenolate. Although Azathioprine has an indication for rheumatoid arthritis, it is as last string. Cyclosporine has an indication for plaque psoriasis, but it should be used for patients who have failed standard therapies. Cyclosporine and Mycophenolate are available as different salts, but the products are not interchangeable. In December, there were 110 claims: 27% for Azathioprine, 26% for Mycophenolate Mofetil, 18% for Tacrolimus and Hydras, and the rest were less than 10%. At the last review, a motion for therapeutic alternatives passed with one opposed. Significant changes include Zortess has been associated with angioedema, impaired wound healing, hyperlipidemia, and fluid accumulation. REMS includes both a medication guide and a communication plan. Patients taking Mycophenolate products may develop severe neutropenia and should be monitored. The FDA is investigating a possible relationship between Mycophenolate products and the development of progressive multifocal leukoencephalopathy, a rare disorder that affects the central nervous system in patients with immune systems suppressed by either disease or medications. Rapamune requires the dispensing of a medication guide.

In response to Dr. Gardener, Dr. Demain said the majority of these drugs were used for patients with organ transplants, but also for rheumatoid arthritis, psoriasis, and other uses. While it would be nice to have all agents available for organ transplant patients, the medically necessary clause could always be utilized.

Dr. Carlson said that the drugs in this class acted differently and had different side effects, so preferring one to another was difficult.

MR. GREAR MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. RILEY. THE MOTION PASSED UNANIMOUSLY.

8. Re-Review of Acne Agents, Topical (Blue Category)

There were no public testimonies.

Dr. Hope noted that three acne agent classes had been combined into a single category this year.

Dr. Pritchard gave the Magellen presentation on Acne Agents, Topical. Aczone, which is Dapsone 5% topical gel, is indicated for the treatment of acne vulgaris. Topical retinoids are the preferred primary treatment option, but an antibiotic can be added to inflammatory lesions for synergy and faster clearing. The exact mechanism of action is unknown, but it is thought to work via suppression of nutrifill recruitment oxidation, which may aid in the prevention of production of toxic respiratory and secretory products. Some anti-microbial activity may also occur. In December, there were 9 claims for Aczone. At the last review, a motion for class effect passed unanimously.

The Retinoids were reviewed. Per the 2009 guidelines, topical retinoids should be the foundation of treatment in most patients with acne as they target the microcomedone, the precursor of all acne lesions. When used from the beginning of therapy, retinoids significantly increase the speed of resolution of acne lesions. Retinoid monotherapy, or in combination with Benzoyl Peroxide, is recommended as maintenance therapy. In December, there were 76 claims: 42% for Tretinoin, 17% for Epiduo, 13% for Retin-A Micro, and the rest had less than 10%. At the last review, a motion for class effect passed unanimously.

For the Benzoyl Peroxide/Clindamycin combinations, Benzoyl Peroxide has bactericidal, keratolytic, and comedolytic activity and has been useful as a single agent and in combination with antibiotics or retinoids in decreasing the number of lesions in mild to moderate acne. In December, there were 73 claims: 47% for Clindamycin Benzoyl gel, 36% to BenzaClin, and 18% for Duac. Significant changes include Clindamycin has been shown to have neuromuscular blocking properties that may enhance the neuromuscular blocking properties of other agents so caution should be used when patients are taking other neuromuscular blocking drugs. At the last review, a motion for class effect passed unanimously.

In response to Dr. Riley, Dr. Hope said topical antibiotics were covered in a different class. These are just the products that are FDA approved for acne treatment.

Dr. Demain said the combination agents with Clindamycin should probably be reflected in antibiotics since there are three different antibiotic preparations.

DR. BERGESON MOVED THAT THE DRUGS IN THIS CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY MS. GARDNER.

Dr. Hope pointed out that there was a full page of products for this class, but there are several hundred products on the market. There are many generic medications within the class. The likelihood of seeing a variety of products with a therapeutic alternative motion is good, but was unsure how the Aczone segment would fall out.

The committee discussed the difference between a motion for therapeutic alternatives and breaking each class out separately.

DR. BERGESON AMENDED THE MOTION TO BE THERAPEUTIC ALTERNATIVES WITH AT LEAST ONE DRUG FROM EACH SUB-CLASS. THE SECOND CONCURRED.

The committee further discussed breaking the class up into individual categories and moving a class effect within each category.

THE MOTION PASSED UNANIMOUSLY.

9. Re-review of Androgenic Agents (Blue Category)

ANNIE OGOSTALICK: A representative of Abbott Laboratories discussed AndroGel. The committee is encouraged to review the full prescribing information. AndroGel is testosterone gel 1 and 1.62 percent. They are both FDA approved for the replacement of therapy in adult males for conditions associated with deficiency or absence of endogenous testosterone due to primary or secondary hypogonadism. AndroGel 1.62 percent was recently approved by the FDA. It is a clear, colorless and odorless testosterone gel. It provides patients the opportunity to reduce the total massive gel applied. Suggested doses were reviewed. Several studies and their outcomes were reviewed. AndroGel carries similar box warnings as other prescription topical testosterone gel products in its class relative to secondary exposure and virilization reported in children due to this. The most common side effects reported were increased PSA, emotional liability, hypertension, increased red blood cell count, and contact dermatitis. Application site reactions were reported in about 1 percent of patients. No discontinuations occurred due to application site reactions. Guidelines recommend patient preference, pharmacokinetics and treatment burden be taken into consideration when initiating therapy as it may provide opportunity for compliance in this population. AndroGel has demonstrated the ability to manage the symptoms of hypogonadism in males and remains the most prescribed treatment. We requested the committee include AndroGel on the PDL.

Dr. Pritchard gave the Magellen presentation Androgenic Agents. Oral forms are ineffective due to first pass metabolism so injectable and transdermal formulations are ideal delivery methods. All are indicated for testosterone replacement therapy in males with a deficiency or absence of indigenous testosterone. Application sites and dosing recommendations are not interchangeable. In December, there were 10 claims: 90% for AndroGel and 10% for Androderm. At the last review, a motion for class effect passed unanimously. Significant changes are Fortesta and Axiron became available. AndroGel now offers a 1.62 percent formulation. Androderm now offers a 2- and 4-milligram strength formulation.

In response to Dr. Demain, Dr. Hope said the topical and injectable formulations were more commonly prescribed than other alternatives.

DR. RILEY MOVED A CLASS EFFECT. SECONDED BY DR. MICHAUD. THE MOTION PASSED WITH ONE ABSTENTION.

Break from 9:03 a.m. to 9:18 a.m.

10. Re-Review of Ulcerative Colitis Agents (Green Category)

Dr. Pritchard gave the Magellen presentation on Ulcerative Colitis Agents. The 2010 Practice Guidelines of the American College of Gastroenterology reflect differences in treatment based on severity of disease. The combination of oral and topical mesalamine is more effective than either alone. Patients with active disease should start with oral Sulfasalazine or an alternate aminosalicylate. In December, there were 62 claims: 39% for Asacol, 32% for Sulfasalazine immediate release, 11.3% for Pentasa, and the other drugs were less than 10%. At the last review, a motion for therapeutic alternatives to include Sulfasalazine and one delayed release product passed unanimously. Significant changes include Asacol and Asacol HD should be used in pregnancy only if the benefits outweigh the risks. These agents have been associated with external and skeletal malformations and adverse effects on the male reproductive system, but that was an animal study using greater than 80 times the human dose related to an inactive ingredient used in the enteric coating of these branded products.

MS. GARDNER MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

11. Re-review of Hypoglycemics, Alpha-Glucosidase Inhibitors (Green Category)

Dr. Pritchard gave the Magellen presentation on Hypoglycemics, Alpha-Glucosidase Inhibitors. The 2011 update to the consensus algorithm does not list these drugs citing relative clinical inferiority with respect to lowering glucose levels. However, these agents are an option in select patients to assist with glycemic control. These agents work by preventing the breakdown of sucrose and complex carbohydrates in the small intestine, prolonging absorption, which gives a net effect of reducing postprandial glucose concentrations while fasting glucose levels are unchanged. In December, there were 2 claims for Acorbose. At the last review, a motion for class effect passed unanimously.

DR. MCCORMICK MOVED A CLASS EFFECT. SECONDED BY DR. BRIGGS.

The committee discussed why an inferior drug was included on the PDL and Dr. Hope explained that it had to do with the bundling of the classes.

THE MOTION PASSED UNANIMOUSLY.

12. Re-review of Hypoglycemics, Insulins (Green Category)

Dr. Pritchard gave the Magellen presentation on Hypoglycemics, Insulins. Exogenous insulin products supplement deficient levels of insulin when the body cannot produce enough. Insulin is needed to properly utilize carbohydrates, fats, and proteins. All insulins can cause a shift in potassium from extracellular to intracellular space, possibly leading to hypokalemia and should be used with caution in patients at risk for this. In December, the total utilization was 830 claims. For the long-acting insulins: 48% for Lantus solistar and 46% for Lantus vial. For the rapid-acting insulins: 36% for Novolog flex pen and 29% for Novolog vial. For the mixes, which are not to be voted on: 46% for Novolog Mix 70/30, 63% for Novolin 70/30 vial, 53% Novolin N vial, and 52% Novolin R vial. At the last review, a motion for class effect, preferring Lantus, passed with two opposed. Significant changes include the 2011 Diabetes Care Guidelines recommends that insulin be used for all type 1 diabetics and in type 2 diabetics when non-insulin therapy fails to achieve target control. Long-acting basal insulin should be

the first choice in most cases of type 2 diabetes. Short- or rapid-acting may be considered with postprandial hyperglycemia.

In response to Dr. Demain, Dr. Pritchard said there were no submissions this year from endocrinologists regarding Lantus, as this was a green class.

Mr. Greear said Lantus was preferred last year because it was a once-a-day formulation. He suggested separating the long-acting and rapid-acting formulations as separate groups.

DR. RILEY MOVED A CLASS EFFECT, TO INCLUDE AT LEAST ONE FORMULATION FROM THE FOLLOWING SUB-CLASSES: LONG-ACTING, RAPID-ACTING, INSULIN MIX, INSULIN 70/30, N AND R. SECONDED BY MS. GARDNER.

Mr. Greear said he was uncomfortable in not preferring Lantus, because it was superior to Levemir.

Dr. Briggs said she was uncomfortable with class effect, because the drugs were not equivalent, and the term “alternatives” should be used.

DR. RILEY AMENDED THE MOTION TO CLASS EFFECT TO INCLUDE AT LEAST ONE FORMULATION FROM THE FOLLOWING SUB-CLASSES: LONG-ACTING, RAPID-ACTING, INSULIN MIX, INSULIN 70/30, N AND R, AND PREFERENTIALLY INCLUDING LANTUS. THE SECOND CONCURRED. THE MOTION PASSED WITH ONE OPPOSED.

13. Re-review of Hypoglycemics, Meglitinides (Green Category)

Dr. Pritchard gave the Magellen presentation on Hypoglycemics, Meglitinides. These agents are used in type 2 diabetes mellitus to help lower glucose levels by stimulating insulin release from the pancreas. They accomplish this by binding to non-sulfonylurea binding sites on the beta cells, which closes the ATP-dependent potassium channels leading to calcium channels opening. The increased calcium induces insulin secretion. This process is highly selective with little effect on heart or skeletal muscle tissue. In December, there were 3 claims for the Meglitinides: 67% for Nateglinide and 33% for Prandin. At the last review, a motion for class effect passed unanimously. Significant changes include PrandiMet is taken zero to 30 minutes before a meal, two to four times daily.

DR. BRIGGS MOVED A CLASS EFFECT. SECONDED BY DR. GREEAR. THE MOTION PASSED UNANIMOUSLY.

14. Re-review of Hypoglycemics, Sulfonylureas (Green Category)

Dr. Pritchard gave the Magellen presentation on Hypoglycemics, Sulfonylureas. These agents enhance response of beta cells in the pancreatic islet to glucose. They bind to the plasma membranes of functioning beta cells, resulting in a decrease in potassium permeability that increases membrane depolarization, thereby causing an influx of calcium ions. This results in secretion of insulin and subsequent lowering of blood glucose. In December, there were 389 claims: 36% for Glyburide, 24% for Glipizide, 20% for Glimpiride, and the rest were less than 10%. At the last review, a motion for therapeutic alternatives passed with one opposed.

The committee discussed why last year's motion was therapeutic alternative rather than class effect.

MR. GREEAR MOVED A CLASS EFFECT. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

15. Re-review of Hypoglycemics, Thiazolidinediones (TZDs) (Green Category)

Dr. Pritchard gave the Magellen presentation on Hypoglycemics, Thiazolidinediones (TZDs). The two TZDs are Rosiglitazone, which is Avandia, and Pioglitazone, which is Actos. Both come in combination with Metformin or Glimepiride. In December, there were 189 claims. For the TZDs: 68% for Actos 30 and 45 milligram, and 31% for Actos 15 milligram. For the TZD Metformin combinations there were 4 claims for Actoplus Met. For the TZD combination, there were no claims, because in 2011 the FDA issued a safety announcement stating that using Actos for longer than one year may be associated with an increased risk for bladder cancer. Rosiglitazone-based medications were withdrawn from retail pharmacies effective November 18, 2011, and are now under a restricted access program. At the last review, a motion for therapeutic alternatives, excluding Avandia, passed unanimously.

Dr. Hope said he announced at the last meeting that the PDL was being updated. It has gone through public comment, been adopted by the department, and is waiting for legal review and final approval of the lieutenant governor.

The committee discussed which drugs were currently preferred and what would change when the updated PDL was released. Actos 15 milligram is preferred, whereas the 30 and 45-milligram tablets are not preferred due to cost. Mr. Greear said he had never seen specific strengths of a preferred medication being excluded. Dr. Pritchard said the 30 and 45-milligram tablets could be prescribed utilizing the medically necessary clause.

Dr. Demain said a drug that was excluded due to identified with potential risks and concerns should have a fast-track method and not be held up by the Legislature for the next year. Dr. Hope said Alaska was unique in that their PDL was adopted into reference and regulation. Other states maintain a PDL that is a living, breathing document that can be frequently updated. If everything goes right in Alaska, an update can be implemented in 120 days, but more commonly takes six months or more due to the approval process. The committee further discussed a means of fast tracking such decisions. Practitioners can be alerted of such decisions through the DUR Program. The committee discussed possible liability issues associated with the PDL.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, EXCLUDING AVANDIA. SECONDED BY MS. GARDNER. THE MOTION PASSED UNANIMOUSLY.

16. Re-review of Ophthalmics, Glaucoma Agents (Green Category)

Dr. Pritchard gave the Magellen presentation on Ophthalmics, Glaucoma Agents. Glaucoma is the second most common cause of blindness in the U.S. and the most common cause among African-Americans. In 2010, the American Academy of Ophthalmology stated prostaglandin analogs are the most efficacious for lowering intraocular pressure and should be considered first-line in primary open

angle glaucoma. In December, there were 84 claims. For the alpha 2 adrenergic agents: 77% for Alphagan P. For the beta-blockers: 44% to Timolol drops. For the carbonic anhydrase inhibitors: 60% for Dorzolamide Timolol combination. In the prostaglandin analogs: 44% for Travatan Z. At the last review, a motion for therapeutic alternatives passed unanimously. Significant changes include Lumigan and Travatan should not be used in patients under 16 years of age due to risk of increase pigmentation. Alphagan P is contraindicated in patients less than 2 years of age.

MS. GARDNER MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE AGENT FROM EACH SUB-CLASS. SECONDED BY DR. MCCORMICK. THE MOTION PASSED UNANIMOUSLY.

17. Re-review of Angiotensin Modulators: ACE Inhibitors and Direct Renin Inhibitors (Green Category)

Dr. Pritchard gave the Magellen presentation on Angiotensin Modulators: ACE Inhibitors and Direct Renin Inhibitors. Direct renin inhibitors are approved as antihypertensives and work by targeting the renin angiotensin-aldosterone system at the point of activation, thereby lowering blood pressure by decreasing plasma renin activity. This class is an alternative, but evidence to date does not show a clear advantage over ACEs or ARBs. In December, there were 35 claims: 86% for Tekturna. At the last review, a motion for class effect passed unanimously. Significant changes include Novartis has stopped the Altitude Study, which included patients with type 2 diabetes and renal impairment at high risk for cardiovascular and renal events. They stopped the study as of December 2011 due to higher adverse events occurring when given with ACEs and ARBs in this population. Aliskiren-based medications are no longer promoted in conjunction with ACEs or ARBs. The Angiotensin modulators and ACE inhibitors can be used as first-line therapy in the treatment of hypertension. ACEs have been shown to slow the progression of diabetic nephropathy, reduced mortality in CHF, and reduced risk of adverse cardiovascular outcomes in high-risk patients. In December, there were 1,788 claims. For the non-combination products: 92% for Lisinopril. For the ACE inhibitor diuretic combinations: 97% for Lisinopril with Hydrochlorothiazide. At the last review, a motion for class effect passed unanimously.

DR. RILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE AGENT FROM EACH SUB-CLASS. SECONDED BY DR. MICHAUD.

Dr. Hope noted that when the primary drugs were approved, combination products that are not cost prohibitive would be included, so combinations products are not voted on.

THE MOTION PASSED UNANIMOUSLY.

18. Re-review of Calcium Channel Blockers (Green Category)

Dr. Pritchard gave the Magellen presentation on Calcium Channel Blockers. This class is available in combination with ACEs, ARBs, and Atorvastatin. All except for Nimodipine, which is indicated to reduce ischemic deficits associated with subarachnoid hemorrhage, are indicated for treatment of hypertension. There have not been any significant differences noted between agents. In December, there were 807 claims. In the dihydropyridine: 91% for Amlodipine Vessilate. In the nondihydropyridines: 29% for Diltiazem CD. In the ACE inhibitor calcium channel blockers: 87% for

Amlodipine Vessilate with Benazepril. In the ARB and calcium channel blockers combination: 87% for Xforge. At the last review, a motion for therapeutic alternatives passed unanimously.

MS. GARDNER MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE DIHYDROPYRIDINE AND ONE NONDIHYDROPYRIDINE. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

19. Re-review of Beta-Blockers (Green Category)

Dr. Pritchard gave the Magellen presentation on Beta-Blockers. This class has various indications, but all have the indication for hypertension with similar efficacy. Other indications vary by drug. In December, there were 1,886 claims: 26% for Atenolol and 22% for Metoprolol Succinate. At the last review, a motion for class effect passed unanimously.

In response to Dr. Riley, Dr. Hope explained why Atenolol was not preferred. In 2009, the motion was to exclude Atenolol due to articles published regarding the potential increase adverse event that was later found not to be associated with Atenolol. The PDL that is pending approval includes Atenolol as a preferred product.

DR. BERGESON MOVED A CLASS EFFECT. SECONDED BY MS. GARDNER. THE MOTION PASSED WITH ONE ABSTENTION.

20. Re-review of Analgesics/Anesthetics, Topical (Green Category)

Dr. Pritchard gave the Magellen presentation on Analgesics/Anesthetics, Topical. Voltaren, Fector, Pennsaid were separate from Lidoderm last year. NSAIDs are used to treat osteoarthritis pain, as well as other mild to moderate pains of various etiologies. Topical NSAIDs offer an alternative to oral agents for those who are at high risk of gastrointestinal events or for other reasons unable to take oral formulations. In December for the topical NSAIDs there were 146 claims: 60% for Voltaren Gel, 33% for Flector, and the rest went to Pennsaid. At the last review, a motion for class effect passed unanimously. Significant changes include Diclofenac formulations carry a black box warning for cardiovascular and gastrointestinal risk. Pennsaid requires a medication guide to be given upon dispensing the medication.

For the topical anesthetic Lidoderm, both Lidoderm and Capsaicin patches are indicated for use in those patients with post herpetic neuralgia or painful diabetic neuropathy. Lidoderm has varied absorption depending on the duration of application and the surface area. In December, there were 2 claims for Lidoderm. At the last review, a motion for class effect passed unanimously.

In reasons to Dr. Riley, Dr. Hope said Lidoderm was not covered regardless of the diagnosis. It is on a very tight prior authorization for post herpetic neuralgia only.

MR. GREEAR MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

Dr. Briggs noted that Voltarian Gel was being used more often, because people believe there are no adverse events related to it since it is topical. She questioned if the DUR Committee could look at Voltaren Gel's utilization, appropriate use, and possible risk factors.

21. Re-review of Immunomodulators, Atopic Dermatitis (Green Category)

Dr. Pritchard gave the Magellen presentation on Immunomodulators, Atopic Dermatitis. Atopic dermatitis can develop at any age, but the majority of cases develop before age 5 years of age. These agents exert action on the T-cells by suppressing cytokine transcription, which leads to a decrease in skin inflammation. Rare cases of malignancies have been reported with both agents. The FDA recommends short-term, intermittent use. Neither product demonstrates a clear advantage over the other. In December, there were 69 claims: 61% for Elidel and the rest to Protopic. At the last review, a motion for therapeutic alternatives passed unanimously. Both are currently approved on the PDL.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

22. Review Minutes from November 2011 Meeting

Dr. Hope referenced item 24, the discussion concerning how to handle letters from out of state providers, advocacy groups, or comments received after the informational packets were produced. All of those will be printed and distributed to prevent reading lengthy letters into the record and not because they are out of state Medicaid providers.

DR. BERGESON MOVED TO APPROVE THE NOVEMBER 2011 MEETING MINUTES AS CORRECTED. SECONDED BY MS. GARDNER. THE MOTION PASSED UNANIMOUSLY.

23. Comments from Committee Members or Chair

Dr. Demain felt it was more respectful to acknowledge all letters written by local providers and briefly summarize their positions on the record. Dr. Hope felt that all letters, including out of state providers, needed to be treated equally. The volume of letters received varies depending on what drug classes are being reviewed. The committee further discussed the issue and decided all letters would be acknowledged and a brief summary provided at the beginning of each class reviewed.

Dr. Demain announced that the next meeting would be on April 20, 2012, at 1:00 p.m. He welcomed Dr. Claudia Phillips back to the committee.

24. Adjourn

Without objection, the meeting adjourned at 10:19 a.m.