ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE

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

FINAL MINUTES OF MEETING
January 16, 2009
8:00 a.m.

Committee Members Present:
Marvin Bergeson, MD
Heidi Brainerd, MS R.Ph.
Amber L. Briggs, Pharm.D.
Richard E. Brodsky, MD
Kelly C. Conright, MD
Jeffrey G. Demain, MD
Traci Gale, PharmD. (telephonic)
Vincent Greear, R.Ph.
Daniel P. Kiley, DDS, MPH
Diane Liljegren, MD (telephonic)
Andrzej Maciejewski, MD
Claudia Phillips, MD
Janice L. Stables, MSN, ANP
Trish D. White, R.Ph. (telephonic)

Committee Members Absent:
Dharna Vakharia Begich, Pharm.D.
Robert H. Carlson, MD
Lucy Curtiss, MD
Sherrie D. Richey, MD

Others Present:
David Campana, R.Ph.
Melinda Sater, Pharm.D., First Health

1. Call to Order – Chair

The meeting was called to order at 8:08 a.m.

2. Roll Call

A quorum was present.

3. Public Comment – Local Public / Health Practitioners

Dr. Nolan: Discussed the diabetes drugs to be reviewed. The protocols at Providence and Regional Hospitals are doing very well with Lantus as our base insulin and we would like to see it remain on the PDL. We also use a lot of Novolog and Humalog. A new drug on the market is Apidra, which has been very effective and should be available on the PDL. With regard to injected insulin, Exenatide has been very effective in selected populations and is an incredible drug in about 60% of the people who use it. Another good alternative is Symlin, which is effective and has a positive effect on weight and control.

With regard to the oral agents, Piogiltzazone has been very effective and helpful in select populations. It needs to be used very carefully, but has been effective in helping to reduce glycemic. A newer drug is the DPP-4 inhibitor, Sitagliptin. I initially had some doubts on its safety issues, but I have seen very few side effects and it has been very effective.

Dr. Samuel Bonte (ph): A physician from Wasilla agreed with Dr. Nolan, but wanted the committee to know that the recent joint consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes unanimously advised against the use of Rosiglitazone when a TZD was going to be used.

4. Review of Immunosuppressants (Red Category)

There were no public testimonies.

Dr. Sater gave the First Health review of Immunosuppressants. This is a new classification. There are five chemical entities and seven different products. Cyclosporine and Mycophenolate are available in different salts, but the products are not interchangeable. There is a variety of indications, but they are all effective for prophylaxis of organ rejection. Gengraf and Neoral have additional indications for rheumatoid arthritis and refractory plaque psoriasis. The drugs in this class have significant adverse drug reaction profiles. Not all the agents are similarly effective for all patients. Transplant protocols vary widely by transplant institution. In December there were 96 claims: 26% for CellCept, 26% for Prograf, 19% for Azathioprine, 8% for Neoral, 7% for Myfortic, 6% for generic Cyclosporine, 5% for Gengraf, and 2% for Rapamune. There was no previous discussion as this is a new class. In talking to a colleague at a transplant institution, he emphasized that protocols varied widely, the drugs were not effective for all people or interchangeable.

DR. KILEY MOVED THAT THE DRUGS WERE THERAPEUTIC ALTERNATIVES AND NO PREFERENCE BE STATED. SECONDED BY DR. BERGESON.

In response to Dr. Conright, Dr. Sater said no physicians expressed concerns in this category, because they follow the protocols provided by transplant institutes and typically do not initiate therapy for transplant patients.

Dr. Maciejewski said certain local physicians prescribed these drugs and initiated therapy for a small percentage of patients with other conditions. When it comes to those other conditions, most of the other drugs are being used with a variety of intensity, except for Rapamune. Imuran is also being used less and less often.

THE MOTION PASSED UNANIMOUSLY.

5. Review of Testosterone Topical Agents (Red Category)

There were no public testimonies.

Dr. Sater gave the First Health presentation on Testosterone Topical Agents. There is one chemical entity, Testosterone. There are three products, two topical gels and one transdermal system. They are all effective for the treatment of both primary and secondary hypogonadism. The adverse drug

reactions are similar, with the exception of the localized irritation with the transdermal system. In December there were 15 claims: 60% for Androgel, 33% for Androderm, and 1 for Testim. There was no previous discussion as this is a new class. No physicians wanted to discuss this class.

DR. KILEY MOVED A CLASS EFFECT. SECONDED BY DR. CONRIGHT. THE MOTION PASSED UNANIMOUSLY.

6. Review of Topical Retinoids (Red Category)

There were no public testimonies.

Dr. Sater gave the First Health presentation on Topical Retinoids. There are three chemical entities: Tretinoin, Adapalene, and Tazarotene. There are many different products, both branded and generic. The mechanisms differ, but they are all effective. The adverse drug reaction profiles are similar. In December there were 48 claims: 46% for Differin, 27% for generic Tretinoin, 12.5% for Retin-A Micro, 8% for Aveta, 4% for Atralin, and 2% for Tazorac. Dr. Ernstrom uses primarily Tazorac, but that is for psoriasis patients whereas the other drugs are used primarily for acne patients.

DR. BRAINERD MOVED A CLASS EFFECT. SECONDED BY DR. CONRIGHT. THE MOTION PASSED UNANIMOUSLY.

7. Review of Ulcerative Colitis (Red Category)

There were no public testimonies.

Dr. Sater gave the First Health presentation on Ulcerative Colitis. There are five available chemical entities and many different products. They are all metabolized to 5-ASA. There are extended and immediate release forms of the drugs. There is a variety of indications. They are all effective for the treatment of ulcerative colitis. The pill burden and the dosing regimens are more attractive for the delayed release forms. In December there were 30 claims: 70% for Asocol, 20% for Pentasa, and 3% each for Balsalazide, Colazal, and Dipentum. There was no previous discussion since this is a new class. No physicians wanted to discuss this class.

DR. LILJEGREN MOVED THE DRUGS WERE THERAPEUTIC ALTERNATIVES, BUT ONE SULFASALAZINE AND ONE DELAYED RELEASE PRODUCT SHOULD BE PREFERENTIALLY INCLUDED ON THE PDL. SECONDED BY DR. DEMAIN. THE MOTION PASSED UNANIMOUSLY.

Break from 8:33 a.m. to 8:50 a.m.

8. Re-review of Incretin Mimetics (Blue Category)

Esther Paek: A representative of GlaxoSmithKline discussed Januvia and Janumet. Januvia increases incretin hormones GLP-1 and GIP, which are naturally produced in the intestines by inhibiting the enzyme DPP-4. As monotherapy, Januvia does not cause hypoglycemia or weight gain. It should not be confused with incretin mimetics or analogs. It is an oral agent belonging to the class of DPP-4

inhibitors. Three new studies on Januvia were reviewed. Januvia and Janumet should be retained on the PDL.

Dr. Sater gave the First Health presentation on Incretin Mimetics. There are three distinct entities in this class and one combination product. Two products are injections and one is oral. The mechanisms are different, impacting amylin secretion, incretin hormone stimulation and dipeptidyl peptidase-4 inhibition. In December there were 156 claims: 77% for Januvia, 13.5% for Byetta, 8.3% for Janumet, and 1.2% for Symlin. There was limited discussion at the last review about having all the available tools on the PDL to treat diabetes. The motion to prefer all drugs passed unanimously. There is limited new information in this class, mostly extensions of previous studies looking at safety and efficacy data, which were comparable to previous studies.

DR. MACIEJEWSKI MOVED TO CONTINUE THE MOTION FROM LAST YEAR AND INCLUDE ALL THE SINGLE ENTITY DRUGS ON THE PDL. DR. DEMAIN SECONDED.

Dr. Liljegren questioned the need to prefer the combination product. Past policy said that if two drugs were approved individually then the combination would be included if it was advantageous in the bidding process. Dr. Sater noted that last year only the three single entities were considered so the motion would be to include the single entities on the PDL, not necessarily the combination.

THE MOTION PASSED UNANIMOUSLY.

9. Re-Review of Insulins (Green Category)

Chris Hanson: A representative of Novo Nordisk asked that the insulin class be maintained with its current status. We recognize that various insulins behave differently in various patients. A brief review of the new studies and updates was given. Trials have shown that in type two diabetes there is no benefit to going to BID dosing and causes the patient to require much more insulin, so we recommend for type two diabetes patients that Levemir be used as daily dosing only. We have also found that when patients are taken to BID dosing there is no improvement in efficacy or fasting glucose. We have also noted that Levemir promotes less weight gain and we are actively seeking the reasons behind this indication or finding. We have seen that utilization of pre-dinner glucose and adding a second dose with a sugar of 108 is an inappropriate strategy. We have had some interest in whether Levemir was equivalent in dosing units or in duration to insulin glargine and a study showed fairly equivalent dosing utilization and effectiveness. Novolog Mix 70/30 is indicated in the use for treatment of diabetes. Studies have consistently shown that this insulin can be utilized in both type one and type two diabetes. Novolog is now a category B drug for pregnancy, in addition to being in pediatrics, 2 to 18, and being available for a wide spectrum of patients. We are releasing a new pen that will be color coded and have a 30% less push, which will reduce medication errors in hospitals and make it easier for patients to use.

Dr. Sater gave the First Health presentation on Insulins. There are six types of insulin being considered. There is short acting, intermediate acting, and pre-mixed combinations in the recombinant group; and rapid acting, long acting and pre-mixed combinations in the biosynthetic group. Previously the committee considered each group separately. In December there were 906 claims. Among the long acting insulins almost 70% of the claims were for Lantus vials, 16.5% for Lantus solostar (ph), 6.7% for the Levemir pens, 5% for the Lantus cartridges, and 1.7% for Levemir vials. In the rapid acting insulins, 42% for Novolog vials, 23% for Novolog pens, 18% for Humalog vials, 10% for Humalog

pens, 3% for Novolog cartridges, 2.23% for Apidra vials, and less than 1% for Apidra and Humalog cartridges. Among the biosynthetic pre-mixed combinations, 54% for Novolog 70/30 pens, 25% for Novolog 70/30 vials, 14% for Humalog 75/25 vials, and 7% for Humalog 75/25 pens. For 70/30 insulin, 59% for Novolin 70/30, 17% for Humulin 70/30, 17% for Relion (ph) 70/30, and 7% for Novolin 70/30 cartridges. In the NPH class, 70% for Novolin N. In the R class, 70% for Novolin R. There was no discussion at the last review. A motion for a class effect in each distinct subclass, and to grandfather patients currently using Lantus if it is not preferred, passed unanimously. Since the last review, all the drugs in the biosynthetic insulin class are now preferred for pediatric indications.

Dr. Demain said the programs at Providence and Regional utilize Lantus so that drug needs to be included as a preferred agent on the PDL. Dr. Sater said there were physicians in the community that had very strong feelings about the true once-a-day pharmacokinetics of Lantus versus the more marginal once-a-day of Levemir.

In response to Dr. Maciejewski, Dr. Sater said the long-acting pens were almost triple the price of a vial, however some feel that using pens is a more cost effective measure for people who use a very little bit of insulin, because they last longer than the vials.

DR. CONRIGHT MOVED TO CONTINUE THE MOTION FROM LAST YEAR TO DECLARE A CLASS EFFECT IN EACH DISTINCT SUBCLASS, AND TO GRANDFATHER PATIENTS CURRENTLY USING LANTUS IF IT WAS NOT PREFERRED. SECONDED BY DR. KILEY.

The committee discussed whether Lantus should be preferred in deference to the programs at Providence and Regional hospitals. Dr. Maciejewski said the recommended conversions between Lantus and Levemir was on a unit-to-unit basis. He has done the conversion on occasion and had no problems. The committee discussed potential problems with transitioning hospitalized patients using Lantus and to outpatients using Levemir. Dr. Brodsky said the Alaska Native Medical Center used all the Novo Nordisk products plus Lantus. Mr. Campana pointed out that a patient who was grandfathered on Lantus would remain on Lantus, but new patients would need to use the medically necessary clause to get Lantus if it was not preferred.

Dr. Gale felt the committee should make their decisions based on the whether the drugs were equivalent and not what other people were doing. Dr. Brodsky pointed out that the committee also considered the wishes of the medical community when making decisions. Dr. Liljegren noted that the medically necessary clause could always be used if Lantus was not preferred.

The committee discussed the differences between hospital care and outpatient care.

THE MOTION PASSED WITH ONE OPPOSED.

10. Re-Review of TZDs (Green Category)

Robert Pearson: A representative of GlaxoSmithKline discussed Avandia. Avandia is the only oral anti-diabetic agent that has been proven to provide sustained glycemic control for up to five years. It is the most well studied oral anti-diabetic medication. Several clinical trials were discussed. The American Association of Clinical Endocrinologists includes Avandia as an add-on treatment option in

their diabetes roadmap. Based on this evidence and the wealth of efficacy information around Avandia, it should be accessible to the Medicaid patients in Alaska.

Dr. Sater gave the First Health presentation on TZDs. There are two TZDs currently available, Rosiglitazone and Pioglitazone. Both are available in combination with Metformin and Glimepiride. Indications vary. The adverse drug reaction profiles and efficacy are similar. In December there were 470 claims: 84% for Actos, 12% for Avandia, 2.6% for Actoplus Met, .85% for Avandamet, and .43% for Avandaryl. At the last review there was very little discussion. A comment was made that the community should carefully watch the results of further review on this class and re-review as needed. The motion for a class effect passed with one opposed. Since the last review, there has been more information on the safety of drugs in this class, but it is a complicated issue without a distinct conclusion.

Dr. Brainerd noted that there was information in the packet on the 2008 updates to the ADA treatment algorithm under Tab 5, page 1, and Tab 7, page 2.

DR. CONRIGHT MOVED A CLASS EFFECT. SECONDED BY DR. MACIEJEWSKI.

Dr. Liljegren felt Actos should be preferred, because it is a better drug than Avandia, it has fewer safety concerns, and it has a beneficial effect on lipids.

Dr. Maciejewski said he used both Actos and Avandia. He discussed Dr. Nissen's meta analysis of Avandia and noted that there was nothing to support his analysis and perhaps it was a mistake. He felt it was a class effect and an agent should not be preferred without some strong data.

THE MOTION PASSED WITH ONE OPPOSED.

11. Re-review of ACE Inhibitors (Green Category)

Dr. Sater gave the First Health presentation on ACE Inhibitors. There are 10 available products. They are all FDA approved for the treatment of hypertension. All but three are available in combination with Hydrochlorothiazide. They have similar efficacy. In December there were 1,665 claims: 1,427 for Lisinopril, the remaining percentage for the others with the highest percentage being for Enalapril. The currently preferred agents are Lisinopril, Enalapril, Benazepril, and Captopril. The motion for class effect, to include Lisinopril, passed without discussion and unanimously.

DR. DEMAIN MOVED TO CONTINUE LAST YEAR'S MOTION TO DECLARE A CLASS EFFECT AND INCLUDE LISINOPRIL ON THE PDL. SECONDED BY MS. STABLES.

In response to an Dr. Conright, Dr. Sater said there had been no discussion of why Lisinopril was preferred on the PDL and it was highly unlikely that it would be removed even if it was not included in the motion. Dr. Demain felt the number of people using the drug warranted preferring it on the PDL.

THE MOTION PASSED UNANIMOUSLY.

12. Re-review Alpha-Glucosidase Inhibitors (Green Category)

Dr. Sater gave the First Health presentation on Alpha-Glucosidase Inhibitors. There are two products available, Precose and Glyset. Precose is available generically. In December there were 2 claims, both for generic Acorbose.

DR. CONRIGHT MOVED A CLASS EFFECT. SECONDED BY DR. MACIEJEWSKI. THE MOTION PASSED UNANIMOUSLY.

13. Re-Review of Angiotension II Receptor Blockers (Green Category)

Dr. Sater gave the First Health presentation on Angiotension II Receptor Blockers. There are seven available products. The indications vary, although clinically all the drugs are used for all the indications. They have similar pharmacokinetic profiles and clinical efficacy. In December there were 594 claims: 38% for Diovan, 25% for Cozaar, 14% for Micardis, 12% for Benicar, 10% for Avapro, 1.1% for Atacand, and .67% for Teveten. The motion to declare a class effect passed with one opposed.

DR. CONRIGHT MOVED A CLASS EFFECT. SECONDED BY DR. BRIGGS. THE MOTION PASSED WITH ONE OPPOSED.

14. Re-Review of Benzoyl Peroxide/Clindamycin Combos (Green Category)

Dr. Sater gave the First Health presentation on Benzoyl Peroxide/Clindamycin Combos. There is one available combination and two branded products, which are used for the treatment of inflammatory acne. The efficacy is similar as they are exactly the same product. In December there was 61 claims: 89% for Benzamycin and 11% for Duac. The motion for a class effect passed unanimously with no discussion.

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

15. Re-Review of Biguanides (Green Category)

Dr. Sater gave the First Health presentation on Biguanides. There is one available entity and many formulations for this drug. Metformin is available generically. In December there were 1,012 claims: 85% for immediate release Metformin, 14.5% for generic extended release Metformin. The motion for a class effect passed unanimously.

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

16. Re-Review of Calcium Channel Blockers (Green Category)

Dr. Sater gave the First Health presentation on Calcium Channel Blockers. There are nine available agents in this class. They are available in combinations with ACE inhibitors, ARBs and Atorvastatin. All, except Nimodipine, are indicated for the treatment of hypertension. The other indications vary by agent. In December for the nondihydropyridine class there were 213 claims: 57% for generic Diltiazem extended release, and 27% for Verapamil. For the dihydropyridine class there was 556 claims: 84%

for generic Amlodipine. There were 50 claims for the combination products. The motion to declare a class effect in each category when treating hypertension, to include both a dihydropyridine and a nondihydropyridine, and to include at least Amlodipine, Verapamil and one Diltiazem product passed unanimously.

DR. CONRIGHT MOVED TO DECLARE A CLASS EFFECT WHEN TREATING HYPERTENSION, AND TO INCLUDE AT LEAST AMLODIPINE, VERAPAMIL AND DILTIAZEM. SECONDED BY DR. MACIEJEWSKI. THE MOTION PASSED UNANIMOUSLY.

17. Re-Review of Glaucoma Agents (Green Category)

Dr. Sater gave the First Health presentation on Glaucoma Agents. At the last review, the committee moved for a class effect in all the groups, preferentially including Xalatan in the Prostaglandin Analog group, which passed with one opposed. The ophthalmologists felt Xalatan was a superior drug and wanted it to be a preferred agent.

DR. CONRIGHT MOVED THAT THE DRUGS WERE ALL THERAPEUTIC ALTERNATIVES WITHIN THEIR RESPECTIVE CLASSES. SECONDED BY DR. MACIEJEWSKI. THE MOTION PASSED UNANIMOUSLY.

18. Re-review of Meglitinides (Green Category)

Dr. Sater gave the First Health presentation on Meglitinides. There are two available agents. Starlix and Prandin are both preferred. In December there were 10 claims: 9 for Starlix and 1 for Prandin. There was no previous discussion. The motion for class effect passed unanimously.

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

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

Dr. Sater gave the First Health review of Oral Beta-Blockers. There are 14 available entities. The indications vary between agents. They have different receptor activities and specificities. In December there were 2,001 claims: 39% for Atenolol, 16% for generic Toprol, 12% for generic Toprol tartrate immediate release, 10% for Propranolol, 8% for generic Coreg, 3.8% for Propranolol sustained release, 3% for Coreg, 2.5% for Nebivolol, and less than 5% for all the rest of the drugs in this class. At the last review there was a lot of discussion about the new drug Bystolic. There were many differing motions. The final motion to declare a class effect passed with two opposed.

In response to Dr. Brodsky, Dr. Sater said there were 25 claims for Bystolic in December.

Dr. Maciejewski said there was evidence that some of the beta-blockers were inferior. Atenolol, the most utilized one on the list, has problems. The mortality and morbidity in the cardiovascular population is worse. The mechanism of Atenolol is unknown. It has more arrhythmias, which leads to more strokes. Statistically speaking, we are doing a disservice to patients by treating them with

Atenolol. The FDA has not addressed this concern, because it is relatively new even though the information has been around for over a year.

Dr. Liljegren asked that information on Atenolol be provided to the committee and this issue tabled at a later time.

DR. BERGESON MOVED TO TABLE THE RE-REVIEW OF ORAL BETA-BLOCKERS. SECONDED BY DR. DEMAIN. THE MOTION PASSED UNANIMOUSLY.

20. Re-Review of Renin Inhibitors (Green Category)

Dr. Sater gave the First Health presentation on Renin Inhibitors. There is one available agent, which is also available in combination with Hydrochlorothiazide. In December there were 35 claims: 97% for the single entity and 1 claim for the combination. At the last review there was very little discussion. The motion for a class effect passed unanimously.

DR. CONRIGHT MOVED A CLASS EFFECT. SECONDED BY DR. KILEY. THE MOTION PASSED UNANIMOUSLY.

21. Re-Review of Topical Immunomodulators (Green Category)

Dr. Sater gave the First Health presentation on Topical Immunomodulators. There are two available products, both are currently preferred. The indications differ slightly. In December there were 79 claims: 58% for Elidel and 42% for Protopic. At the last review there was little discussion, centering mostly around the boxed warnings for these drugs and the differentiation of mild to moderate to severe eczema. The motion for a class effect, with both products preferred, failed. The final motion for a class effect passed with five opposed.

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

22. Re-Review of Sulfonylureas (Green Category)

Dr. Sater gave the First Health presentation of Sulfonylureas. There are three available entities and several different preparations, both immediate and extended release. All the entities are now available generically. In December there were 463 claims: 41% for Glyburide, 20% for Glipizide, 19% for extended release Glipizide, 16% for Glimepiride, 4% for Micronase Glyburide, and 1 claim each for branded Glucotrol and Micronase. There was some discussion about the need to prefer both a long-acting and short-acting agent, but the amended motion to declare a class effect and include a Glipizide product passed unanimously.

Dr. Maciejewski explained that Glipizide had been preferred because of its effect on kidney disease.

In response to Dr. Bergeson’s question on whether declaring a class effect was beneficial if they were all available generically, Dr. Sater said not preferring the branded products and shifting the usage to generic products was a method of cost control.

DR. LILJEGREN MOVED TO PREFER ONE LONG-ACTING AND ONE-SHORT ACTING AGENT. THE MOTION FAILED DUE TO LACK OF A SECOND.

DR. CONRIGHT MOVED A CLASS EFFECT, AND INCLUDE AT LEAST ONE GLIPIZIDE PRODUCT ON THE PDL. SECONDED BY DR. MACIEJEWSKI.

Dr. Liljegren asked why the committee did not want to prefer a long-acting and short-acting agent. Based on the current PDL, Dr. Brodsky said it appeared they would all make the list even if they were not preferred.

THE MOTION PASSED WITH ONE OPPOSED.

23. Review Minutes from November 2008 Meeting

Mr. Campana reviewed a few corrections to the meeting minutes.

DR. BERGESON MOVED TO APPROVE THE MEETING MINUTES OF NOVEMBER 2008 AS CORRECTED. SECONDED BY DR. DEMAIN. THE MOTION PASSED UNANIMOUSLY.

24. Comments from Committee Members or Chair

Mr. Campana said the next meeting would be April 17. Clinical submissions by the manufacturers must be received by March 13. The list to drugs to be addressed at the next meeting was reviewed.

Dr. Brodsky announced that Dr. Conright would be resigning from the committee, because she was relocating to Nevada. Dr. Conright said she would submit a good geriatric replacement for consideration.

Mr. Campana thanked Dr. Conright for her service on the committee.

25. Adjourn

The meeting adjourned at 10:07 a.m.