# NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES MEDICAID AND HEALTH CHOICE PREFERRED DRUG LIST REVIEW PANEL MEETING

Tuesday, September 25, 2012, 10:30 a.m. – 2:00 p.m.

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#### I. WELCOME AND INTRODUCTIONS

Dr. Lisa Weeks opened the meeting at 10:30 a.m. on September 25, 2012. She welcomed everyone to the 2012 annual NC Medicaid and Health Choice Preferred Drug List Review Panel meeting, the third year of the program. It was noted that the Division of Medical Assistance, (DMA), submitted the first report to CMS for the NC Medicaid and Health Choice Preferred Drug List and Prior Authorization programs. DMA is required to evaluate each year the overall impact of these programs on beneficiary use of medical services and savings resulting from the programs.

Since 2010 through SFY 2011, DMA's evaluation shows approximately \$105 million have been saved with no significant differences in use of medical services when comparing beneficiaries impacted by the PDL program to those not impacted by the PDL program for some of the most commonly used therapeutic drug categories. If anyone is interested in reviewing the report, it is located on the Statistics and Reports webpage on the NC Division of Medical Assistance's website at <a href="http://www.ncdhhs.gov/dma/pub/index.htm">http://www.ncdhhs.gov/dma/pub/index.htm</a>.

#### II OVERVIEW OF PANEL ACTIVITIES AND PROCEDURES

Dr. Weeks provided an overview of the processes and procedures for today's meeting. For each drug class review, if there are speakers registered to speak about a drug, they will be allowed time to share their comments before the panel members discuss and make recommendations about the drug class. Speakers should provide their name, affiliation and disclose any conflicts of interest. Speakers should be mindful of the time limitations of this meeting. Dr. Weeks reserved the right to intervene in order to ensure the meeting continued to move forward in a timely manner. A brief summary of the comments received through the DMA website during the 45-day public comment period would be provided during the meeting. The panel members received a copy of the public comments prior to the meeting. DMA did receive some comments for drug classes that are not on the agenda; however, according to the approved guidelines and procedures, these would not be discussed but the panel members did receive them as part of the comment packet. A brief description of the proposed recommendations for each drug class including information on market share would be provided by Dr. Weeks. Panel members would then have an opportunity for discussion. A vote would then occur on whether or not to approve the proposed decisions as presented or with changes proposed by the panel. Panel members should recuse themselves from voting on a drug class if they have any conflicts of interests.

There are three new members on the Panel: Dr. Burt Johnson representing the NC Psychiatric Association, Dr. William Sheridan representing research-based pharmaceutical companies and Dr. Tom Wroth, representing Community Care of North Carolina. The current members are serving a two year term which began in July 2012 and will end in July 2014.

#### Panel members introduced themselves:

- 1. Dr. Cedric Bright, Representative for the Old North State Medical Society
- 2. Dr. Paul Bush, Representative for Hospital-Based Pharmacy
- 3. Dr. Stefanie Ferreri, Representative for the North Carolina Association of Pharmacists
- 4. Dr. Theresa Flynn, Representative for the North Carolina Pediatric Society
- 5. Dr. Byron Hoffman, Representative for the North Carolina Chapter of the American College of Physicians
- 6. Dr. Burt Johnson, Representative for the North Carolina Psychiatric Association
- 7. Dr. Robert (Chuck) Rich, Representative for the North Carolina Academy of Family Physicians
- 8. Dr. William Sheridan, Representative for Research-Based Pharmaceutical Companies
- 9. Dr. Beat Steiner, Representative for the Physician Advisory Group Pharmacy and Therapeutics Committee
- 10. Dr. Lisa Weeks, Representative for the North Carolina Division of Medical Assistance
- 11. Dr. Tom Wroth, Representative for Community Care of North Carolina

There are 67 drug classes to review.

# III. DRUG CLASS REVIEWS

# 1. NSAIDs

- There are no registered speakers for this drug class.
- There were no comments received for this drug class.
- This drug class has been expanded so that older brand name medications with preferred generic equivalents are included on the non-preferred side except for Duexis and Sprix. These are relatively new brands for this drug class with very little utilization. Generic diclofenac potassium has been added to the preferred side.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed; (Dr. Byron Hoffman not present for voting, but arrived before the next agenda item)

#### 2. LONG ACTING NARCOTIC ANALGESICS

- Two speakers were registered to speak:
  - 1. Dr. Allison Ogonowski, Covidien (Exalgo) (Commented on new strength of Exalgo)
  - 2. Dr. Victoria Valdez, Johnson and Johnson (Nucynta ER) (Requested Nucynta ER to be preferred)
- There were no comments received for this drug class.
- Two generics, generic morphine ER which is the generic for Kadian and oxymorphone ER which is the generic for Opana ER, have been added to the non-preferred side. These two generics have been non-preferred since they are new to the marketplace since our last meeting. We are only updating the PDL to reflect their statuses. These are two non-preferred generics with preferred brands. Brand Nucynta ER is being recommended as non-preferred, also.
- Discussion No evidence that supports Exalgo or Nucynta ER as first line agents.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

#### 3. SHORT ACTING SCHEDULE II ANALGESICS

- No registered speakers for this class.
- No comments were received during the public comment period.
- A couple of generics with more costly dosage formulations are proposed to be added to the non-preferred side along with a new brand called Oxecta and two older brands, Primlev and Roxicet. These drugs have low utilization.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

# 4. SCHEDULE III-IV ANALGESIC COMBINATIONS

- No registered speakers for this class.
- No comments were received during the public comment period.
- This drug class has been expanded to include more costly generics and brands that have been in the marketplace for some time. They all have less than 1% of the market share and all are recommended to be non-preferred.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

#### 5. TRAMADOL

- No registered speakers for this class.
- No comments were received during the public comment period.
- The only changes recommended to this drug class are the addition of Conzip and the generic version of Ryzolt to non-preferred status. Market share of these two drugs combined is less than 1%.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

#### 6. SECOND GENERATION ANTICONVULSANTS

- One speaker was registered to speak:
  - 1. Jodi Jensen, UCB (Vimpat)
    - (Commented on the need for Vimpat for seizures and maintaining unrestricted access)
- Three comments were received for this drug class. All three comments were about Lyrica. The comments were requesting the removal of the prior authorization criteria and requirement to fail other products. The prior authorization criteria for Lyrica exempts patients with seizure disorders and requires prior authorization for use for other indications such as neuropathic pain, fibromyalgia and anxiety disorders.
- Two generics have been added to the preferred side. Several brand name drugs with preferred generic equivalents have been added to the non-preferred side along with two new-to-market brand name seizure drugs, Onfi and Potiga.
- Discussion Panel stated that all seizure medications are available without restriction. Panel asked DMA to look at the PDL list and to enhance the ability for providers to know that medications used for seizures have no restrictions if it is possible. The Panel noted that unrestricted access to anticonvulsants is good and it is good policy for those products with unique mechanisms of action to be available for use. Dr. Weeks clarified that red wording in a class is a notice of criteria required

or exemptions for the class. In addition, Dr. Weeks also clarified that the yellow highlights on the PDL are a Policy Development format at DMA. The yellow highlights indicate a change, with additions underlined and deletions struck through. The panel discussed the commented request for removal of the prior authorization (PA) criteria on Lyrica, but the panel did not agree.

- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

# 7. <u>CEPHALOSPORINS AND RELATED ANTIBIOTICS</u>

- No registered speakers for this class.
- No comments were received during the public comment period.
- Brand Augmentin XR and Keflex have been added to the non-preferred side and both have very low utilization (less than 1%). Both have generic equivalents that are preferred.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

#### 8. LINCOSAMIDES/OXAZOLIDINONE ANTIBIOTICS

- No registered speakers for this class.
- No comments were received during the public comment period.
- Three injectable formulations (brand Cleocin, brand Lincocin and generic clindamycin injections) have been added to the non-preferred side. All have low utilization (less than 1% market share).
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

#### 9. MACROLIDES AND KETOLIDES ANTIBIOTICS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The only changes to this drug class are addition of brand Eryped and E.E.S. to the preferred side and brand Ery-Tab and PCE to the non-preferred side. The two non-preferred additions have less than 1% market share.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

# 10. NITROMIDAZOLE ANTIBIOTICS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The drug class has been expanded to include several brands on the non-preferred side as well as a costly generic formulation of metronidazole (capsule form). The drugs proposed to be added to the non-preferred side have low utilization. Generic metronidazole tablets have more than 94% of the market share for this drug class.
- Discussion The panel questioned if at point-of-sale would the metronidazole capsule be rejected and the answer is yes. The panel questioned if a capsule could be substituted with a tablet and this was not determined. A physician may have to be called. The panel asked about liquid formulation of metronidazole not being on the PDL. It was clarified that liquids would have to be compounded from the tablet as they are not commercially available. The PDL was informed that only nine

prescriptions in the quarter of review were filled for the capsules. The panel inquired on vancomycin utilization and the answer was that it was low.

- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

# 11. QUINOLONE ANTIBIOTICS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The proposed changes to this drug class include changing generic levofloxacin to preferred status and moving brand Avelox to non-preferred status. Brand Avelox has about 17% of the market share for this drug class. Most of the market share is with generic ciprofloxacin (about 78%). The PDL changes approved at this meeting will go into effect around November but we will go ahead and make generic levofloxacin tablet preferred as soon as possible because this has been a change that providers have wanted to occur to prevent disruption of care.
- Discussion Panel was informed that the P&T felt that this was another case of yearly switching, which can be annoying to providers, but that this switch was a positive one.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

#### 12. ORAL ANTIFUNGALS

- No registered speakers for this class.
- No comments were received during the public comment period.
- This drug class has been expanded to add one brand and three generics as non-preferred. One of the generics (voriconzale) is a new to market generic so has been non-preferred. All of these drugs have very low utilization (less than 1%).
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

#### 13. <u>HEPATITIS C ANTIVIRALS</u>

- One speaker was registered to speak:
  - 1. Mr. Gregory Conner, Physician Assistant Practitioner (RibaPak) (Commented on adherence and pill burden for this disease state and how RibaPak lessens that burden and increases adherence)
- Six comments were received for this drug class. All comments were related to disagreement with the recommendation to make Ribapak non-preferred and concern with non-compliance risks due to increase pill burden.
- The recommended changes include moving Pegasys Convenience Pack to non-preferred status and addition of Pegasys Proclick to preferred status. Pegasys products have about 74% of the market share with Pegasys Convenience Pack being the majority of this. Changes also include moving Rebetol, Ribapak and Ribasphere from preferred to non-preferred status. Of these three ribavirin products, Ribapak has the highest market share around 16%. In addition to these changes, we propose adding prior authorization criteria to two new drugs, Incivek and Victrelis. The prior authorization criteria follow FDA guidelines for patients with a confirmed diagnosis of HCV with genotype 1.
- Discussion The panel inquired if there was evidence that the use of ribavirin with Peg-interferon is required and the speaker answered yes. The panel asked as to what are the downsides of trying

ribavirin first and those that fail go to RibaPak and the speaker answered that the increased cost and having to start over on RibaPak is not desirable because of the side-effects. In addition, with the protease inhibitor you get one chance to cure the patient. A panel member commented that as a clinician you want to put your best foot forward in the first round. Dr Weeks noted that for ribavirin versus RibaPak, the cost savings is significant but compared to the entire spend on triple therapy, it is not as significant. The speaker noted there is no difference in toxicity between the pill burden of ribavirin and that of RibaPak. The panel asked what would a provider have to do to get RibaPak and Dr. Weeks answered that a PA form would need to be filled out. A panel member asked if a provider could stratify patients for pill burden versus potential non-adherence and the speaker stated it could be possible. The panel asked if there are other classes where DMA takes pill burden into account and the answer was no. An industry representative for a protease medication for this class stated that if a patient stops ribavirin while on triple therapy the process is over and the patient does not get a second chance with triple therapy. A panel member stated that it seems as if you get people to cure you cut costs in the long run.

- Motion to move RibaPak back to preferred, leaving all others medications as presented with a second to the motion.
- Vote: Eleven in favor, Zero opposed

#### 14. HERPES ANTIVIRALS

- No registered speakers for this class.
- No comments were received for this drug class.
- The changes recommended include moving brand Valtrex to the non-preferred side. The class represents generics as preferred and brands as non-preferred.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

# 15. ACE INHIBITOR CALCIUM CHANNEL BLOCKER COMBINATIONS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendation is to move generic trandolapril/verapamil combination which is brand Tarka to the preferred side.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

#### 16. ANGIOTENSIN II RECEPTOR BLOCKERS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendation is to add generic eprosartan (generic Teveten) and generic irbesartan (generic Avapro) to the non-preferred side. These are two new-to-market generics that have been non-preferred since they entered the market place.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

### 17. ANGIOTENSIN II RECEPTOR BLOCKER DIURETIC COMBINATIONS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendation is to add Edarbyclor and a new-to-market generic irbesartan/HCT (generic Avalide) to the non-preferred side.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

# 18. ANGIOTENSIN II RECEPTOR BLOCKER COMBINATIONS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendation is to move brand Azor, Tribenzor and Twynsta to the non-preferred side. Drugs in this class in general have low utilization.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

#### 19. ANTI-ARRHYTHMICS

- No registered speakers for this class.
- No comments were received during the public comment period.
- This drug class has expanded with addition of older generic drugs to the preferred side with brand equivalents on the non-preferred side.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

#### 20. <u>BETA BLOCKER DIURETIC COMBINATIONS</u>

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendation is to move brand Ziac to the non-preferred side. Its market share is less than 1% primarily because there is a generic equivalent available. The recommendation also includes addition of the new brand name drug, Dutoprol, the non-preferred side.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

#### 21. BILE ACID SEQUESTRANTS

- Two speakers were registered to speak:
  - 1. Dr. Jamie Jolly, Daiichi Sankyo (Welchol) (Commented that Welchol is the only bile acid sequestrant that has indications for lipid lowering and diabetes control. In addition, it has a pediatric indication for lipid lowering.)
  - 2. Dr. A. Clark Gaither, Family Physician (Welchol) (Commented on where you go when a patient cannot take a statin and on the side effects of Questran and its drug-drug interactions which Welchol does not have.)
- Two comments were received for this drug class. Both comments were in support of keeping Welchol as a preferred agent due to its ability to lower LDL.

- The recommendations include adding generic colestipol granules (generic Colestid) and moving brand Welchol to the non-preferred side. Both drugs have low utilization in the class (around 5%). I would like to point out that it was our intention to list Prevalite on the non-preferred side when we removed it from the preferred side.
- Discussion A panel member asked what other products have diabetes indications and the speaker answered that no other product has this indication. The panel questioned if Welchol has any outcomes studies and the answer was no. A speaker commented that tolerability of Questran can be an issue and the panel stated that a provider can fill out the PA form to get Welchol. A panel member asked if grandfathering of patients on Welchol is possible and DMA answered yes, but would have to be voted on. Another panel member stated that grandfathering causes confusion.
- First and second motions were made to approve as presented.
- Vote: Ten in favor; One opposed Opposition- Dr. Cedric Bright.

#### 22. CHOLESTEROL LOWERING AGENTS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendation is to add generic atorvastatin to the preferred side and to change brand Crestor to non-preferred. Generic atorvastatin recently became available and is currently a non-preferred generic; however, if this proposal is approved, we will move this generic quickly to preferred status. Generic atorvastatin currently has about 1% market share. Crestor has about 8% market share. We also propose removing the prior authorization criteria for the entire statin drug class now that generic atorvastatin will be available as a preferred agent.
- Discussion A panel member stated that simvastatin has had some clinical problems and that a lot of people do not tolerate atorvastatin mainly because of negative reports in the media, thus feels that people should not be moved off Crestor. Another panel member stated that this would be grandfathering and as stated during another class review this is a problem. A panel member stated that risk should be taken into the process and the moving of patients off of Crestor should not happen. A concern was mentioned about the continued changes that seem to occur yearly. A panel member reminded everyone that they should consider research evidence and not the media.
- First and second motions were made to approve as presented.
- Vote: Eight in favor, Three opposed-Opposition Dr. Cedric Bright, Dr. Stefanie Ferreri, Dr. Byron Hoffman

#### 23. CORONARY VASODILATORS

- No registered speakers for this class.
- No comments were received during the public comment period.
- This drug class has been expanded to add two additional brands to the non-preferred side which have less than 1% market share. Brand Nitrostat is recommended as preferred and has about 27% of the market share.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

#### 24. NON-DIHYDROPYRIDINE CALCIUM CHANNEL BLOCKERS

- No registered speakers for this class.
- No comments were received during the public comment period.

- The proposed changes to this drug class included moving brand name drugs with generic equivalents to the non-preferred side. These brands have low utilization (around 1% market share.)
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

#### 25. ORAL PULMONARY HYPERTENSION AGENTS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendation includes moving Revatio to the non-preferred side. Revatio has the most utilization out of the oral and inhaled PAH agents (about 54% market share) however the numbers of prescriptions are low about 230 at the time of our review of the data. Adcirca has about 42 prescriptions which represents about 10% market share. The remaining market share is with all other PAH agents which are in the endothelin receptor antagonists and inhaled prostacyclin analogs.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

#### 26. PLATELET INHIBITORS

- One speaker registered for this class.
  - 1. Dr. Rick Stouffer, Interventional Cardiologist, UNC Hospitals (Effient) (Comment read by Dr. Lisa Weeks wants Effient to be preferred based on need for patients who are clinically observed through genetic testing to be clopidogrel non-responders)
- One comment was received for this drug class. The comment was related to making Effient a preferred drug. The information presented was from the manufacturer of Effient providing clinical trial data comparing Effient to clopidogrel. Effient is indicated to reduce the rate of thrombotic cardiovascular events (including stent thrombosis) in patients with ACS who are to be managed with PCI. Effient represents about 2% of market share with most utilization with Plavix. Due to recent release of generic Plavix, expect the utilization to shift to the lower cost generic.
- Discussion Panel stated that DMA should utilize the CCNC network to coordinate care for patients leaving inpatient settings using Effient. The panel discussed the utilization of the PA form to obtain the Effient when clinically needed and when genotyping has determined a patient to be a non-responder to clopidogrel. The panel asked if Smart PA can be used to identify these patients and was answered that Smart PA does not capture inpatient medication usage, but that the use of the PA form would provide access for these patients.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

#### 27. ANTIMIGRAINE AGENTS

- No registered speakers for this class.
- No comments were received during the public comment period.
- There is only one change recommended to this drug class this year. It is the addition of a new-to-market brand called Sumavel DosePro. It is a needle-free, subcutaneous formulation of sumatriptan.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

# 28. <u>ANTINARCOLEPSY/ANTIHYPERKINESIS AGENTS</u>

- No registered speakers for this class.
- No comments were received during the public comment period.
- The change recommended to this drug class is to add the new-to-market generic modafinil to the non-preferred side.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

# 29. ANTIPARKINSON AND RESTLESS LEG SYNDROME AGENTS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The changes recommended for this drug class include moving brand Mirapex, Mirapex ER and Requip XL to the non-preferred side. Market share of these drugs combined is less than 1%. In addition to these changes, the changes recommend adding the new-to-market generic version of Stalevo and brands Horizant and Parcopa to the non-preferred side. Magellan has expanded this drug class to include these two brands. All of these drugs have low utilization since they are new to the marketplace.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

#### 30. MULTIPLE SCLEROSIS AGENTS

- One registered speaker for this class:
  - 1. Abby Carter Emanuelson, National Multiple Sclerosis Society (Commented that all disease modifying agents should be added to the preferred list and that Ampyra should be separated out as it is a symptomatic medication)
  - 2. Dr. Tanner Odom, PharmD, Novartis (Gilenya) (Commenter requested Gilenya be moved to non-preferred because of its unique mechanism of action and that it is indicated as first line therapy)
  - 3. Dr. Deena Kegler-Ebo, PhD, MBA, Acorda (Ampyra) (Commenter requested Ampyra be moved to preferred because it is for the improvement in walking for MS patients and not a disease modifying agent)
- Five comments were received for this drug class. One physician provided comments disagreeing with the movement of any of the preferred agents to non-preferred status due to limited choice in the drug class. The same physician and the MS Society commented on the status of Ampyra and the fact that it is not a DMD. The three additional comments were from providers (1 physician assistant and 2 physicians) disagreeing with the recommendation to move Rebif from preferred to non-preferred status.
- The changes recommended for this drug class include moving Rebif to the non-preferred side. Rebif has about 16% market share according to the analysis done for this class. Utilization is shared among the drugs in this class: Avonex products (20%), Copaxone (29%), Ampyra (5%), Betaseron (19%) and Gilenya (11%). As a reminder, Ampyra and Gilenya require a trial and failure of one preferred agent instead of two if a patient has an injection site reaction to the tried product.

# 30. MULTIPLE SCLEROSIS AGENTS (Continued)

- Dr. Weeks informed the panel members that Magellan provided updated information since the time the proposed PDL changes were posted for the public comment period. They recommend Avonex Pen as a preferred product so the recommendation for this product has been changed to preferred in line with the other Avonex products.
- Discussion The panel asked for a clarification on how Gilenya works and how much better than Avonex it was. The speaker stated that Gilenya works on lymphocytes keeping it from attacking the CNS giving it 52% reduction in relapse versus Avonex. The panel asked about comparative studies to Rebif and the speaker stated there were no studies comparing Rebif. A panel member stated that Ampyra is not a first line medication because it is not a disease modifier but could be used after a trial of a disease modifier as an addition or to help those who have progressive disease where a disease modifier does not work. The speaker stated that a progressive patient could start out on Ampyra without starting a disease modifier. A panel member stated this could be done with the use of the PA form. A panel member stated that the red criteria stating the use of Ampyra after one preferred with documented injection site reaction does not make sense because of the nature of Ampyra to be an add on agent. It was clarified that to use Ampyra the patient must try and fail 2 preferreds unless they have an injection site reaction with one preferred. The panel stated that this makes no sense with Ampyra because it is a symptom modifier and the speaker was asked if Ampyra could be added to a disease modifier and the speaker answered yes that it could be used with or without a disease modifier. A panel member discussed the lack of knowledge in general on MS and how to properly treat the disease and mentioned again about not understanding the need for the injection site criteria. The panel discussed removing the red criteria about injection site reaction and use the PA form to state a patient has a high disease burden that warrants the use of Ampyra when there is a special circumstance. The speaker clarified that Ampyra works in all multiple sclerotic patients and not just those with high burden. A panel member asked for the market share on the MS and it was restated as above and there was a reminder that both products are substantially more expensive that the preferreds. It was mentioned that with the removal of the injections site criteria on the PDL it would be simpler to use the PA form to obtain Ampyra than to create new criteria. A panel member stated that although this is a tragic disease, you would still work to find the proper combination (of medications) that help with the disease. A panel member stated that the trial and failure of the disease modifying agents seems to makes sense, but that the disease modifying agent comparison between Gilenya and the interferons does not because of the evidence that got Gilenya approved. In addition Gilenya has a different mechanism of action that should be taken into consideration. It was noted that once the disease does damage a patient never gets back to baseline. A panel member stated that in consultation with a neurologist, Rebif, a high dose interferon, should be preferred because it is a normal next step in the treatment of the disease. It was noted that the dose of interferon does matter in this disease. A question was posed by the panel on the number of patients on these products. An answer of 56 scripts of Ampyra per quarter was provided. The use of the PA form and how it works was clarified that if a provider needs a nonpreferred product because of a clinical need, they just need to fill out the form.
- Motion to move Rebif and Avonex Pen to preferred side, remove the red clinical criteria from the PDL, and to use the standard PDL form to obtain the non-preferred products, leaving the proposal as is, with a second to the motion.
- Vote: Eleven in favor, Zero opposed
- Second vote in October 8, 2012 email clarification of vote: Ten in favor, One opposed –
   Opposition Dr. William Sheridan

### 31. SEDATIVE HYPNOTICS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The changes recommended to this drug class include adding the new brand drug Intermezzo to the non-preferred side as well as generic temazepam 7.5mg and 22.5mg strengths with low utilization (~2% market share).
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

# 32. GROWTH HORMONES

- One registered speaker for this class:
  - 1. Dr. Marsha Davenport, NC Practitioner (Genotropin)
    (Commented on the problems with switching products on patients because of the complexities between products and the fact that patients had to do this 2 years ago can be unnerving for patients and families)
- Eleven comments were received for this drug class. All comments were from prescribers and were in support of keeping Genotropin as a preferred product.
- The changes recommended for this drug class include moving the Genotropin products to the non-preferred side and the Norditropin products to the preferred side. Market share for these products are about 42% for Genotropin and about 9% for Norditropin.
- Discussion The panel asked about the time it takes in the office to switch a patient on products due to the delivery device and the speaker stated that it is substantial leading to more costs that are not accounted for. The panel discussed how all of these products are essentially the same with the difference being in how it is delivered. A concern of the panel is that the switching of products could occur every 2 to 3 years due to rebate contracting making this problematic for providers.
- First and second motions were made to approve as presented.
- Vote: Seven in favor, Four opposed Opposition- Dr. Robert Rich, Dr. Theresa Flynn, Dr. William Sheridan, Dr. Stefani Ferreri

#### 33. AMYLIN ANALOGS

Magellan provided updated information since the time the proposed PDL changes were posted for the public comment period which will change the recommendations. We recommend that both Symlin products remain preferred.

- One speaker registered to speak:
  - 1. Mr. Michael Boskello, RPh, Amylin (Symlin) (Commenter gave back his time)
- No comments were received during the public comment period.
- The changes recommended for this drug class include moving Symlin and Symlin Pen to the nonpreferred side. However, updated information from Magellan indicates we should keep both as preferred agents.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eleven in favor, Zero opposed

### 34. GLP-1 RECEPTOR AGONISTS

- Three speakers are registered:
  - 1. Mr. Michael Boskello, RPh, Amylin (Bydureon) (Commenter requested Bydureon to be added to the preferred list)
  - Dr. James Parsons, MD, NC Practitioner (Victoza)
     (Commenter requested Victoza to be preferred due to his positive experiences in use of this drug with his patients)
  - 3. Mr. Howard Stallings, PA, NC Practitioner (Victoza) (Commenter requested Victoza to be preferred due to his positive experiences in use of this drug with his patients)
  - 4. Dr. Joseph Sheehan, MD, Novo Nordisk (Victoza) (Commenter requested that Victoza to be preferred)
- Nine comments were received for this drug class. All comments were in support of making Victoza
  a preferred agent. Other comments in support of making Victoza preferred were received; however,
  they are not officially in the public comments because they did not make the 45-day comment
  period.
- The recommendation is to keep Byetta preferred and Victoza non-preferred and add the new brand Bydureon to the non-preferred side. Market share for Byetta is around 10%, Victoza around 15% and Bydureon less than 1%. The remaining and most significant utilization is with oral DPP-IV Inhibitors which Magellan combines with the GLP-1 Receptor Agonists. NC separates out these classes to assist prescribers.
- Discussion A panel member feels that this class has firm clinical evidence and a good metaanalysis from June 2012 Clinical Therapeutics is available. There are no outcomes data on these
  medications. The panel questioned the volume of prescriptions of Byetta versus Victoza and the
  answer was that most beneficiaries receive Victoza. It was noted that the side effects of Byetta can
  be a consideration, but the patient should try it first due to the cost savings and no clinical evidence
  from head to head trials. A panel member indicated that there should be considerations on
  adherence due to dosing, but the PA process should be sufficient to get the product. A panel
  member stated that the number of Victoza scripts should give us pause as to what is happening in
  the clinical world and another member stated that the panel should consider actual research to make
  our decisions. The panel discussed how the clinical criteria to allow continuation of therapy with
  documentation that clinical goals have been met were put in place to help keep people on products
  that are working for them, thus if a patient is already on Victoza, they can stay on it. It was
  concluded that the PA form is a viable option to allow providers to get Victoza for their patients.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, One opposed Opposition: Dr. Byron Hoffman

#### 35. <u>BIGUANIDES</u>

- No registered speakers for this class.
- No comments were received during the public comment period.
- The proposed changes are to include generic glipizide-metformin combination and glyburide-metformin combination to the preferred side and add brand Glucovance to the non-preferred side.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting.

#### 36. DPP-IV INHIBITORS AND COMBINATIONS

Magellan provided updated information since the time the proposed PDL changes were posted for the public comment period recommending Janumet XR, Jentadueto and Juvisync as preferred products. This would make all products in this class preferred except that each requires a trial and failure of metformin before use.

- Registered speaker Ms. Erica Jessie
  - 1. Erica Jessie, Boehringer Ingelheim (Jentadueto) (Ms. Jessie did not speak as the product became preferred)
- Two comments were received for this class. Both comments are from physicians supporting Tradjenta remaining as preferred drug.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting.

# 37. <u>MEGLITINIDES</u>

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendation includes moving Starlix from a preferred drug to a non-preferred drug. It has about 5% of the market share for this drug class.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

A panel member opened up a discussion on insulin pens and asked why some cartridges and pens are preferred and non-preferred, stating that this class was skipped. Dr. Weeks clarified that according to the PDL guidelines and procedures, insulins were not under consideration because there were no recommended changes this year. Dr. Weeks explained that based on recommendations from the panel members at a previous meeting, we were to add at least one cost effective pen option to each class when available, but all pens are not preferred.

#### 38. PANCREATIC ENZYMES

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendation includes moving brand Zenpep from the non-preferred to preferred side.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

#### 39. PROTON PUMP INHIBITORS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendations include moving brand Nexium to the non-preferred side and adding the new OTC generic version of Prevacid to the preferred side. This would leave the drug class with generics and OTCs as preferred. Nexium market share is around 20%. Remaining market share is primarily with the generics and OTCs.
- Discussion: A panel member is concerned about more medications moving back and forth between preferred and non-preferred, especially when there are brand names on the preferred side when a

generic is available. The panel member recommends to not having preferred brand name drugs when a generic is available. Dr. Weeks clarified that this is a rebate issue and will not go away.

- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

# 40. BENIGN PROSTATIC HYPERPLASIA TREATMENTS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendation includes moving brand Avodart and Rapaflo to non-preferred status. Market share for Avodart is about 5.5% and for Rapaflo is 2.5%. A new-to-mark generic, alfuzosin which is the generic for Uroxatral remains non-preferred. The recommendations include new prior authorization criteria for Cialis for use only for its new indication for benign prostatic hyperplasia after trial and failure of all preferred agents. We have to ensure that it is not used for erectile dysfunction since this is a non-covered indication.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

# 41. ELECTROLYTE DEPLETERS

- No registered speakers for this class.
- No comments received for this drug class.
- The recommendation was to add Magnebind and Phoslyra to the non-preferred side. Both of these medications have very low utilization (less than 1%).
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

# 42. INJECTABLE ANTICOAGULANTS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendation includes adding generic fondaparinux (generic Arixtra) to the non-preferred side. This generic has come to the market place since our last panel meeting and has been non-preferred since it was introduced.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

#### 43. ORAL ANTICOAGULANTS

- No registered speakers for this class.
- There were six comments received during the public comment period. All six comments were in support of making Pradaxa a preferred drug. All comments came from physicians. One physician commented in support of making Xarelto a preferred drug.
- The recommendation is to make both Pradaxa and Xarelto preferred drugs.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

### 44. OPHTHALMIC ALLERGIC CONJUNCTIVITIS AGENTS

- One speaker registered to speak:
  - 1. Dr. Tracy Smith, PharmD, Bausch and Lomb (Bepreve) (Dr. Smith gave her time back)
- No comments were received during the public comment period.
- The recommendation includes moving brand name drugs Alamast, Alocril, Alomide and Patanol to the non-preferred side and adding a generic, epinastine (generic for Elestat) to the non-preferred side. This generic has been added to the market place since our last meeting. About 58% of the market share is with Pataday. Market shares for the remaining ones proposed to be non-preferred are 36% with Patanol and less than 1% with the others.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

#### 45. OPHTHALMIC ANTIBIOTICS

- One speaker is registered to speak:
  - 1. Dr. Tracy Smith, PharmD, Bausch and Lomb (Besivance) (Commenter requested that Besivance be preferred due its ability to stay on the eye longer and because it is the only branded Opthalmic antibiotic indicated for pseudomonas aeruginosa.)
- No comments were received during the public comment period.
- The recommendation includes moving brand Moxeza to the preferred side and adding generic neomycin/bacitracin/polymixin combination product to the preferred side. Brand Bleph-10 and generic sulfacetamide ointment, generic for Bleph-10, have been added to the non-preferred side. Both have low utilization.
- Discussion The panel stated that the only comparative trial is with Vigamox and both were similar. The speaker stated that Vigamox is not indicated with pseudomonas.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

#### 46. OPHTHALMIC ANTI-INFLAMMATORIES

- One speaker registered to speak:
  - 1. Dr. Tracy Smith, PharmD, Bausch and Lomb (Lotemax) (Commenter requested that Lotemax Ointment be preferred like the Lotemax Drops as an option for providers and patients looking for a preservative free option and as an option for those who have trouble with drops.)
- No comments were received during the public comment period.
- The recommendations for this drug class include moving brand Durezol and FML to the non-preferred side. The non-preferred side has been expanded to also include other brand name anti-inflammatories with low utilization. More than 60% of the utilization in this drug class is with the preferred agents Lotemax and prednisolone.
- Discussion A panel member was concerned about the separation of dosage forms of the same drugs and asked why this is done. Dr. Weeks states it is because of cost. A panel member feels that there would be a need for ointment option especially for pediatrics. It was noted that an ointment option is available with FML S.O.P. The panel recommends that DMA signify this product on the list as an ointment.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

#### 47. <u>OPHTHALMIC BETA BLOCKER AGENTS</u>

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendation includes moving brand Betoptic S to the non-preferred side. This drug has less than 1% market share.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

# 48. OPHTHALMIC CARBONIC ANHYDRASE INHIBITORS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendation includes moving brand Cosopt and Trusopt to the non-preferred side and also adding brand Cosopt PF to the non-preferred side. These brands have less than 1% market share.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

#### 49. OPHTHALMIC PROSTAGLANDIN AGONISTS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendations include adding brand Travatan to the preferred side and adding brand Zioptan to the non-preferred side. Zioptan was added to the market place since our last panel meeting. It has low utilization.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

#### 50. BONE RESORPTION SUPPRESSION AGENTS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendation was to add generic etidronate (generic for Didronel) and brand Evista to the preferred side and add brand Didronel and to keep the new generic ibandronate (generic ror Boniva) as non-preferred. These two drugs have less than 1% market share.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

#### 51. OTIC ANTIBIOTICS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendation is to add brand Cortisporin ointment to the non-preferred. This is an older brand with low utilization.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

#### 52. <u>BETA-ADRENERGIC LONG-ACTING INHALERS</u>

- One registered speaker for this class:
  - 1. Dr. Tanner Odom, PharmD, Novartis (Arcapta) (Commenter requests Arcapta be preferred because of the less dosing requirements and rapid onset of relief of symptoms gives reassurance to patients it is working)
- No comments were received during the public comment period.
- The recommendation is to add Arcapta Neohaler to the non-preferred side. This drug has very low utilization.
- Discussion The panel asked what the market share is for Arcapta and the answer was zero percent. The panel feels more evidence is needed.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

#### 53. BETA-ADRENERGIC SHORT-ACTING INHALERS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendation includes moving brand Ventolin HFA to the non-preferred side and moving brand ProAir HFA to the preferred side. Market share is ProAir HFA (0.7%), Proventil HFA (15%) and Ventolin HFA (48%).
- Discussion DMA reached out to distributors to ask about inventory switch over and that it could be turned over in 30 days. In addition DMA researched that a dose counter will be available for ProAir HFA in December 2012. It was noted that Ventolin utilization is substantial. A panel member asked about Ventolin prescriptions written and about refills being switched at the pharmacy. It was noted that it becomes a pharmacist's professional choice to switch the products due to products not being A/B rated. The panel's recommendation was to wait until April 1, 2013 to implement to get through the upcoming winter season when there is a spike in usage of this type of medication and since a dose counter is important enough to wait until there is one available. This will give DMA time for the education of providers to write for ProAir HFA and for pharmacy and pharmacy wholesalers to change over inventory.
- A motion to approve as proposed with a start date of April 1, 2013 with a second to the motion.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

#### 54. BETA-ADRENERGIC ORAL AGENTS

- No registered speakers for this class.
- No comments were received during the public comment period.
- This is a new drug class to the PDL. The recommendations include generic albuterol tablets and syrups as preferred and also generic metaproterenol syrup and terbutaline as preferred. The non-preferred side includes albuterol ER (generic for Vospire ER), brand Vospire ER and generic metaproterenol tablets. These drugs that are recommended as non-preferred have under 1% market share
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

#### 55. COPD AGENTS

- One speaker registered to speak on this drug class:
  - 1. Dr. Wilson Lui, PharmD, Forest Pharmaceuticals (Daliresp)
    (Commenter request that Daliresp could stay non-preferred, but because it is adjunct therapy to the preferred anti-cholinergic products and to be compliant with the GOLD guidelines for COPD, Daliresp should be allowed to be used after failure of one COPD agent and not two.)
- No comments were received during the public comment period.
- The recommendation includes moving generic ipratropium-albuterol combination (generic for Duoneb) to the preferred side.
- Discussion The panel discussed the need for the PA to be changed to reflect that only one preferred agent needs to be used before adding Daliresp. The panel had some discussion on ensuring the use of albuterol, but clinically this is already done.
- A motion was made to allow Daliresp after using only one preferred product, leaving all other recommendation as presented and there was a second to the motion.
- Vote: Ten in favor, Zero opposed Dr. Cedric Bright left the meeting

#### 56. CORTICOSTEROID AND COMBINATIONS

- Two speakers registered to speak on this drug class:
  - 1. Dr. Deogun, NC practitioner (Dulera)
    (Commenter request Dulera to be a preferred drug because it is another high dose steroid option and there is no reason to move to the lower strength steroid in Symbicort when high dose Advair fails.)
  - 2. Dr. Karen Malamut, Medical Director for Merck (Dulera) (Commenter request Dulera to be a preferred drug)
- Twelve comments were received for this drug class. Eleven comments supported Dulera as a preferred agent and one comment supported generic budesonide suspension as a preferred agent. Comments were from physicians and one physician assistant.
- The recommendation includes moving brand Pulmicort Respules to the preferred side and moving the generic version of Pulmicort Respules to the non-preferred side. This would be a scenario where there would be a preferred brand with a non-preferred generic. We would include messaging at the point-of-sale to pharmacists to allow substitution. If approved, we will update the prior authorization criteria for this drug class to reflect the change in Pulmicort and generic budesonide products. Market share for brand Pulmicort is less than 1% compared to the generic which is about 20%.
- Discussion During the discussion, members understood that patients are able to get any
  combination orally inhaled steroid if a patient's condition warrants combination therapy use or if
  the patient is already on a combination agent. Motion to approve the recommendation as proposed
  was made with clarification that DMA will ensure that the PA criteria is operating correctly and use
  of the PA form to obtain the non-preferred orally inhaled steroid combination product is working
  correctly.
- First and second motions were made to approve as presented.
- Vote: Nine in favor, Zero opposed Dr. Cedric Bright and Dr. William Sheridan left the meeting
- Second vote in October 8, 2012 email clarification of vote: Eleven in favor, Zero opposed

#### 57. <u>INTRANASAL RHINITIS AGENTS</u>

- One registered speaker for this class:
  - 1. Shane Perrilloux, Teva Pharmaceuticals (QNasl) (Commenter requested QNasl be preferred based on its dry formulation)

- No comments were received during the public comment period.
- The recommendations include adding QNasl and generic triamcinolone (generic Nasacort AQ) to the non-preferred side. This generic has less than 1% market share.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eight in favor, Zero opposed Dr. Cedric Bright, Dr. William Sheridan, and Dr. Robert Rich left the meeting

#### 58. LEUKOTRIENE MODIFIERS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendations include moving brand Zyflo CR to non-preferred status. Brand Zyflox CR has less than 1% market share. Please note that the new generic formulation of Singulair was added as a preferred agent in August due to the significant financial implications of this new drug. This drug will be added to the preferred side of the PDL once the final PDL is posted. Along with the PDL recommendations, there is a recommended change to the prior authorization criteria for this drug class. The recommendations include changing the minimum age requirement for Singulair for exercise-induced bronchoconstriction from 15 years of age and older to 6 years of age and older according to FDA guidelines. This change will be made at the same time the PDL is updated with approved changes.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eight in favor, Zero opposed Dr. Cedric Bright, Dr. William Sheridan, and Dr. Robert Rich left the meeting

#### 59. TOPICAL ACNE AGENTS

- No registered speakers for this class.
- No comments were received during the public comment period.
- This drug class has been expanded to include several brand name drugs as well as more costly generic formulations with low utilization to the non-preferred side. There are good clinical alternatives available on the preferred side.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eight in favor, Zero opposed Dr. Cedric Bright, Dr. William Sheridan, and Dr. Robert Rich left the meeting

#### 60. TOPICAL ANTIFUNGALS

- No registered speakers for this class.
- No comments were received during the public comment period.
- Just as with topical acne agents, the topical antifungals have been expanded to include several brand name drugs to the non-preferred side that have low utilization.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eight in favor, Zero opposed Dr. Cedric Bright, Dr. William Sheridan, and Dr. Robert Rich left the meeting

#### 61. TOPICAL PSORIASIS AGENTS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendations include addition of a new generic version of Vectical.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Eight in favor, Zero opposed Dr. Cedric Bright, Dr. William Sheridan, and Dr. Robert Rich left the meeting

Dr. Weeks asked the Panel if all topical steroid classes could be reviewed before voting. The recommendations in these 4 drug classes include expansion of the non-preferred side with brands and more costly generic formulations. The preferred side for each class includes several choices.

### 62. TOPICAL LOW POTENCY STEROIDS

- No registered speakers for this class.
- No comments were received during the public comment period.
- There was no discussion by the panel.

#### 63. TOPICAL MEDIUM POTENCY STEROIDS

- No registered speakers for this class.
- No comments were received during the public comment period.
- There was no discussion by the panel.

# 64. <u>TOPICAL HIGH POTENCY STEROIDS</u>

- No registered speakers for this class.
- No comments were received during the public comment period.
- There was no discussion by the panel.

#### 65. TOPICAL VERY HIGH POTENCY STEROIDS

- No registered speakers for this class.
- No comments were received during the public comment period.
- There was no discussion by the panel.

Motion to vote on all the classes together was seconded and approved.

- First and second motions were made to approve as presented.
- Vote: Eight in favor, Zero opposed Dr. Cedric Bright, Dr. William Sheridan, and Dr. Robert Rich left the meeting

#### 66. INJECTABLE IMMUNOMODULATORS

- Two speakers registered to speak on this drug class:
  - 1. Dr. Erica Wurtz, UCB (Cimzia)
    - (Commenter requested Cimzia to be preferred)
  - 2. Dr. Iram Ahmad, Bristol-Myers-Squibb (Orencia) (Commenter requested Cimzia to be preferred)
- Two comments were received during the public comment period. Comments were in support of keeping Orencia SQ as preferred.

- The recommendations include adding Orencia SQ to the non-preferred side.
- Discussion The panel discussed that with little to none head to head trials it is hard to differentiate between products and that all products are available through either trial and failure or a PA form.
- First and second motions were made to approve as presented.
- Vote: Seven in favor, Zero opposed Dr. Cedric Bright, Dr. William Sheridan, Dr. Robert Rich, and Dr. Theresa Flynn left the meeting

#### 67. SKELETAL MUSCLE RELAXANTS

- No registered speakers for this class.
- No comments were received during the public comment period.
- The recommendations include moving preferred generic versions of Soma to the non-preferred side along with brands and more costly generic formulations. These products have low utilization except for carisoprodol which is generic Soma. Market share of this drug is around 20%.
- There was no discussion by the panel.
- First and second motions were made to approve as presented.
- Vote: Seven in favor, Zero opposed Dr. Cedric Bright, Dr. William Sheridan, Dr. Robert Rich, and Dr. Theresa Flynn left the meeting

The meeting is adjourned at 3:10 pm September 25, 2012