NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES 2017 PREFERRED DRUG LIST REVIEW PANEL MEETING THURSDAY SEPTEMBER 21, 2017 10:00AM – 5PM THE STATE LIBRARY BUILDING 109 EAST JONES STREET RALEIGH, NC 27601

I. WELCOME AND INTRODUCTIONS

The meeting opened with Mr. John Stancil, Director of the Medicaid Outpatient Pharmacy Program asking members of the panel to introduce themselves. Introductions were done by the PDL Review Panel members.

- Mr. John Stancil, Pharmacist, Pharmacy Director, representing Division of Medical Assistance
- Dr. Seung Kim, Physician, representing Old North State Medical Society
- Dr. Ann McGee, Pharmacist, representing Hospital-Based Pharmacy
- Dr. Casey Johnson, Pharmacist, representing N.C. Association of Pharmacists
- Dr. Anna Miller-Fitzwater, Physician, representing N.C. Pediatric Society
- Dr. Theodore Zarzar, Physician, representing N.C. Psychiatric Association
- Dr. Byron J. Hoffman, Physician, representing N.C. Chapter of the American College of Physicians
- Dr. Robert L. (Chuck) Rich Jr., Physician, representing N.C. Academy of Family Physicians
- Dr. Oren Cohen, Physician, representing Research-Based Pharmaceutical Company
- Dr. Lawrence Greenblatt, Physician, representing N.C. Physician Advisory Group Pharmacy and Therapeutics Committee

After the panel introductions, Mr. Stancil invited the Medicaid pharmacy program staff and the Magellan Health staff to introduce themselves.

- Dr. Desiree Elekwa-Izuakor, PharmD
- Dr. Amy Williams-Phelps, PharmD
- Dr. Harita Patel, PharmD
- Ms. Krista Kness, RPh
- Ms. Charlene Sampson, RPh
- Dr. Stephanie Christofferson, PharmD, (Magellan Health)

Mr. Stancil thanked the audience for attending the meeting and the Panel members for their service. He stated the recommendations approved during the meeting will be presented to the DHHS Secretary for approval. It is anticipated that the new PDL will implement in November 2017.

Mr. Stancil then presented the following highlights of SFY 2017 for the Medicaid program and the outpatient pharmacy program.

- Medicaid enrollment increased 4.8% exceeding 2 million beneficiaries
- Gross pharmacy expenditure growth outpaced total Medicaid expenditure growth increasing by 3.2% exceeding \$1.9 billion and representing 13.5% of total Medicaid expenditure
- Paid prescriptions increased 1.3% to nearly 17 million
- Drug rebates increased 8.7% to nearly \$1.2 billion and representing 62.3% of gross pharmacy expenditure
- Net pharmacy expenditure decreased 5.8% to ~\$723 million representing 5.1% of total Medicaid expenditure making it less than the net pharmacy expenditure in last three state fiscal years

The collaborative, thorough and transparent PDL review process allows for the careful selection of drugs on the PDL to provide access to the right drugs at the most advantageous cost. The result is a 95% compliance to the PDL which provides the best overall value to beneficiaries, providers and the State.

DMA provides an annual report as required by the State's Centers of Medicare and Medicaid Services (CMS) state plan that evaluates the overall impact of the State's PDL and supplemental rebate program, which is enforced by clinical prior authorization criteria. From SFY 2011 through SFY 2015, more than \$550 million (\$190.3 million State dollars) 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.

In closing, Mr. Stancil implored speakers to present clinical evidence about the drug during their allotted time.

The meeting was turned over to Dr. Desiree Elekwa-Izuakor, Pharmacy Program Manager, who provided an overview of the procedures for reviewing each class. For each drug class reviewed, the proposed changes would be stated, followed by a summary of the public comments and announcement of registered speakers. After the speakers, the Panel would make comments, ask questions, recommend changes to the proposed update, and conclude each class discussion with a motion and vote. Dr. Elekwa-Izuakor stated voting will be done by show of hands. Speakers were asked again to present clinical information and reminded about the three- minute time limit.

II. DRUG CLASS REVIEWS

ANALGESICS

OPIOID ANALGESICS (LONG ACTING)

- Recommendations: Move Kadian Capsule from preferred to non-preferred; add Morphabond ER, Xtampza ER capsule, Arymo ER to non-preferred; remove Opana ER tablet from non-preferred (Opana ER is discontinued); noted opioid is replacing narcotic in the PDL class names.
- Public Comments: Four (one general comment pertaining to all opioid classes and three comments about the long acting class)
- Speakers: Two
 - Sandhya Thomas-Montilus, MD, Internal Medicine Physician Hysingla
 - o Brittney Jalphers, Daiichi Sankyo, Inc, Morphabond ER
- Discussion: A comment was made that abuse deterrent products are available in both preferred and non-preferred options. Use of abuse deterrent products should be encouraged. It was pointed out that Butrans which is preferred is long acting with anti-abuse properties. It is important to be mindful of cost that may be incurred by adding another agent to preferred choices. Physicians are already familiar with step processes when prescribing opioids. If already tried on a short acting product, basically have meet criteria for prior authorization approval.
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

OPIOID ANALGESICS ORALLY DISINTEGRATING /ORAL SPRAY SCHEDULE II

- Recommendations: Move Actiq Lozenge from non-preferred to preferred; move Fentora Buccal tablet from preferred to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: Belbuca prescribed twice daily does not fit in this class around the requirement of trial and failure of two preferred agents. Clinically, it is not an alternative to the other agents of

the class. Recommended move Belbuca (Buccal) to Long Acting. It was stated there is an exception for cancer patients for pain medication.

- Motion with second: Approve all recommendations; move Belbuca to opioid analgesic long acting class.
- Vote: All in favor. None opposed.

OPIOID ANALGESIC SHORT ACTING SCHEDULE II

- Recommendations: Move oxycodone concentrated solution (generic for Roxicodone Intensol) from preferred to non-preferred; add oxycodone/APAP suspension to non-preferred.
- Public Comments: None
- Speakers: None
- Panel Discussion Inquired about the usage of oxycodone concentrated solution. The utilization is very small.
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

OPIOID ANALGESIC SHORT ACTING SCHEDULE III – IV ANALGESIC COMBINATIONS

- Recommendation: Remove carisoprodol compound with codeine tablet (generic for Soma Compound with Codeine) from non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: Per Dr. Elekwa-Izuakor change included for informational purposes only.
- No vote taken.

NSAIDS

- Recommendations: Add Inflammacin Tablet to non-preferred, move Celebrex Capsule from preferred to non-preferred, move celecoxib capsule (generic for Celebrex) from non-preferred to preferred.
- Public Comments: None
- Speakers: None
- Panel Discussion None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

ANTICONVULSANTS

CARBAMAZEPINE DERIVATIVES

- Recommendations: Move oxcarbazepine suspension (generic for Trileptal) from non-preferred to preferred; move Carbatrol Capsule from preferred to non-preferred; move Trileptal Suspension from preferred to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: The panel sought confirmation regarding the seizure diagnosis exemption for anticonvulsant products. It was confirmed a beneficiary with a seizure disorder is exempt and may use any anticonvulsant product. The exemption applies for all anticonvulsant products.
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

FIRST GENERATION

- Recommendation: Move Felbamate suspension/tablet (generic for Felbatol) from preferred to non-preferred.
- Public Comments: One
- Speakers: None
- Discussion: None
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

SECOND GENERATION

- Recommendations: Add Briviact Tablet and Solution, Fycompa Tablet / Kit/Suspension, Spritam Tablet to non-preferred; move lamotrigine starter kits (generic for Lamictal) from preferred to non-preferred.
- Public Comments: One
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

ANTI-INFECTIVE SYSTEMIC

ANTIBIOTICS - CEPHALOSPORINS AND RELATED

- Recommendations: move Cedax Capsule/Suspension from preferred to non-preferred; move cefadroxil tablet (generic for Duricef) from preferred to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

ANTIBIOTICS - LINCOSAMIDES AND OXAZOLIDINONES

- Recommendations: Move linezolid suspension (generic for Zyvox) from non-preferred to preferred; move Zyvox Suspension from preferred to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

ANTIBIOTICS - MACROLIDES AND KETOLIDES

- Recommendation: Add erythromycin es 200mg suspension (generic for E.E.S. Suspension) to preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

ANTIBIOTICS - NITROMIDAZOLES

• Recommendations: Move Vancocin Capsule from preferred to non-preferred; move vancomycin capsule (generic for Vancocin) from non-preferred to preferred.

- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

ANTIBIOTICS – TETRACYCLINE DERIVATIVES

- Recommendations: Add Doryx MPC Tablet and doxycycline monohydrate 40mg capsules (generic for Oracea Capsules) to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

<u>ANTIVIRALS – HEPATITIS B AGENTS</u>

- Recommendations: Move Baraclude Tablet from preferred to non-preferred; move entecavir tablet (generic for Baraclude) from non-preferred to preferred; move Epivir HBV Tablet from preferred to non-preferred; move lamivudine HBV tablet (generic for Epivir HBV) from non-preferred to preferred; add Vemlidy tablet to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: A question was asked about preferred drug Tyzeka being discontinued. No response.
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

ANTIVIRALS – HEPATITIS C AGENTS

- Recommendations: Added as preferred the following agents outlined as below:
 - All genotypes without cirrhosis Mayvret (8 weeks of therapy)
 - All genotypes with compensated cirrhosis (Child Pugh-A) Mayvret (12 weeks of therapy)
 - All genotypes with decompensated cirrhosis (Child-Pugh B and C) Epclusa Tablet in combination with ribavirin
 - All genotypes previously treated with an HCV regimen containing an NS5A inhibitor or genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor - Vosevi
 - Moved Epclusa Tablet (for genotypes 1, 4, 5 and 6) from non-preferred to preferred per outline above
 - Moved Technivie Dose Pack (for genotype 4), Viekira Pak, Viekira XR Tablet and Zepatier Tablet from preferred to non-preferred status
 - Harvoni Tablet (for completion of therapy initiated prior to November 1, 2017) will remain preferred until 4/30/2108. It will become non-preferred from 5/1/2018.
- Public Comments: None
- Speakers: Three
 - Andrea Hume, MD, Abbvie Mavyret
 - Nichole Kiziah, PharmD, AAHIVP, Gilead Sciences Vosevi
 - Roderick Teat, Pharm D, Merck Medical Affairs Director Zepatier

- Discussion: Mr. Stancil provided background information about the class. He stated the class reflects a recently FDA approved drug. For this reason, DMA waited to get clinical reviews and financial bids before recommending updates for this class. These recommended updates are currently posted for public comment through October 28, 2017. The recommendations, if approved today, will become effective in November along with all other updates to the PDL. For informational purposes, it was stated fibrosis scoring will also be removed from criteria in November. Harvoni was reported to currently have the highest utilization, but pangenotypic products have opened a new treatment spectrum which impacted PDL recommendations. Another factor contributing to the recommendations was the Wholesale Acquisition Cost (WAC) for each product which may be used to determine pharmacy reimbursement. A question was asked about these products and pregnancy and breast feeding. It was stated there is no contraindication, but clinical trials do not include pregnant women. It was stated the real-world data is of interest. The Step 1–3 headers are removed from the class formatting to ensure no suggestion of step therapy.
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

HERPES TREATMENTS

- Recommendations: Move acyclovir suspension (generic for Zovirax) from non-preferred to preferred; move Zovirax Suspension from preferred to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

ANTIBIOTICS INHALED

- Recommendations: Note: New class to PDL. Preferred products are Kitabis Pak (tobramycin inhalation solution), Bethkis (tobramycin inhalation solution); non-preferred products are Cayston, tobramycin solution / pak and Tobi.
- Public Comments: None
- Speakers: None
- Discussion: A question was asked about why Cayston was non-preferred. Utilization was a factor. It was stated that trial and failure of one should apply for this class since both preferred agents are tobramycin products.
- Motion with second: Approve all recommendations; make class trial and failure of one preferred.
- Vote: All in favor. None opposed.

BEHAVIORAL HEALTH

ANTIDEPRESSANTS – OTHER

- Recommendations: Move Nardil Tablet from preferred to non-preferred; add Marplan to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

ANTIHYPERKINESIS/ADHD

- Recommendations:
- Move clonidine ER tablet (generic for Kapvay), DesoxynTablet (methamphetamine HCl), dextroamphetamine ER capsule (generic for Dexedrine Spansules), all methylphenidate ER tablets, Ritalin LA Capsule (methylphenidate 20 mg, 30 mg, 40 mg, 60 mg) from preferred to non-preferred status; move Quillichew ER Oral (methylphenidate), Aptenzio XR from nonpreferred to preferred status; added Adzenys XR ODT (amphetamine ER) as a new nonpreferred product; remove Metadate CD capsules as they are discontinued
- Public Comments: Four
- Speakers: Two
 - o Corey Hebert, MD, Rhodes Pharmaceuticals Aptensio XR
 - Dr. Marsie Ross, PharmD, Tris Dyanavel XR
- Discussion: Moving Vyvanse Chewable Tablets from non-preferred to preferred was added as an addendum to the proposed recommendation for the PDL Panel's consideration. Questions and comments exchanged about the readiness of the manufacturer of Aptensio XR to be the preferred methylphenidate extended release drug on the PDL. There was assurance from manufacturer representatives all resources for a smooth transition will be in place. Questions were asked about how many beneficiaries are affected by changes in this class; if one methylphenidate product could stay preferred and if a grace period was warranted. It was stated the changes represent an additional three million in savings which weighed heavily. It was stated a liquid formulation has advantages because gives ability to do intermediate doses. A liquid formulation sometimes work better with younger age. Within a class most products work similarly. Clinical justification factors are considered when a provider requests coverage for a non-preferred agent.
- Motion with second: Approve recommendations; with exception move Vyvanse Chewable Tablet to preferred.
- Vote: All in favor. None opposed.

ATYPICAL ANTIPSYCHOTICS - ORAL

- Recommendations: Move Fanapt Tablet and Latuda Tablet from preferred to non-preferred; add Nuplazid Tablet and Vraylar Capsule to non-preferred
- Public Comments: Twenty
- Speakers: Six speakers
 - o Dr. Mona Gupta, Gupta Psychiatry Latuda
 - Jeffrey B. Childers, MD, Psychiatrist Latuda
 - Adan Sosa, PharmD, Director of Health Economics and Outcome Research Sunovion Pharmaceuticals – Latuda
 - John Beyer, Duke Latuda (no show)
 - Sherry Andes, Acadia Pharmaceuticals Nuplazid
 - o Jason Swartz, RPh, MBA, Otsuka Rexulti
- Discussion: Questions were asked about Nuplazid, because of indication for Parkinson psychosis, having to fail one or if will approved based on clinical criteria. Nuplazid clinical justification will align with label indications. A question was asked about the advantages of Latuda for adolescents and pregnancy and what other atypicals are indicated for psychosis for children. A Latuda adolescent advantage may be the metabolic profile; Latuda tends to be prescribed for pregnant women; aripiprazole and risperidone are approved for adolescent psychosis; a carve out for women, adolescents and children for Latuda was mentioned.
- Motion with second: Approve recommendations with exception keep Latuda preferred.
- Vote: All in favor. None opposed.

CARDIOVASCULAR

ACE INHIBITORS

- Recommendation: Add Qbrelis Solution to non-preferred.
- Public Comments: None
- Speakers: One
 - o Trey Gardner, PharmD, Silvergate Pharmaceuticals
- Discussion: There is no liquid formulation on preferred side. Qbrelis as a liquid formulation has a place for younger patients.
- Motion with second: Approve recommendation; add Qbrelis exemption for < 12 years of age and under.
- Vote: All in favor. None opposed.

ACE INHIBITOR DIURETIC COMBINATIONS

- Recommendation: Move benazepril-HCTZ tablet (generic for Lotensin HCT) from preferred to none preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

ANGIOTENSIN II RECEPTOR BLOCKER COMBINATIONS

- Recommendation: Add amlodipine/olmesartan tablet (generic for Azor) to non-preferred
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

ANTI-ARRHYTHMICS

- Recommendation: Add dofetilide capsule (generic for Tikosyn) to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

BETA BLOCKER DIURETIC COMBINATIONS

- Recommendations: Move metoprolol-HCTZ tablet (generic for Lopressor HCT), propranolol-HCTZ tablet (generic for Inderide) from preferred to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

CHOLESTEROL LOWERING AGENTS

- Recommendations: Move rosuvastatin tablet (generic for Crestor) from non-preferred (not rated) status to preferred; add ezetimibe (generic for Zetia) to non-preferred
- Public Comments: None
- Speakers: None

- Discussion: Questions were asked why both brand and generic of Zetia are non-preferred and what is required to get prior approval. It was stated there was discussion, without a final internal recommendation, when redoing this class about making both products non-preferred. The failure of two preferred products applies to this class or clinical justification. It was stated use of Ezetimibe as add on therapy is clinical justification. Ezetimibe should not be an initial therapy. A prior authorization request for either product can be approved with clinical justification. Moving the brand product to preferred is least cost impactful to the state.
- Motion with second. Approve recommendations with exception move Zetia to preferred.
- Vote: All in favor. None opposed.

CORONARY VASODILATORS

- Recommendation: Add Gonitro Sublingual Powder to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

NIACIN DERIVATIVES

- Recommendations: Move Niaspan ER Tablet from preferred to non-preferred, move niacin ER tablet (generic for Niaspan) from non-preferred to preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

NON-DIHYDROPYRIDINE CALCIUM CHANNEL BLOCKERS

- Recommendations: Move diltiazem LA tablet (generic for Cardizem LA) from preferred to nonpreferred; move Verelan PM Capsule from preferred to non-preferred; add verapamil 360mg capsule to non-preferred
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

PLATELET INHIBITORS

- Recommendations: Add aspirin/dipyridamole ER capsule (generic for Aggrenox) and Yosprala Tablet to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

ANTIANGINAL & ANTI-ISCHEMIC

- Recommendations: Name change to class from Antianginal to Antianginal & Anti-Ischemic; add Corlanor Tablet (not rated) as non-preferred.
- Public Comments: None

- Speakers: None
- Discussion: Per Dr. Elekwa-Izuakor the name change update from Antianginal to Antianginal & Anti-Ischemic will be the only change for the panel to consider at this meeting. Corlanor Tablet will be taken back to put in a different class.
- Motion with second: Approve name change only.
- Vote: All in favor. None opposed.

TRIGLYCERIDE LOWERING AGENTS

- Recommendations: Move fenofibrate tablet (Tricor) and fenofibric acid capsule /tablet (Trilipix) from non-preferred to preferred; move Tricor tablet and Trilipix Capsule from preferred to non-preferred; add fenofibrate tablet (generic for Fenoglide) to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

CENTRAL NERVOUS SYSTEM

ANTIMIGRAINE AGENTS

- Recommendations: Remove sumatriptan cartridge from preferred; added frovatriptan tablet (generic for Frova), Migranow Kit, Onzetra Xsail Nasal Powder, Zecuity Transdermal, Zembrace SymTouch, sumatriptan kit (generic for Imitrex) to non-preferred
- Public Comments: None
- Speakers: One
 - Pam Sardo, PharmD, BS, Avanir Pharmaceuticals Onzetra Xsail Nasal Powder
- Discussion: A comment was made about Zecuity Transdermal being discontinued.
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

ANTINARCOLEPSY

- Recommendations: Move Nuvigil Tablet from non-preferred to preferred; add armodafinil tablet (generic for Nuvigil) to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

ANTIPARKINSON AND RESTLESS LEG SYNDROME AGENTS

- Recommendations: Add rasagiline (generic for Azilect) and tolcapone tablet (generic for Tasmar) to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

MULTIPLE SCLEROSIS

• Recommendation: Add Ocrevus and Zinbryta Injection to non-preferred.

- Public Comments: One
- Speakers: One
 - Manuel Nunez, PharmD, BS, Sanofi Genzyme Aubagio
- Discussion: A question was asked about the availability of head to head data for drugs in this class compared to newer agents like Ocrevus. No response. It was stated changes in the class were financial based. A comment was made that there are many preferred options that likely would have been tried for many patients to meet the trial and fail of two.
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

SEDATIVE HYPNOTICS

- Recommendations: Move estazolam tablet (generic for Prosom) and triazolam tablet (generic for Halcion) from preferred to non-preferred; add zolpidem SL tablet (generic for Intermezzo) and zolpimist oral spray to non-preferred
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

SMOKING CESSATION

- Recommendations: Move Nicorette Gum /Lozenge (buccal) from preferred to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

ENDOCRINOLOGY

GROWTH HORMONE

- Recommendations: Move Genotropin Cartridge /Miniquick from non-preferred to preferred; move Nutropin AQ Pen/ Nuspin from preferred to non-preferred.
- Public Comments: Two
- Speakers: None
- Discussion: Questions were asked if the recommended changes were financial primarily and what was the utilization. It was stated that utilization is over eighty percent Norditropin.
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

HYPOGLYCEMICS INJECTABLE – RAPID ACTING INSULIN

- Recommendations: move Humalog Kwikpen from preferred to non-preferred.
- Public Comments: Three
- Speakers: One
 - David Warren, United States Bankruptcy Judge, Diabetes Sisters General comments unrelated to any specific agent of the class.
- Discussion: A question was asked if the recommended changes were financial primarily. Response was yes and low utilization.
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

HYPOGLYCEMIC INJECTABLE – SHORT ACTING INSULIN

- Recommendation: Add Humulin R-U500 Kwikpen to non-preferred
- Public Comments: None
- Speakers: None
- Discussion: A question was asked about the requirement to get the U500 insulin. The trial and failure of the one preferred drug or clinical justification was the response. A question was asked if a patient without the dexterity to draw up insulin from a vial meet clinical justification. It was stated it is up to the clinician to determine what constitutes clinical justification for any prior authorization request for a patient. The utilization for the Humulin R-U500 Kwikpen was less than one percent.
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

HYPOGLYCEMICS INJECTABLE – INTERMEDIATE ACTING INSULIN

- Recommendation: Move Humulin N Pen from preferred to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: A question was asked about utilization for the Humulin N Pen. Stated less than one percent.
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

HYPOGLYCEMICS INJECTABLE – LONG ACTING INSULIN

- Recommendation: Add Basaglar Kwikpen to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: Dr. Elekwa-Izuakor pointed out this class is trial and failure of only one preferred drug or clinical justification. It was stated that some commercial plans are preferring Basaglar based on their financials. It was stated Basaglar and Lantus are similar.
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

HYPOGLYCEMICS INJECTABLE – PREMIXED 70/30 COMBINATION INSULIN

- Recommendation: Move Humulin 70/30 Pen from preferred to non-preferred
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

HYPOGLYCEMICS INJECTABLE – GLP-1 RECEPTOR AGONISTS AND COMBINATIONS

- Recommendations: Add Adlyxin Injection, Soliqua Injection, Xultophy Injection to non-preferred.
- Public Comments: Four
- Speakers: Four
 - o Kerry Desai, PharmD, Sanofi Adylixin
 - Kerry Desai, PharmD, Sanofi Soliqua
 - Tammy Kell, PharmD, Novo Nordisk Victoza
 - Tammy Kell, PharmD, Novo Nordisk Xultophy

- Discussion: It was asked if there was consideration to putting a combination product on the preferred side. It was stated that the two individual products are cheaper than the combination. A comment was made that having more good treatment options to individualize therapy is always better, but balance against resource constraints is necessary. A question was asked about the bar to get non-preferred drug. It was stated Medicaid covers any drug having a manufacturer rebate agreement with CMS. It is not difficult to obtain a non-preferred when it is in the best interest of the patient and the clinical judgement of the physician. It was stated the message that the preferred side is not an absolute should be amplified. It was stated many diabetes products are similar having modest differences. A question about finances impacting the changes was asked. It was stated insulins are in the top spend and have had significant price increases recently. A manufacturer willingness to offer better pricing has impact on PDL placement. It was stated that utilization and pricing is monitored continuously for these drugs. Studies around cardiovascular benefit are keep in mind as well. A comment was made that Tanzeum is being discontinued. It was stated the discontinuation is sometime during 2018.
- Motion with second: Approve all recommendations
- Vote: All in favor. None opposed.

HYPOGLYCEMICS ORAL – ALPHA GLUCOSIDASE INHIBITORS

- Recommendation: Add miglitol tablet (generic for Glyset) to non-preferred
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

HYPOGLYCEMICS ORAL – BIGUANIDES AND COMBINATIONS

- Recommendation: Add metformin ER tablet (generic for Glumetza) to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

HYPOGLYCEMICS ORAL – DPP IV INHIBITORS AND COMBINATIONS

- Recommendations: Add alogliptin tablet (generic for Nesina), alogliptin-metformin tablet (generic for Kazano), alogliptin-pioglitazone tablet (generic for Orseni), Jentadueto XR Tablet to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

<u>HYPOGLYCEMICS ORAL – SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2)</u> <u>INHIBITOR AND COMBINATIONS</u>

- Recommendations: Move Invokamet Tablet, Invokana Tablet from preferred to non-preferred; move Farxiga Tablet and Jardiance Tablet from non-preferred to preferred; add Invokamet XR tablet, Synjardy XR Table to non-preferred.
- Public Comments: Seven
- Speakers: Seven

- o Julie O'Malley, MSN, Boehringer Ingelheim Jardiance
- Melissa Doyle, FNP-BC, Owner/Clinician Progressive Diabetes Care, PLLC, Johnson & Johnson/Jannsen Pharmaceuticals – Jardiance
- Steve Vacalis, MD, primary care Charlotte Gastonia region Invokana
- o Darlene Wilkins, RN, Med, CDE, E. Brooks Wilkins Family Medicine, PA Invokana
- Charlie Foster, MD, Janssen Invokana
- Michael Pfeifer, MD, Janssen Invokana
- o Dr. Ritesh Patel, CPP, RPh, CDE, BC-ADM, Invokana, Invokamet, Invokamet XR
- Discussion Multiple comments and questions resulted from speaker statements about patients achieving better A1C lowering on Invokana. A comment was made that the relationship between A1C and cardiovascular risk is unclear. The study showing increased risk for amputation with Invokana was mentioned. It was asked if the Invokana safety data was the basis for the change. It was stated that proposing changes to this class was delayed until the Invokana study was published. It was said there was a concern about preferring a drug with a box warning. Additionally, the amputation risk was a concern of the internal medical advisors for the PDL. It was acknowledged that studies are continuing for these drugs but the decision was based on currently available safety and clinical outcome data. Current studies are with Invokana against placebo. Future studies with Invokana compared to other drugs may compel differently. A question about Jardiance and Invokana both having preferred status was asked. It was stated that a negative financial impact could result with utilization shifts. It was stressed that financials did not drive the recommendation. The change was based on the cardiac benefits of Jardiance in the trial and safety concerns around Invokana in the trial study. It was stated that the physician of a patient stable on Invokana can submit a prior authorization request and get approval based on the clinical justification of 'at risk to change therapy'.
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

GASTROINTESTINAL

ANTIEMETIC-ANTIVERTIGO AGENTS

- Recommendations: Move metoclopramide ODT (generic for Reglan) from preferred to nonpreferred; Add metoclopramide ODT (generic for Metozolv), Sustol Injection to non-preferred, move Emend Trifold Pack from preferred to non-preferred; add aprepitant capsule/pack (generic for Emend), Emend Powder Packet to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

BILE ACID SALTS

- Recommendations: Move ursodiol capsule (generic for Actigall) from preferred to nonpreferred; move ursodiol tablet (generic for Urso) from non-preferred to preferred; add Ocaliva Tablet to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

H. PYLORI COMBINATIONS

- Recommendation: Move lansoprazole-amoxicillin-clarithromycin pack (generic for Prevpac) from preferred to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: A question was asked about the tolerability of the preferred and what is the need for a proton pump inhibitor to be taken with the preferred. It was said that Pylera has less tolerability. It was said the cost of the combination is more than covering the ingredients separately.
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

PROTON PUMP INHIBITORS

- Recommendations: Remove Nexium OTC Capsule and Zegerid OTC Capsule from PDL.
- Public Comments: None
- Speakers: None
- Discussion: Per Dr. Elekwa-Izuakor products are not rebateable so removed from PDL.
- Vote: No vote taken

SELECTIVE CONSTIPATION AGENTS

- Recommendations: Move Movantik Tablet from non-preferred to preferred; add Relistor oral Tablet and Trulance to non-preferred.
- Public Comments: Seven
- Speakers: One
 - o Remberto Espinosa, Synergy Pharmaceuticals Trulance
- Discussion: A question about the risk of adverse effects for Trulance and mechanism of action compared to competitor products. It was stated the difference between Trulance and placebo meeting the trial clinical endpoint was modest. A question asked if the mechanism of action for Trulance and Linzess are similar. Trulance and Linzess both work on receptors. Trulance is a human analog with stronger receptor binding. Utilization for Trulance is low and the financial savings are significant.
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

ULCERATIVE COLITIS

- Recommendation: Add mesalamine tablet (generic for Asacol HD) to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

BENIGN PROSTATIC HYPERPLASIA TREATMENTS

- Recommendations: Move dutasteride capsule (generic Avodart) from non-preferred to preferred; add dutasteride/ tamsulosin capsule (generic Jalyn capsule) to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

ELECTROLYTE DEPLETERS

- Recommendation: Move Renvela Powder Pack from non-preferred to preferred.
- Public Comments: None
- Speakers: None
- Discussion: Dr. Elekwa-Izuakor stated the change for this Class was done earlier but wanted to bring to panel for discussion. Panel had no comments.
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

GENITOURINARY / RENAL

URINARY ANTISPASMODICS

- Recommendation: Add darifenacin ER tablet (generic for Enablex) to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

GOUT

ANTIHYPERURICEMICS

- Recommendations: Move colchicine tablet (generic for Colcrys) from preferred to nonpreferred; move colchicine capsule (generic for Mitigare) from non-preferred to preferred; Add Zurampic Tablet to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: A question was asked "is colchicine really an antihyperuricemic". Dr. Elekwa-Izuakor said this class could be renamed. The suggestion was to remove the heading antihyperuricemics and retain the heading Gout.
- Motion with second: Approve all recommendations with suggestion of only retaining the heading "Gout."
- Vote: All in favor. None opposed

HEMATOLOGIC

THROMBOPOIESIS STIMULATING AGENTS

- Recommendations: Neumega Vial is discontinued. Removing from PDL
- Public Comments: None
- Speakers: None
- Vote: No vote taken

OPHTHALMIC

ALLERGIC CONJUNCTIVITIS AGENTS

- Recommendations: Move Pataday Drops, Pazeo Drops from preferred to non-preferred; add olopatadine drops (AG generic for Patanol) to preferred
- Public Comments: None
- Speakers: None

- Discussion: A question was asked if the change was cost based. Response was yes. It is easier to administer once a day but understand cost consideration.
- Motion with second: Approve all recommendations
- Vote: All in favor. None opposed.

ANTI-INFLAMMATORY / IMMUNOMODULATOR

- Recommendations: Add Restatis and Restasis (multidose) to preferred; add Xiidra to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: A question was asked if the placement of drugs in the class was cost based. Response was yes.
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

ANTI INFLAMMATORY / IMMUNOMODULATOR – BETA BLOCKER AGENTS

- Recommendation: Add Betimol Drops to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

OSTEOPOROSIS

BONE RESORPTION SUPPRESSION AND RELATED AGENTS

- Recommendations: Move raloxifene tablet (generic for Evista) from preferred to non-preferred; move Evista Tablet from non-preferred to preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

OTIC

ANTIBIOTICS

- Recommendations: Add Otiprio Suspension, Otovel Drops to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: A question was asked if Otiprio Suspension use in pediatrics should be considered. It was stated the drug is physician administered and billable under physician drug program.
- Motion with second: Approve all recommendations
- Vote: All in favor. None opposed.

RESPIRATORY

BETA ADRENERGIC HANDHELD LONG ACTING

- Public Comments: None
- Speakers: None

- Recommendations: Remove Foradil Aerolizer Capsule from PDL; no longer made.
- Vote: No vote taken.

BETA ADRENERGIC HANDHELD SHORT ACTING

- Recommendation: Add Proair Respiclick to non-preferred
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

COPD AGENTS

- Recommendations: Move Combivent Respimat Inhalation Spray from preferred to nonpreferred; move Stiolto Respimat Inhalation Spray from non-preferred to preferred; add Bevespi Aerosphere to non-preferred.
- Public Comments: None
- Speakers: Two
 - Julie O'Malley, MSN, Boehringer Ingelheim Stiolto
 - Ed Palewonsky, PharmD, Glaxo Smith Kline Anoro Elipta Inhaler and Incruse Elipta Inhaler
- Discussion –It was stated that moving Combivent to non-preferred was done with some concern because of the utilization. A comment was made that commercial payers have moved Combivent to non-preferred status already. It was stated consideration could be given to delaying the implementation of changes in this class to allow transition time.
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

CORTICOSTEROID COMBINATION

- Recommendations: Move Advair HFA Inhaler from preferred to non-preferred
- Public Comments: None
- Speakers: One
 - o Ed Palewonsky, PharmD, Glaxo Smith Kline Breo Elipta
- Discussion: Questions were asked about Breo. It was stated the utilization of Breo is less than one percent and the finances impacted the recommendation. A comment was made that Symbicort is indicated for asthma and COPD. Advair HFA has 6% utilization and it was mentioned easier to use than Diskus so choice for children. It was stated that Symbicort inhaler is approved for six years of age and is a preferred option.
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

INTRANASAL RHINITIS AGENTS

- Recommendations: Move Astepro Nasal Spray, Nasonex Nasal Spray from preferred to nonpreferred; move azelastine spray (generic for Astepro) from non-preferred to preferred; add mometasone nasal spray (generic for Nasonex) to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

LEUKOTRIENE MODIFIERS

- Recommendations: Move Accolate Tablet from preferred to non-preferred; add Zileuton to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

LOW SEDATING ANTIHISTAMINES

- Recommendations: Add Claritin Solution OTC to preferred; move cetirizine OTC syrup 1mg/1ml (generic for Zyrtec OTC Syrup), loratadine OTC ODT / solution (generic for Claritin OTC) from preferred to non-preferred; remove Allegra Allergy OTC Tablet, Allegra Allergy Suspension OTC, cetirizine OTC chewable (generic for Zyrtec OTC), Zyrtec, Claritin OTC from non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: Dr. Elekwa-Izuakor mentioned some products no longer rebateable were removed from the class to clean things up.
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

LOW SEDATING ANTIHISTAMINE COMBINATIONS

- Recommendations: Remove Allegra-D 24 Hour OTC Tablet, Claritin D 12 hour OTC Tablet, Claritin D 24 hour OTC Tablet, fexofenadine-D 12 Hour OTC Tablet (generic for Allegra-D 12 Hour OTC), Zyrtec-D OTC Tablet from non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: Dr. Elekwa-Izuakor mentioned some products no longer rebateable were removed from the class
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

TOPICALS

ACNE AGENTS

- Recommendations: Move clindamycin phosphate gel/lotion (generic for Cleocin-T) from preferred to non-preferred; add clindamycin/benzoyl peroxide with pump (generic for Benzaclin), clindamycin/tretinoin (generic for Veltin), tazarotene Cream to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

NSAIDS

- Recommendations: Add Klofensaid II, Vopac MDS, Xrylix to non-preferred.
- Public Comments: None
- Speakers: None

Discussion: This is a new Class. Products from Anesthetics Class were move here or into the Neuropathic Pain Class. The products keep their PDL status with the move. A question was asked if with change now must fail duloxetine and gabapentin to get lidocaine patches. Response was yes. It was commented the financial impact to make lidocaine patch preferred was significant so remains non-preferred.

- Motion with second: Approve all recommendations
- Vote: All in favor. None opposed.

ANESTHETICS

• Agents in this Class were have moved into the Neuropathic Pain and Topical NSAIDS. No review.

ANTIBIOTIC – VAGINAL

- Recommendation: Move Clindese Vaginal Cream from non-preferred to preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

ANTIFUNGAL

- Recommendations: Move clotrimazole RX solution (generic for Lotrimin RX) from preferred to non-preferred; add Dermacin RX Therazole Pak, Loprox suspension/cream/kit, oxiconazole cream (generic for Oxistat, Xolegel Gel to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

IMMUNOMODULATORS ATOPIC DERMATITIS

- Recommendations: Add Dupixen, Eucrisa 2% Ointment to non-preferred
- Public Comments: Two
- Speakers: One
 - Julie Ann Gouveia-Pisano, BS Pharm, PharmD, BCPS, CPEHR, Pfizer Eucrisa (stand in for registered speaker Dr. Jeffrey Scales, Pfizer who had to leave before Class review.)
- Discussion: Eucrisa does not have black box warning which is very important to prescribers. Elidel has a black box warning which is a concern especially related to children. It was stated with one only preferred agent in this Class trial and failure of one would apply. It was stated Eucrisa data reflected no utilization. Moving Eucrisa to preferred will not impact finance significantly. It was stated that Eucrisa is not a first line option and clinical criteria is in place. It was said thought should be given to having a preferred agent with a black box warning and a non-preferred that does not have the warning.
- Motion with second: Approve recommendations with exception make Eurcisa preferred.
- Vote: All in favor. None opposed.

IMMUNOMODULATORS IMIDAZQUINOLINAMINES

- Recommendations: Move Aldara Cream from preferred to non-preferred; move imiquimod cream packet (generic for Aldara) from non-preferred to preferred
- Public Comments: None

- Speakers: None
- Discussion: A question was asked about the concentrations for the products. It was stated the PDL status applies to all concentrations of the drug.
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

ROSACEA AGENTS

- Recommendations: Move metronidazole cream (generic for MetroCream), metronidazole lotion (generic for MetroLotion) from preferred to non-preferred; move MetroCream from non-preferred to preferred; add Rhofade to non-preferred
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

STEROIDS LOW POTENCY

- Recommendations: Move desonide cream/ointment (generic for DesOwen) from preferred to non-preferred; add Micort-HC Cream to non-preferred
- Public Comments: None
- Speakers: None
- Discussion: A question was asked about recommendations being fiscally based. Response yes. It was stated that desonide is prescribed for use on face, commonly used in pediatrics, and is the intermediary between hydrocortisone and triamcinolone.
- Motion with second: Approve all recommendations; add age exemption for desonide exemption for < 12 years of age and under.
- Vote All in favor. None opposed.

STEROIDS MEDIUM POTENCY

- Recommendations: Add flurandrenolide cream/lotion (generic for Cordran SP cream and Cordran lotion, flurandrenolide ointment (generic for Cordran ointment), Locoid Lotion to non-preferred
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed

STEROIDS HIGH POTENCY

- Recommendations: Move fluocinonide cream/emollient cream/gel (generic for Lidex /Lidex E) from preferred to non-preferred; add Sernivo Spray, Dermacin Silapak, Dermacin RX Silazone, Sanaderm RX Solution, Silazone II, triamcinolone spray (generic for Kenalog Spray), Ellzia to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed

STEROIDS VERY HIGH POTENCY

- Recommendation: Add Ultravate Lotion to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with Second: Approve recommendation.
- Vote: All in favor. None opposed

MISCELLANEOUS

ANTIPSORIATICS, ORAL

- Recommendations: Move Methoxsalen Rapid (generic for Oxsoralen-Ultra), Soriatane from preferred to non-preferred; move Acitretin (generic for Soriatane) from non-preferred to preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed

EPINEPHRINE, SELF INJECTED

- Recommendations: Move Adrenaclick Auto Injector, epinephrine auto injector (generic for Adrenaclick), from preferred to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: Question was asked if change was financial. The move was around utilization strongly favoring epinephrine.
- Motion with second: Approve all recommendations.
- Vote: All in favor. None opposed.

ESTROGEN AGENTS, VAGINAL PREPARATIONS

- Recommendation: Add Yuvafem to non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: None
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

Glucocorticoid Steroids, Oral

- Recommendation: Add Emflaza to non-preferred
- Public Comments: None
- Speakers: One
 - Syed Mahamud, MD, MPH, PTC Therapeutics Emflaza
- Discussion: A question was asked if diagnosis based clinical criteria will apply for Emflaza. It was stated the internal clinical review has not completed. Prior approval for Emflaza will require clinical justification. It was stated the cost of Emflaza is extremely high and supposedly cost significantly less outside of the US. It was stated there is a difference between Emflaza and prednisone. A comment was made most patients will have tried two preferred products and criteria will be specific to the drug so approval can be obtained. There is no intent for patients to have to retry older products for this class. A fail one preferred for Emflaza only, not the entire class, was suggested. Response was that can be considered in the internal review process.

- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

IMMUNOMODULATORS, SYSTEMIC

- Recommendations: Add Arcalyst SQ Syringe, Orencia SQ Clickjet, Orencia Vial, Ilaris Injection, Inflectra Vial, Remicade Injection, Talz Auto-injector/syringe, XeljanzXR and Siliq to non-preferred. Removal of trial and failure of only one preferred agent required.
- Public Comments: Five
- Speakers: Three
 - o Leanne Skipper, Arthritis Foundation, North Carolina Immunomodulators in general
 - Rebecca Widdicombe, Pfizer Xeljanz
 - o Shilpa Patel, PharmD, Novartis Cosentyx
- Discussion: Dr. Elekwa-Izuakor mentioned these injections are available through the physician drug program without prior authorization. A question was asked if the clinical criteria is based on indication. It was stated that each drug in this class has criteria specific to the drug. This class is heavily dependent on indications since some of the drugs have one indication only. It was clarified methotrexate is not on the PDL and does not require prior authorization. The rationale to try more than one Tumor Necrosis Factor (TNF) drug was discussed. Currently class is trial and failure of two preferred. It was said trying more than one TNF may not be real world practice and may not mirror current treatment steps. A purpose for this PDL class is management when these drugs are obtained through a specialty pharmacy
- Motion with second: Approve all recommendations; keep class trial and failure of one (clinical criteria remains).
- Vote: All in favor. None opposed.

IMMUNOSUPPRESANTS

- Recommendations: Add Gengraf Capsule / Solution added to preferred.
- Public Comments: None
- Speakers: Two
 - Daniel Stevens, PharmD, Veloxis Pharmaceuticals Envarsus XR (waived time to speak)
 - Mark Mocerion, Veloxis Pharmaceuticals, Envarsus XR (waived time to speak)
- Discussion: None
- Motion with second: Approve recommendation.
- Vote: All in favor. None opposed.

SKELATAL MUSCLE RELAXANTS

- Recommendations: Remove carisoprodol tablet /compound tablet (generic for Soma /Compound) and Soma Tablet from non-preferred.
- Public Comments: None
- Speakers: None
- Discussion: Per Dr. Elekwa-Izuakor included for informational purposes only.
- Vote: No vote taken.

Everyone was thanked for their attendance and service.

The meeting adjourned at 4:24PM.