

**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PREFERRED DRUG LIST REVIEW PANEL MEETING  
THURSDAY APRIL 11, 2024 1:00PM – 5:00PM  
VIRTUAL ONLINE MEETING PLATFORM**

**I. WELCOME, INTRODUCTIONS, OVERVIEW**

Facilitator, Dr. Randall Johnson, the NC Medicaid Outpatient Pharmacy lead pharmacist for the Preferred Drug List (PDL) began the virtual meeting by welcoming all attendees to the second quarterly PDL review meeting for 2024. Dr. Johnson thanked the PDL panel members for their important contribution to the PDL, to the NC Medicaid program and to beneficiary health. He acknowledged their dedication and graciously volunteered time to serve on the PDL Review Panel. A roll call of the PDL Panel members followed. The PDL panel members in attendance and organization representing are listed:

- Angela B. Smith, PharmD, DHA, FACHE, Pharmacist, Pharmacy Director, NC Division of Health Benefits
- Matt Webber, PharmD, Pharmacist, Hospital-Based Pharmacy
- Aaron Garst, PharmD, Pharmacist, Community Care of North Carolina
- Arpit Bhatt, PharmD, Pharmacist, NC Association of Pharmacists
- Anna Miller-Fitzwater, MD, Physician, NC Pediatric Society
- Duncan Vincent, MD, FACP, Physician, NC Chapter of the American College of Physicians
- Jessica Triche, MD, Physician, NC Academy of Family Physicians
- Lawrence Greenblatt, MD, Physician, NC Physician Advisory Group; Pharmacy and Therapeutics Committee

Procedures and guidelines for the meeting were reviewed. Within 7 days after the meeting, participants with comments about the PDL or its content can send an email to [Medicaid.PDL@dhhs.nc.gov](mailto:Medicaid.PDL@dhhs.nc.gov).

The guidelines for making a motion and voting were stated for the PDL panel review members. Voting is verbal by responding Aye or Nay to the motion. The procedures and guidelines for the registered speakers were explained. Speakers must state their name, affiliation, if being compensated for the product presentation, and any potential conflicts. Three minutes are allowed to present, and information should focus on recent changes or updates for the drug. Panel members can ask questions after the presentation.

Brief historical information about the PDL and the PDL Panel Review Committee was given.

- 2009 - PDL was authorized by NC Legislation to ensure access to cost efficient and medically appropriate drug therapies that maximize health outcomes for all NC Medicaid beneficiaries.
- 2010 - PDL Review Panel established by legislation. An open meeting was mandated to review PDL recommendations and written public comments received.
- 2023 - General Assembly codified the PDL as G.S. 108A-68.1A [Session Law 2023-134, Sections 9E.17(a)-(d)]. The Legislation establishes the composition of the Review Panel, the cadence of PDL Review Panel meetings [once per quarter], a public comment period, and procedure for the Review Panel to make recommendations to the Secretary of DHHS.
- 2023 - DHB shortened the PDL public comment period from 45 to 30 days to accommodate quarterly review.

The recommendations approved by the PDL Review Panel are submitted to the DHHS Secretary for final approval. The PDL with recommendations from this meeting become effective July 1, 2024. The next PDL panel review meeting will be July 11, 2024. The PDL Panel meetings will occur in January, April, July, and October.

Dr. Johnson did an overview of the PDL prior to starting the category reviews.

- The general guidance is trial and failure of two preferred products. Exceptions are noted on the PDL document.
- Clinical criteria requirements, in addition to trial and fail, are indicated in red writing.

- Color coding on the PDL is informational and serves to identify the type of change.
- On file additions are recommendations when the NDC for the drug was already on the PDL file with the status indicated in the recommendation but the drug name did not appear on the PDL external document.
- Brand Generic Switch: the brand product and equivalent generic product switch PDL status.
- Off-Cycle Change: Product status change made outside of the scheduled PDL review cycle. Off-cycle changes are allowed when there is 1) significant financial impact for the State, 2) a product shortage or other access issue, 3) patient safety is at risk.
- Beginning in 2022, every PDL category is reviewed at least once annually, even if there are no recommended changes from the State. The categories are open for discussion and a PDL panel member can introduce a motion for change.

## **II. CATEGORY REVIEWS**

### **ANALGESICS**

#### **SHORT ACTING SCHEDULE III – IV OPIOIDS / ANALGESIC COMBINATIONS**

- Recommendation: Add the new to market product tramadol tablet (25 mg) as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

#### **NEUROPATHIC PAIN**

- Recommendation: Add the new to market products Lidocan™ II / III (lidocaine) Patch as Non- Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

**MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR SHORT ACTING SCHEDULE III – IV OPIOIDS / ANALGESIC COMBINATIONS AND NEUROPATHIC PAIN.**

**VOTE: ALL IN FAVOR. NONE OPPOSED.**

### **ANTICONVULSANTS**

#### **SECOND GENERATION**

- Recommendation: Add the new to market product Motopoly XR™ (lacosamide extended release) Capsule as Non-Preferred; Generic Over Brand Switch: move rufinamide suspension (generic for Banzel®) to Preferred and move Banzel® Suspension to Non-Preferred; On file addition: add Vigadrone® (vigabatrin) Tablet as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

**MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR SECOND GENERATION ANTICONVULSANTS.**

**VOTE: ALL IN FAVOR. NONE OPPOSED.**

### **ANTI-INFECTIVES – SYSTEMIC ANTIBIOTICS**

#### **LINCOSAMIDES AND OXAZOLIDINONES**

- Recommendation: OPEN CLASS – NO RECOMMENDATIONS

- Public Comments: None
- Speakers: None
- Discussion: None

#### **NITROMIDAZOLES (GASTROINTESTINAL ANTIBIOTICS)**

- Recommendation: Add the new to market product Likmez™ (metronidazole) Suspension as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

#### **ANTIVIRALS (HERPES TREATMENTS)**

- Recommendation: OPEN CLASS – NO RECOMMENDATIONS
- Public Comments: None
- Speakers: None
- Discussion: None

### **BEHAVIORAL HEALTH**

#### **ANTIDEPRESSANTS, OTHER**

- Recommendation: Add the new to market product Zurzuvae™ (zuranolone) Capsule as Non-Preferred; Generic-Over-Brand Switch: move vilazodone tablet (generic for Viibryd®) to Preferred and move Viibryd® Tablet to Non-Preferred
- Public Comments: Two
- Speakers: Two
  - Ronnie DePue, Axsome Therapeutics, Inc, Auvelity
  - Daphne Ni, Biogen, Zurzuvae
- Discussion Points:
  - The possibility of an exemption for Zurzuvae for postpartum depression diagnosis was raised.
  - Ensuing discussion concluded lack of studies with direct comparison of Zurzuvae with current standard of care is a significant consideration.
  - More information may be available in the future to drive a change to Preferred status.
  - Trial and failure of two preferred drugs applies to drugs within the category.

#### **MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR NITROMIDAZOLES (GASTROINTESTINAL ANTIBIOTICS) AND ANTIDEPRESSANTS, OTHER (THIS MOTION EXCLUDED ZURZUVAE RECOMMENDATION)**

**VOTE: ALL IN FAVOR. NONE OPPOSED.**

**MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATION TO ADD ZURZUVAE AS NON-PREFERRED.**

**VOTE: ALL IN FAVOR. NONE OPPOSED.**

#### **ANTIHYPERKINESIS / ADHD**

- Recommendation: Add the new to market product amphetamine salt combo ER capsule (generic for Mydayis®) as Non-Preferred
- Public Comments: One
- Speakers: None
- Discussion Point: None

#### **INJECTABLE ANTIPSYCHOTICS, LONG ACTING**

- Recommendation: Add the new to market product risperidone ER vial (generic for Risperdal® Consta) as Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

#### **ATYPICAL ANTIPSYCHOTICS, ORAL / TOPICAL**

- Add the new to market product Rexulti® (brexpiprazole) 7-Day / 14-Day Titration Pack as Non-Preferred; Generic-Over-Brand Switch: move paliperidone ER tablet (generic for Invega®) to Preferred and move Invega® Tablet to Non-Preferred
- Public Comments: One
- Speakers: One
  - Margaret Martin, IntraCellular Therapies, Caplyta
- Discussion: None

#### **MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ANTIHYPERKINESIS / ADHD, INJECTABLE ANTIPSYCHOTICS - LONG ACTING, AND ATYPICAL ANTIPSYCHOTICS, ORAL / TOPICAL**

**VOTE: ALL IN FAVOR. NONE OPPOSED.**

#### **CARDIOVASCULAR**

##### ***ACE INHIBITOR / DIURETIC COMBINATIONS***

- Recommendation: OPEN CLASS – NO RECOMMENDATIONS
- Public Comments: None
- Speakers: None
- Discussion: None

##### ***ANGIOTENSIN II RECEPTOR BLOCKER COMBINATIONS***

- Recommendation: OPEN CLASS – NO RECOMMENDATIONS
- Public Comments: None
- Speakers: None
- Discussion: None

##### ***ANGIOTENSIN II RECEPTOR BLOCKER DIURETIC COMBINATIONS***

- Recommendation: OPEN CLASS – NO RECOMMENDATIONS
- Public Comments: None
- Speakers: None
- Discussion: None

##### ***ANGIOTENSIN II RECEPTOR / NEPRILYSIN BLOCKER COMBINATIONS***

- Recommendation: OPEN CLASS – NO RECOMMENDATIONS
- Public Comments: None
- Speakers: None
- Discussion: None

##### ***ANTI-ARRHYTHMICS***

- Recommendation: OPEN CLASS – NO RECOMMENDATIONS
- Public Comments: None
- Speakers: None
- Discussion: None

### ***BETA BLOCKERS***

- Recommendation: OPEN CLASS – NO RECOMMENDATIONS
- Public Comments: None
- Speakers: None
- Discussion: None

### ***BETA BLOCKERS DIURETIC COMBINATIONS***

- Recommendation: OPEN CLASS – NO RECOMMENDATIONS
- Public Comments: None
- Speakers: None
- Discussion: None

### ***BILE ACID SEQUESTRANTS***

- Recommendation: OPEN CLASS – NO RECOMMENDATIONS
- Public Comments: None
- Speakers: None
- Discussion: None

### **CHOLESTROL LOWERING AGENTS**

- Recommendation: Add the new to market product pitavastatin tablet (generic for Livalo®) as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion Points:
  - Pitavastatin was studied as primary prevention for people living with HIV disease. It showed benefits. It showed a favorable drug to drug interaction profile with antiretroviral therapy. Making it available for an individual on HIV therapy is a plus.
  - Treatment with a statin is a pretty universal recommendation for people over 40 living with HIV disease. Pitavastatin is the best studied and safest within the statins with concomitant ART therapy.
  - Cost is considered in the evaluation process to determine PDL status for a product. Newer generics can be more costly initially compared to the brand product.
  - The brand product, Livalo® is Non-Preferred on the PDL.

**MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR CHOLESTROL LOWERING AGENTS. ADD A TRIAL AND FAILURE EXEMPTION FOR CONCOMITANT ANTIRETROVIRAL THERAPY IN PATIENTS DIAGNOSED WITH HIV.**

**VOTE: ALL IN FAVOR. NONE OPPOSED.**

## **ENDOCRINOLOGY**

### **LONG-ACTING INSULIN**

- Recommendation: Add the new to market product insulin glargine SoloStar® / Max SoloStar® (generic for Toujeo®) as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

### **DPP-IV INHIBITORS AND COMBINATIONS**

- Recommendation: Add the new to market product Zituvio™ (sitagliptin) Tablet as Non-Preferred
- Public Comments: None

- Speakers: None
- Discussion: None

#### **SGLT2 INHIBITOR AND COMBINATIONS**

- Recommendation: Add the new to market products dapagliflozin tablet (generic for Farxiga®) and dapagliflozin / metformin ER tablet (generic for Xigduo® XR) as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

#### **MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR LONG-ACTING INSULIN, DPP-IV INHIBITORS AND COMBINATIONS, SGLT2 INHIBITOR AND COMBINATIONS**

**VOTE: ALL IN FAVOR. NONE OPPOSED**

### **GASTROINTESTINAL**

#### **ANTIEMETIC-ANTIVERTIGO AGENTS**

- Recommendation: On-file additions - Add Promethegan® (promethazine) Suppository (12.5 mg and 25 mg) as Preferred; add Promethegan® Suppository (50 mg) as Non-Preferred
- Public Comments: One
- Speakers: None
- Discussion: None

#### **H. PYLORI COMBINATIONS**

- Recommendation: Add the new to market product Voquezna® (vonoprazan) Tablet / Dual Pak (vonoprazan / amoxicillin) / Triple Pak (vonoprazan / amoxicillin / clarithromycin) as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

#### **ELECTROLYTE DEPLETERS (KIDNEY DISEASE)**

- Recommendation: Add the new to market product Xphozah® (tenapanor) Tablet as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

#### **MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ANTIEMETIC-ANTIVERTIGO AGENTS, H. PYLORI COMBINATIONS AND ELECTROLYTE DEPLETERS (KIDNEY DISEASE)**

**VOTE: ALL IN FAVOR. NONE OPPOSED.**

### **GENITOURINARY / RENAL**

#### **URINARY ANTISPASMODICS**

- Recommendation: On file addition - add oxybutynin solution (generic for Ditropan®) as Preferred
- Public Comments: None
- Speakers: One
  - Jeffrey Nesheim, Sumitomo-Pharma America, Gemtesa
- Discussion: None

## **HEMATOLOGIC**

### **COLONY STIMULATING FACTORS**

- Recommendation: Add the new to market product Udenyca® (pegfilgrastim-cbqv) On-Body as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

## **OPHTHALMIC**

### **ANTI-INFLAMMATORY**

- Recommendation: Add the new to market products bromfenac 0.07% drops (generic for Prolensa®) and loteprednol 0.2% drops (generic for Alrex®) as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

### **MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR URINARY ANTISPASMODICS, COLONY STIMULATING FACTORS AND ANTI-INFLAMMATORY (OPHTHALMIC)**

**VOTE: ALL IN FAVOR. NONE OPPOSED**

### **ANTI-INFLAMMATORY / IMMUNOMODULATOR**

- Recommendation: Add the new to market product Vevye® (cyclosporine) Drops as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

## **OSTEOPORESIS**

### **BONE RESORPTION SUPPRESSION AND RELATED AGENTS**

- Recommendation: On file addition - add Binosto® (alendronate sodium) Effervescent Tablet and risedronate DR tablet (generic for Atelvia®) as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

## **RESPIRATORY**

### **BETA ADRENERGIC HANDHELD, SHORT-ACTING**

- Recommendation: On file addition - add ProAir® (albuterol sulfate) HFA inhaler as Preferred
- Public Comments: None
- Speakers: None
- Discussion Point:
  - Active NDCs were found for ProAir® HFA so adding back to PDL in preferred status

### **MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ANTI-INFLAMMATORY / IMMUNOMODULATOR (OPHTHALMIC), BONE RESORPTION SUPPRESSION AND RELATED AGENTS, AND BETA-ADRENERGIC HANDHELD, SHORT-ACTING**

**VOTE: ALL IN FAVOR. NONE OPPOSED.**

## **TOPICALS**

### **ACNE AGENTS**

- Recommendations: Add the new to market products Cabtreo™ (clindamycin / adapalene / benzoyl peroxide) Gel and clindamycin-benzoyl peroxide pump (generic for Onexton®) as Non-Preferred Move BP® 10-1 Wash / Cleansing Wash from Preferred to Non-Preferred Add Sumadan® (sodium sulfacetamide-sulfur) Wash as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

**MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ACNE AGENTS**

**VOTE: ALL IN FAVOR. NONE OPPOSED.**

### **ANTIFUNGALS**

- Recommendation: On file addition - add Klayesta® (nystatin) Powder as Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

### **IMMUNOMODULATORS - ATOPIC DERMATITIS**

- NOTE: RECOMMENDATION RESCINDED AFTER PDL POSTED FOR PUBLIC COMMENT.
- Public Comments: None
- Speakers: One
  - Joe Cirrincione, Incyte, Opzelura
- Discussion Points: The posted recommendation [add new to market product Zoryve® (roflumilast) Foam as Non-Preferred] was rescinded. Dr. Johnson shared, after the PDL was posted for public comment, DHB learned the Zoryve® Foam is currently indicated only for seborrheic dermatitis, not atopic dermatitis. The PDL does not have an appropriate market basket and clinical position for it at this time. It is covered by NC Medicaid and is treated as preferred. It will not be reviewed nor require a vote. Zoryve® will be left as non-reviewed.

### **IMIDAZOQUINOLINAMINES**

- Recommendation: Add the new to market product podofilox gel (generic for Condylox®) as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

## **MISCELLANEOUS**

### **GLUCOCORTICOID STEROIDS, ORAL**

- Recommendations: Move Emflaza® Tablet from Non-Preferred to Preferred
- Public Comments: None
- Speakers: None
- Discussion Points:
  - The reason for not moving Emflaza suspension to Preferred also was asked.
  - Children on Emflaza that cannot take tablets need the suspension.



- The generic for Emflaza tablet is more costly than the brand at this time; there is no generic available for Emflaza suspension currently.

**MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ANTIFUNGALS, IMIDAZOQUINOLINAMINES AND GLUCOCORTICOID STEROIDS, ORAL. ADD A TRIAL AND FAILURE EXEMPTION FOR PATIENTS <12 YEARS OF AGE FOR EMFLAZA® SUSPENSION**

**VOTE: ALL IN FAVOR. NONE OPPOSED**

**CYTOKINE AND CAM (CELL ADHESION MOLECULE) ANTAGONISTS**

- Recommendations: Add the following new to market products as Non-Preferred: Bimzelx® (bimekizumab-bkzx) Autoinjector / Syringe; Cosentyx® (secukinumab) Vial; Entyvio® (vedolizumab) Pen; Omvoh™ (mirikizumab-mrkz) Pen / Vial; Velsipity® (etrasimod) Tablet  
Add the following new to market products (Humira® biosimilars) as Non-Preferred: Abrilada™ (adalimumab-afzb) Pen / Syringe; adalimumab-aacf Pen; Yuflyma® (adalimumab-aaty) Crohn's-UC-HS Autoinjector
- Public Comments: None
- Speakers: Two
  - Uche Ndefo, UCB, Inc., Bimzelx
  - Olaide Akingbade, AbbVie, Skyrizi and Rinvoq
- Discussion Points:
  - The drugs in this category were listed previously as “Immunomodulators, Systemic”
  - The category name was changed to help distinguish the wide range of immunomodulator products on the PDL.
  - Trial and failure of only one preferred drug is required in this category.

**MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR CYTOKINE AND CAM ANTAGONISTS**

**VOTE: ALL IN FAVOR. NONE OPPOSED**

**MOVEMENT DISORDERS**

- Recommendation: Add the new to market product Austedo® XR (deutetrabenazine) Titration Kit as Preferred
- Public Comments: None
- Speakers: None
- Discussion Point:
  - Adding the XR Titration Kit as Preferred allows providers to transition patients from the titration kit to the standalone Austedo® XR tablets (also Preferred).

**DIABETIC CONTINUOUS GLUCOSE MONITOR SUPPLIES**

**CONTINUOUS GLUCOSE MONITOR TRANSMITTERS / RECEIVERS / READERS**

- Recommendation: Off-cycle change: add the new to market product Freestyle Libre™ 3 Reader as Preferred
- Public Comments: None
- Speakers: None
- Discussion Points:
  - The reader was added to the PDL off-cycle to provide Freestyle Libre™ 3 access for beneficiaries who may not have or want to use a smartphone to monitor their glucose readings.

**MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR MOVEMENT DISORDERS AND CONTINUOUS GLUCOSE MONITOR TRANSMITTERS / RECEIVERS / READERS.**

**VOTE: ALL IN FAVOR. NONE OPPOSED**

**PRODUCT REMOVAL SUMMARY**

The following products indicated on the posted PDL in purple highlight are removed from the PDL due to manufacturer discontinuation of the product or removal from CMS' list of rebateable products.

Kadian <sup>®</sup> Capsule	Adlyxin <sup>®</sup> Pen
Sezaby <sup>™</sup> Vial	cimetidine solution (generic for Tagamet <sup>®</sup> )
Suprax <sup>®</sup> Capsule / Chewable	Phoslyra <sup>®</sup> Solution
minocycline ER capsule (Generic for Ximino <sup>™</sup> ER)	Ditropan <sup>®</sup> XL Tablet
Hepsera <sup>®</sup> Tablet	Ciloxan <sup>®</sup> Drops
Viekira <sup>™</sup> Pak	Tobrex <sup>®</sup> Drops
Adhansia <sup>™</sup> XR Capsule	Qalsody <sup>™</sup> Vial
Catapres <sup>®</sup> TTS Patch	FML <sup>®</sup> S.O.P. Ointment
Onzetra <sup>™</sup> Xsail <sup>™</sup> Nasal Powder	Boniva <sup>®</sup> Tablet
Treximet <sup>®</sup> Tablet	Promiseb <sup>®</sup> Topical Cream
Silenor <sup>®</sup> Tablet	Tretin-X <sup>™</sup> Combo Pack / Cream
Zorbtive <sup>®</sup> Vial	Loprox <sup>®</sup> Shampoo
Humalog <sup>®</sup> U-100 Tempo Pen <sup>™</sup>	ivermectin lotion (generic for Sklice <sup>®</sup> )
Lyumjev <sup>™</sup> Tempo Pen <sup>™</sup>	Luxiq <sup>®</sup> Foam
Basaglar <sup>®</sup> Tempo Pen <sup>™</sup>	Sanaderm <sup>®</sup> Rx Solution
Olux <sup>®</sup> E-Foam	Temovate <sup>®</sup> Cream
Veozah <sup>™</sup> Tablet	Ortikos <sup>™</sup> Capsule
Omnipod GO <sup>™</sup>	Dexcom G7 <sup>®</sup> Transmitter
neomycin-polymyxin-HC ointment (generic for Ocutricin <sup>®</sup> )	
sodium sulfacetamide-sulfur kit (generic for Sumadan <sup>®</sup> )	

**ADJOURNMENT**

- Recommendation: PDL Review is completed. Adjourn meeting 2:50 PM.
- Motion with second: Adjourn meeting.
- Vote: All in favor. None opposed.