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

I. WELCOME, INTRODUCTIONS, OVERVIEW

Moderator, 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 third 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 represented 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
- Linda Johnson, BSN, RN, Nurse, Research-Based Pharmaceutical Company
- Lawrence Greenblatt, MD, Physician, NC Physician Advisory Group; Pharmacy and Therapeutics Committee

Guidance for meeting attendees was 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.

The procedures 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. Speaker guidelines 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.

A brief legislative history about the PDL and the PDL Panel Review Committee was shared.

- 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 was established by legislation to review the PDL recommendations received from the Department of Health and Human Services, North Carolina Medicaid and the Physician Advisory Group Pharmacy and Therapeutics Committee to classify prescription medications as either Preferred or Non-Preferred on the PDL. An open meeting was mandated to review the 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 policy shortened the PDL public comment period from 45 to 30 days to accommodate the quarterly review cadence.
- Legislation mandates the PDL Review Panel consist of the Director of Pharmacy for North Carolina Medicaid and individuals appointed by the Secretary of the Department of Health and Human Services representing the

organizations listed in legislation. Individuals appointed to the PDL Review Panel, except for the Director of Pharmacy for North Carolina Medicaid, shall serve a two-year term.

The recommendations approved by the PDL Review Panel are submitted to the DHHS Secretary for final approval.

The PDL with recommendations from this meeting will become effective on October 1, 2024.

The next PDL panel review meeting will be held on Thursday October 10, 2024. The PDL Panel meetings occur quarterly in January, April, July and October.

An overview of the PDL was provided prior to starting the category reviews:

- Trial and failure of two Preferred drugs is required unless only one Preferred option is listed, or a trial and failure exemption is otherwise indicated on the document.
- Clinical criteria requirements are indicated in red writing.
- Color coding on the PDL posted for public comment 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 external PDL document.
- Brand-Generic Switch: the brand product and equivalent generic product switch PDL status.
- Off-Cycle Update: 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.
- 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

LONG-ACTING OPIOIDS

- Recommendation: Add Methadose™ (methadone) Oral Concentrate / Tablet as Non-Preferred (on-file addition)
- Public Comments: None
- Speakers: None
- Discussion: None

SHORT ACTING SCHEDULE III – IV OPIOIDS / ANALGESIC COMBINATIONS

- Recommendation: Add Qdolo™ (tramadol) Solution as Non-Preferred (on-file addition)
- Public Comments: None
- Speakers: None
- Discussion: None

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

VOTE: ALL IN FAVOR. NONE OPPOSED.

NSAIDS

- Recommendation: Add Naprosyn® (naproxen) Suspension and tolmetin capsule (generic for Tolectin® DS) as Non-Preferred (on-file additions), Move naproxen sodium tablet (generic for Anaprox®) from Non-Preferred to Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

NEUROPATHIC PAIN

- Recommendation: Add the new to market product gabapentin ER tablet (generic for Gralise®) as Non-Preferred, Add Tridacaine™ (lidocaine) Patch as Non-Preferred (on-file addition)
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR NSAIDS AND NEUROPATHIC PAIN.

VOTE: ALL IN FAVOR. NONE OPPOSED.

ANTICONVULSANTS

CARBAMAZEPINE DERIVATIVES

- Recommendation: Move carbamazepine suspension / tablet / XR tablet (generic for Tegretol®/ XR) from Non-Preferred to Preferred, Move carbamazepine ER capsule (generic for Carbatrol®) from Preferred to Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

FIRST GENERATION

- Recommendation: Add Sezaby® (phenobarbital sodium) Vial as Non- Preferred (on-file addition)
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR CARBAMAZEPINE DERIVATIVES AND FIRST-GENERATION ANTICONVULSANTS.

VOTE: ALL IN FAVOR. NONE OPPOSED.

SECOND GENERATION

- Recommendation: Add Vigpoder™ (vigabatrin) Powder Packet as Non-Preferred (on-file addition)
- Public Comments: None
- Speakers: None
- Discussion: None

ANTI-INFECTIVES – SYSTEMIC ANTIBIOTICS

NITROMIDAZOLES (GASTROINTESTINAL ANTIBIOTICS)

- Recommendation: Move vancomycin oral solution (generic for Firvanq®) from Non-Preferred to Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR SECOND GENERATION ANTICONVULSANTS AND NITROMIDAZOLES (GASTROINTESTINAL ANTIBIOTICS).

VOTE: ALL IN FAVOR. NONE OPPOSED.

BEHAVIORAL HEALTH

ANTIDEPRESSANTS / OTHER

- Recommendation: Move Pristiq® ER Tablet from Preferred to Non-Preferred
- Public Comments: Two
- Speakers: Two
  - Ronnie DePue, Axsome Therapeutics, Inc, Auvelity
  - Daphne Ni, Biogen, Zurzuvae
- Discussion Points:
  - The Non-Preferred position for Zurzuvae is appropriate at this time from a clinical perspective, particularly when comparing the drug to the other, more established and experienced treatment options in this category.

ATYPICAL ANTIPSYCHOTICS, ORAL / TOPICAL

- Add Nuplazid® (pimavanserin) Tablet / Capsule as Non-Preferred (on-file addition)
- Public Comments: Two
- Speakers: One
  - Timothy Birner, Alkermes, Lybalvi
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ANTIDESPRESSANTS / OTHER AND ATYPICAL ANTIPSYCHOTICS, ORAL / TOPICAL

VOTE: ALL IN FAVOR. NONE OPPOSED.

CARDIOVASCULAR

BETA BLOCKERS

- Recommendation: Move Hemangeol® Solution and nebivolol tablet (generic for Bystolic®) from Non-Preferred to Preferred
- Public Comments: None
- Speakers: None
- Discussion Point:
  - With the move from non-preferred to preferred, a diagnosis exemption for infantile hemangioma is no longer needed for Hemangeol®.

DIHYDROPYRIDINE CALCIUM CHANNEL BLOCKERS

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

ENDOTHELIN RECEPTOR ANTAGONISTS

- Recommendation: Add new to market product Opsynvi® (macitentan / tadalafil) Tablet as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR BETA BLOCKERS AND ENDOTHELIN RECEPTOR ANTAGONISTS

VOTE: ALL IN FAVOR. NONE OPPOSED.

INHALED PROSTACYCLIN ANALOGS

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

NIACIN DERIVATIVES

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

NITRATE COMBINATION

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

NON-DIHYDROPYRIDINE CALCIUM CHANNEL BLOCKERS

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

ANTI-ANGINAL & ANTI-ISCHEMIC

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

SYMPATHOLYTICS AND COMBINATIONS

- Recommendation: Add Nexiclon™ (clonidine) XR Tablet as Non-Preferred (on-file addition)
- Public Comments: None
- Speakers: None
- Discussion: None

TRIGLYCERIDE LOWERING AGENTS

- Recommendation: Add Fibricor® (fenofibric acid) Tablet as Non-Preferred (on-file addition)
- Public Comments: None
- Speakers: None
- Discussion Points: None

CARDIOVASCULAR, OTHER

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

CENTRAL NERVOUS SYSTEM

AMYOTROPHIC LATERAL SCLEROSIS (ALS) AGENTS

- Recommendation: Add Qalsody® (tofersen) Vial as Non-Preferred (on-file addition), Off-cycle change: Remove Relyvrio™ Powder Packet

- Public Comments: None
- Speakers: None
- Discussion Points:
  - Trial and failure of an ALS drug is largely determined by the clinician and details on the patient's response to therapy (or lack thereof) would be provided in the PA request for a non-preferred drug.
  - Relyvrio™ was voluntarily discontinued and removed from market by manufacturer effective April 2024.

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR SYMPATHOLYTICS AND COMBINATIONS, TRIGLYCERIDE LOWERING AGENTS AND AMYOTROPHIC LATERAL SCLEROSIS (ALS) AGENTS

VOTE: ALL IN FAVOR. NONE OPPOSED.

SMOKING CESSATION

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

ENDOCRINOLOGY

SHORT-ACTING INSULIN

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

GLP-1 RECEPTOR AGONISTS AND COMBINATIONS

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

HYPOGLYCEMICS – ORAL - DPP-IV INHIBITORS AND COMBINATIONS

- Recommendation: Add new to market product sitagliptin tablet (generic for Januvia®) as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

GASTROINTESTINAL

SELECTIVE CONSTIPATION AGENTS

- Recommendation: Off-cycle change: Move lubiprostone capsule (generic for Amitiza®) from Non-Preferred to Preferred
- Public Comments: None
- Speakers: None
- Discussion Point:
  - The off-cycle update was due to an access concern stemming from discontinuation of brand Amitiza® by original manufacturer in April 2024.

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR DPP-IV INHIBITORS AND COMBINATIONS AND SELECTIVE CONSTIPATION AGENTS

VOTE: ALL IN FAVOR. NONE OPPOSED

GENITOURINARY / RENAL

URINARY ANTISPASMODICS

- Recommendations: Add new to market product mirabegron ER Tablet (generic for Myrbetriq®) as Non-Preferred with a trial and failure exemption for diagnosis of dementia or mild cognitive impairment, Move tolterodine tablet / ER capsule (generic for Detrol® / LA) and fesoterodine ER tablet (generic for Toviaz®) from Non-Preferred to Preferred
- Public Comments: None
- Speakers: None
- Discussion Points:
  - Brand Myrbetriq® has a trial and failure exemption for diagnosis of dementia or mild cognitive impairment
  - The population of beneficiaries aged 65 or older using the Medicaid drug benefit is likely very low. Mirabegron is preferred for individuals aged 65 and over in general, even without dementia or cognitive impairment.
  - A trial and failure exemption for beneficiaries aged 65 and older for mirabegron should be considered. DHB would also need to consider updating the trial and failure criteria for Myrbetriq®.

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR URINARY ANTISPASMODICS AND ADD A TRIAL AND FAILURE EXEMPTION FOR BENEFICIARIES AGED 65 AND OLDER FOR MIRABEGRON ER TABLET (GENERIC FOR MYRBETRIQ®).

VOTE: ALL IN FAVOR. NONE OPPOSED

HEMATOLOGIC

COLONY STIMULATING FACTORS

- Recommendation: Move Fulphila® Syringe from Non-Preferred to Preferred, Move Nyvepria™ Syringe from Preferred to Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

THROMBOPOIESIS STIMULATING AGENTS

- Recommendation: Add new to market product Alvaiz™ (eltrombopag) Tablet as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

OPHTHALMIC

ANTI-INFLAMMATORY

- Recommendation: Add new to market product bromfenac 0.075% drops (generic for BromSite®) as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR COLONY STIMULATING FACTORS, THROMBOPOIESIS STIMULATING AGENTS, AND

ANTI-INFLAMMATORY

VOTE: ALL IN FAVOR. NONE OPPOSED

ANTI-INFLAMMATORY / IMMUNOMODULATOR

- Recommendation: Move Eysuvis® Drops from Preferred to Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

PROSTAGLANDIN AGONISTS

- Recommendation: Add iDose® TR (travoprost intracameral) Implant as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

TOPICALS

ACNE AGENTS

- Recommendation: Move clindamycin phosphate gel / lotion (generic for Cleocin-T®, Clindagel®) from Non-Preferred to Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

HIGH POTENCY STEROIDS

- Recommendation: Move fluocinonide cream / gel (generic for Lidex®) from Non-Preferred to Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ANTI-INFLAMMATORY / IMMUNOMODULATOR, PROSTAGLANDIN AGONISTS, ACNE AGENTS, AND HIGH POTENCY STEROIDS

VOTE: ALL IN FAVOR. NONE OPPOSED

MISCELLANEOUS

WEIGHT MANAGEMENT AGENTS

- Recommendation: Off-Cycle Update: Add Wegovy® (semaglutide) Pen as Preferred [covered only for the cardiovascular risk reduction indication]
- Public Comments: One
- Speakers: One
    - Lydia Wang, Novo Nordisk, Wegovy
- Discussion Points:
    - Weight Management Agents is a new PDL category.
    - Pediatric beneficiaries currently have access to weight loss medication through EPSDT.
    - Real world study data for weight loss medications show discontinuation rates around 75% after two years.
    - Even though preferred, PA is required for Wegovy coverage. It will not have auto approved PAs.
    - Wegovy is currently covered by NC Medicaid only for the reduction of major adverse cardiovascular [CV] events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV disease who are either obese or overweight.

- Full coverage of weight loss agents by the State is pending.

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATION FOR WEIGHT MANAGEMENT AGENTS

VOTE: ALL IN FAVOR. NONE OPPOSED

ESTROGEN AGENTS, ORAL / TRANSDERMAL

- Recommendation: Add Osphena® (ospemifene) Tablet as Non-Preferred (on-file addition)
- Public Comments: None
- Speakers: None
- Discussion: None

GLUCOCORTICOID STEROIDS, ORAL

- Recommendation: Add new to market products deflazacort tablet (generic for Emflaza®) and Eohilia® (budesonide) Suspension as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion Points:
  - According to the manufacturer, Eohilia® is the only FDA-approved oral treatment for eosinophilic esophagitis in patients 11 years of age and older.
  - A trial and failure exemption for the diagnosis should be considered to make it clear to providers that preferred products do not have to be trued first.

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ESTROGEN AGENTS, ORAL / TRANSDERMAL. APPROVE PROPOSED RECOMMENDATIONS FOR GLUCOCORTICOID STEROIDS, ORAL WITH TRIAL AND FAIL EXEMPTION FOR EOHILIA FOR DIAGNOSIS OF EOSINOPHILIC ESOPHAGITIS.

VOTE: ALL IN FAVOR. NONE OPPOSED

CYTOKINE AND CAM (CELL ADHESION MOLECULE) ANTAGONISTS

- Recommendations:
  - Add the following new to market products as Non-Preferred: adalimumab-aaty Autoinjector / Syringe; adalimumab-ryvk Autoinjector; Simlandi® (adalimumab-ryvk) Autoinjector; Spevigo® (spesolimab-sbzo) Syringe; Tyenne® (tocilizumab-aazg) Vial and Zymfentra™ (infliximab-dyyb) Pen / Syringe
  - Move from Non-Preferred to Preferred: adalimumab-adaz Pen / Syringe, adalimumab-fkjp Pen / Syringe, Hadlima™ Syringe / PushTouch, and Otezla® Starter Pack / Tablet
- Public Comments: None
- Speakers: Two
  - Olaide Akingbade, AbbVie, Rinvoq
  - Olaide Akingbade, AbbVie, Skyrizi
  - Mimo Odebiyi, Teva Pharmaceuticals, Simlandi
- Discussion: None

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

VOTE: ALL IN FAVOR. NONE OPPOSED

DISPOSABLE INSULIN DELIVERY DEVICES

DISPOSABLE INSULIN DELIVERY DEVICES

- Recommendation: Off-cycle change: Add new to market product Omnipod 5® G7 Pods / G7 Intro Kit as Preferred
- Public Comments: None
- Speakers: None
- Discussion Point:
  - The off-cycle update was made to provide beneficiaries with access to products compatible for use with their Dexcom system.

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATION FOR DISPOSABLE INSULIN DELIVERY DEVICES

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.

Mobic® Tablet
Gabitril® Tablet
Viibryd® Starter Pack
Desoxyn® Tablet
Minitran® Patch
Antara® Capsule
Zomig® ZMT® Tablet
Humalog® 50/50 Mix Vial
metoclopramide ODT
Renagel® Tablet
Jalyn® Capsule
Avita® Cream
Metrogel® Vaginal Gel
clocortolone pump (generic for Cloderm®)

ADJOURNMENT

- Recommendation: PDL Review is completed. Adjourn meeting 2:52 PM.
- Motion with second: Adjourn meeting.
- Vote: All in favor. None opposed.