

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
2022 PREFERRED DRUG LIST REVIEW PANEL MEETING
THURSDAY JULY 13, 2023 1:00PM – 5PM
VIRTUAL ONLINE MEETING PLATFORM

I. WELCOME AND INTRODUCTIONS

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 PDL review meeting scheduled for 2023. 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
- Tommy Newton, MD, Physician, Community Care of North Carolina
- Arpit Bhatt, PharmD, Pharmacist, NC Association of Pharmacists
- Anna Miller-Fitzwater, MD, Physician, NC Pediatric Society
- Theodore Zarzar, MD, Physician, NC Psychiatric Association
- Duncan Vincent, MD, FACP, Physician, NC Chapter of the American College of Physicians
- Jessica Triche, MD, Physician, NC Academy of Family Physicians
- Linda Johnson, BSN, RN, Nurse, Research-Based Pharmaceutical Company
- Lawrence Greenblatt, MD, Physician, NC Physician Advisory Group; Pharmacy and Therapeutics Committee

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 comments 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 was given. The PDL was authorized by NC Legislation in 2009. It was implemented to ensure access to cost efficient, as well as medically appropriate drug therapies that maximize health outcomes for all NC Medicaid beneficiaries. Legislation established the PDL Review Panel in 2010 and mandated an open meeting to review recommendations along with written public comments received during the 45 day posting period for public comment. The recommendations approved by the PDL Review Panel are submitted to the DHHS Secretary for final approval.

Dr. Angela Smith, the Medicaid Pharmacy Director, shared an updated about the Tailored Plan implementation. The six Tailored Plans (TP) will not launch on October 1, 2023, as planned. A new launch date is not yet determined. The Division remains committed to the implementation of TPs which will service approximately 160,000 individuals who have complex behavioral health conditions, intellectual and developmental disabilities (IDD), and traumatic brain injury (TBI).

In late February 2023, DHHS identified three key areas necessary for a smooth transition for beneficiaries into a TP.

- LME MCO provider network and technical capabilities readiness.

- DHHS equipped with the appropriate legal tools to ensure the well-being and safety of members if an LME MCOs is failing to provide services adequately.
- LME MCO focused on providing services for the population they are best positioned to manage successfully.

Individuals expected to enter TP enrollment will continue to receive behavioral health, IDD and TBI and physical health care as they do today. DHB will continue to work closely with the LME MCOs to launch tailored plans on the fastest timeline that can guarantee a smooth transition.

Dr. Johnson provided some key upcoming dates for the pharmacy program. The next PDL update will post October 1, 2023, and will reflect recommendations approved today. The next PDL meeting is January 11, 2024. The next DUR Board meeting is July 27, 2023.

Dr. Johnson did an overview of the PDL prior to starting the Category review.

- The general guidance is trial and failure of two preferred products. Exceptions are noted on the PDL.
- 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 Move - Product status change made in accordance with Legislative guidance permitting changes outside of schedule PDL Panel cycle. Off cycle moves are allowed when there is significant financial impact to the State, there is a product shortage/access issue, or patient safety is at risk.
- Beginning in 2022, every PDL category is reviewed annually. Open categories without recommendations meet the annual review cycle cadence. The categories are open for discussion and a Panel member can introduce a motion for changes.

II. CATEGORY REVIEWS

ALZHEIMER'S AGENTS

- Recommendation: Add new to market product Leqembi[®] (lecanemab-irmb) Vial as Non-Preferred.
- Public Comments: None
- Speakers: None
- Discussion:
 - Drug coverage approval for the Alzheimer's category is according to the approved clinical criteria for the drug.
 - The criteria approved for coverage in the Alzheimer Agent category does not include trial and failure of a non-preferred.
 - Coverage of Leqembi[®] as a first line agent would be evaluated case by case, according to the approved criteria.
 - Clinical Criteria apply will appear for Leqembi[®] on the updated PDL, pursuant to approval of proposed recommendations.

ANALGESICS

LONG ACTING OPIOIDS

- Recommendation: OPEN CLASS
- Public Comments: None
- Speakers: None
- Discussion: None

ORALLY DISENGRATING /ORAL SPRAY SCHEDULE II OPIOIDS

- Recommendation: OPEN CLASS
- Public Comments: None
- Speakers: None
- Discussion: None

SHORT ACTING SCHEDULE II OPIOIDS

- Clinical criteria apply to all drugs in this class
- Recommendation: Add Prolate[®] (oxycodone/acetaminophen) Solution and Roxybond[®] (oxycodone) Tablet as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ALZHEIMER'S AGENTS AND ANALGESICS - SHORT ACTING SCHEDULE II OPIOIDS

VOTE: ALL IN FAVOR. NONE OPPOSED.

NEUROPATHIC PAIN

- Recommendation: On-file addition - add Gralise[®] (gabapentin) Tablet as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

ANTICONVULSANTS

CARBAMAZEPINE DERIVATIVES

- Recommendation: Move Trileptal[®] Suspension from Non-Preferred to Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

SECOND GENERATION

- Recommendation: Add the new to market product topiramate ER capsule (generic for Trokendi XR[®]) as Non-Preferred with trial and failure criteria (trial and failure of Trokendi XR[®] Capsule); move Subvenite[®] Tab Start Kit from Non-Preferred to Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR NEUROPATHIC PAIN, ANTICONVULSANTS - CARBAMAZEPINE DERIVATIVES, AND SECOND GENERATION.

VOTE: ALL IN FAVOR. NONE OPPOSED.

ANTI-INFECTIVES – SYSTEMIC ANTIBIOTICS

PENICILLINS, CEPHALOSPORINS AND RELATED

- Recommendation: Add Augmentin[®] (amoxicillin-clavulanate) Suspension / ES-600 / XR Tablet as Non-Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

MACROLIDES AND KETOLIDES

- Recommendations: Move Eryped[®] 200/400 Suspension from Preferred to Non-Preferred and move erythromycin ethylsuccinate (200 mg and 400 mg) from Non-Preferred to Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

NITROMIDAZOLES (GASTROINTESTINAL ANTIBIOTICS)

- Recommendation: Add the new to market product vancomycin oral solution (generic for Firvanq[™]) as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ANTI-INFECTIVES – PENICILLINS, CEPHALOSPORINS AND RELATED, MACROLIDES AND KETOLIDES, AND NITROMIDAZOLES (GASTROINTESTINAL ANTIBIOTICS).

VOTE: ALL IN FAVOR. NONE OPPOSED.

QUINOLONES

- Recommendation: OPEN CLASS
- Public Comments: None
- Speakers: None
- Discussion: None

SYSTEMIC ANTIFUNGALS

- Recommendation: Add the new to market product Noxafil[®] (posaconazole) DR suspension packet as Non-Preferred; on file addition - add Oravig[®] (miconazole) Buccal Tablet as Non-Preferred.
- Public Comments: None
- Speakers: None
- Discussion Points: None

ANTIVIRALS (HEPATITIS C AGENTS)

- Recommendation: Move Pegasys[®] Vial from Non-Preferred to Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR SYSTEMIC ANTIFUNGALS AND ANTIVIRALS (HEPATITIS C AGENTS).

VOTE: ALL IN FAVOR. NONE OPPOSED.

ANTIVIRALS (INFLUENZA)

- Recommendation: Move Tamiflu® Capsule / Suspension from Preferred to Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None.

ANTIBIOTICS, INHALED

- Recommendation: Move tobramycin inhalation solution (generic for Tobi™) from Non-Preferred to Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ANTIVIRALS (INFLUENZA) AND ANTIBIOTICS, INHALED.

VOTE: ALL IN FAVOR. NONE OPPOSED.

BEHAVIORAL HEALTH

ANTIDEPRESSANTS, OTHER

- Recommendations: Add the new to market product Auvelity® (dextromethorphan/bupropion) Tablet as Non-Preferred, move Viibryd® Tablet from Non-Preferred to Preferred
- Public Comments: One
- Speakers: Two
 - Charlotte Wincott, Axsome Therapeutics - Auvelity®
 - Alexandra Infanzon, Hickory Psychiatric Center - Auvelity®
- Discussion Points:
 - Trial and failure of a SSRI and SNRI product would be considered in the clinical review for coverage.
 - Starter Paks can be more expensive. The recommendation to move the Viibryd® Tablet and not the Start Pak was most likely related to cost.

SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRI)

- Recommendation: Move paroxetine suspension (generic for Paxil® Suspension) from Preferred to Non-Preferred and move Paxil® Suspension from Non-Preferred to Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ANTIDEPRESSANTS – OTHER AND SRRI.

VOTE: ALL IN FAVOR. NONE OPPOSED.

ANTIHYPERKINESIS / ADHD

- Recommendation: Add the new to market products Xelstrym[®] (dextroamphetamine) Patch and methylphenidate ER tablet 45 mg and 63 mg - Branded Product Named as a Generic per FDA as Non-Preferred; Move Focalin[®] Tablet / XR Capsule from Preferred to Non-Preferred; Move dexmethylphenidate tablet / ER capsule (generic for Focalin[®] / XR) from Non-Preferred to Preferred; move methylphenidate solution (generic for Methylin[®]) from Non-Preferred to Preferred; Off-cycle changes: Move Adderall[®] Tablet, amphetamine salt combo XR capsule (generic for Adderall[®] XR), and methylphenidate ER tablet (generic for Concerta[®] Tablet) from Non-Preferred to Preferred.
- Public Comments: None
- Speakers: None
- Discussion Point: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ANTIHYPERKINESIS / ADHD.

VOTE: ALL IN FAVOR. NONE OPPOSED.

ATYPICAL ANTIPSYCHOTICS ORAL / TOPICAL

- Recommendation: Add the new to market product lurasidone tablet (generic for Latuda[®]) as Preferred; Move Latuda[®] Tablet from Preferred to Non-Preferred
- Public Comments: None
- Speakers: One
 - Margaret Martin, IntraCellular Therapies - Caplyta[®]
- Discussion: None

CARDIOVASCULAR

ACE INHIBITOR

- Recommendation: OPEN CLASS
- Public Comments: None
- Speakers: None
- Discussion: None

ACE INHIBITOR / CALCIUM CHANNEL BLOCK COMBINATIONS

- Recommendation: OPEN CLASS
- Public Comments: None
- Speakers: None
- Discussion: None

CHOLESTEROL LOWERING AGENTS

- Recommendation: Add the new to market product Atorvaliq[®] (atorvastatin) Suspension as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ATYPICAL ANTIPSYCHOTICS ORAL / TOPICAL AND CHOLESTEROL LOWERING AGENTS.

VOTE: ALL IN FAVOR. NONE OPPOSED.

ORAL PULMONARY HYPERTENSION

- Recommendation: Add the new to market products Tadliq[®] (tadalafil) Suspension and Orenitram[®] (trepostinil) Titration Kit as Non-Preferred
- Public Comments: None
- Speakers: One
 - Kimberly Simpson, United Therapeutics - Orenitram[®]
- Discussion: None

PLATELET INHIBITORS

- Recommendation: On file addition - add aspirin-omeprazole DR tablet as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

SYMPATHOLYTICS AND COMBINATIONS

- Recommendation: Add the new to market product clonidine ER tablet (generic for Nexiclon[™] XR) as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ORAL PULMONARY HYPERTENSION, PLATELET INHIBITORS, AND SYMPATHOLYTICS AND COMBINATIONS.

VOTE: ALL IN FAVOR. NONE OPPOSED.

TRIGLYCERIDE LOWERING AGENTS

- Recommendation: Move omega-3 acid ethyl esters capsule (generic for Lovaza[®]) and Vascepa[®] Capsule from Non-Preferred to Preferred; (removal of exemption for patients with triglycerides \geq 500mg/dl from Lovaza[®] Capsule, accordingly)
- Public Comments: None
- Speaker: None
- Discussion: None

CENTRAL NERVOUS SYSTEM

ANTIMIGRAINE AGENTS

- Recommendations: Add the new to market product diclofenac potassium powder packet (generic for Cambia[®]) as Non-Preferred with trial and failure criteria (trial and failure of 2 preferred NSAIDs, in addition to trial and failure of 2 preferred triptans in the Antimigraine Agents class).
 - Public Comments: None
 - Speakers: None
 - Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR TRIGLYCERIDE LOWERING AGENTS AND ANTIMIGRAINE AGENTS.

VOTE: ALL IN FAVOR. NONE OPPOSED.

ANTIMIGRAINE AGENTS; CGRP BLOCKERS/MODULATORS: PREVENTATIVE

- Recommendation: Move Ajovy[®] Injection and Nurtec[®] ODT from Non-Preferred to Preferred
- Public Comment: One
- Speakers: One
 - Nicole Abolins, Pfizer - Nurtec[®] ODT
- Discussion: None

ANTIMIGRAINE AGENTS; CGRP BLOCKERS/MODULATORS: ACUTE TREATMENT

- Recommendation: Move Nurtec[®] ODT from Non-Preferred to Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

ANTI-PARKINSON AND RESTLESS LEG SYNDROME AGENTS

- Recommendations: On file additions - add bromocriptine capsule (generic for Parlodel[®]) as Preferred, add Kynmobi[™] (apomorphine) Titration Kit as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ANTIMIGRAINE AGENTS CGRP BLOCKERS/MODULATORS PREVENTATIVE AND ACUTE TREATMENT AND ANTI-PARKINSON AND RESTLESS LEG SYNDROME AGENTS

VOTE: ALL IN FAVOR. NONE OPPOSED.

MULTIPLE SCLEROSIS: INJECTABLE

- Recommendations: Add the new to market product Briumvi[™] (ublituximab-xiiy) Vial as Non-Preferred, move Kesimpta[®] Injection from Non-Preferred to Preferred
- Public Comments: None
- Speakers: Two
 - Kristin Duffey, Novartis - Kesimpat[®]
 - Vynedra Smith, Genentech - Ocrevus[®]
- Discussion: None

MULTIPLE SCLEROSIS: ORAL

- Recommendations: Add the new to market products fingolimod capsule (generic for Gilenya[®]) and teriflunomide tablet (generic for Aubagio[®]) as Preferred, move Gilenya[®] Capsule from Preferred to Non-Preferred.
- Public Comments: None
- Speakers: One
 - Daphne Ni, Biogen - Vumerity[®]
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR MULTIPLE SCLEROSIS: INJECTABLE AND MULTIPLE SCLEROSIS ORAL

VOTE: ALL IN FAVOR. NONE OPPOSED.

AMYOTROPHIC LATERAL SCLEROSIS (ALS) AGENTS

- Recommendations: Note - New drug category addition. Add riluzole tablet (generic for Rilutek®) as Preferred; add Exservan™ (riluzole) Oral Film, Tiglutik® (riluzole) Suspension, Radicava® (edaravone) Injection / ORS® Suspension, Relvyrio™ (sodium phenylbutyrate / taurursodiol) Suspension as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR AMYOTROPHIC LATERAL SCLEROSIS (ALS) AGENTS.

VOTE: ALL IN FAVOR. NONE OPPOSED.

SEDATIVE HYPNOTICS

- Recommendations: Add tasimelteon capsule (generic for Hetlioz®) as Non-Preferred with trial and failure criteria (Trial and Failure of Hetlioz® Capsule); on file additions - add Doral® Tablet and quazepam tablet (generic for Doral®) as Non-Preferred; Move eszopiclone tablet (generic for Lunesta®), ramelteon tablet (generic for Rozerem® Tablet), zaleplon capsule (generic for Sonata®) from Non-Preferred to Preferred:
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR SEDATIVE HYPNOTICS.

VOTE: ALL IN FAVOR. NONE OPPOSED

ENDOCRINOLOGY

GROWTH HORMONE

- Recommendation: Move Serostim® Vial from Preferred to Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

HYPOGLYCEMICS – INJECTABLE - RAPID ACTING INSULIN

- Recommendation: Add the new to market products Humalog® (insulin lispro) Tempo Pen™ and Lyumjev® (insulin lispro-aabc) Tempo Pen™ as Non-Preferred; move Humalog® U-100

Cartridge and insulin aspart U-100 FlexPen® / vial (generic for Novolog®) from Non-Preferred to Preferred

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

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR GROWTH HORMONE AND HYPOGLYCEMICS – INJECTABLE RAPID ACTING INSULIN.

VOTE: ALL IN FAVOR. NONE OPPOSED

HYPOGLYCEMICS – INJECTABLE - INTERMEDIATE ACTING INSULIN

- Recommendation: Add Novolin® N FlexPen® and ReliOn® N FlexPen® as Non-Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

HYPOGLYCEMICS – INJECTABLE - LONG ACTING INSULIN

- Recommendations: Add the new to market products Basaglar® (insulin glargine) Tempo Pen™ and Rezvoglar™ (insulin glargine-aglr) Kwikpen® as Non-Preferred; on file addition - add Levemir® FlexPen® as Preferred; off-cycle change: move Lantus® Solostar® / Vial from Non-Preferred to Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR HYPOGLYCEMICS – INJECTABLE - INTERMEDIATE ACTING INSULIN AND INJECTABLE - LONG ACTING INSULIN.

VOTE: ALL IN FAVOR. NONE OPPOSED

DPP-IV INHIBITORS AND COMBINATIONS

- Recommendation: Move Jentadueto® XR Tablet from Non-Preferred to Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

GASTROINTESTINAL

ANTIEMETIC-ANTIVERTIGO AGENTS

- Recommendation: Add the new to market product Aponvie™ (aprepitant) Vial as Non-Preferred; On file addition - add metoclopramide ODT as Non-Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

H. PYLORI COMBINATIONS

- Recommendation: Add the new to market product bismuth / metronidazole / tetracycline capsule (generic for Pylera®) as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussions: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR DDP-IV INHIBITORS AND COMBINATION; ANTIEMETIC-ANTIVERTIGO AGENTS AND H.PYLORI COMBINATIONS

VOTE: ALL IN FAVOR. NONE OPPOSED.

PROTON PUMP INHIBITORS

- Recommendation: Add the new to market product Konvomep™ (omeprazole / sodium bicarbonate) Suspension as Non-Preferred; move Dexilant® Capsule from Non-Preferred to Preferred; on file addition - add Aciphex® Tablet and omeprazole / sodium bicarbonate packet as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None.

SELECTIVE CONSTIPATION AGENTS

- Recommendation: Move Movantik® Tablet from Preferred to Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

ULCERATIVE COLITIS – RECTAL

- Recommendation: Move Canasa® Suppository from Preferred to Non-Preferred and move mesalamine suppository (generic for Canasa® Suppository) from Non-Preferred to Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None.

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR PROTON PUMP INHIBITORS, SELECTIVE CONSTIPATION AGENTS AND ULCERATIVE COLITIS – RECTAL

VOTE: ALL IN FAVOR. NONE OPPOSED

ELECTROLYTE DEPLETERS (KIDNEY DISEASE)

- Recommendation: Move Renvela® Powder Pack from Non-Preferred to Preferred and move sevelamer carbonate powder pack (generic for Renvela® Powder Pack) from Preferred to Non-Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

GENITOURINARY / RENAL

BENIGN PROSTATIC HYPERPLASIA TREATMENTS

- Recommendation: Add the new to market product Entadfi™ (finasteride / tadalafil) Capsule as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

URINARY ANTISPASMODICS

- Recommendation: Add the new to market product oxybutynin tablet (2.5 mg tablet) as Non-Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ELECTROLYTE DEPLETERS (KIDNEY DISEASE), BENIGN PROSTATIC HYPERPLASIA TREATMENTS AND URINARY ANTISPASMODICS

VOTE: ALL IN FAVOR. NONE OPPOSED

GOUT

- Recommendation: Add the new to market product allopurinol tablet (200 mg) as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

HEMATOLOGIC

ANTICOAGULANTS – ORAL

- Recommendation: Add the new to market product Pradaxa® (dabigatran) Pellet Pack as Non-Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

COLONY STIMULATING FACTORS

- Recommendation: Add the new to market products Fylnetra® (pegfilgrastim-pbbk) Syringe and Stimufend® (pegfilgrastim-fpgk) Syringe as Non-Preferred, on file addition - add Rolvedon™ (eflapegrastim-xnst) Syringe as Non-Preferred, move Nivestym™ Syringe from Preferred to Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR GOUT, ANTICOAGULANTS – ORAL, AND COLONY STIMULATING FACTORS.

VOTE: ALL IN FAVOR. NONE OPPOSED

HEMATOPOIETIC AGENTS

- Recommendation: Move Epogen[®] Vial and Retacrit[®] Vial from Non-Preferred to Preferred; move Procrit[®] Vial from Preferred to Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

OPHTHALMIC

ALLERGIC CONJUNCTIVITIS AGENTS

- Recommendation: Move olopatadine drops (generic for Patanol[®]) from Non-Preferred to Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR HEMATOPOIETIC AGENTS AND ALLERGIC CONJUNCTIVITIS AGENTS.

VOTE: ALL IN FAVOR. NONE OPPOSED

ANTI-INFLAMMATORY

- Recommendation: Move Durezol[®] Drops from Preferred to Non-Preferred and move difluprednate drops (generic for Durezol[®]) from Non-Preferred to Preferred, move Nevanac[®] Droptainer from Non-Preferred to Preferred, move Ilevro[®] Drops from Preferred to Non-Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATION FOR OPHTHALMIC ANTI-INFLAMMATORY.

VOTE: ALL IN FAVOR. NONE OPPOSED.

ANTI-INFLAMMATORY / IMMUNOMODULATOR

- Recommendation: Add the new-to-market product Verkazia[®] (cyclosporine) Eye Emulsion as Non-Preferred.
- Public Comments: None
- Speakers: One
 - Rebecca Wenig, Santen - Verkazia[®]

- Discussion:
 - A clinical exemption can be recommended for a new to market drug added to the PDL.

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATION FOR OPHTHALMIC ANTI-INFLAMMATORY / IMMUNOMODULATORS; IN ADDITION, ADD AN EXEMPTION FOR VERKAZIA® FOR VERNAL KERATOCONJUNCTIVITIS (VKC) .

VOTE: ALL IN FAVOR. NONE OPPOSED.

ALPHA 2 ADRENERGIC AGENTS

- Recommendation: OPEN CLASS
- Public Comments: None
- Speakers: None
- Discussion: None

CARBONIC ANHYDRASE INHIBITORS / COMBINATIONS

- Recommendation: OPEN CLASS
- Public Comments: None
- Speakers: None
- Discussion: None

PROSTAGLANDIN AGONISTS

- Recommendation: Add the new to market products tafluprost drops (generic for Zioptan®) and Durysta® (bimatoprost) Implant (intracameral) as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

RHO KINASE MODIFIERS / COMBINATIONS

- Recommendation: OPEN CLASS
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR PROSTAGLANDIN AGONISTS.

VOTE: ALL IN FAVOR. NONE OPPOSED.

BONE RESORPTION SUPPRESSION AND RELATED AGENTS

- Recommendation: OPEN CLASS
- Public Comments: None
- Speakers: None
- Discussion: None

OTIC

ANTIBIOTICS

- Recommendation: OPEN CLASS
- Public Comments: None
- Speakers: None
- Discussion: None

ANTI-INFECTIVES AND ANESTHETICS

- Recommendation: OPEN CLASS
- Public Comments: None
- Speakers: None
- Discussion: None

RESPIRATORY

BETA-ADRENERGIC HANDHELD, LONG ACTING

- Recommendation: OPEN CLASS
- Public Comments: None
- Speakers: None
- Discussion: None

BETA-ADRENERGIC HANDHELD, SHORT ACTING

- Recommendation: Move Xopenex[®] HFA Inhaler from Non-Preferred to Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

BETA-ADRENERGIC, NEBULIZERS

- Recommendation: Change category to trial and failure of only one preferred drug.
- Public Comments: None
- Speakers: None
- Discussion: None

BETA-ADRENERGIC, ORAL

- Recommendation: Move albuterol tablets (generic for Proventil[®] Repetabs) from Non-Preferred to Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR BETA-ADRENERGIC HANDHELD SHORT ACTING, BETA ADRENERGIC NEBULIZERS AND BETA ADRENERGIC ORAL.

VOTE: ALL IN FAVOR. NONE OPPOSED.

ORALLY INHALED ANTICHOLINERGICS / COPD AGENTS

- Recommendation: Add the new to market product roflumilast tablet (generic for Daliresp[®]) as Preferred, move Bevespi[®] Aerosphere[®] from Preferred to Non-Preferred; move Incruse[®] Ellipta[®] Inhaler from Non-Preferred to Preferred

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

INHALED CORTICOSTEROID COMBINATIONS

- Recommendation: Add the new to market product fluticasone/salmeterol HFA inhaler (generic for Advair® HFA) as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ORALLY INHALED ANTICHOLINERGICS / COPD AGENTS AND INHALED CORTICOSTEROID COMBINATIONS.

VOTE: ALL IN FAVOR. NONE OPPOSED

INTRANASAL RHINITIS AGENTS

- Recommendation: Move Dymista® Nasal Spray from Non-Preferred to Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

LEUKOTRIENE MODIFIERS

- Recommendation: OPEN CLASS
- Public Comments: None
- Speakers: None
- Discussion: None

LOW SEDATING ANTIHISTAMINES

- Recommendation: On file addition - add cetirizine OTC soft gel as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR INTRANASAL RHINITIS AGENTS AND LOW SEDATING ANTIHISTAMINES.

VOTE: ALL IN FAVOR. NONE OPPOSED

FIRST GENERATION ANTIHISTAMINES

- Recommendation: Note - New PDL drug category; add carbinoxamine solution, cyproheptadine syrup / tablet, hydroxyzine capsule / solution / tablet as preferred; add carbinoxamine tablet, clemastine tablet, Karbinal™ ER (carbinoxamine) Suspension with trial and failure criteria (Trial and failure of Immediate release carbinoxamine solution and cetirizine syrup), RyClora™

(dexchlorpheniramine) Solution, RyVent™ (carbinoxamine) Tablet, Vistaril® (hydroxyzine pamoate) Capsule as Non-Preferred.

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

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR FIRST GENERATION ANTIHISTAMINES.

VOTE: ALL IN FAVOR. NONE OPPOSED.

TOPICALS

ACNE AGENTS

- Recommendations: Add the new to market product Zma Clear™ (sulfacetamide sodium/sulfur) Cleanser as Non-Preferred; move erythromycin gel (generic for Emcin®, Erycette®, EryDerm®, EryGel®, EryMax®), adapalene / benzoyl peroxide (generic for Epiduo® Gel), Finacea® Gel from Non-Preferred to Preferred; move adapalene gel pump (generic for Differin®) and Retin-A® Micro Pump Gel from Preferred to Non-Preferred, on file additions - add Avar-E® LS (sodium sulfacetamide/sulfur) Cream and Clindacin® P (clindamycin) Foam as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion:
 - Finacea® Gel is indicated for Acne and Rosacea. It is also in the Rosacea PDL category.

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR ACNE AGENTS.

VOTE: ALL IN FAVOR. NONE OPPOSED.

ANDROGENIC AGENTS

- Recommendation: Off-cycle change: Move testosterone gel pump (generic for AndroGel® Pump, Fortesta®) from Non-Preferred to Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

ANTIBIOTICS

- Recommendation: OPEN CLASS
- Public Comments: None
- Speakers: None
- Discussion: None

ANTIFUNGALS

- Recommendation: On file addition - add salicylic acid ointment (generic for Bensal HP®) as Non-Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR TOPICAL ANDROGENIC AGENTS AND ANTIFUNGAL AGENTS.

VOTE: ALL IN FAVOR. NONE OPPOSED

ANTIPARASITICS

- Recommendation: OPEN CLASS
- Public Comments: None
- Speakers: None
- Discussion: None

ANTIVIRAL

- Recommendation: Add new to market product penciclovir cream (generic for Denavir[®] Cream) as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

IMMUNOMODULATORS - ATOPIC DERMATITIS

- Recommendation: Move Dupixent[®] Injection and Dupixent[®] Pen from Non-Preferred to Preferred
- Public Comments: None
- Speakers: One
 - Tenicia Talley, Sanofi - Dupixent[®]
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR TOPICAL ANTIVIRAL AND IMMUNOMODULATORS – ATOPIC DERMATITIS

VOTE: ALL IN FAVOR. NONE OPPOSED.

PSORIASIS

- Recommendations: Move calcipotriene solution (generic for Dovonex[®]) from Non-Preferred to Preferred
- Public Comments: None
- Speakers: None
- Discussion Point: None

ROSACEA AGENTS

- Recommendations: Add the new to market product brimonidine gel pump (generic for Mirvaso[®]) as Non-Preferred, move Finacea[®] Gel and Rosadan[®] Cream / Gel from Non-Preferred to Preferred
- Public Comments: None
- Speakers: None
- Discussion: None.

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR PSORIASIS AND ROSACEA AGENTS.

VOTE: ALL IN FAVOR. NONE OPPOSED

STEROIDS - LOW POTENCY

- Recommendations: Move desonide cream / ointment (generic for DesOwen®) from Non-Preferred to Preferred (removal of the exemption for children < 12 years of age, accordingly).
- Public Comments: None
- Speakers: None
- Discussion: None.

STEROIDS - MEDIUM POTENCY

- Recommendation: OPEN CLASS
- Public Comments: None
- Speakers: None
- Discussion: None.

STEROIDS - HIGH POTENCY

- Recommendation: Move fluocinonide ointment (generic for Lidex® ointment) and fluocinonide solution (generic for Lidex® solution) from Non-Preferred to Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

STEROIDS - VERY HIGH POTENCY

- Recommendation: On file addition - add ApexiCon® E (diflorasone) Cream as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR STERIODS – LOW POTENCY, STEROIDS HIGH POTENCY AND STEROIDS VERY HIGH POTENCY

VOTE: ALL IN FAVOR. NONE OPPOSED

MISCELLANEOUS

EPINEPHRINE, SELF-INJECTED

- Recommendation: On file addition - add Auvi-Q® (epinephrine) Auto Injector as Non-Preferred, move epinephrine auto injector (generic for Epi-Pen® Auto Injector) and epinephrine JR (generic for Epi-Pen® JR Auto Injector) from Non-Preferred to Preferred.
- Public Comments: None
- Speakers: None
- Discussion Point:

PROGESTATIONAL AGENTS

- Recommendation: Off-cycle change: Remove Makena® (hydroxyprogesterone caproate injection) Auto Injector, hydroxyprogesterone caproate injection (generic for Makena®) single

dose vial, hydroxyprogesterone caproate injection (generic for Makena[®]) multi dose vial, and Compounded 17P

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

ESTROGEN AGENTS ORAL / TRANSDERMAL

- Recommendation: Add the new to market product estradiol gel packet (generic for Divigel[®]) as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion Point:

ESTROGEN AGENTS VAGINAL PREPARATIONS

- Recommendation: OPEN CLASS
- Public Comments: None
- Speakers: None
- Discussion: None.

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR EPINEPHRINE, SELF INJECTED, PROGESTATIONAL AGENTS AND ESTROGEN AGENTS - ORAL / TRANSDERMAL

VOTE: ALL IN FAVOR. NONE OPPOSED.

IMMUNOMODULATORS, SYSTEMIC

- Recommendations: Add the new to market product Amjevita[™] (adalimumab-atto) Syringe / Autoinjector as Non-Preferred, move infliximab injection (generic for Remicade[®]) from Non-Preferred to Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

MOVEMENT DISORDERS

- Recommendation: Add the new to market product Austedo[®] XR (deutetrabenazine) Tablet as Non-Preferred
- Public Comments: None
- Speakers: One
 - Olawemimo Odebiyi, Teva Pharmaceuticals - Austedo[®] XR
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR IMMUNOMODULATORS – SYSTEMIC AND MOVEMENT DISORDERS.

VOTE: ALL IN FAVOR. NONE OPPOSED

HEREDITARY ANGIOEDEMA (HAE) PROPHYLAXIS AGENTS

- Recommendation: Note - New drug category addition, add Haegarda® (C1 Esterase Inhibitor Subcutaneous [Human]) Vial and Orladeyo® (berotralstat) Capsule as Preferred, add Cinryze® (C1 Esterase Inhibitor [Human]) Vial and Takhzyro® (lanadelumab-flyo) Vial / Syringe as Non-Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

HEREDITARY ANGIOEDEMA (HAE) TREATMENT AGENTS

- Recommendation: Note - New drug category addition, add Berinert® (C1 Esterase Inhibitor [Human]) Vial, icatibant injection (generic for Firazyr® Injection), and Kalbitor® (ecallantide) Vial as Preferred, add Firazyr® (icatibant) Injection and Ruconest® (C1 esterase inhibitor [recombinant]) Vial as Non-Preferred.
- Public Comments: None
- Speakers: None
- Discussion: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR HEREDITARY ANGIOEDEMA (HAE) PROPHYLAXIS AGENTS AND HEREDITARY ANGIOEDEMA (HAE) TREATMENT AGENTS

VOTE: ALL IN FAVOR. NONE OPPOSED

SKELETAL MUSCLE RELAXANTS

- Recommendations: Add the new to market product baclofen suspension (generic for Fleqsuvy™) as Non-Preferred, On file additions – add Norgesic™ (orphenadrine/aspirin/caffeine) Tablet, orphenadrine-aspirin-caffeine tablet, and Orphengesic® Forte (orphenadrine/aspirin/caffeine) Tablet as Non-Preferred
- Public Comments: None
- Speakers: None
- Discussion: None

DIABETIC CONTINUOUS GLUCOSE MONITOR SUPPLIES

CONTINUOUS GLUCOSE MONITOR TRANSMITTERS / RECEIVERS / READERS

- Recommendation: Off-cycle addition: Add the new to market product Dexcom G7® Receiver as Preferred
- Public Comments: None
- Speakers: None
- Discussion Point: None

CONTINUOUS GLUCOSE MONITOR SENSORS

- Recommendation: Off-cycle addition: Add the new-to-market product Dexcom G7® Sensor as Preferred
- Public Comments: None
- Speakers: None

- Discussion Point: None

MOTION WITH SECOND: APPROVE PROPOSED RECOMMENDATIONS FOR SKELETAL MUSCLE RELAXANTS, CONTINUOUS GLUCOSE MONITOR TRANSMITTERS / RECEIVERS / READERS AND CONTINUOUS GLUCOSE MONITOR SENSORS

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.

Lorcet[®] Tablet / HD Tablet
oxycodone oral syringe
Tolmetin capsule (generic for Tolectin[®])
Keflex[®] Capsule
Flagyl[®] Tablet
maprotiline tablet (generic for Ludiomil[®])
Brisdelle[®] Capsule
Adzenys[®] ER Suspension
amphetamine ER suspension (generic for Adzenys[®])
nitroglycerin ER capsule
nadolol-bendroflumethiazide tablet (generic for Corzide[®])
Adalat[®] CC Tablet
Niaspan[®] ER Tablet
Zontivity[®] Tablet
Catapres[®] Tablet
Imitrex[®] Vial
Humatrope[®] Vial
Semglee[™] Pen / Vial
ActoPlus Met[®] XR Tablet
Aloxi[®] Vial
nizatidine solution (generic for Axid[®])
Pancreaze[®] Capsule
Gelnique[®] Gel
Lastacaft[®] Drops
Blephamide[®] S.O.P. Ointment
Pred-G[®] S.O.P. Ointment / Suspension
metaproterenol syrup (generic for Alupent[®] Syrup)
Seebri[®] Neohaler[®]
loratadine OTC soft gel
Semprex-D[®] Capsule
Aczone[®] Gel
adapalene solution (generic for Differin[®])
Epiduo[®] Gel
Avar[®] Cleanser
Avar[®] LS Cleansing Pads / LS Foam
Sumadan[®] Wash
Tazorac[®] Cream / Gel
Oxistat[®] Cream

imiquimod cream pump (generic for Aldara®)

Epsolay® Cream Pump

Trianex® Ointment

naloxone ampule (generic for Narcan®)

erythromycin pledgets (generic for Emcin®, Erycette®, EryDerm®, EryGel®, EryMax®)

ACCU-CHEK® Softclix lancing device kit (Blue)

ACCU-CHEK® Multiclix lancing device kit

ACCU-CHEK® Compact Plus clear glucose control solution (2 levels)

ACCU-CHEK® Multiclix 102 ct Lancets

ADJOURNMENT

- Recommendation: PDL Review is completed. Adjourn meeting 3:42PM.
- Motion with second: Adjourn meeting.
- Vote: All in favor. None opposed.