New York State Medicaid
Drug Utilization Review (DUR) Board
Meeting Summary for May 13, 2021

The Medicaid DUR Board met on Thursday, May 13, 2021 from 9:00am to 1:00pm. In consideration of COVID–19 guidelines, the meeting was held virtually and available for public viewing by way of a live audio-video webcast.

An archived audio cast of the meeting proceedings is available on the Department of Health website: http://www.health.ny.gov/events/webcasts/

A. Welcome and Introduction

Approx. Webcast Time 00:00:24

Department of Health

Douglas Fish, MD – DUR Board Chairperson
Amir Bassiri
Robert Correia, PharmD
Kimberly Laurenzo, PharmD
Anthony Merola, RPh, MBA
Jacqueline Nahlik, HPA
Robert Sheehan, RPh
Monica Toohey, RPh

DUR Board Members

Lisa Anzisi, PharmD
Peter Lopatka, FSA
Donna Chiefari, PharmD
Marla Eglowstein, MD
James Hopsicker, RPh, MBA
Renante Ignacio, MD
Jill Lavigne, PhD, MS, MPH
Jacqueline Jacobi, RPh
Jadwiga Najib, PharmD
John Powell
Casey Quinn, PhD
Tara Thomas, RPh, MBA, MPA
Deborah Wittman, PharmD, MBA

SUNY – University at Buffalo

Linda Catanzaro, PharmD
Barbara Rogler, PharmD, MS

B. Public Comment Period

Approx. Webcast Time 00:10:24

The following speakers provided public comment to the DUR Board:

1	Elizabeth Lubelczyk, PharmD	Lilly	Antimigraine Agents - Other
2	Dan Flores, PharmD, MS	Amgen	Antimigraine Agents - Other
3	Joseph Coe	Global Healthy Living Foundation	Antimigraine Agents - Other

4	Charles E. Argoff, MD	Physician	Antimigraine Agents - Other
5	Paul J. Isikwe	Teva Pharmaceuticals	Antimigraine Agents - Other
6	Paul J. Isikwe	Teva Pharmaceuticals	Colony Stimulating Factors
7	Bethany Boyd, RPh, PhD	Pfizer	Colony Stimulating Factors
8	Beth D'Ambrosio, PharmD	Novartis	Anti-inflammatories/Immunomodulators - Ophthalmics

C. Preferred Drug Program (PDP) Clinical Review
Approx. Webcast Time 00:55:28

1. Triglyceride Lowering Agents - Linda Catanzaro, PharmD

Dr. Catanzaro began her presentation by addressing previously reviewed guidelines and the implementation of step therapy in December 2011. Step therapy was required prior to the initiation of either Lovaza (and generic omega-3 ethyl esters) or Vascepa (and generic icosapent ethyl) agents. Step therapy requirement was based upon guidelines from the 2002 National Cholesterol Education Panel Adult Treatment Panel which advocated the use of fibrates and niacin as first and second line agents for the treatment of severe hypertriglyceridemia. Omega-3 fatty acids were considered as alternate/adjunct treatment standards.

In 2018 guidelines changed focusing on the use of omega-3 fatty acids along with fibrates for the management of blood cholesterol (as recommended by the American College of Cardiology and the American Heart Association). In 2019 the American Heart Association recommended prescription omega-3 fatty acids as mono or adjunct therapy for the treatment of hypertriglyceridemia and the National Lipid Association recommended treatment for reducing the risk for atherosclerotic cardiovascular disease with icosapent ethyl. The presentation concluded that trials with fibric acid derivatives or niacin are not consistent with current guidelines. It was recommended that step therapy requirement be removed as a prerequisite for the use of omega-3 ethyl esters and icosapent ethyl products.

D. Executive Session (PDP Financial Reviews)

The DUR Board recessed to executive session at 10:50 am and reconvened to the public session at 11:50 am. Clinical discussion of the agenda topics did not occur during this period.

E. DUR Board PDP Recommendations
Approx. Webcast Time 02:11:38

Based on clinical and financial information, the DUR Board recommended the following to the Commissioner of Health for final determination:

Recommendations of the DUR Board	Commissioner's Final Determination
1. Non-Steroidal Anti-inflammatory Drugs (NSAIDs) **Preferred**: diclofenac 1% gel, diclofenac sodium, ibuprofen Rx(tab), ibuprofen OTC (susp), indomethacin, ketorolac, meloxicam (tablet), naproxen (tablet), piroxicam, sulindac **Non- Preferred**: Arthrotec, Cambia, Celebrex, celecoxib, Daypro, diclofenac epolamine (generic Flector), diclofenac/misoprostol, diclofenac potassium, diclofenac sodium ER, diclofenac topical solution, diflunisal, Duexis, etodolac, etodolac ER, Feldene, fenoprofen, Flector patch, flurbiprofen, ibuprofen Rx (susp), Indocin, indomethacin ER, ketoprofen, ketoprofen ER, ketorolac nasal spray (generic Sprix), Licar, meclofenamate, mefenamic acid, meloxicam caps (generic Vivlodex), Mobic, nabumetone, Nalfon, Naprelan, naproxen (susp), naproxen CR, naproxen EC, naproxen-esomeprazole, naproxen sodium, oxaprozin, Pennsaid, Qmiiz ODT, Relafen DS, Sprix, Tivorbex, Tolmetin, Vimovo, Vivlodex, Voltaren Gel, Zipsor, Zorvolex Vote: 14 yes, 0 no, 0 abstentions	Approved as Recommended
2. Inhaled Antibiotics **Preferred:** Bethkis, Cayston, Kitabis Pak, Tobi Podhaler **Non-Preferred:** Tobi Solution, tobramycin solution (generics for Bethkis, Kitabis, and Tobi) Vote: 14 yes, 0 no, 0 abstentions	Approved as Recommended
3. Triglyceride Lowering Agents **Preferred:** gemfibrozil, fenofibrate tab (generic Tricor), fenofibric acid (generic Trilipix), fenofibrate (generic Lofibra), omega-3 ethyl esters **Non-Preferred**: Antara, fenofibrate (generic Antara, Fenoglide, Lipofen), icosapent ethyl (generic Vascepa), Lipofen, Lopid, Lovasa, Tricor, Trilipix, Vascepa Vote: 13 yes, 1 no, 0 abstentions	Approved as Recommended

4. Anti-Migraine Agents - Other **Preferred:** Ajovy, Emgality 120 mg (pen, syringe) **Non-Preferred:** Aimovig, Emgality syringe (100mg syringe, 3 Pak) Vote: 14 yes, 0 no, 0 abstentions	Approved as Recommended
5. Colony Stimulating Factors **Preferred:** Neupogen, Nyvepria **Non-Preferred:** Fulphila, Granix, Leukine, Neulasta, Nivestym, Udenyca, Zarxio, Ziextenzo Vote: 14 yes, 0 no, 0 abstentions	Approved as Recommended
6. Anti-inflammatories, Immunomodulators – Ophthalmic **Preferred:** Restasis, Restasis Multidose, Xiidra **Non-Preferred**: Cequa Vote: 14 yes, 0 no, 0 abstentions	Approved as Recommended
7. Fluoroquinolones - Otic **Preferred:** Cipro HC, Ciprodex, ofloxacin **Non-Preferred:** ciprofloxacin, ciprofloxacin/dexamethasone (generic Ciprodex), ciprofloxacin/fluocinolone (generic Otovel), Otovel Vote: 14 yes, 0 no, 0 abstentions	Approved as Recommended
8. Anti-Hyperuricemics **Preferred:** allopurinol, colchicine (tablet), probenecid, probenecid/colchicine **Non-Preferred**: colchicine capsules, Colcrys, febuxostat, Gloperba (solu), Mitigare, Uloric, Zyloprim Vote: 14 yes, 0 no, 0 abstentions	Approved as Recommended

G. Final Comments and Adjournment
Approx. Webcast Time 3:29:12

Douglas Fish, MD
Amir Bassiri
Anthony Merola, RPh, MBA

Board members were reminded that the transition of the pharmacy program from Medicaid Managed Care to Medicaid Fee for Service has been delayed. The final enacted budget delayed the transition for 2-years to April 1, 2023.

Contact for meeting and meeting summary questions: DUR@health.ny.gov or 518-486-3209

Meeting adjourned at 11:30am

H. Commissioner Final Determinations

The impact of the final determinations on the PDP is as follows:

State Public Health Population:

- Minimal effect on Medicaid beneficiaries, as a large majority of beneficiaries currently utilize preferred products. Non-preferred products remain available with prior authorization.

Program Providers:

- No impact on prescribers when utilizing preferred products. Prescribers, or their agents, will need to initiate the prior authorization process when ordering non-preferred products.

State Health Program:

- Annual gross savings associated with the PDP therapeutic class reviewed, and associated preferred or non-preferred status modifications, are estimated at $105K. The savings would be achieved through utilization changes and the receipt of supplemental rebates from pharmaceutical manufacturers.