New York State Medicaid
Drug Utilization Review (DUR) Board
Meeting Summary for February 13, 2020

The Medicaid DUR Board met on Thursday, February 13, 2020 from 9:00am to 4:00pm. Meeting Room 6, Concourse, Empire State Plaza, Albany, New York

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 Introductions

Audio Cast Time 0:03:02 to 0:05:17

Department of Health (DOH)

Douglas Fish, MD - Chairperson
Tracy Berger, RPh
Robert Correia, PharmD
Monica Toohey, RPh
Anthony Merola, RPh, MBA
Robert Sheehan, RPh
Janet Zachary-Elkind

DUR Board Members

Lisa Anzisi, PharmD
Donna Chiefari, PharmD
Peter Deane, MD
Marla Eglowstein, MD
James Hopsicker, RPh, MBA
Renante Ignacio, MD
Jadwiga Najib, PharmD
Jackie Jacobi, PharmD
Peter Lopaka, FSA
John Powell, FSA
Tara Thomas, RPh, MBA, MPA
Deborah Wittman, PharmD
Jamie Wooldridge, MD

State University of New York (SUNY) at Buffalo

Linda Catanzaro, PharmD
Kalpesh Desai, PharmD
Michael Krajewski, PharmD
Barbara Rogler, PharmD
Diana Negrecha, PharmD
Irene Reilly, PharmD

B. Public Comment Period

Audio Cast Time 0:08:07 to 0:13:53

The following speakers provided public comment to the DUR Board:

1. Dana Canning	GlaxoSmithKline	Nucala
2. Alex Schlesinger	AstraZeneca	Fasenra

C. Drug Utilization Reviews (DUR)

The DUR Board reviewed the following topics and recommended clinical criteria and/or interventions to ensure appropriate drug utilization:

1. Management of Non-Acute Pain – Utilization of Opioids and Morphine Milligram Equivalent Parameters. Audio Cast Time 0:29:13 to 0:57:52

Presented by Dr. Barbara Rogler from SUNY at Buffalo, guidelines for prescribing opioids in patients with chronic pain from the Centers for Disease Control and Prevention were summarized, including initiating or continuing opioids, opioid selection, dosage, follow-up and discontinuation, and assessing risk and addressing harms of opioid use. The purpose of the review was to evaluate the use of opioids for non-acute pain, defined as pain extending past 7 days, in both Medicaid Fee-for-Service (FFS) and Managed Care (MC) programs, and establish maximum daily morphine milligram equivalent (MME) safety edits for the treatment of non-acute pain.

This was a retrospective evaluation of members receiving an opioid during the period from July 1, 2018 to September 30, 2018. The parameters were defined as a member's continuous enrollment in Medicaid for the 3-month period before and after their index opioid claim where the index opioid claim was the member's first claim during that time frame. This population was then divided into those identified as either opioid naïve or non-opioid naïve members. The results were summarized into three parts: opioid naïve members, non-opioid naïve members receiving 8-90 days of opioid therapy, and non-opioid naïve members receiving greater than 90 days of opioid therapy.

In conclusion, recommendations were presented to consider an automated point-of-service (POS) safety edit requiring provider intervention for members utilizing greater than or equal to 90 MME per day. Providers for members receiving greater than or equal to 90 MME per day will need to attest to the presence of an annual treatment plan in accordance with NYS Public Health Law 3331 implemented January 1, 2020. Members with a diagnosis of cancer, sickle cell disease, or those receiving hospice care would be excluded from the safety edit as well as members currently established on greater than or equal to 90 MME per day for the management of chronic, non-cancer pain.

DOH Recommendation to the DUR Board

Audio Cast Time 0:54:44 to 1:04:24

Management of Non-Acute Pain: Utilization of Opioid and Morphine Milligram Equivalent (MME) Parameters

DOH Recommendation:

Prior authorization is required when utilizing greater than or equal to 90 MME per day.

- Non-acute pain is defined as greater than 7 days of opioid therapy.
- Prior authorization will not be required for members established on ≥ 90MME per day.
- The MME parameter will not apply for members with cancer, sickle cell disease, or receiving hospice care.

DUR Board vote: Yes 14 No 0 Abstentions 0

2. Management of Eosinophilic Asthma (EA) – Utilization of Medication for EA and Place in Asthma Therapy. Audio Cast Time 1:40:54 to 2:22:19

The Management of Eosinophilic Asthma review was presented to the DUR Board by Dr. Linda Catanzaro from SUNY at Buffalo. The presentation was initiated by a review of the biologic agents used in treating this condition (benralizumab, dupilumab, and mepolizumab) in the context of data from the New York State Medicaid population inclusive of the Fee-For-Service (FFS) and Managed Care (MC) programs. The second part of the review was to evaluate the place in therapy of these medications as supported by the Food and Drug Administration (FDA) approved labeling and asthma treatment guidelines. A synopsis of background material focusing on the chronic nature of the disease, its pathogenesis, identified inflammatory phenotypes of the disease as well as the biomarkers of those phenotypes, inclusive of Type 2 inflammation. Also included was a review of the FDA approved agents with respect to each agent's formulation, dose, and approved indication. It was noted that there are no additional compendia-supported uses for any of these agents. Pharmacology and safety were discussed for each of the drugs along with use in identified populations.

The Global Initiative for Asthma (GINA) guidelines were reviewed including the role of eosinophilic asthma agents in the management of this condition. The use of these three agents was considered safe and effective as "add-on" therapy with little difference between them.

The next area of presentation involved the overall utilization of the drugs Dupixent (dupilumab), Fasenra (benralizumab), and Nucala (mepolizumab), used in the treatment of eosinophilic asthma. Utilization of these agents in members with asthma, eosinophilic phenotype, and concurrent use as add-ons with members being treated with oral corticosteroids, inhaled corticosteroids, and inhaled corticosteroids with long acting beta agonists was presented.

Conclusions from the data presented were summarized for the DUR Board. All three agents are approved for add-on maintenance therapy based upon severity of asthmatic condition or eosinophilic phenotype. Asthma treatment guidelines recommend phenotypic assessment and add-on therapy when asthma is not adequately controlled using high dose therapy of first-line agents used in the treatment of asthma. It was noted that 90% of FFS and MC members did have claims for phenotypic assessments with blood eosinophil count and/or fractional exhaled nitric oxide measurement during a one-year look-back period. In addition, about 87% of FFS and MC members had a history of the utilization of other anti-asthmatic agents (inhaled corticosteroids, inhaled corticosteroids with long acting beta agonists, as well as oral corticosteroids) during the year prior to or concurrent use with an eosinophilic asthma agent.

Two recommendations were suggested for the use of the eosinophilic asthma agents: confirm diagnosis of FDA-approved use, and step therapy for uncontrolled, severe asthma with a patient's history of and concurrent use of a corticosteroid.

DOH Recommendation to the DUR Board
Audio Cast Time 2:22:24 to 2:26:22 **Drug Utilization Review: Management of Eosinophilic Asthma (EA) – Utilization of Medications for EA and Place in Therapy** **DOH Recommendation:** Prior authorization is required when there is: 1) no history of corticosteroid utilization and 2) no concurrent use of a corticosteroid DUR Board vote: Yes 10 No 2 Abstentions 2

The DUR Board recessed for lunch at 12:00 pm
No official business was conducted.
The DUR Board returned from lunch at 1:00 pm.

3. Management of Oral Second-Generation Antipsychotics (SGAs) – Utilization of SGAs and Maximum Daily Dosages (MDD). Audio Cast Time 2:27:26 to 2:54:55

A drug utilization review by Dr. Irene Reilly, from SUNY at Buffalo, was presented to the DUR Board. The purpose was to examine the utilization of oral Second-Generation Antipsychotics (SGAs) and characterize the utilization in relation to MDDs recommended in the respective product labeling. Data was inclusive of the Medicaid Fee-For-Service (FFS) and Managed Care (MC) programs. Information regarding Food and Drug Administration (FDA) approved products, approved uses, approved age recommendations, maximum doses, compendia supported uses as well as respective pharmacology of the drugs in the review were outlined. This was followed by reference to selected guidelines (World Federation of Societies of Biological Psychiatry, Canadian Schizophrenia Guidelines and the Canadian Agency for Drugs and Technologies in Health) and literature reviews addressing low and high doses of selected products. The presentation then addressed SGA status within the New York Medicaid Fee-for-Service Preferred Drug Program as well as the current clinical criteria (step therapy, frequency, quantity and duration limits) relevant to these agents.

The utilization review of the SGA's included the period from April 1, 2016 to June 30, 2019. A summary of oral SGA utilization by member as well as by claim was presented. Data presented was inclusive of both FFS and Managed Care utilization. A summary was also presented highlighting individual claims where oral SGAs exceeded their recommended maximum daily dose as well as identifying the oral SGAs prescribed in those claims.

Subsequent charts presented SGAs exceeding their highest maximum doses based on patient age and psychiatric diagnoses.

It was summarized that most guidelines addressing dosing of SGAs recommend dose ranges found in the respective product labels. Few studies are available that addressed effects of high-dose SGAs even though there are significant safety concerns relating to dosing with this drug class. It was concluded that in the FFS and MC population, from State Fiscal Year 2017 through State Fiscal Year 2019, the number of members with equal to or greater than one claim for an oral SGA increased slightly. However, the number of claims for an oral SGA in the FFS population decreased slightly. The percentage of doses exceeding the MDD (as stated in the respective product label) was relatively low (below 2.4%) across the Medicaid population (FFS and MCO). The drug olanzapine was noted as having the highest percentage of claims exceeding the maximum daily dose in State Fiscal Year 2019. It was recommended to consider quantity limits for all oral SGAs consistent with the highest maximum daily doses recommended in the respective product label.

DOH Recommendation to the DUR Board
Audio Cast Time 2:55:06 to 2:57:09 **Drug Utilization Review: Management of Oral Second-Generation Antipsychotics (SGA) – Utilization of SGA and Maximum Daily Dosages (MDD)** **DOH Recommendation:** Prior authorization is required when an oral SGA is utilized above the highest MDD according to FDA labeling. • Prior authorization will not be required for members established on a dose greater than the highest MDD. DUR Board vote: Yes 13 No 0 Abstentions 0

D. Clinical Editing Updates

The DUR Board was provided with updates on and evaluations of the following topics and, if applicable, recommended changes to the clinical editing:

1. Utilization Trends for Products Used for the Treatment of Opioid Use Disorder
Audio Cast Time 1:04:57 to 1:33:55

An edit evaluation of utilization trends for products used in the treatment of opioid use disorder was presented by Dr. Barbara Rogler from SUNY at Buffalo. The purpose was to assess the impact of currently employed clinical edits on opioid use disorder medications

within the New York State Medicaid Program inclusive of both the Fee-For-Service (FFS) and Managed Care (MC) populations.

Background information included relevant state legislation, current coverage of medications used for opioid use disorder (OUD) therapy in the FFS program including Preferred Drug Program status, as well as patient diagnoses during the period in which they are treated. Utilization analysis was inclusive of both the FFS and MC programs.

State Fiscal Years (SFY) 2017 through 2020 (partial year) were reviewed. Utilization data was presented in six parts. Part 1 presented the age and gender of members on OUD therapy in the FFS and MC programs. The data revealed that of those members undergoing OUD therapy, 60% were female and 40% were male. Part 2 presented claims utilization for all the products used by members being treated for OUD in the FFS and MC programs. Except for buprenorphine implants, the use of agents for OUD increased in both programs during the period reviewed. Part 3 to illustrated where the number of claims exceeded quantity limits established by the FFS and MC programs. On average 60% of the female members exceeded the quantity limit (the current edit exempts female members who are pregnant and/or breast feeding from the quantity limit) however utilization for greater than 180 days decreased to 26.6% over the review period. Part 4 followed treatment duration of members using the different medication OUD therapies. Part 5 showed the progression of members from OUD therapy with buprenorphine SL to buprenorphine/naloxone. This combination is the preferred maintenance treatment and the percentage of progression remained stable during the period of review. Part 6 looked at the effect of the current edit on members receiving buprenorphine products along with an opioid or a benzodiazepine for greater than or equal to 5 days. During the period of review, a 1% average increase in members was found to overlap with opioids and a 17.3% average decrease in members was found to overlap with a benzodiazepine.

In conclusion, it was recommended to the DUR Board that the current FFS quantity limits and duration edits established for the products used for OUD in the Medicaid program remain in effect. In addition, a 30-day maximum supply of 60 tablets and 30 tablets be placed on the product buprenorphine/naloxone SL tablets (Zubsolv) 8.6mg/2.1 mg and 11.4mg/2.9 mg respectively.

2. Utilization Trends for Long-Acting Opioids Used for the Management of Pain.
Audio Cast Time 0:14:42 to 0:29:06

Dr. Barbara Rogler from SUNY at Buffalo presented a utilization review of Trends for Long Acting Opioids Used for the Management of Pain. Data was included from both the Medicaid Fee for Service (FFS) and Managed Care (MC) programs.

A background review focused on the current criteria for opioid monitoring in the Medicaid FFS program. The purpose of the review was to evaluate long acting opioid (LAO) therapy exceeding the individual LAO quantity limit and to determine the average morphine milligram equivalents (MME) per day calculated for LAO claims. This review was a retrospective analysis with a timeframe of April 1, 2018 to March 21, 2019. In both FFS and MC, members

with a diagnosis of cancer or sickle cell disease were excluded. The review showed that of the members receiving LAOs (both FFS and MCO), only 9% exceeded the quantity limits established by the Medicaid Program.

Data was presented establishing the calculated morphine milligram equivalents per day based upon Food and Drug Administration (FDA) approved dosing information. Data identified that of members taking opioids for non-acute pain, 3.0% of opioid naïve members had an average equal to or greater than 90 MME and 8.7% of non-opioid naïve members utilized equal to or greater than 90 MME.

In summary, it was concluded that current NYS Medicaid LAO quantity limits have been effective, 9% of members exceeded the NYS Medicaid LAO quantity limits per claim during this time frame. It was recommended to continue with current LAO quantity limits.

E. General Program Updates

The DUR Board was provided information associated with the following initiative and programs:

1. Medicaid Retrospective Drug Utilization Review (RetroDUR) – Fluoroquinolone Project.
Audio Cast Time 2:57:19 to 3:15:36

A RetroDUR Program update was presented by Dr. Michael Krajewski from SUNY at Buffalo. The update was an assessment of a mailed letter intervention to promote appropriate use of the fluoroquinolone class of antibiotics.

In 2016 the Food and Drug Administration (FDA) issued a warning regarding the risks associated with the use of fluoroquinolone antibiotics. It stated that the risks of therapy with this class of antibiotics outweighs their benefit in selected infectious processes (acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and uncomplicated urinary tract infections). The intervention letter was intended to reinforce the FDA message and labeling changes. Aggregated pharmacy claims were reviewed to assess the letter's effect and the results were reported to the Board.

Background information of FDA warnings was reviewed beginning from the class' entry into the marketplace to the latest warning of aortic ruptures or tears. The letter's contents detailed the FDA safety communications and the nature of adverse events associated with fluoroquinolone use, as well as therapeutic alternatives to the fluoroquinolone class. Fluroquinolone utilization pre- and post- intervention was evaluated.

The report concluded that the educational letter appears to have had a modest effect (15.1%) on decreasing potentially inappropriate fluoroquinolone prescribing in targeted prescribers. It was acknowledged that the letter may not have been the only influence for any changes in prescribing habits during this time period.

2. Medicaid Prescriber Education Program – Antibiotic Stewardship

Audio Cast Time 3:15:45 to 3:30:55

An update of the New York State Medicaid Prescriber Education Program (NYSMPEP) was presented to the Board by Dr. Diana Negrecha. The presentation provided an overview of the NYSMPEP activities, including the newest educational module, Antibiotic Stewardship. The goal of the program is to optimize the quality of care for NYS Medicaid members by providing the most current, unbiased, evidence-based information on best practices in pharmacotherapy. NYSMPEP resources and current available educational modules were identified.

Both the NYS Antibiotic Resistance Task Force and the NYS Stop Antibiotic Resistance Roadmap (STARR) target the prevention of antibiotic resistance including unnecessary prescribing of antibiotics by primary care providers, emergency departments, and hospitals. This newest NYSMPEP educational module focuses on two key messages: the promotion of appropriate antibiotic use in a routine practice and the use of "delayed prescribing" or "watchful waiting". The role of proper hand and respiratory hygiene remains an important foundation for infection control. Statewide Academic Educators (AE) are currently undergoing training and the program is awaiting Accreditation Council for Continuing Medical Education (ACCME) approval. It is expected that the outreach for educational contacts with prescribers will occur during the months of February and March.

Additional activities performed by the Prescriber Education Program (PEP) were highlighted. Emphasis was placed upon current program CME modules and related Customer Relations Management Software (CRM). It was explained that CRM enhances the CME program through its tracking and e-mail capabilities.

In conclusion, DUR Board Members were welcomed to schedule visits with NYSMPEP Academic Educators regarding the available modules that are in current circulation. Additional contact information was also provided.

F. Final Comments and Adjournment Audio Cast Time 3:31:00 to 3:33:13

Janet Zachary-Elkind, Deputy Director
Douglas Fish, MD - Chairperson
Anthony Merola, RPh, MBA

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

Meeting adjourned at 2:30 pm