New York State Medicaid
Drug Utilization Review (DUR) Board
Meeting Summary for February 14, 2019

The Medicaid DUR Board met on Thursday, February 14, 2019 from 9:00 am to 4:00 pm in 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: https://www.health.ny.gov/events/webcasts/archive/

A. Welcome and Introductions

Total Audio Cast time 3:08:57

Department of Health
Gregory Allen, MSW
Robert Correia, PharmD
Douglas Fish, MD (DUR Board Chair)
Anthony Merola, RPh, MBA
Robert Sheehan, RPh
Monica Toohey, RPh
Janet Zachary-Elkind, BA

DUR Board Members
Lisa Anzisi, PharmD
Donna Chiefari, PharmD
Jacqueline Jacobi, RPh
Marla Eglowstein, MD
Jill Lavigne, PhD, MS, MPH
Peter Lopatka, FSA
Christopher Murphy, MD
Jadwiga Najib, PharmD
John Powell
Casey Quinn, PhD
Asa Radix, MD
Tara Thomas, RPh, MBA

SUNY – University at Buffalo (UB)
Holly Coe, PharmD
Terry Dunn, PharmD
Barbara Rogler, PharmD, MS

B. Public Comment Period

Audio Cast time -3:05:06 to -3:04:52

There were no speakers registered for public comment to the DUR Board at this meeting.

C. Drug Cap Overview

Audio Cast time -3:02:44 to -2:59:30

Janet Zachary-Elkind provided a Drug Cap overview including background information and the charge of the DUR Board. Drugs piercing the Drug Cap are identified per legislation followed by the Department of Health (DOH) initiating rebate negotiations with the pharmaceutical manufacturer. Should negotiations prove ineffective, the drug can then be referred to the DUR Board for review. Based upon that review the DUR Board may recommend a supplemental rebate target amount.

D. Drug Cap Review of Remicade (infliximab)

Audio Cast time: -2:59:20 to -2:32:50

Dr. Barbara Rogler, SUNY UB, presented a clinical and utilization review of Remicade (infliximab), whose expenditures were identified as piercing the Drug Cap. The purpose of the presentation was to evaluate the utilization of Remicade, across the entire New York State Medicaid population (Fee-For-Service [FFS] and Managed Care [MC]) and to assist in the formulation of a supplemental rebate target.

The review outlined Remicade's place in therapy with indications for Rheumatoid Arthritis, Ankylosing Spondylitis, Plaque Psoriasis and Psoriatic Arthritis, Ulcerative Colitis and Crohn's Disease. Utilization data was also provided. An overview of biosimilars noted that two biosimilar products to Remicade (i.e. Inflectra and Renflexis), are currently available in the marketplace. A biosimilar being highly similar to and having no clinically meaningful difference from the existing Food and Drug Administration {FDA} reference product. A cost comparison of the biosimilar products to Remicade was presented using publicly available pricing. The review concluded with the consideration of utilizing a reference-based pricing strategy to assist in the formulation of a supplemental rebate target amount for Remicade.

E. Executive Session

Recess to Executive Session Audio Cast time -2:26:47

The DUR Board recessed at 10:00 AM to review confidential financial information relating to a supplemental rebate target amount for Remicade. No official action was taken in the Executive Session. The DUR Board reconvened to the public session at 10:45 AM.

F. DUR Board Drug Cap Recommendation

Audio Cast time -2:25:00 to -2:20:15

Prior to discussing and voting, it was announced publicly by the Chairperson that no conflicts or potential conflicts of interest had been identified and no DUR Board members have recused themselves from the voting on any of the meeting's agenda items.

Based on clinical and financial information associated with the Drug Cap review, the DUR Board recommended the following:

The supplemental rebate target amount is the value resulting in a unit price* equal to the lowest cost biosimilar (net of all rebates).

* the rebateable unit is per vial

13 Voting Members: 13 Yes 0 No 0 Abstentions

Commissioner's Final Determination: Approved as Recommended

G. Drug Utilization Review – Gabapentin/Pregabalin and Opioid Concurrent Utilization

Audio Cast Time -2:20:00 to -56:30

Dr. Holly Coe, SUNY UB, presented the review evaluating the utilization and safety concerns of the concurrent use of gabapentinoids (gabapentin and pregabalin) with opioids across the entire New York State Medicaid population (FFS and MC).

FDA approved indications for both drugs were presented along with concerns regarding the abuse and misuse of both drugs as reported by Centers for Medicare & Medicaid Services (CMS), Centers for Disease Control and Prevention (CDC) and the FDA. Literature reviews for both drugs were presented outlining safety concerns when used concurrently with opioids. Graphic representations were used to show concurrent gabapentinoid use with opioids within the NY Medicaid Program (FFS and MC). Data included doses for gabapentin, in conjunction with opioid therapy, greater than 2400mg/day but less than 3600mg/day and doses greater than 3600 mg/day. Similar data was presented for concurrent opioid therapy with pregabalin dosing greater than or equal to 600mg. Using the above dosing parameters for each of the gabapentinoids, additional data was presented using concurrent opioid dosing greater than or equal to 50 morphine milligram equivalents (MME).

Additional data showed that concurrent use of gabapentin with an opioid greater than or equal to 31 days increased from State Fiscal Year (SFY) 14 to SFY 18 within the FFS and MC populations. Concurrent pregabalin and opioid use greater than or equal to 31 days decreased over the same period for the same population. However, over that same period, concurrent therapy with an opioid showed an increase in the use of gabapentin doses greater than 3600mg as was the same for pregabalin where the dose range was greater than 600mg per day.

The review concluded with the following SUNY UB recommendations: 1) prior authorization when an opioid is initiated for a patient currently receiving pregabalin or gabapentin, 2) a prior authorization when either gabapentin or pregabalin is initiated for a patient currently receiving an opioid, 3) setting a maximum dose of 600mg for pregabalin IR and 660 mg for pregabalin CR, and 4) an educational letter outlining the safety concerns regarding concurrent opioid /gabapentinoid usage.

DOH presented four recommendations for review and discussion. The DUR Board recommended the following:

DOH recommendation #1:

Require prescriber intervention for the initiation of gabapentin or pregabalin in patients currently on an opioid.

DUR Board modified the DOH recommendation

DUR Board recommendation #1:

Require prescriber intervention for the initiation of gabapentin >900mg/day or pregabalin >150mg/day in patients currently on an opioid >50mme/day.

13 voting members: 9 Yes 2 No 2 Abstention

DOH recommendation #2:

Require prescriber intervention for continuation of opioid therapy beyond seven days in patients established on gabapentin or pregabalin.

Note: NYS Public Health law § 3331 5(b) limits an initial prescription of an opioid for acute pain to a 7-day supply

DUR Board modified the DOH recommendation

DUR Board recommendation #2:

Require prescriber intervention for continuation of opioid therapy beyond an initial 7-day supply in patients established on gabapentin or pregabalin.

13 voting members: 9 Yes 2 No 2 Abstentions

DOH recommendation #3:

Institute quantity limits for pregabalin:
pregabalin IR: 600mg per day
pregabalin ER: 660mg per day

13 voting members: 12 Yes 0 No 1 Abstention

DOH recommendation #4:

Send a targeted educational letter to prescribers highlighting safety concerns associated with opioids when used concurrently with gabapentin or pregabalin.

13 voting members: 13 Yes 0 No 0 Abstention

H. Drug Utilization Review – Program Updates

Audio Cast Time: -54:30 to -40:30

Two drug utilization reviews updates were presented. Both updates were the results of additional questions posed by DUR Board at a previous meeting and required additional research.

1. Prevention of Migraine Headaches and Concurrent Triptan Use

Audio Cast Time: -54:30 to -43:40

Dr. Holly Coe presented information regarding triptan utilization in response to follow-up questions from the DUR Board during the September 20, 2018 Meeting. The information focused on members switching triptans and potentially exceed monthly FFS quantity limits, having multiple claims for various triptans within a 30-day period.

The analysis identified 4.2% of members using triptans exceeded the FFS recommended monthly quantity limits. Of these 1.7% of members received greater than or equal to 2 triptan agents or strengths. In addition, it was noted that 10.7% of members received greater than 1 claim per month yet did not exceed the monthly quantity limit (18 units per 30-day period). The analysis also show 2.5% of members received greater than or equal to 2 triptan agents or different strengths. The data showed that there may be some overutilization of triptans by way of utilizing different strengths and or agents to receive dosage units above monthly quantity limits.

2. Utilization of Systemic Immunomodulators

Audio Cast Time: -43:15 to -40:30

Dr. Barbara Rogler presented an analysis to assess if products in the systemic immunomodulator class were being used for FDA approved indications. This also was in response to follow-up questions from the DUR Board at the September 20, 2018 meeting regarding the class review of the Systemic Immunomodulators.

The data presented characterized the results, indicating that five agents accounted for approximately 85% of the overall claims volume for the therapeutic class. The top five agents were commonly used for FDA-approved indications.

I. Clinical Edit Reviews

Audio Cast Time -40:10 to -1:25

Dr. Barbara Rogler presented utilization data illustrating the role of current pharmacy criteria/intervention initiatives and their associated effects on the use of opioids for pain management as well the use of medications for opioid dependence.

Multiple graphs were presented illustrating the effects that clinical editing had on opioid prescribing in New York State. Accompanying that data was an overview of legislative actions enacted as related to opioid prescribing trends from July 2012 to August 2017.

Graphically displayed statistics (representing overall member utilization of opioid analgesics, opioid analgesic claim volume per million, opioid analgesic units dispensed per million), demonstrated a downward trend for the Medicaid Program (FFS and MC). The graphs reflected data obtained through SFY14 through SFY18.

Data was also presented for buprenorphine containing products used by members identified with a substance use disorder. The data showed an increase in members utilizing buprenorphine containing products.

Lastly, the presentation summarized the benefits that legislative initiatives and pharmacy management programs have had regarding the use of opioids in the Medicaid program.

J. Adjournment/Final Comments

Audio Cast Time: -1:25 to 0:00

Medicaid Pharmacy staff thanked the DUR Board members and the Department's DUR Board support staff for their meeting preparation and participation.

Meeting adjourned at 2:45 PM