**New York State Medicaid**
**Drug Utilization Review (DUR) Board**
**Meeting Summary for February 11, 2021**

The Medicaid DUR Board met on Thursday, February 11, 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 00:01:56

Department of Health

Douglas Fish, MD – DUR Board Chairperson
Amir Bassiri
Robert Correia, Pharm D
Anthony Merola, RPh, MBA
Robert Sheehan, RPh
Mark Shutts
Monica Toohey, RPh
Janet Zachary-Elkind

DUR Board Members

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

SUNY – University at Buffalo

Holly Coe, PharmD
Linda Catanzaro, PharmD
Terry Dunn, PharmD
Barbara Rogler, PharmD., MS

## B. Public Comment Period

Approx. Webcast Time 00:06:57

The following speakers provided public comment to the DUR Board:

1. Tara Gonzalez, MD — Sobi North America — Synagis

**C. Clinical Drug Review Program** Approx. Webcast Time 00:12:14

1. Overview

Anthony Merola, RPh, MBA presented an overview of the Clinical Drug Review Program (CDRP). Public Health Law (PHL) 274 was enacted in 2005 and created the CDRP. PHL 274 authorizes the Commissioner of Health to require prior authorization for drugs in instances:

a. where monitoring of a prescribed protocol is required to protect the long-term efficacy of a drug and the public health,
b. where a potential for overuse, abuse, drug diversion, or illegal utilization of a drug can occur,
c. where inconsistent utilization of a drug with approved indications is found or may have the potential to occur.

Mr. Merola explained that the prior authorization (PA) process has undergone significant enhancements through automation. Automation provides the ability to lessen the need for written questionnaires used to obtain clinical information required for prospective drug utilization monitoring. It was explained that 3 drugs and 4 drug classes will be "transitioned" to an automated format of clinical monitoring. The monitoring parameters for each of these agents will remain the same and will be able to be captured prospectively using automated claim system technology. The remaining drugs/drug classes are managed by way of an upfront documentation PA process. Clinical criteria documentation for these drugs/drug classes are unable to be automated at this time.

2. Drug/Drug Class Presentations

Palivizumab - Synagis

Barbara Rogler, PharmD., MS, from the State University of New York (SUNY) at Buffalo, presented a review of the history of the placement of palivizumab within the CDRP, guidelines for its use, and utilization data of the drug within the Medicaid program.

The drug was reviewed by the Medicaid Pharmacy and Therapeutics (P&T) Committee and the DUR Board in 2009 and placed on the CDRP to assure its use was within the October - March respiratory syncytial virus season and to children less than 2 years old. The clinical criteria were adopted from the American Academy of Pediatrics (AAP) clinical guidelines. Subsequent changes to the guidelines of the AAP from 2012 to 2014 were incorporated into the CDRP criteria. In 2019 the AAP reaffirmed criteria suggested in 2014. A graph of the utilization of palivizumab in the Medicaid Fee for Service Program and Managed Care Organizations (FFS+MCO) was presented. Prior to and after its placement in the CDRP, the graph showed a continuing decline in the number of members using the drug as well as the number of claims. Upfront documentation (gestational age for prophylaxis determination) required for prior authorization was presented to the DUR Board for review. The presentation concluded that palivizumab should remain in the CDRP.

Sodium Oxybate - Xyrem

Holly Coe, PharmD. from SUNY at Buffalo, presented a review of the drug Xyrem focusing on the background of the drug's incorporation within the CDRP, guidelines for its use, its place in therapy, and its utilization in the Medicaid Program.

The drug was reviewed by the Medicaid P&T Committee in 2005 and 2009, being placed in the CDRP in 2010. Placement in the CDRP was to assure medical necessity and to deter potential drug diversion and illegal use. Indication guidelines were incorporated in the CDRP from the American Academy of Sleep Medicine in 2007 and the European Federation of Neurological Studies in 2011. The potential for misuse and abuse led to the Federal establishment of a boxed warning for the drug as well as the adoption of a Risk Evaluation and Mitigation Strategy Program associated with the drug's use. Additionally, it carries a unique bifurcated FDA controlled substance scheduling- the drug is a Schedule III Controlled Substance, but Schedule I penalties apply to non-medical use of the drug. A graphic illustrated the combined effects membership and associated claims had on the Medicaid Program since the time the drug was placed on the CDRP. Also mentioned was the availability of a recently marketed (approved July 21, 2020) agent, Xywav, which was described as having similar indications and the same active moiety as Xyrem but containing less sodium. It was specified that several upfront parameters need to be obtained as part of the PA process for Xyrem. The presentation concluded that sodium oxybate should remain in the CDRP. In addition, it was recommended that the CDRP criteria also apply to Xywav.

Somatropin - Serostim

Terry Dunn, PharmD, from SUNY at Buffalo, presented a review of the drug. The objective was to evaluate the background of the drug's addition to the CDRP, the drug's utilization trends within the Medicaid Program as well as the required CDRP clinical criteria.

Somatropin was reviewed by the P&T Committee in January 2002 and included in the CDRP in October 2006. The drug was placed in the CDRP to assure medical necessity and to deter the potential for diversion and illegal use. It was reviewed again by the P&T Committee in November 2006. There were no relevant guidelines identified for the drug but a long list of warnings and precautions were mentioned. Drug indications were identified and parameters for use in HIV wasting syndrome were addressed. The current CDRP clinical criteria for the drug were reviewed emphasizing numerous clinical parameters. A graph illustrated the use of somatotropin in the Medicaid Program. The graph showed a considerable decrease in members receiving somatropin as well as the number of claims subsequent to CDRP inclusion. The presentation concluded that criteria for somatropin (Serostim) was consistent with product labeling. It was recommended that somatropin remain in the CDRP.

Anabolic Steroids

Linda Catanzaro, PharmD. from SUNY at Buffalo presented a review of the class of anabolic steroids listed on the CDRP. The objectives identified included background information on the class, the class members and their indications, a review of the clinical criteria currently on the CDRP, guidelines associated with the use of this class of drugs, as well as a class utilization review within the Medicaid Program.

The class of anabolic steroids was reviewed by both the DUR Board and the P&T Committee in 2011 and 2012 respectively. In 2013, the class was added to the CDRP to assure appropriate use consistent with approved indications. It was noted that anabolic steroids are controlled substances as determined by both Federal (Schedule III) and New York State (Schedule II) laws. Emphasis was placed on indications for the treatment of hypogonadism and delayed puberty in males and the potential for abuse and misuse of these drugs. In 2020, position statements from the American Association of Clinical

Endocrinologists (AACE) as well as the American College of Endocrinology (ACE) were presented to emphasize their observations of abuse and misuse of anabolic steroids within these indications as well as off label use. The required upfront documentation established for prior authorization illustrated that the CDRP criteria documentation addressed these concerns for illicit use. A review depicting the overall utilization of anabolic steroids in the Medicaid Program was graphically illustrated. The graph revealed that over the period from 2012 to 2019 members receiving anabolic steroids decreased slightly while the number of claims increased. The presentation concluded that the CDRP criteria was consistent with FDA labeling, the nature of the criteria cannot be automated and will still require up front documentation, and that the position statements of the AACE and ACE maintain the need to curtail misuse and abuse. The class of anabolic steroids should remain in the CDRP.

Fentanyl Mucosal Agents

Barbara Rogler, PharmD., MS from SUNY at Buffalo presented a review of the fentanyl mucosal agents. Similar to previous presentations, the objectives of the presentation were the same in addressing review of the CDRP criteria associated with this class, place in therapy, evaluation of existing guidelines and a review of utilization data.

Fentanyl mucosal agents (often referred to as transmucosal immediate release fentanyl or TIRF) were reviewed by the P&T Committee in February 2008. The class was placed on the CDRP in July 2008 to assure use was appropriate and consistent with approved indications. Due to the nature and prescribing of these agents the Food and Drug Administration (FDA) in 2011 issued a Risk Evaluation Mitigation Strategy (REMS) Access Program. In 2020 the REMS program was updated requiring prescribers and pharmacists to assess a patient's tolerance to opioids. Dr. Rogler emphasized that TIRF agents are not intended for use in opioid-naïve patients and are not considered "first line" therapy for the management of cancer pain. Graphic presentations illustrated utilization data during the post implementation of the CDRP criteria for these agents. A general reduction was seen in the number of members receiving TIRF agents as well as a decrease in the number of claims, post implementation of CDRP criteria. It was also noted that during that same period, the REMS program as well as the NY State prescription monitoring program, I-Stop, were implemented which may also have contributed to the decline. Dr. Rogler presented the CDRP criteria noting areas which could not be easily automated, requiring upfront documentation to assess clinical rationale which would comply for prior authorization requests. In summary, Dr. Rogler affirmed that fentanyl mucosal agents are approved for use in the treatment of breakthrough pain in opioid tolerant individuals, are subject to the TIRF REMS Access Program, and that current CDRP clinical criteria are consistent with FDA approved product information and guidelines. The class of fentanyl transmucosal agents should remain in the CDRP program.

Growth Hormone Agents

Holly Coe, PharmD. from SUNY at Buffalo, presented a review of growth hormones, their placement on the CDRP Program, indications for their use, safety concerns with long term use, potential off-label uses and graphicly illustrated utilization trends in the Medicaid Program.

The class was reviewed by the DUR Board as well as the P&T Committee in 2009 and placed in the CDRP, based upon concerns for inappropriate use (fraud, misuse, abuse, and diversion), requiring upfront documentation to process PA requests. CDRP guidelines for their use were adopted from the American Association of Clinical Endocrinologists (AACE)

and the American College of Endocrinologists (ACA). Guidelines from 2009 identified "transition patients" (adolescents with childhood onset growth hormone deficiency) as between 15 and 25 years of age who have reached final adult height. The age of 21 was selected and PA requests were granted to recipients equal to or greater than 21 years based upon those guidelines. In 2019, those guidelines were updated, and the range was reduced to 15 -18 years of age for reaching final adult height. In summary, Dr. Coe noted that upfront documentation for this class of agents is still necessary to comply for required prior authorizations. Updated guidelines from the AACE now define "transition patients" as being between 15 and 18 years of age and should be reflected in the age required for PA. It was suggested that the growth hormone class remain in the CDRP Program with a change to the age parameter. A recommendation was put forth by the Department of Health that the prior authorization age be changed from equal to or greater than 21 years of age to equal to or greater than 18 years of age.

| **Recommendations of the DUR Board** | **Commissioner's Final Determination** |
|---|---|
| **Clinical Drug Review Program: Growth Hormone**<br><br>**DOH Recommendation:**<br><br>Prior authorization is required when prescribed for members 18 years of age or older.<br>Note: Reduction of age from 21 years or older.<br><br>Vote: 16 yes, 0 no, 0 abstentions<br>Unanimous | Approved as Recommended |

The Board unanimously approved of lowering the required age to equal to or greater than 18 years of age.

## D. Medicaid Pharmacy Program Updates

Approx. Webcast Time 02:01:52

1. Drug Cap Initiative

The Drug Cap review was a presentation by Janet Zachary-Elkind and Mark Shutts to the DUR Board. Their presentation focused on Drug Cap background, legislation and a status update which included Drug Cap data.

Janet Zachary-Elkind, noted the purpose of the legislation was to limit drug spending growth within the Medicaid Program. Expenditure growth was limited to a 10-year rolling average of the medical component of the Consumer Price Index plus 4%, less the State share rebate target. In addition, the legislation authorized the Department of Health (DOH) to negotiate rebates with drug manufacturers, and to the extent applicable under current law allow the Commissioner of Health to refer certain drugs to the DUR Board.

New statutory provisions were enacted further affecting rebates as well as administrative provisions. Manufacturer rebate negotiations can be based upon established cost-effective

studies, be further negotiated when warranted by significant market changes or State or Federal regulatory changes and be set without consideration of other drugs made by the same manufacturer. Administrative efficiencies are achieved through aligning DUR Board reporting requirements with the State Fiscal Year (SFY).

Mark Shutts focused on the financial portion of the initiative. Drug Cap savings were illustrated in bar and linear graphs. For SFY 2019-20 Drug Cap savings amounted to $2.7M. The data demonstrated that year to date, fourth quarter expenditures for that period were approximately $21.3M dollars over the target amount. New Drug Cap rebates collected during SFY 19-20 totaled approximately $24.0M. Drug Cap savings therefore amounted to $2.7M (the difference between new Drug Cap rebates and the excess dollar expenditure above the target amount).

2. Pharmacy Benefit Carve-Out from Managed

Monica Toohey, RPh, presented an overview of the upcoming carve out of the pharmacy benefit. It was explained that effective April 1, 2021 the pharmacy program is planned to be moved from the Medicaid Managed Care Program to the Medicaid Fee-for-Service Program. Guidance of the Program's approach to the change was illustrated using the Pharmacy Carve-out documents publicly available on the MRT II home site, Pharmacy Carve-out: https://health.ny.gov/health_care/medicaid/redesign/mrt2/meetings/index.htm/. Each subject area emphasized the degree to which communication and outreach was conducted with stakeholders.

**E. Final Comments and Adjournment** Approx. Webcast Time 02:39:15

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

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

**Meeting adjourned at 12:05 PM**