Minutes
Drug Utilization Review Board Meeting
DATE: March 10, 2021

Meeting Purpose: Quarterly Drug Utilization Board Meeting
Meeting opened at 6:00 p.m. by Sarah M McGee, MD

The meeting was conducted under Massachusetts Public Meeting Law requirements.

Attendance: Melissa Coyle, PharmD; Timothy Fensky, RPh; James Gagnon, RPh, PharmD; Colleen Labelle, MSN, RN-BC, CARN; Lori Lewicki, RPh; Greg Low, RPh, PhD; Sarah M McGee, MD; Julita Mir, MD; Karen Ryle, MS, RPh; Laura Spring, MD; Christy Stine, MD, PhD; Michael Thompson, MD

Absent: None

Agenda Items:
- Welcome and Introductory Remarks
- Annual Pipeline Continuing Education Program
- Compounding Quality Assurance Analysis
- MHDL Update
- DUR Operational Update
- MassHealth Update
- Progesterone Agents Quality Assurance Analysis

Agenda Item	Discussion	Conclusions/Follow Up
Annual Pipeline Continuing Education Program	**Annual Pipeline Continuing Education Program by Dr Mckenzie Taylor and Dr Warren Smith** The Pipeline Update provided an overview of clinical and/or regulatory updates regarding select pharmaceutical pipeline agents in late-stage development.	**Follow Up** Informational/Advisory

Action	Discussion
	• Pipeline Trends: FDA-approved New Molecular Entities
	  ○ First-cycle approvals granted for 92% (49/53) NMEs
	  ▪ Does not include gene therapies or immunotherapies (reported by CBER)
	  ○ First-in-class approvals: 40% (21/53)
	  ○ Approvals for orphan diseases: 58% (31/53)
		Conclusion
		The board reviewed and accepted the presentation.

- Of 53 new drugs, 36 (68%) were approved using the expedited approval method
- 32% were approved using the fast track method.
- 42% were approved using the breakthrough method.
- 57% were approved using priority review.
- 23% were approved using accelerated approval.

- Orphan Diseases Pipeline
  - Almost one-third of drugs in development are for 608 diseases
  - Mean cost per patient per year of the top 100 orphan drugs in the US in 2018 was $150,854 vs $33,654 for other drugs.
- Oncology
  - Idecabtagene Vicleucel
  - Ciltacabtagene autoleucel (cilta-cel)
  - Improvements to first generation CAR-T therapies
    - High cost to manufacturer and administered treatment
    - High rates of CRS/NT that is also costly to manage
    - Up to three weeks to manufacturer and payer approval
    - Newly approved therapy:
      - Breyanzi (lisocabtagene maraleucel): delayed occurrence of CRS making outpatient administration possible
  - Infectious Diseases
    - Limited activity in antibiotic pipeline
    - HIV pipeline may offer
      - Less frequent dosing
      - Options for multi-drug resistant disease and pre-exposure prophylaxis
  - Non-alcoholic Fatty Liver Disease
    - Prevalence ~15 million adults
    - Largely asymptomatic
    - Diagnosed by liver biopsy
    - May progress to cirrhosis and require liver transplant
    - No FDA-approved treatments
  - Immunology
    - Systemic Lupus Erythematosus
      - Anifrolumab
    - Chronic Graft-Versus-Host Disease
      - Belumosudil
    - Acute Graft-Versus-Host Disease
      - Leukotac (inolimomab)
    - Psoriasis
      - Deucravacitinib
  - Hematology
    - Anemia in Chronic Kidney Disease

	- Roxadustat - Chronic Immune Thrombocytopenia - Rozanolixizumab - Hemophilia - Roctavian (valoctocogene roxaparvovec) - Paroxysmal Nocturnal Hemoglobinuria - Pegcetacoplan - Central Nervous System - Myasthenia Gravis - Efgartigimod - Amyotrophic Lateral Sclerosis - Multiple Sclerosis - Ublituximab - Endocrine and Metabolic - Type I Diabetes Mellitus - Teplizumab - Cushing's Disease - Levoketoconazole - Achondroplasia - Gene Therapy - Beta-Thalassemia - Lentiglobin (betibeglogene autotemcel) - Severe Combined Immunodeficiency - OTL-101 - Choroideremia - AAV2-REP1 - Conclusions - Immuno-oncology and drugs for rare diseases continue to lead the pack for pipeline drug development. - Cell and gene therapy approvals may accelerate. 10 to 20 approvals per year by 2025 - Biosimilar legislation will continue to be an ongoing area of reform within the federal government. Questions - Dr Paul Jeffrey requested clarification about what was stated about the new chemical entity approvals by the FDA and new biologics. - Dr McKenzie Taylor clarified that the graph specifically showed approvals via CBER.	

Agenda Item	Discussion	Conclusions/Follow Up

Compounding Quality Assurance Analysis	**<u>Compounding Quality Assurance Analysis by Dr Stephanie Tran</u>** This overview was an evaluation of current medical literature and provided a brief overview of new guideline recommendations in this disease state.	**<u>Follow Up</u>** Informational/Advisory

Action	Discussion
	• Goal of Management
	  ○ MassHealth will pay for compounds that are medically necessary.
	  ▪ FDA-approved formulation does not exist
	  ▪ Member unable to take FDA-approved commercially available product (*e.g., allergy to dye, inability to swallow tablet/capsule*)
	• Powders flagged for placement on PA
	  ○ Increase in cost
	  ○ Lack of literature
	  ○ Topical route
	• Management Timeline – Compounding Management
	  ○ Preparation (2017)
	  ▪ Claims analysis (ongoing: monthly)
	  ▪ Literature analysis
	  ▪ Outreach to compounding pharmacies
	  ○ Implementation (2018 – present)
	  ▪ Claims monitoring to place high-cost agents on PA
	  ▪ January 2018: amitriptyline, clonidine, gabapentin, lidocaine powders placed on PA
	  ▪ Agents used in topical/transdermal compounds were subsequently placed on PA
	  ○ Outcomes (2019 – present)
	  ▪ Decrease in spend per cost analysis
	  ▪ Data presented at ADURS and EMPAA in 2020
	• QA Methods & Results
	  ○ Utilization: January 2020 to December 2020
	  ▪ Agents requiring PA
	  ⊕ Unique utilizers: 444
	  ⊕ Paid claims: 3,579
	  ⊕ Total amount paid: $174,599
	  ○ PAs: January 2020 to December 2020
	  ▪ PA requests: 251
	  ▪ Majority of requests for:
	  ⊕ Ketotifen powder (31)
	  ⊕ Baclofen powder (17)
	  ⊕ Topiramate powder (16)
		<u>Conclusion</u>
		The board reviewed and accepted the presentation.

	- Levocarnitine powder (15) - Naltrexone powder (15) - Biotin powder (12) - Coenzyme Q10 (11) - Overall Trends: April 2017 to August 2020 - Decrease in per member per month spend - Decrease in cost per member per year for ingredients placed on PA - Question for the Audience - How have the MassHealth Managed Care Organizations (MCOs) managed compounded pharmaceuticals? - Conclusions - Coding pending to require PA for - Not administered by medically necessary ROA - Age ≥ 19 years - Total ingredient cost ≥ $200 - QA Recommendations: - Continue monitoring on a monthly basis for high-cost ingredients - Require PA for antimicrobials powders used in topical/transdermal compounds Questions - Dr Andrew Colby from Health New England responded to the question from the presentation and stated that they have put in a low dollar threshold and have seen the same decrease. - Dr Paul Jeffrey stated that setting a dollar threshold is a common mechanism for managing compounding pharmaceuticals in the marketplace. Dr Paul Jeffery stated that we will pay up to a certain dollar amount for the drug, and then it will need a prior authorization after that. - Dr Darcy Jones from Fallon stated that they have a dollar threshold and if it is above that, it will reject for a prior authorization and will review for medical necessity. - Dr Greg Low commented that on the ACO side, very few prescribers get asked to sign a fax that came from a pharmacy requesting a product that was not prescribed, and when informing the prescribers, they were surprised.	

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MHDL Update	**<u>MHDL Update by Dr Phuong Luc</u>** MHDL Overview including new additions, changes in Prior Authorization (PA) status, and related attachment updates to be implemented with a recent publication rollout.	**<u>Follow Up</u>** Informational/Advisory

Action	Discussion
	• There were 16 additions to the MHDL Drug list effective as of March 22, 2021.
	• Of the 16 additions, 13 will require prior authorization and three will not require prior authorization.
	• Changes in prior authorization status
	  ○ One acne and rosacea agent will no longer require prior authorization while another will require prior authorization.
	  ○ One topical nonsteroidal anti-inflammatory drug (NSAID) agent will no longer require prior authorization.
	  ○ One bowel preparation agent will no longer require prior authorization.
	  ○ One anticoagulant agent will no longer require prior authorization.
	  ○ Two anti-Parkinson agents will no longer require prior authorization within quantity limits.
	  ○ One benzodiazepine agent will no longer require prior authorization within quantity limits. Pediatric Behavioral Health Medication Initiative criteria will still apply.
	• Changes to the MassHealth Brand Name Preferred Over Generic Drug List
	  ○ Three agents will be added to the MassHealth Brand Name Preferred Over Generic Drug List.
	• Changes to Miscellaneous Documents on the MassHealth Drug List
	  ○ One agent has been removed from the MassHealth Supplemental Rebate/Preferred Drug List.
	  ○ Updates have been made to two agents on the MassHealth ACPP/MCO Unified Pharmacy Product List.
		<u>Conclusion</u>
		The board reviewed and accepted the presentation.

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DUR Operational Update	**<u>DUR Operational Update by Dr Patricia Leto</u>** DUR Operational Overview including statistics associated with Prior Authorization	**<u>Follow Up</u>** Informational/Advisory

	(PA) review and PA response, and Call Center metrics.	
Action	Discussion • MassHealth prior authorization requests from 2017 to 2021 (calendar year to date) showing with COVID leniencies initiated in March 2020 and then removed in August 2020. • MassHealth call center volume from 2017 to 2021 (calendar year to date) showing with COVID leniencies initiated in March 2020 and then removed in August 2020. • The monthly average from prior authorizations from 2017 to 2021 (to date) were reviewed. Peak average of 10,547 per month in 2018 while currently 2021 (to date) average per month is 8,718. • Abandonment rate generally in the 2% range • Average wait time of answered call generally in the 20 second range • Average treatment time consistently around four minutes • MassHealth Appeals: Current monthly average is four • Provider Outreach Volume: Current monthly average is 845 calls • Top Ten Medications Requested for Prior Authorization – October 1, 2019 to September 30, 2020 1. Clindamycin 2. Pregabalin 3. Methylphenidate 4. Clonazepam 5. Clonidine 6. Tretinoin 7. Testosterone 8. Latuda 9. Linzess 10. Botulinum Toxin • Prior Authorization Compliance Response Time – January 2020 to December 2020 ○ Total requests: 95,986 requests ○ 60% of all PAs decisions with in six hours. ○ 99.4% of all PAs decisions in less than 24 hours. • Prior Authorization Compliance Response Time during Call Center hours – January 2020 to December 2020 ○ Total requests: 95,986 requests ○ 81% of all PAs decisions with in six hours. ○ 98% of all PAs decisions in less than nine hours.	**Conclusion** The board reviewed and accepted the presentation.

Agenda Item	Discussion	Conclusions/Follow Up

MassHealth Update	**<u>MassHealth Update by Dr Paul Jeffrey</u>** The MassHealth Update was a brief summary of recent developments in MassHealth in the context of pharmacy, managed care, or public health.	**<u>Follow Up</u>** Informational/Advisory

Action	Discussion
	• Near the expiration of the 1115 waiver
	  ○ Waiver refers to the way MassHealth operates its Medicaid program. Exceptions to the standard rules for Medicaid need a waiver.
	  ○ Waiver is going to expire on December 31, 2022
	  ○ Typically, waivers are five-year approvals.
	  ○ Plan on how MassHealth is to be operated needs to be submitted by July 1, 2021 to CMS
	  ○ Foundation to run the Medicaid program 2023 and beyond
	  ○ Process has already started including stakeholder meetings–
	  ▪ Currently a couple concepts MassHealth is considering
	  Carving the pharmacy benefit out of the managed care plans
	  ❖ Already began through the stake holder group to socialize, including one on one discussions
	  ❖ Carve the behavioral health benefit out of the managed care plans
	• Implementing a new version of POPS processing system (POPS IV)
	• As of March 14, 2021, phase one of the POPS IV implementation was completed successfully.
	  ○ Phase one was called “lift and shift.”
	  ○ POPS III was “lifted” into the cloud and POPS IV will be shifted into place.
	  ○ No issues have been reported with this process of phase one.
	  ○ Phase two will include enhancements (e.g., real time benefit checks, electronic PA, etc.) and will be in process until about April 2022.
	• Direct negotiating authority
	  ○ 45 drugs under contract with $157 million savings annually
	  ○ Have met budget target ($150 million)
	  ○ Seven of these contracts are value based
	• New DME products added to the pharmacy benefit (e.g., continuous glucose monitors).
	  ○ Payment tied to DME unit rates. In order to separate, would need to procure contracts with manufacturers through pharmacy.
	• Through MBHP (PPC members) and DUR (FFS members), MassHealth is reaching out to membersthat were identified as having received one
		<u>Conclusion</u>
		The board reviewed and accepted the presentation.

	vaccination and are due or past due for second shot. This is the first time DUR has made outbound calls to members. Questions • Dr Julita Mir inquired if the calls that were made to patients were based on pharmacy claims or were from MIIS. • Dr Paul Jeffrey stated that yes, the information was based solely on pharmacy claims data. Working to get MIIS data into MMIS. • Dr. Tim Fensky inquired about billing COVID vaccines for limited or Health Safety Net patients. • Dr Paul Jeffrey responded that you cannot bill MassHealth for limited, but you can still bill HRSA (Health Resources and Services Administration). MassHealth does pay for HSN claims at eligible pharmacies. ○ NB: Subsequent to this Board meeting, MassHealth commenced paying for vaccine administration for Limited benefit members in accordance with new federal guidance. • Dr Colleen Labelle inquired if the DUR program can text patients and if it has other language capabilities? • Mr. Justin Peristere responded that they do have some language capabilities but not all; though the number of calls that had a language barrier has been small percentage. • Dr Colleen Labelle stated that doing Telehealth, most of the prescribers have seen that patients prefer texting than to answer a phone.	

Agenda Item	Discussion	Conclusions/Follow Up
Progesterone Agents Quality Assurance Analysis	**<u>Progesterone Agents Quality Assurance Analysis by Dr Soumya Vishwanath</u>** This overview was an evaluation of current medical literature and will provide a brief overview of new guideline recommendations in this disease state.	**<u>Follow Up</u>** Informational/Advisory

Action	Discussion
	• Preterm birth is the birth of a baby < 37 completed weeks of pregnancy
	• Risk Factors
	  ○ History of prior preterm birth
	  ○ Pregnancy with multiples
	  ○ Abnormalities associated with uterus or cervix
	• Preterm birth can lead to multiple complications
	• QA Results: Prior Authorization Approvals
	  ○ Approval Overview
		<u>Conclusion</u>
		The board reviewed and accepted the presentation.

	▪ Approvals for 10 members were randomly selected and reviewed ▪ Requests submitted between 13 weeks and 20 weeks gestation ▪ Ninety percent of patients had subsequent paid claims for the approved medication. ⚓ Three members did not all have subsequent claim • QA Results: Prior Authorization Denials ○ Denial Overview ▪ Denials for 10 members were reviewed ⚓ Six requests for Makena ⚓ Three requests for Crinone ⚓ One request for progesterone powder ▪ Reasons for denials ⚓ Inappropriate diagnosis ⚓ Missing documentation (e.g., gestational age, dose/duration of therapy requested) ⚓ No trial with least costly alternative • PA Subanalysis: Twin Pregnancy ○ Subanalysis Overview ▪ Requests for Makena for four members with either current twin pregnancy or history of preterm labor and/or delivery with twin pregnancies were reviewed. ▪ Two members with current twin pregnancies and history of pre-term deliveries ⚓ One approved based on literature ⚓ One denied due to lack of information ▪ Two members currently pregnant with a singleton with a history of preterm delivery with twins ⚓ Both approved and had single live births • Conclusions ○ Progesterone supplementation reduces the risk of preterm birth by about one-third in women ▪ with singleton pregnancy who have had a previous spontaneous singleton preterm birth ▪ with a short cervix on ultrasound examination in the current pregnancy ○ Literature includes support for and against starting progesterone treatment in individuals currently or previously pregnant with multiples ○ No clinical updates recommended at this time ○ FDA's decision on Makena may impact class management • Questions	

	○ Dr Tim Fensky inquired if the powder was for the progesterone suppositories or the injection. ○ Dr Soumya Vishwanath responded that it was for the suppositories not the injection. ○ Dr Tim Fensky inquired about paying for the brand versus the generic injection. ○ Dr Soumya Vishwanath replied she will double check on that. Currently the understanding is that if the prescriber is inquiring about the generic injection, the indication for the generic is different from the brand name injection.	

Meeting adjourned at 8:00 p.m.

Respectfully submitted by Mylissa Price

Date: _____