

Minutes

Drug Utilization Review Board Meeting

DATE: September 13, 2023



Meeting Purpose: Quarterly Drug Utilization Board Meeting
Meeting opened at 6:00 p.m. by Timothy Fensky, RPh

The meeting was conducted under Massachusetts Public Meeting Law requirements.

Attendance: Mehmet Furkan Burbak, MD; Melissa Coyle, PharmD; Timothy Fensky, RPh; Colleen Labelle, MSN, RN-BC, CARN; Lori Lewicki, RPh; Greg Low, RPh, PhD; Laura Spring, MD; Rebekah Rice, RPh, CDCES; Karen Ryle, MS, RPh; Christy Stine, MD, PhD

Absent: James Gagnon, RPh, PharmD; Sarah M McGee, MD

Agenda Items:

- Welcome and Introductory Remarks
- Guest Speaker
- Minutes
- Pipeline Update
- Annual Special Populations Update
- Respiratory Agents, Inhaled Quality Assurance Analysis
- Respiratory Syncytial Virus Treatment Updates
- MHDL Update
- DUR Operational Update
- MassHealth Update
- Open Forum

Agenda Item	Discussion	Conclusions/Follow Up
Guest Speaker	Dr. Reema Sbitany spoke on behalf of Sobi on the topic of Synagis and the RSV season.	Follow Up Minutes are approved.

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Minutes	Motion to approve the minutes for June 2023 was made by Greg Low, RPh, PhD and seconded by Christy Stine, MD, PhD.	Follow Up Minutes are approved.

Agenda Item	Discussion	Conclusions/Follow Up
Pipeline Update	<u>Pipeline Update by Dr. Kyle Semmel</u> This pipeline update provided a brief overview of clinical and regulatory updates regarding select pharmaceutical pipeline agents in late-stage developments.	<u>Follow Up</u> Informational/Advisory
Action	Discussion <ul style="list-style-type: none"> • Investigational Agents <ul style="list-style-type: none"> ○ Fidanacogene elaparovec <ul style="list-style-type: none"> ▪ Manufacturer – Pfizer Inc. and Spark Therapeutics ▪ FDA Designations – breakthrough therapy, orphan drug, regenerative medicine advanced therapy (RMAT) ▪ Mechanism of Action (MOA) – gene therapy ▪ Route of Administration – single intravenous injection ▪ Proposed Indication – adults with hemophilia B ▪ Summary of Update <ul style="list-style-type: none"> • Biologic License Application (BLA) was accepted in June 2023; FDA is expected mid-year 2024. Population: Patients 18 to 65 years of age with moderately severe-to-severe hemophilia B • Place in Therapy <ul style="list-style-type: none"> ○ If approved, fidanacogene elaparovec would be the second gene therapy for hemophilia B, and the first direct competitor to Hemgenix® (etranacogene dezaparovec). ○ Given similarities in trial design and safety and efficacy outcomes data, it is unclear if there will be a definitively preferred agent among providers at this time. ○ Tabelecleucel (tab-cel) <ul style="list-style-type: none"> ▪ Manufacturer – Atara Biotherapeutics ▪ FDA Designations – breakthrough therapy 	<u>Conclusion</u> The board reviewed and accepted the presentation.

Agenda Item	Discussion	Conclusions/Follow Up
	<ul style="list-style-type: none"> ▪ MOA - allogeneic CAR-T cell immunotherapy ▪ Route of Administration – single intravenous injection ▪ Proposed indication: relapsed or refractory Epstein-Barr virus (EBV)-positive post-transplant lymphoproliferative disease (relapsed or refractory [r/r] EBV+ post-transplant lymphoproliferative disease [PTLD]) ▪ Summary of Update <ul style="list-style-type: none"> • BLA anticipated; FDA decision is expected first half of 2024. • Population: patients with r/r EBV+ PTLD after failure of rituximab with or without chemotherapy • Place in Therapy <ul style="list-style-type: none"> ○ Currently tacelecleucel is approved in Europe, and real-world data from 24 patients is available. ○ If approved, tacelecleucel would be the first allogeneic CAR-T cell therapy approved in the United States for r/r EBV+ PTLD. ○ Use would be reserved for patients who have failed standard therapy with rituximab +/- cytotoxic chemotherapy. <p>Questions</p> <ul style="list-style-type: none"> • Low inquired about the two gene therapies for hemophilia—if there were any characteristics that made one better or worse than the other, and how patients and providers would choose. <ul style="list-style-type: none"> ○ Semmel responded that both are currently similar in efficacy and that until more data comes out, it is unclear which will be preferred in this space. 	

Agenda Item	Discussion	Conclusions/Follow Up
Annual Special Populations Update	<p><u>Annual Special Populations Update by Dr. Kaelyn Boss</u></p> <p>This overview was a summary of the current structure of the Drug Utilization Review Special Populations Program. It summarized the clinical outcomes of the program over the past year.</p>	<p><u>Follow Up</u></p> <p>Informational/Advisory</p>

Agenda Item	Discussion	Conclusions/Follow Up
Action	<p>Discussion</p> <ul style="list-style-type: none"> • Special Populations Services <ul style="list-style-type: none"> ○ Services that are currently provided: <ul style="list-style-type: none"> ▪ Pharmacy consultation ▪ Medication review ▪ Team support at weekly community case management (CCM) meetings ▪ Education ○ The operational team supports ability to provide vital medication procurement support. ○ Consults that have been received between July 1, 2022, and June 30, 2023 <ul style="list-style-type: none"> ▪ Total consults: 259 ▪ Operational consults: 245 ▪ Clinical consults: 10 ▪ Clinical and operational consults: four <p>Concluding Recommendations</p> <ul style="list-style-type: none"> • The Clinical Pharmacy Services CPS Special Populations Program encourages collaboration among ForHealth Consulting departments; outcomes suggest that the collaboration has a positive impact on members and ForHealth Consulting. • Plan to continue evaluation of the CPS Special Populations Program to identify opportunities to expand services and evaluate outcomes. 	<p><u>Conclusion</u> The board reviewed and accepted the presentation.</p>

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Respiratory Agents, Inhaled Quality Assurance Analysis	<p><u>Respiratory Agents, Inhaled Quality Assurance Analysis by Dr. Karen Stevens</u></p> <p>This overview was an evaluation of current medical literature and provided a brief overview of new guideline recommendations in this disease state.</p>	<p><u>Follow Up</u> Informational/Advisory</p>
Action	<p>Discussion</p> <ul style="list-style-type: none"> • Provide overview of current MassHealth management for class. • Present current MassHealth utilization and PA summaries. • Review guideline updates for asthma and COPD. 	<p><u>Conclusion</u> The board reviewed and accepted the presentation.</p>

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	<ul style="list-style-type: none"> Evaluate environmental impact of inhalers Discuss recommendations following QA analysis <p>Concluding Recommendations</p> <ul style="list-style-type: none"> Remove PA for Anoro® Ellipta (umeclidinium/vilanterol), Arnuity® Ellipta (fluticasone furoate), and Serevent® Diskus (salmeterol) due to similar net cost to comparative products available without PA. Brand Flovent® will be discontinued 12/31/23 by the manufacturer; therefore, place generic fluticasone propionate on PA (Brand Flovent® will continue to pay without PA while supplies are available). Update approval criteria for Breo® Ellipta in asthma due to age expansion. Update Trelegy® Ellipta criteria to require previous trial of either 1) Breo® Ellipta and Incruse® Ellipta or 2) Anoro® Ellipta and Arnuity® Ellipta. 	

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Respiratory Syncytial Virus Treatment Updates	<p><u>Respiratory Syncytial Virus (RSV) Treatment Update by Dr. Warren Smith</u></p> <p>This overview was an evaluation of current medical literature and provided a brief overview of new guideline recommendations in this disease state.</p>	<p><u>Follow Up</u></p> <p>Informational/Advisory</p>
Action	<p>Discussion</p> <ul style="list-style-type: none"> Review newly approved agents to prevent RSV. Discuss American Academy of Pediatrics (AAP) and Advisory Committee on Immunization Practices (ACIP) recommendations. Provide an overview of the RSV pipeline. <p>Concluding Recommendations</p> <ul style="list-style-type: none"> There are now multiple agents to prevent RSV lower respiratory tract disease (LRTD) in infants (Beyfortus®, Synagis®, maternal immunization with Abrysvo®). For the 2023-2024 RSV season, PA criteria for Synagis® will not change: Beyfortus® will be available without PA for members <8 months, based on recommendation; Beyfortus will require PA for members 8 to 19 months of age, including members with certain comorbidities: <ul style="list-style-type: none"> Severely immunocompromised; Cystic fibrosis with manifestations of severe lung disease; American Indian or Alaska Native descent; 	<p><u>Conclusion</u></p> <p>The board reviewed and accepted the presentation.</p>

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	<ul style="list-style-type: none"> ○ CLD of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the six-month period before start of RSV season or bronchopulmonary dysplasia; ○ Congenital diaphragmatic hernia and comorbid chronic lung disease; ○ Down syndrome and comorbid congenital heart disease, chronic lung disease, airway clearance issues, or prematurity; ○ Congenital abnormality of the airway or neuromuscular disease; ○ Congenital heart disease; or ○ Underwent cardio-pulmonary bypass procedure <ul style="list-style-type: none"> • Abrysvo[®] and Arexvy[®] are available for adults ≥60 years of age; shared clinical decision making between provider and patients should be utilized to determine who receives vaccine. • Abrysvo[®] was approved 8/21/23 for active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through six months of age. • Other agents in the pipeline have the potential to impact the RSV prevention landscape even further. <p>Questions</p> <ul style="list-style-type: none"> • Low inquired about the estimates about the projected Beyfortus utilization, as he read that numbers have increased in New Hampshire and wanted to know if one medication would be preferred over the other. <ul style="list-style-type: none"> ○ Smith responded that at that point in time, it was not clear, as some prescribers may still prefer Synagis over Beyfortus. However, with the recommendation in all infants <8 months of age, the number may be high compared to what has been seen with Synagis utilization (which is indicated in infants with comorbidities). 	

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MassHealth Drug List (MHDL) Update	<u>MHDL Update by Dr. Chris Nelson</u> MHDL overview included 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

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Action	<p>Discussion</p> <ul style="list-style-type: none"> • There were 10 additions to the MHDL Drug list effective October 2, 2023 (including six new drugs that will require PA). • Changes in PA Status for Compounded Products <ul style="list-style-type: none"> ○ A compounded pharmaceutical product with a total allowed ingredient cost < \$100 and non-topical route of administration compounded product will not require PA. ○ A compounded pharmaceutical product with a total allowed ingredient cost ≥ \$100 will require PA. ○ A compounded pharmaceutical product with topical route of administration will require PA. • Changes in Coverage Status <ul style="list-style-type: none"> ○ Enjaymo (sutimlimab-jome), Soliris, Padcev, Uplinza, and Vyvgart will be available through medical billing only and will no longer be available through pharmacy billing. • Changes to the MassHealth Brand Name Preferred Over Generic Drug List <ul style="list-style-type: none"> ○ Exelderm (sulconazole) and Invega (paliperidone tablet) will be removed from the MassHealth Brand Name Preferred Over Generic Drug List. • New FDA “A”-rated Generics <ul style="list-style-type: none"> ○ The generic of Mozobil, plerixafor, was added. • Changes to the MassHealth 90-day Initiative <ul style="list-style-type: none"> ○ Acamprosate, Canasa (mesalamine suppository), Catapres-TTS (clonidine patch), Intelence (etravirine), and Prezista (darunavir) have been added to the 90-day supply allowable list. ○ Alfuzosin extended-release, Timoptic Ocudose (timolol ophthalmic unit dose solution), and Zioptan (tafluprost) have been added to the 90-day supply mandatory list. • Miscellaneous Updates and Changes to the MassHealth Drug List <ul style="list-style-type: none"> ○ The introduction to the MassHealth Drug List has been updated with additional language to address exceptions to step therapy and to include additional language regarding the MassHealth policy around stability on samples. ○ All PA request forms will be updated with a new Step Therapy section. This section provides a space for providers to document additional rationale for an exception to alternative drug trials. ○ Omnipod Go will require PA and has been added to the MassHealth Non-Drug Product List. 	<p><u>Conclusion</u> The board reviewed and accepted the presentation.</p>

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	<ul style="list-style-type: none"> ○ Uzedy (risperidone extended-release subcutaneous injection) has been added to the MassHealth Supplemental Rebate/Preferred Drug List. ○ The generic gastrointestinal agent calcium polycarbophil will be added to the MassHealth Over-the-Counter Drug list. Once the initial dose of 30 days has been dispensed, it is required that the medication be filled for 90 days. ○ Effective August 16, 2023, the generic opioid reversal agent Narcan (naloxone) 4 mg nasal spray was added to the MassHealth Over-the-Counter Drug list. ○ A new document was added that lists prescription and over-the-counter naloxone products that are covered by MassHealth without PA. 	

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DUR Operational Update	<p><u>DUR Operational Update by Dr. Arthur Lam</u> DUR operational overview included statistics associated with PA review and PA response, and call center metrics.</p>	<p><u>Follow Up</u> Informational/Advisory</p>
Action	<p>Discussion</p> <ul style="list-style-type: none"> • MassHealth PA requests from 2020 to 2023 (calendar year to date) showing that with COVID leniencies to PAs initiated in March 2020, there was a decrease in PAs and then an increase in August 2020 with some leniencies removed. • MassHealth call center volume from 2020 to 2023 (calendar year to date) showing that with COVID leniencies initiated in March 2020, there was a decrease and then an increase when some leniencies removed in August 2020. • The monthly average for PAs from 2018 to 2023 (to date) were reviewed. The peak average was 10,547 per month in 2018 while currently in 2023 (to date), the average per month is 9,436. • Call abandonment rate is generally less than 2% (overall average is 1.3%). • Average wait time of answered call is generally under the 30-second range (overall average is 13 seconds). 	<p><u>Conclusion</u> The board reviewed and accepted the presentation.</p>

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	<ul style="list-style-type: none">Average treatment time is consistently around four minutes.MassHealth appeals: current monthly average is five.Provider outreach volume: current monthly average is 460 calls.Top 10 products requested for PA – July 1, 2022, to June 30, 2023:<table><tr><td>1. Dexcom PA</td><td>6. Pregabalin PA</td></tr><tr><td>2. Freestyle Libre PA</td><td>7. Methylphenidate PA</td></tr><tr><td>3. Ozempic PA</td><td>8. Botulinum PA</td></tr><tr><td>4. Tretinoin Age Restriction</td><td>9. Dextroamp-Amphetamine PA</td></tr><tr><td>5. Omnipod PA</td><td>10. Testosterone PA</td></tr></table>PA Compliance Response Time – July 2022 to June 2023<ul style="list-style-type: none">Total requests:106,574 requests73% of all PA decisions within six hours99.8% of all PA decisions in less than 24 hoursOver 50% of all PA decisions in less than three hoursPA Compliance Response Time during Call Center Hours – July 2022 to June 2023<ul style="list-style-type: none">Total requests: 106,574 requests95% of all PA decisions within six hours99% of all PA decisions in less than nine hours	1. Dexcom PA	6. Pregabalin PA	2. Freestyle Libre PA	7. Methylphenidate PA	3. Ozempic PA	8. Botulinum PA	4. Tretinoin Age Restriction	9. Dextroamp-Amphetamine PA	5. Omnipod PA	10. Testosterone PA	
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MassHealth Update	<p><u>MassHealth Update by Dr. Kimberly Lenz</u></p> <p>MassHealth update is a summary of recent developments in MassHealth in the context of pharmacy, managed care, or public health.</p>	<p><u>Follow Up</u></p> <p>Informational/Advisory</p>
Action	<p>Discussion</p> <ul style="list-style-type: none"> Medication Coverage <ul style="list-style-type: none"> Naloxone 	<p><u>Conclusion</u></p> <p>The board reviewed and accepted the presentation.</p>

Agenda Item	Discussion	Conclusions/Follow Up
	<ul style="list-style-type: none"> ▪ MassHealth and its Managed Care plans cover most prescription and all current OTC naloxone formulations without PA, without quantity limits, and with no copays. ▪ DPH will be issuing an updated standing order and bulletin to clarify the coverage of the OTC products. ▪ Pharmacy fax from MassHealth has been sent to pharmacies. ▪ Notify MassHealth of any issues. ○ Covid boosters have been approved and will be covered once they are in First Databank. • Compounding Management – October <ul style="list-style-type: none"> ○ PA may be required for compounded products based on the cost of the compound and the route of administration. ○ Pharmacy Fax to be sent out to provide specifics. • Legislative Updates <ul style="list-style-type: none"> ○ MassHealth is continuing to move forward with the redetermination process. <ul style="list-style-type: none"> ▪ Pharmacy Fax has been sent out to pharmacies to post for members to make sure they can update their eligibility. ▪ MassHealth has enhanced their call center so that they can withstand the volume increase. • MCO/ACPP Plans <ul style="list-style-type: none"> ○ Contract changes have been in process to go live as of January 1, 2024. • As of September 2023 <ul style="list-style-type: none"> ○ Supplemental rebate contracts for 63 drugs with 22 manufacturers ○ Eight value-based contracts with manufacturers ○ Over \$350 million (annualized) savings in total <p>Questions and comments</p> <ul style="list-style-type: none"> • Lenz asked the DUR Board if any of the members had experienced the shortage of Naloxone, as well as if they had received any feedback. <ul style="list-style-type: none"> ○ Labelle responded that they cut their supply in half and ordered directly from the pharmacy, not utilizing the OTC formulations. ○ Fensky responded that they check every other day. He also stated that they order from three different suppliers. ○ McVeigh responded that one contributory factor may be suppliers shifting their manufacturing from prescription to OTC. ○ Lenz followed up by asking that any issues be brought to the attention of MassHealth. 	

Agenda Item	Discussion	Conclusions/Follow Up
Open Forum	<u>Open Forum</u>	<u>Follow Up</u> Informational/Advisory
Action	Discussion <ul style="list-style-type: none"> This presentation was tabled until the next DUR Board meeting. 	<u>Conclusion</u> N/A

Meeting adjourned at 8:00 p.m.

Respectfully submitted by Mylissa Price

Date: _____