Iowa Medicaid Pharmaceutical and Therapeutics Committee
Minutes

Date: April 15, 2021

Chairperson: Mark Graber, M.D.
Erin Halverson, IME staff, assisted in running the meeting with the Chairperson due to the virtual format.

Time: 9:32 a.m. to 11:03 a.m.

Location: WebEx Teleconference (due to COVID-19)

Committee Members Present: Mark Graber, M.D.; Charles Wadle, D.O.; Carole Frier, D.O.; Kevin de Regnier, D.O.; Bruce Alexander, Pharm.D.; Holly Randleman, Pharm.D.; and Kellen Ludvigson, Pharm.D.

Iowa DHS Staff Present: Susan Parker, Pharm.D., Pharmacy Consultant

Iowa Medicaid Enterprise (IME) Staff Present: Steve Liles, Pharm.D.; Jacquelyn Hedlund, MD., MS; Erin Halverson, R.Ph.; Gina Kuebler, R.Ph.; Pam Smith, R.Ph.; and Melissa Biddle.

Managed Care Organization (MCO) Staff Present: Lisa Todd, Amerigroup Iowa; Emily Rogers, Iowa Total Care.

Chairperson Mark Graber called the meeting to order.

I. Mark Graber asked that each committee and DHS and IME staff member introduce themselves to the public. Kevin de Regnier disclosed that he was on the speaker's bureau for Novo Nordisk, and would be abstaining from any votes on their products and competitor products due to the conflict of interest. He also asked that the November 19, 2020 minutes be amended to clarify that competitor products were included in his abstentions when applicable, and that the full closed session motion language ought to be included rather than just a reference to Iowa Code section 21.5(1)(a), as decreed by Iowa Code section 21.5(2): "The vote of each member on the question of holding the closed session and the reason for holding the closed session by reference to a specific exemption under this section shall be announced publicly at the open session and entered in the minutes. A governmental body shall not discuss any business during a closed session which does not directly relate to the specific reason announced as justification for the closed session." He then made the motion to approve the August minutes as amended with his suggested changes, and Bruce Alexander and Carole Frier both seconded. The motion passed with no objections.

II. PDL and Drug Rebate Issues (Dr. Liles): Recent Federal legislation passed that would remove the cap on Medicaid rebates, but has been delayed again and will not go into effect until 2024. As most drugs that will be impacted by the change are older and used less often, Steve Liles did not think there would be a significant impact to the Medicaid program. There was also a recommendation on Medicaid rebates related to drugs that receive accelerated approval from the FDA, specifically that they be subject to a higher Medicaid rebate while under the conditional approval, until full approval is granted following confirmatory trials. The recommendation did also allow that some drugs would be excluded from this, potentially limiting the intended impact to encourage manufacturers to complete the work required to gain full approval. As Medicaid is

required to cover FDA approved drugs, even for the accelerated approval program, this would provide some relief to Medicaid in terms of higher rebates, and put the onus on the manufacturer to get the confirmatory trials done to get full approval for the drug in order to lower the rebate.

III. PA Criteria/Pro-DUR Edits (Dr. Parker): Susan Parker reviewed the informational letters that had been sent out since the last P&T Meeting in November, all posted online at http://iowamedicaidpdl.com/informational_letters and http://iowamedicaidpos.com/latest_news. Providers received Informational Letter 2190-MC-FFS regarding pharmacist administered vaccines. Informational Letter 2192-MC-FFS was related to PDL changes that went into effect January 1, 2021, following the November P&T Meeting. The committee also received a copy of the letter sent to the Department of Human Services from the DUR Commission after their March meeting, which included recommended criteria for: Elagolix Products; Select Anticonvulsants; and Satralizumab (Enspryng).

IV. Legislation (Dr. Parker): There were no updates, but likely will be some at the August meeting.

V. IME Updates: There was nothing notable to report.

VI. Public Comment: As this meeting was purely virtual, only written public comment was accepted. The committee members reviewed the received comments, which are posted at: http://www.iowamedicaidpdl.com/public-comments. They were also forwarded manufacturer comments as they were received via email prior to the meeting.

Provider Comment Received:
Excessive Prior Authorizations: Medications for common dermatologic diseases
Manufacturer Comments Received:
Oriahnn, Entresto, Phexxi

At 9:47, Kevin de Regnier motioned to go to closed session as authorized by Iowa Code Section 21.5(1)(a) of the Open Meetings Law to review or discuss economic records associated with the PDL which are required or authorized to be kept confidential. Carole Frier seconded, and the motion passed with unanimous roll call approval. Open session resumed at 10:40.

VII. PDL Discussion and Deliberation (Dr. Hedlund): All subsequent recommendations (with numbering as provided on agenda attachment 2) were made to maximize cost savings to the program unless otherwise noted.

1. Recommend to change Sunosi to Preferred with Conditions with step through armodafinil or modafinil.

Holly Randleman motioned to accept the recommendation, and Kevin de Regnier seconded. The decision was unanimous.

VIII. Newly Released Drugs (Dr. Hedlund): All following recommendations (with numbering as provided on agenda attachment 3) were made to maximize cost savings to the program unless otherwise noted. Complete new drug monographs can be found on the April meeting page at http://www.iowamedicaidpdl.com/schedule_page/april-15-2021. Dr. Hedlund reviewed the new drugs, and the recommendations were as follows:

1. Gavreto- Recommend status on the PDL as Non-Recommended with Conditions
2. Lampit- Recommend status on the PDL as Preferred
3. Oriahnn- Recommend status on the PDL as Non-Preferred with Conditions
4. Orladeyo- Recommend status on the PDL as Preferred with confirmation of diagnosis
5. Phexxi Gel- Recommend status on the PDL as Non-Preferred
6. Verquvo- Recommend status on the PDL as Non-Preferred

Holly Randleman motioned to accept the recommendations above, with the addition of referring Verquvo to the DUR Commission for development of PA criteria to confirm the appropriate diagnosis and clinical parameters for use, and Bruce Alexander seconded. The decision was unanimous.

IX. Newly Released Generic Drugs (Dr. Hedlund): All following recommendations were made to maximize cost savings to the program unless otherwise noted.

Drug Name	PDL/RDL Recommendation
Asenapine	Non-Preferred Step 3
Deferiprone	Non-Preferred
Efavirenz/ Emtricitabine/ Tenofovir	Preferred
Emtricitabine/ Tenofovir	Non-Preferred
Fosfomycin	Non-Preferred
Icosapent	Non-Preferred
Ivermectin Lotion	Non-Preferred
Lapatinib	Non-Preferred
Levothyroxine Capsules	Non-Preferred
Lubiprostone	Non-Preferred with Conditions
Meloxicam Capsules	Non-Preferred with Conditions
Metyrosine	Non-Preferred
Naproxen Sodium ER Tab 750mg	Non-Preferred with Conditions
Nitazoxanide	Non-Preferred
Rufinamide	Non-Preferred
Sapropterin	Non-Preferred with Conditions
Tavaborole	Non-Preferred with Conditions
Timolol Maleate Preservative Free Ophthalmic Solution	Non-Preferred
Tobramycin Neb 300mg/4mL	Non-Preferred

Bruce Alexander motioned to accept the recommendations above. Kevin de Regnier seconded, and all members were in favor.

X. New Drug Dosage Forms/Strengths/Combinations/BioSimilars (Erin Halverson): All following recommendations were made to maximize cost savings to the program unless otherwise noted.

Drug Name	PDL/RDL Recommendation
Alkindi Sprinkle	Non-Preferred with Conditions
Eysuvis	Non-Preferred
Impeklo	Non-Preferred with Conditions
Licart	Non-Preferred with Conditions
Lyumjev	Non-Preferred
Lyumjev KwikPen	Non-Preferred
Mycapssa	Non-Preferred
Nyvepria	Preferred with Conditions
Reditrex	Non-Preferred with Conditions
Sumansetron	Non-Preferred with Conditions
Sutab	Non-Preferred
Thyquidity	Non-Preferred
Trilociclo	Non-Preferred
Tyblume	Non-Preferred
Xywav	Non-Preferred with Conditions

Kevin de Regnier has a conflict of interest on Lyumjev and Lyumjev KwikPen, as they are manufactured by a Novo Nordisk competitor Eli Lilly, so he requested they be removed for separate consideration as per a parliamentary procedure consent agenda, so he could participate in as much of the voting as possible. Holly Randleman motioned to accept all the rest of the recommendations above, minus those two lines. Kellen Ludvigson seconded, and the decision was unanimous. Kellen Ludvigson then motioned to accept just the Lyumjev and Lyumjev KwikPen recommendations, with Bruce Alexander seconding, and Kevin de Regnier abstaining due to his conflict of interest as explained above. All other members were in favor.

A motion was made by Kellen Ludvigson to adjourn the meeting. It was seconded by Kevin de Regnier, and all in attendance approved. The meeting adjourned at 11:03 a.m. The next scheduled meeting is tentatively set for August 19, 2021.