Iowa Medicaid Pharmaceutical and Therapeutics Committee
Minutes

Date: November 16, 2017

Chairperson: Mark Graber, M.D.

Time: 9:30 a.m. to 1:00 p.m.

Location: Capitol Room 116, Des Moines, Iowa

Committee Members Present: Mark Graber, M.D.; Charles Wadle, D.O.; Carole Frier, D.O.; Bruce Alexander, Pharm.D.; Jolene Kelly, PA-C; Heidi Price-Eastman, R.Ph.; Kevin de Regnier, D.O.; 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: David Smith, M.D.; Steve Liles, Pharm.D.; Jacquelyn Hedlund, MD., MS; Erin Halverson, R.Ph.; and Gina Kuebler, R.Ph.

Managed Care Organization (MCO) Staff Present: Sandy Pranger, Amerigroup Iowa; Jennifer Schonhorst, AmeriHealth Caritas Iowa, and Karrie Hansotia, United Healthcare Plan of the River Valley.

Chairperson Mark Graber called the meeting to order.

I. Mark Graber asked that each committee, DHS, and IME staff member introduce themselves to the public. The August 17, 2017, open session minutes were reviewed. Jolene Kelly made the motion to approve the minutes, and Holly Randleman and Carole Frier both seconded. The motion passed with no objections.

II. Updated By-Laws: In addition to a typo correction, Kevin de Regnier proposed that the following bullet points be added to Article II:

- The pharmaceutical and therapeutics committee shall recommend a preferred drug list to the department.
- The committee shall develop the preferred drug list by considering each drug's clinically meaningful therapeutic advantages in terms of safety, effectiveness, and clinical outcome.
- The committee shall use evidence-based research methods in selecting the drugs to be included on the preferred drug list.
- The committee shall periodically review all drug classes included on the preferred drug list and may amend the list to ensure that the list provides for medically appropriate drug therapies for medical assistance recipients and achieves cost savings to the medical assistance program.

He then proposed these be stricken from Article II:

- The committee shall advise and make recommendations to the State on the development and maintenance of a preferred drug list.

- The committee shall advise and make recommendations to the state in the state's review and maintenance of a preferred drug list.
- The DHS will periodically make policy recommendations to the committee in order to promote efficiency.
- The DHS shall keep the committee informed on budget, program development, and policy needs.

He also proposed that the seventh bullet point under Article VI be revised to state:

- The P & T Committee shall conduct its meeting according to parliamentary procedures outlined in the most recent edition of *Robert's Rules of Order, Newly Revised*.

Originally, only one revised sentence under Article VI was tracked as an update, specifying that tentative agendas were now posted at the IME rather than the Hoover building. Dr. de Regnier will email his suggested changes to Erin Halverson, and a new draft will be brought to the next meeting for committee vote and approval.

III. Conflict of Interest Disclosure (Dr. Kevin de Regnier): Dr. de Regnier stated that since the last meeting he had been made aware that there might be an ongoing concern regarding a potential conflict of interest that exists between his work on this committee and his relationships with the pharmaceutical manufacturers, specifically Novo Nordisk. He appreciates the opportunity to address that concern. He fully agrees and acknowledges that potential conflict of interest exists. He said that was why, prior to his first meeting in August, he declared that potential conflict in writing on the forms provided by the State and disclosed that relationship. It's also why during the discussions on the committee, when they got to the point where that became relevant, he verbally informed the entire committee of that potential conflict and sought advice from the committee as to how best to proceed. And that's why on two separate occasions subsequent to that, he says he abstained from voting on matters that related to products manufactured by Novo Nordisk and its competitors (though there's only one abstention on record last meeting). He believes that he has conducted himself in an ethical manner and has at all times complied with the rules and laws of ethics that apply to membership of the committee. To him, the question at hand is, in light of that potential conflict of interest, can he be an effective member of the Iowa Medicaid P&T Committee. He values the work of this committee and would not want anything to bring that work into question, but he does believe that he can make a positive contribution to the work of the committee and do so without bringing the ethics of the committee into question. To ensure that he doesn't inadvertently stray from a potential conflict of interest into a true conflict of interest, he would ask that each of the committee members hold him accountable for his words and his actions. If at any time, any of them believes that he is about to cross that line between potential and true conflict, he asked that they would immediately call it to his attention, so that together, they can move the good work of the committee forward. He appreciates the confidence the governor expressed in him through his appointment to this committee and he looks forward to working with all of the members to earn their trust and confidence as well. He then offered to answer any questions. Chuck Wadle asked if any questions or concerns had been addressed to him, and he replied there had been. Mark Graber said that made a lot of sense, but also requested that a list of drugs made by Novo Nordisk and its subsidiaries be sent to the committee members, so they would know when discussing those products to ask Kevin de Regnier to excuse himself, to hold him accountable as he requested. Dr. Regnier agreed that made perfect sense.

IV. PDL and Drug Rebate Issues (Dr. Liles): This is the annual review for the PDL that will go into effect January 1, 2018. The annual SSDC pool meeting was done in August to review manufacturer offers. States are looking to expand the PDL to include classes with a lot of growth and new drug launches, such as Oncology, a class with significant costs to the state. The new gene therapies are also under consideration.

V. PA Criteria/Pro-DUR Edits (Dr. Parker): Informational Letter 1824-MC-FFS listed changes to the Preferred Drug List (PDL), new ProDUR quantity limits, and new and/or changing prior authorization (PA) criteria for: Rayaldee, Eucrisa, Emflaza, GLP-1 Agonist/Basal Insulin Combinations, Zurampic, New to Market Drugs, Kuvan, Viberzi, and Hepatitis C Treatments. Additionally, providers received three faxed notifications regarding PDL status changes. The committee also received copies of the letter sent to the Department of Human Services from the DUR Commission after their October meeting, which included a new recommended age edit on all tramadol-containing medications to restrict use in members under 18 years of age (with no 72-hour emergency override), as well as recommended criteria for Dupixent.

VI. Legislation (Erin Halverson): Informational Letter 1818-MC-FFS-D notified providers of the new Drugs for Rare Diseases Outpatient Pharmacy Benefit information request process, developed in response to House File 653 which states: "When making recommendations or determinations regarding beneficiary access to drugs and biological products for rare diseases as defined in the Federal Orphan Drug Act of 1983, publication number 97-414, and drugs and biological products that are genetically targeted, the committee shall request and consider information from individuals who possess scientific or medical training with respect to the drug, biological product, or rare disease." The individuals specified above must now be contacted prior to any recommendations and determinations. The IME will request the information through a public notification posted to the website and through a listserv for both P&T and DUR. A public notification request for comment will direct anyone who has the specified qualifications to prepare their public comment, which can be given in person or provided in writing. All public comments received in response will be posted to the websites and available to the public. The complete process for submitting written public comment was included in the informational letter.

VII. IME Updates: These was nothing in addition to those listed above.

VIII. Public Comment: The public speakers were:

Name	**Representing**	**Drug/Topic**
Tom Peddicord, Pharm.D.	Novartis	Entresto
Jennifer Stoffel, Pharm.D.	Janssen	Xarelto, Invokana
Gia McClean	Celgene	Otezla
Maggie Murphy, Pharm.D., MS	Teva	Austedo, Copaxone
Kim Bogard, Pharm.D.	Takeda	Alunbrig
Donald Nickels, Pharm.D., MSHA	Sanofi Genzyme	Kevzara
Hayley Young	UCB Inc.	Cimzia
Debbie Smith	UCB Inc.	Briviact, Vimpat
Cliff McCurdy III, Ph.D.	Tesaro Inc.	Zejula

Julie McDavitt, Pharm.D.	Boehringer-Ingelheim	Glyxambi, Spiriva, Stiolto
Sandra Dirks, Pharm.D.	Sunovion	Seebri Neohaler, Utibron Neohaler
Michael Nelson, Pharm.D.	Sunovion	Latuda, Aptiom
Kenneth Barry, R.Ph., Pharm.D.	Alkermes	Aristada
Randall Kavalier, D.O.	Neos Therapeutics	Adzenys XR-ODT, Cotempla XR ODT
Elizabeth Hur, Ph.D.	Supernus	Trokendi XR, Oxtellar XR
Marina Kisseleva	CSL Behring	Haegarda
Jason Lurk	Novo Nordisk	Victoza
Tom Brock, Ph.D.	United Therapeutics	Orenitram
Rob Hansen	Pfizer	Xeljanz
Tim Starner, M.D.	University of Iowa Cystic Fibrosis Center	Inhaled Antibiotics for Cystic Fibrosis, Tobi Podhalerf

At 11:18, motion to go to closed session was made by Heidi Price-Eastman and seconded by Chuck Wadle. The motion passed with unanimous approval. Open session resumed at 12:18.

IX. PDL Discussion and Deliberation (Voting Block 1 - Dr. Hedlund): All subsequent recommendations were made to maximize cost savings to the program unless otherwise noted. Recommended changes are as follows: Epaned to Non-Preferred; Bethkis to Preferred; tobramycin nebulization solution, labeler 00093, to Preferred; testosterone gel 1% packets to Preferred with Conditions; Androgel 1% Packets to Non-Preferred with Conditions; Bevespi aerosphere to Preferred; budesonide inhalation solution to Preferred with age edit; Pulmicort inhalation solution to Non-Preferred; Flovent Diskus to Non-Preferred; Asmanex to Non-Preferred; carbamazepine er tablets to Preferred and Tegretol XR to Non-Preferred (existing users with seizure diagnosis grandfathered); Vimpat to Preferred without a step edit ; Trintellix to Preferred; desvenlafaxine er to Preferred; clomipramine to Non-Preferred (authorized generic labeler 00406 remains preferred); desipramine to Preferred; Recombinate to Non-Preferred (existing users grandfathered); Xyntha to Non-Preferred (existing users grandfathered); quetiapine er to Preferred step 2; Abilify Maintena to Preferred step 2; aripiprazole to Preferred step 1; Latuda to Non-Preferred step 3 (grandfather existing users); and acarbose to Preferred. Bruce Alexander motioned to accept the recommendations above, and Chuck Wadle seconded. The decision was unanimous.

X. PDL Discussion and Deliberation (Voting Block 2 - Dr. Hedlund): All subsequent recommendations were made to maximize cost savings to the program unless otherwise noted. Recommended changes are as follows: NovoLog FlexPen to Preferred without Conditions; repaglinide to Preferred; Bydureon to Preferred with Conditions; Farxiga to Preferred with Conditions; Jardiance to Preferred with Conditions; Xigduo XR to Preferred with Conditions; Synjardy to Preferred with Conditions; Synjardy XR to Preferred with Conditions; ofloxacin otic solution to Preferred; ciprofloxacin otic solution to Non-Preferred; Coly-Mycin S to Preferred; Pentasa 250mg to Non-Preferred; Lotronex to Preferred; colchicine capsules to Preferred; Mitigare to Non-Preferred; Neupogen to Non-Preferred with Conditions; Granix to Preferred with Conditions; Sovaldi to Non-Preferred with Conditions; Harvoni to Non-Preferred with Conditions; Technivie to Non-Preferred with Conditions; Viekira Pak to Non-Preferred with Conditions; Viekira XR to Non-Preferred with Conditions; Imitrex subcutaneous solution to Non-

Preferred with Conditions and sumatriptan succinate subcutaneous solution to Preferred with Conditions; Zomig Nasal Spray to Preferred with Conditions; Besivance to Non-Preferred; ofloxacin ophthalmic solution to Non-Preferred; Moxeza to Preferred; and Vigamox to Non-Preferred. Chuck Wadle motioned to accept the recommendations above (with the exception of those for NovoLog FlexPen and Bydureon), and Kellen Ludvigson seconded. All members were in agreement. Chuck Wadle then motioned to accept the recommendations for NovoLog FlexPen and Bydureon, and Holly Randleman seconded. Kevin de Regnier abstained due to his conflict of interest with Novo Nordisk, but all other members were in favor.

XI. PDL Discussion and Deliberation (Voting Block 3 - Dr. Hedlund): All subsequent recommendations were made to maximize cost savings to the program unless otherwise noted. Recommended changes are as follows: Adzenys XR to Non-Preferred with Conditions; dexmethylphenidate er to Non-Preferred with Conditions and Focalin XR to Preferred with Conditions; methylphenidate er capsules (cd) to Non-Preferred with Conditions; Quillivant XR to Preferred with Conditions; Aptensio XR to Preferred with Conditions; armodafinil to Preferred with Conditions; and Buphenyl to Preferred. Bruce Alexander motioned to accept the recommendations above, and Kevin de Regnier seconded. The decision was unanimous.

XII. RDL Discussion and Deliberation (Dr. Hedlund): To maximize cost savings to the program, Epzicom was recommended to change to Non-Preferred. Bruce Alexander motioned to accept this recommendation, and Jolene Kelly seconded. All members were in favor.

XIII. Newly Released Drugs (Dr. Hedlund): All following recommendations were made to maximize cost savings to the program unless otherwise noted. Dr. Hedlund reviewed the new drugs, and then the committee voted unanimously in favor of all the recommendations as follows: Alunbrig, Non-Recommended with Conditions; Austedo, Non-Preferred; Benlysta, Non-Preferred; Idhifa, Non-Recommended with Conditions; Ilaris, Non-Preferred with Conditions; Ingrezza, Preferred; Kevzara, Non-Preferred with Conditions; Mavyret, Preferred with Conditions; Rubraca, Non-Recommended with Conditions; Rydapt, Non-Recommended with Conditions; Seebri Neohaler, Non-Preferred; Siliq, Non-Preferred with Conditions; Tremfya, Non-Preferred with Conditions; Tymlos, Non-Preferred; Utibron Neohaler, Non-Preferred; Vosevi, Non-Preferred with Conditions; Xermelo, Non-Preferred; and Zejula, Non-Recommended with Conditions. Kevin de Regnier motioned to accept the recommendations above, and Holly Randleman seconded. All members were in favor.

XIV. Newly Released Generic Drugs and New Drug Dosage Forms/Strengths/Combinations (Dr. Hedlund): All following recommendations were made to maximize cost savings to the program unless otherwise noted. The following were all recommended to be Non-Preferred with Conditions: adapalene/benzoyl peroxide, eletriptan, testosterone solution, Cotempla, and Mydayis. The following were all recommended to be Non-Preferred: lanthanum, prasugrel, scopolamine patch, vigabatrin, Armonair RespiClick, and Haegarda. Kellen Ludvigson motioned to accept the above recommendations. Jolene Kelly seconded the motion, and all members were in favor.

XV. Additional Committee Business: Holly Randleman proposed that Entresto be referred to the DUR Commission for re-evaluation of PA criteria due to the update in guidelines in 2016 regarding novel agent class 1b recommendation. Mark Graber believed it was already on the December

DUR agenda, but Erin Halverson will also draft a DUR recommendation letter. Susan Parker clarified that when AAC rates are set, they only capture prices for the authorized generic when one is available and preferred; pharmacies are reimbursed based on this pricing. Otherwise, if all generics are available equally, the rate setting process captures pricing for all the generic products that are available in terms of the invoice collection that the rate setting processor does.

A motion was made by Holly Randleman to adjourn the meeting. It was seconded by Heidi Price-Eastman, and all in attendance approved. The meeting adjourned at 1:00 p.m. The next scheduled meeting is tentatively set for April 19, 2018.