Iowa Medicaid Pharmaceutical and Therapeutics Committee
Minutes

Date: August 16, 2018

Chairperson: Mark Graber, M.D.

Time: 9:32 a.m. to 11:30 a.m.

Location: Capitol Room 116, Des Moines, Iowa

Committee Members Present: Mark Graber, M.D.; Charles Wadle, D.O.; Bruce Alexander, Pharm.D.; Jolene Kelly, PA-C; Heidi Price-Eastman, R.Ph.; Kevin de Regnier, D.O.; and Holly Randleman, Pharm.D.

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

Iowa Medicaid Enterprise (IME) Staff Present: Steve Liles, Pharm.D.; Laureen Biczak, D.O.; Erin Halverson, R.Ph.; Gina Kuebler, R.Ph.; and Melissa Biddle.

Managed Care Organization (MCO) Staff Present: Sandy Pranger, Amerigroup Iowa; and Reanna Yenger, 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 April 19, 2018, open session minutes were reviewed. Chuck Wadle made the motion to approve the minutes, and Bruce Alexander seconded. The motion passed with no objections.

II. Committee Elections: Bruce Alexander motioned to retain Mark Graber as chairperson, and Chuck Wadle as vice-chairperson. Kevin de Regnier seconded, and all members in attendance were in favor. Committee members were asked to complete their annual conflict of interest and confidentiality forms if they had not already done so. Kevin de Regnier also disclosed aloud that he was on the speaker's bureau for Novo Nordisk.

III. Committee discussion regarding role of evidence-based guidelines in decision making: At the April meeting, Kevin de Regnier said he would like to discuss the role that evidence-based guidelines and emerging scientific clinical data should play in decision making. The other committee members agreed it could be added to this meeting agenda. In response, Laureen Biczak, Medical Director for Change Healthcare and practicing infectious disease specialist, explained the make-up of the Change Healthcare clinical team and their process for reviewing medications and their recommended placement on the PDL or RDL, including evidence-based principles and criteria for levels of evidence. The Change Healthcare Clinical Executive Council, composed of 3 board-certified actively practicing physicians, a full-time physician biostatistician, pharmacists, and business analysts, oversees all clinical activities at Change Healthcare. The larger clinical team consists of more than 50 pharmacists, 15 nurses, and 4 physicians. The clinical teams look at clinical and financial services and analyses of new and existing drugs for state Medicaid clients, including Iowa. The way Change Healthcare does its scope of work for

Iowa includes looking at new drugs, looking and comparing them to existing drugs, and looking at the evidence, while also looking at the financial information. Good drugs can also be very expensive; cost must be considered along with clinical benefit. Change Healthcare then presents recommendations, including prior authorization requirements or PDL placement, to the appropriate committee. The committees hear the evidence and information and make their recommendation, and the state client, Iowa DHS, makes the final decision. Prior to arriving at the final recommendations presented to the committees, Change Healthcare has a very evidence-based philosophy, and everything they do is based on a clinical analysis of the available literature. A variety of sources are used, including but not limited to: peer-based literature, Cochrane reviews, National Center for Cancer Network, NCCN guidelines, and ICER group analyses. They do literature searches and attempt to come up with clear metrics like number needed to treat (NNT) or number needed to harm (NNH), particularly when writing therapeutic class reviews and preparing new drug reviews. Everything Change Healthcare does starts with clinical information, and then the value is evaluated. Inexpensive drugs will not be preferred just because they're inexpensive if they're also ineffective, though good drugs will likely be preferred, as long as their cost is not too prohibitive. Of course, some value judgements are difficult, such as questioning the value of once-a-day versus twice-a day dosing, twice the cost versus 10 times, or 30% versus 40% efficacy. The answers depend on how serious the consequences of the drug not working are; for instance, when stroke or permanent disability are possible, that matters. If it's more like an improvement of GERD, the value might be different. That's why it's important that the committee not only know the clinical characteristics of the drugs but also see the relative pricing. Price does matter, after clinical efficacy is taken into account. If drugs are the same in terms of efficacy and adverse events, then cost comes into play clearly. When evidence is looked at for the basis of recommendations, it is rated on Change Healthcare's propriety evidence scale. There are a lot of available evidence scales, but what matters to a committee like this is patient-oriented outcomes. Does it lessen mortality, or does it lower blood pressure? The two are not the same. The new beta-blocker may lower blood pressure, but there's no evidence it decreases heart attacks or strokes or mortality. Dr. Barkin, the Change Healthcare psychiatrist, helped write a table that shows criteria needed for 3 different levels of evidence; it compares randomization, risk of bias, whether it's blinded, whether it defined endpoints, whether they're using intent-to-treat analysis, and appropriate handling of drop-outs. Good studies receive a 1 rating, lower quality studies a 2, and case-controlled or expert opinion a 3. However, level 1 evidence is split into 1a and 1b, with 1a being patient-oriented outcomes and 1b being proxy outcomes. There are a lot of diseases where the benefit to patients is unknown. A drug may help them walk farther in 6 minutes, but whether that translates into improved morbidity is really the question. That is looked at as well, and that information used to form a clinical basis for the reviews provided to the committee. It is all evidence-based, and based on full studies. Change Healthcare does not use abstracts and will not generally include information that's only available in poster form or non-published. There is often more information that comes out when the studies are published; outcomes may not be as good as reported when one can see what they did with the drop-outs and so forth. Then Change Healthcare uses its financial modeling tools to see what the cost of the drugs is to the state, which is how the recommendations originate. It is also necessary to do this on an ongoing basis, when drugs get a new indication or new studies come out. The new drug reviews the committee receives are often the lightest touch of Change Heathcare's research, as they're done right after the drug comes out when there are not usually any well accepted evidence-based guidelines available. Recommendations to the state are updated as that information changes. The Hepatitis C category,

for instance, changes month to month. Steve Liles provided as example of how Victoza, which had been non-preferred as it was more expensive than Bydureon, was moved to preferred due to evidence of improved cardiovascular outcomes. Mark Graber pointed out that a lot of the guidelines put out by the different societies were not really evidence-based, and something like 86% of the people involved have conflicts of interest. He thinks not following the action of specialty societies is a good thing, and it's better that the Change Healthcare and DHS staff and committee members evaluate the literature themselves. Laureen Biczak agreed and said that's why Change Healthcare uses a combination of the evidence. The Cochrane collaborative and European NICE usually have good information. Change Healthcare uses the available sources and tries to speak to the evidence when possible. Steve Liles added that the guidelines were worth considering, but they're not the Bible. In summary, the one-line recommendations provided to the committee are the culmination of the clinical process described above, integrating research of literature, expert opinion, Up-to-Date, DynaMed, etc. Kevin de Regnier had several follow-up questions which were also addressed. He said it seemed like a greater emphasis was placed on morbidity and mortality and lower emphasis on quality of life. Laureen Biczak responded that that wasn't necessarily the case and depended upon the disease. For some diseases, quality of life may be the most patient-oriented outcome there is, but would not apply, for instance, to a blood pressure medication. The improved 6-minute walk has not been linked to anything tangible like improved muscular function; however, a patient-oriented outcome of less falls or fewer hospitalizations would be a factor in the decision-making. Steve Liles added that he likes the approach ICER is taking with quality of adjusted life years. Kevin de Regnier then referenced the Iowa Code 249A.20A language that states the committee shall periodically review all drug classes included on the Preferred Dug 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 asked how a reduction in hospitalizations or ER utilizations would be incorporated into the analyses and calculations for the pharmacy and therapeutics budget. Laureen Biczak responded that these are considered, for example with Entresto, and certainly play into a lot of the prior authorization decisions, though they're not necessarily figured into the calculations and reflected on the cost sheets. Kevin de Regnier asked that given the outside expert opinions provided, what the role of the committee having received those was, to simply agree or independently investigate and do the research themselves. Mark Graber responded that evidence-based medicine isn't easy, and he gets paid to do it; he does review the articles himself. However, he doubted that everyone had the same level of knowledge on the subject. Holly Randleman admitted that while she does try to review the information, she would likely focus more attention on medications common to her practice. Chuck Wadle commented that the question was posed as if the committee members could only do one thing or the other, when there have been occasions when recommendations were overturned during meetings due to differing committee opinion. Committee members were reminded that they could always use their own judgement and expertise and reject or suggest alternatives to the recommendations provided by Change Healthcare and DHS staff. Laureen Biczak added that was partly why the meetings were open to the public so that members, providers, advocacy groups, and drug manufacturers could provide their comments prior to committee voting. Kevin de Regnier also asked if the state had done any of its own research on the Medicaid patient population to look into hospitalization and ER visit rates as related to certain medications. Mark Graber replied that was beyond the scope of the committee, but would also be hard to do accurately as other factors besides the drug would come into play. Laureen Biczak added that given the

transient nature of the Medicaid population, it was difficult to follow members over time and verifying data was far harder and costlier than one might think, especially now that medial data is scattered between the fee-for-service and MCO plans. However, the different departments and companies do work together sometimes. A study was done by IME to see how the recent Synagis guideline changes impacted hospitalization rates. Susan Parker pointed out that while the pharmacy and medical programs are separate, they do try to coordinate on certain things that overlap, such as Synagis, which has the same prior authorization criteria for both departments. Both claim sets were utilized for the IME Synagis analysis.

IV. PDL and Drug Rebate Issues (Dr. Liles): The annual SSDC meeting took place 2 weeks ago, and resulting supplemental offers will be reviewed at the annual P&T meeting in November. The PBM industry is currently being reviewed by national and state legislatures, though Change Healthcare is actually a PBA. The Trump administration has a blueprint to control drug costs; one idea reduces the impact of rebates and forces manufacturers to compete on pricing up front. However, this should not impact Medicaid rebates overall per Steve Liles.

V. PA Criteria/Pro-DUR Edits (Dr. Parker): Informational Letter 1902-MC-FFS listed changes to the Preferred Drug List (PDL), new ProDUR quantity limits, guanfacine er tablet age edit, as well as updated prior authorization (PA) criteria for Anti-Diabetic Non-Insulin Agents. Informational Letter 1907-MC-FFS notified providers that effective July 1, 2018, prior authorization would be required for use of high-dose opioids $\geq$ 200 morphine milligram equivalents (MME) per day, and listed the applicable criteria. Informational Letter 1925-MC-FFS explained the increase to the dispensing fee, from $10.02 to $10.07, effective November 1, 2018, or the first day of the month following the approval by CMS. Additionally, providers received a faxed notification regarding a PDL status change for vancomycin capsules. The committee also received copies of the letters sent to the Department of Human Services from the DUR Commission after their June and August meetings, which included recommended criteria for: Vesicular Monoamine Transporter (VMAT) 2 Inhibitors, Hepatitis C Agents, Janus Kinase Inhibitors, Biologicals for Arthritis, Apremilast (Otezla), Methotrexate Injection, Chronic Pain Syndromes, CNS Stimulants and Atomoxetine, Tezacaftor/Ivacaftor (Symdeko), and Letermovir (Prevymis).

VI. Legislation (Dr. Parker): There is nothing notable to report.

VII. IME Updates: There is nothing notable to report.

VIII. Public Comment: The public speakers were:

Name	**Representing**	**Drug/Topic**
Joe Cirrincione, Pharm.D.	Otsuka	Jynarque
Jennifer Wilbanks, Pharm.D.	Sunovion	Lonhala Magnair

At 10:20, motion to go to closed session was made by Holly Randleman and seconded by both Heidi Price-Eastman and Chuck Wadle. The motion passed with unanimous approval. Open session resumed at 11:04.

IX. PDL Discussion and Deliberation (Dr. Biczak): All subsequent recommendations were made to maximize cost savings to the program unless otherwise noted. Recommended changes are as follows: Diclegis, Alprolix, Welchol, and prasugrel to Preferred; and Neupogen vials to Preferred

with Conditions for members less than 18 years of age. Jolene Kelly motioned to accept the recommendations above, and Holly Randleman seconded. The decision was unanimous.

X. RDL Discussion and Deliberation (Dr. Biczak): All subsequent recommendations were made to maximize cost savings to the program unless otherwise noted. Recommended changes are as follows: Zytiga to Non-Recommended with Conditions, Xtandi to Recommended with Conditions, and Norvir tablets to Preferred. Bruce Alexander motioned to accept these recommendations, and Kevin de Regnier seconded. All members were in favor.

XI. Newly Released Drugs (Dr. Biczak): All following recommendations were made to maximize cost savings to the program unless otherwise noted. Dr. Biczak reviewed the new drugs, and the recommendations were as follows: Erleada, Recommended with Conditions; Jynarque, Non-Preferred; Lucemyra, Non-Preferred; Palynziq, Non-Preferred; Rhopressa, Preferred; and Symdeko, Non-Preferred with Conditions. Chuck Wadle motioned to accept the recommendations above, and Heidi Price-Eastman seconded. The decision was unanimous.

XII. Newly Released Generic Drugs and New Drug Dosage Forms/Strengths/Combinations (Dr. Biczak): All following recommendations were made to maximize cost savings to the program unless otherwise noted. The following were all recommended to be Non-Preferred: colesevelam, miglustat, praziquantel, ritonavir, tiagabine, Balcoltra, Bonjesta, Lonhala Magnair, Xhance, and Zypitamag. The following were all recommended to be Non-Preferred with Conditions: memantine er, Gocovri, and Osmolex ER. Cimduo and Symfi Lo were both recommended to be Preferred, Norvir Oral Powder Packets Recommended, and Yonsa Non-Recommended with Conditions. Kevin deRegnier motioned to accept the recommendations above, and Jolene Kelly seconded. All other members were in favor.

A motion was made by Holly Randleman to adjourn the meeting. It was seconded by Bruce Alexander, and all in attendance approved. The meeting adjourned at 11:30 a.m. The next scheduled meeting is tentatively set for November 15, 2018.