Iowa Medicaid Pharmaceutical and Therapeutics Committee
Minutes

Date: August 17, 2017

Chairperson: Mark Graber, M.D.

Time: 9:30 a.m. to 12:18 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.; and Kellen Ludvigson, Pharm.D.

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

Iowa Medicaid Enterprise (IME) Staff Present: Jeffrey Barkin, M.D.; Erin Halverson, R.Ph.; Gina Kuebler, R.Ph.; and Melissa Biddle.

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.

Vice-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 20, 2017, open session minutes were reviewed. Bruce Alexander made the motion to approve the minutes, and Chuck Wadle seconded. The motion passed with no objections.

II. Committee Elections: Carole Frier nominated Mark Graber for chairperson, and Bruce Alexander seconded. All members were in favor. Jolene Kelly then nominated Chuck Wadle for vice-chairperson, and Carole Frier seconded. This decision was unanimous, as well. Committee members were also asked to complete their annual conflict of interest and confidentiality forms if they had not already done so.

III. PDL and Drug Rebate Issues (Dr. Liles): The 12 SSDC pool states met via conference call for a preparatory meeting in June, and then again in August to make decisions about the 2018 contracts. The P&T Committee will be doing the full PDL review, which will include the 2018 offers and updated pricing, at November meeting. Congress passed a law effective the first quarter of 2017 that will impose a rebate inflation penalty on manufacturers when prices on their generic drugs increase faster than the rate of inflation.

IV. PA Criteria/Pro-DUR Edits (Dr. Parker): Informational Letter 1786-MC-FFS listed changes to the Preferred Drug List (PDL), new ProDUR quantity limits, and changes to the prior authorization (PA) criteria for: Exondys 51, Colchicine, Pre-Filled Insulin Pens, and Orkambi. Additionally, providers received a faxed notification regarding a POS system maintenance window, and two notifications regarding PDL status changes. 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 new ProDUR quantity limits as well as recommended criteria for: GLP-1 Agonist/Basal Insulin Combinations; Rayaldee; Zurampic; Kuvan; High Dose Opioids; Emflaza; Hepatitis C Treatments; Eucrisa; Viberzi; and New to Market Drugs.

V. Legislation (Erin Halverson):

1. HF653 Report – Step Therapy Protocol for Prescription Drugs: The legislature is requiring DHS to review the use of step therapy protocols and the application of step therapy override exceptions in the Iowa Medicaid program. In the review the Department may consider the use of step therapy protocols and the application of step therapy override exceptions as provided in Chapter 514F.7 if enacted by 2017 Iowa Acts House File 233 and the potential for improving the quality of life of Medicaid members and increasing efficiencies in the Medicaid program. The Department shall report findings of the review and recommendations to the individuals designated in this Act for submission of reports by November 15, 2017. 514F.7 has to do with those providers that are under the jurisdiction of the insurance commissioner, and Medicaid is not. House File 233 was enacted as part of the legislation under the insurance division section, and defines step therapy as a protocol or program that establishes a specific sequence in which prescription drugs for a specified medical condition, and medically appropriate for a particular covered person, are covered under a pharmacy or medical benefit by a health carrier, health benefit plan, or utilization review organization, including self-administered drugs and drugs administered by a health care professional. Both the IME Pharmacy and Medical benefits will be reviewing this. From a Pharmacy benefit perspective, it would impact the sequence requiring someone to try a preferred medication before allowing them to take a non-preferred medication, as well as some of the established criteria in the PA criteria. IME will be looking at the current process versus the process that is defined in the House File to see if any changes or improvements need to be made, or if requirements are already being met. IME has a relatively transparent process for how it does things, compared to what some of the other insurers do. Erin Halverson believes the language found in section 1, subsections 2 and 3 would be most applicable to the P&T Committee review. With regards to establishment of step therapy protocols, subsection 2 states: "A health carrier, health benefit plan, or utilization review organization shall consider available recognized evidence-based and peer-reviewed clinical practice guidelines when establishing a step therapy protocol. Upon written request of a covered person, a health carrier, health benefit plan, or utilization review organization shall provide any clinical review criteria applicable to a specific prescription drug covered by the health carrier, health benefit plan, or utilization review organization." Erin Halverson noted that both the DUR Commission and P&T Committee already do this for PDL considerations and PA criteria, and all information is also posted to the websites and available to providers. Subsection 3 covers step therapy override exceptions process transparency as follows:

   a. When coverage of a prescription drug for the treatment of any medical condition is restricted for use by a health carrier, health benefit plan, or utilization review organization through the use of a step therapy protocol, the covered person and the

prescribing health care professional shall have access to a clear, readily accessible, and convenient process to request a step therapy override exception. A health carrier, health benefit plan, or utilization review organization may use its existing medical exceptions process to satisfy this requirement. The process used shall be easily accessible on the internet site of the health carrier, health benefit plan, or utilization review organization.

b. A step therapy override exception shall be approved by the health carrier, health benefit plan, or utilization review organization if any of the following circumstances apply:
   1) The prescription drug required under the step therapy protocol is contraindicated pursuant to the drug manufacturer's prescribing information for the drug or, due to a documented adverse event with a previous use or a documented medical condition, including a comorbid condition, is likely to do any of the following:
      (a) Cause an adverse reaction to a covered person.
      (b) Decrease the ability of a covered person to achieve or maintain reasonable functional ability in performing daily activities.
      (c) Cause physical or mental harm to a covered person.
   2) The prescription drug required under the step therapy protocol is expected to be ineffective based on the known clinical characteristics of the covered person, such as the covered person's adherence to or compliance with the covered person's individual plan of care, and any of the following:
      (a) The known characteristics of the prescription drug regimen as described in peer-reviewed literature or in the manufacturer's prescribing information for the drug.
      (b) The health care professional's medical judgment based on clinical practice guidelines or peer-reviewed journals.
      (c) The covered person's documented experience with the prescription drug regimen.
   3) The covered person has had a trial of a therapeutically equivalent dose of the prescription drug under the step therapy protocol while under the covered person's current or previous health benefit plan for a period of time to allow for a positive treatment outcome, and such prescription drug was discontinued by the covered person's health care professional due to lack of effectiveness.
   4) The covered person is currently receiving a positive therapeutic outcome on a prescription drug selected by the covered person's health care professional for the medical condition under consideration while under the covered person's current or previous health benefit plan. This subparagraph shall not be construed to encourage the use of a pharmaceutical sample for the sole purpose of meeting the requirements for a step therapy override exception.

Erin Halverson noted that the IME already gives consideration for the situations listed above through prior authorization, and through the exception to policy process which is available on the website.

- Specifically to subsection 3 b1 (contraindicated) and b3 (prior trial & failure), when proper medical documentation is provided.

- For subsection 3 b2 (expected to be ineffective & compliance) and b4 (established) could also be considered if valid clinical information is provided.
  - Medicaid can only reimburse for medications for a medically accepted indication, so this would open the door for potential off-label use. Medicaid regulations would still have to be followed in addition to the new House File regulations. Erin Halverson also pointed out that Medicaid does not always pay for the most convenient drug, either.
  - In terms of grandfathering, the P&T Committee determines when grandfathering will apply when they review medications and there is a PDL status change. However, their use of grandfathering is very specific and may not be applicable to classes of drugs in general. This would be a change to the current process, and could have the most financial impact. Steve Liles will provide a high-level estimate on costs.

Carole Frier asked if this would encourage more sampling, and Erin Halverson responded that could be seen in the claims histories. Chuck Wadle asked how they were defining adverse reactions, and whether side effects would be included in that definition. Erin Halverson agreed there was no actual definition provided, and that would be a judgement call on the part of whoever was reviewing the prior authorization. She also noted that when these exceptions are applied in private insurance there are consequences such as higher copays to the member that might prevent so many from skipping steps, whereas Medicaid cannot charge higher copays for higher tiers of drugs. Medicaid is also required to only cover usage for FDA approved and compendia indications, so copying the private insurer language directly to Medicaid with no modifications may result in unintended consequences. Kevin de Regnier commented that while he was pleased to hear that Medicaid was already fulfilling many of these bullet points, he believed that was not widely known in the provider community, and that this legislative report request likely reflected their frustration with the PDL and PA processes. He suggested an educational initiative, including informational letters and presentations to organizations, to help clinicians understand the decisions made by the P&T Committee and DUR Commission and hopefully improve patient care. DHS is developing a response to the legislative report request and will incorporate the comments above; the final version will be provided to the P&T Committee.

Additionally, in response to public comment provided by Lon Anderson from Celgene (submitted written version posted on www.iowamedicaidpdl.com) wherein he referenced a survey that had been conducted in regards to providers' experience with step therapy protocols, the committee and IME staff had the following questions and comments:

- Chuck Wadle commented that it sounded like Lon Anderson had referenced a grandfathering phenomenon, that patients were forced to go off of the medication they'd been taking. He admitted this could be an issue, and that the committee tries to grandfather medications when possible. However, his confusion, particularly in psychiatry, with multiple antipsychotics, antidepressants, mood stabilizers, is the supposition that IME is forcing step therapy. He would contend that if there were absolutely no restrictions by payers, that the psychiatrist or prescriber might still do step therapy of their own accord, as they're not

necessarily picking the drug that will work the first time. Therefore, it's an erroneous argument that step therapy is prejudicial, particularly in a world of psychotropics, because there are so many that are potentially equally effective or haven't been demonstrated not to be equally effective. He would also challenge that just because they're failing on the medications, they're not necessarily bouncing into the hospital. In response to Lon Anderson's comment that mental health was way different than just a normal health issue and thus presents the possibility that a drug that would work for one individual won't for another, Chuck Wadle and Susan Parker both reiterated that this could apply to all drug categories.

- Jeff Barkin asked when the data was collected that generated this 96% response. Lon Anderson answered that it was collected over the summer. Susan Parker asked what number of people responded. Bruce Alexander asked how was the survey done and what was the margin of error. Chuck Wadle chimed in that it was in part a solicitation by the Iowa Psych Society. Lon Anderson said that was correct and he would have to get the specifics.

- Jeff Barkin said he thought they did have a couple of good points, but he thinks that they may be more historic. He added that he has been president of the State of Maine Psychiatric Association for 5 years, and he's also the treasurer of the largest mental health agency in the state, so he is familiar with access issues. Nobody would want to have problems in terms of having a sick person get services. When PDLs were started, going back to the early days of 2005-2006, it was very disruptive. He had patients whose clinical course was clearly disrupted, but he thinks that 2 phenomena happened:

  1) Post patent cliff, pretty much anything he needs to prescribe can now be prescribed with generics (across all psychiatric drug classes). He can't think of a single exception. He thinks clozapine should be used a whole lot more than it is. That would be his only criticism of antipsychotics. With antidepressants, he doesn't even know how prescribers decide which medication to choose, there are so many generics. Stimulants, same thing. So he thinks it was disruptive back in the day, but not now.

  2) He thinks that there are big differences between fee-for-service systems and managed care organizations that have different processes. He knows that one of his personal corporate goals is a turn-around time of less than 6 hours. So any prior authorization that gets a denial, or is going to get a denial, is going to come to him. It's just not an issue anymore, because if it's going to be an issue it gets approved. So if this is lobbying but without a problem, that would be helpful to know. He wondered if there were more complaints with managed care than fee-for-service, because as a practicing psychiatrist it's really hard with commercial managed care companies to even get generics approved. He thinks it's important to separate these things out. Lon Anderson conceded that with managed care being so new in Iowa, that may be a part of it. Also, he noted that the bill that passed last year did not

differentiate between brand name drugs and generics, and they weren't attempting to favor brands over generics.

- Steve Liles said if you look at the PDL, most everything is preferred in the areas of psychotropics, antidepressants, and antipsychotics, so he really struggles to understand what the issue is. Occasionally there might be an issue with a PA, but there's not a whole heck of a lot that requires a PA that's not already preferred on the PDL. So to have that be the root cause of all this, he has a little consternation. He has been doing this for a while as well, including back when generics weren't available and brand name drugs were being made non-preferred. He's been down this road before, when it was a more legitimate argument. He asked if there were any specific drugs causing this issue, but Lon Anderson said he would have to get back to him on that.

- Mark Graber said the fact that patients were lobbying for this doesn't give him any hope, because what if they were lobbying for cardiac catheterizations? Patients may not know what's the most appropriate treatment. Lon Anderson responded that the patient advocates that Celgene had been working with had been working very closely with their doctors, so they knew. Chuck Wadle agreed that some of that drive is the direct marketing; he referenced one of his patients that had wanted to try Abilify due to seeing the TV commercial, despite the fact that he was feeling alright on his existing regimen.

- Steve Liles asked if they were also lobbying the manufacturers to keep the drug prices down so that prior authorizations wouldn't be necessary. Lon Anderson's response was "no comment".

- Erin Halverson requested that Lon Anderson send any additional information he wished to share to the info@iowamedicaidpdl.com address. It will then be forwarded to the committee members.

2. HF653 Process – Biologics and Genetically Targeted Drugs: With HF653, the Iowa legislature made a change to the P&T Committee and DUR Commission code language, 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." Section 249A.20A is directed more toward the P&T Committee, and requires that the individuals specified above be contacted prior to any recommendations and determinations. The IME has developed a new process, wherein 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 form is being drafted; it will direct anyone who has the specified qualifications to prepare their public comment, which can be given in person or

provided in writing. Once completed, it will be sent out to the listserv and also posted to the website. All public comments received in response will be posted to the websites and available to the public. An informational letter will go out to providers and both the PDL and DUR websites will be updated in the near future. Kevin de Regnier questioned if the newly designed process actually met the requirements implied by the use of the word "shall", to which Erin Halverson responded that it had been approved by the legal team and that the IME doesn't always know who has the expertise in order to contact them directly. This will definitely impact the review process, especially as the P&T Committee only meets three times per year; 7 drugs were removed from this meeting agenda because of this new policy. Mark Graber commented that the DUR Commission already sends everything out to organizations for comments prior to final recommendations to DHS. Erin Halverson said those societies have been added to the P&T listserv as well. Susan Parker noted that while it may not have been a formal written legislative process requirement, clinical staff already seek input in applicable areas from both manufacturers and providers as part of the administrative review process, before a recommendation is even made. She also stressed that a lot of the orphan drugs have limited specialists, and those might be out of state. Fortunately, public comment is not limited solely to individuals locally in Iowa. Jeffrey Barkin reminded them that Change Healthcare employs several practicing doctors, including himself, a psychiatrist; Laureen Biczak, an infectious disease specialist; and Jacqueline Hedlund, an oncologist, who review medications prior to recommendations. Decisions are not solely financial. Before new drug reviews are created, they've already met with industry representatives and reviewed all of the clinical literature, and likely also met with other specialists. To keep things open, he agreed this was probably the most transparent process, and the Change Healthcare physicians would always be there to back it up and readily accept feedback. He said they would be meeting with neurologists soon to discuss the new multiple sclerosis drugs. He believes the processes used by the staff physicians in combination with the new changes address not just the letter but also the intent of the code language.

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

VII. Public Comment: The public speakers were:

Name	Representing	Drug/Topic
Julie McDavitt	Boehringer-Ingelheim	Synjardy XR
Al Fear	The Eastern Iowa Heroin Initiative	Vivitrol
Kenneth Berry	Alkermes	Vivitrol
Dan Allen	Sanofi-Genzyme	Dupixent
Lon Anderson	Celgene	Step Therapy
Flora Schmidt	Iowa Behavioral Health Association	Vivitrol
Nancy Bell	Pfizer	Eucrisa
Jason Lurk	Novo Nordisk	Xultophy

At 11:07, motion to go to closed session was made by Kellen Ludvigson and seconded by Bruce Alexander. The motion passed with unanimous approval. Open session resumed at 11:56.

VIII. PDL Discussion and Deliberation (Dr. Barkin): All subsequent recommendations were made to maximize cost savings to the program unless otherwise noted. Recommended changes are as follows: epinephrine auto-injector (generic Adrenaclick) to non-preferred and epinephrine auto-injector (authorized generic EpiPen) to preferred; Tikosyn to non-preferred and dofetilide to preferred; Depakote Sprinkles to non-preferred (grandfather existing users with seizure diagnosis) and divalproex sprinkle capsules to preferred; Malarone to non-preferred and atovaquone-proguanil to preferred; atovaquone to preferred and Mepron to non-preferred; Micardis to non-preferred with conditions; Micardis HCT to non-preferred with conditions; Valcyte tablets to non-preferred and valganciclovir tablets to preferred; Lantus SoloStar to preferred (removal of current conditions); Levemir FlexTouch to preferred (removal of current conditions); Baraclude to non-preferred and entecavir to preferred; Zovirax suspension to non-preferred and acyclovir suspension to preferred; Imitrex nasal spray to non-preferred with conditions and sumatriptan nasal spray to preferred with conditions; Ritalin LA to non-preferred with conditions and methylphenidate er capsules (la) to preferred with conditions; clobetasol propionate cream, foam and ointment to preferred; Olux and Olux-E to non-preferred with conditions; Temovate to non-preferred with conditions; and nitrofurantoin monohydrate macrocrystals to preferred. Chuck Wadle motioned to accept the recommendations above, and Bruce Alexander seconded. The decision was unanimous. Additionally, the following drugs were recommended to be removed from coverage under the pharmacy benefit, as they are intended to be administered in a healthcare/office setting (billing through the medical benefit will be required): Aplisol, Cortrosyn, Cosyntropin, Thyrogen, Vivitrol, Dysport, Botox, Myobloc, Xeomin, Sylvant, and Xiaflex. Carole Frier motioned to accept the recommendations above, and Jolene Kelly seconded. All members were in agreement.

IX. RDL Discussion and Deliberation (Dr. Barkin): To maximize cost savings to the program, Temodar was recommended to move to the PDL and change to non-preferred with conditions and temozolomide to preferred with conditions. Bruce Alexander motioned to accept the recommendations above, and Chuck Wadle seconded. The decision was unanimous.

X. Newly Released Drugs (Dr. Barkin): All following recommendations were made to maximize cost savings to the program unless otherwise noted. Dr. Barkin reviewed the new drugs, and then the committee voted unanimously in favor of all the recommendations as follows: Dupixent, non-preferred; Eucrisa, non-preferred with conditions; Kisqali, recommended with conditions; Trulance, non-preferred with conditions; and Xadago, Non-Preferred. Kevin de Regnier motioned to accept the recommendations above, and Bruce Alexander seconded. All members were in favor.

XI. Newly Released Generic Drugs and New Drug Dosage Forms/Strengths/Combinations (Dr. Barkin): All following recommendations were made to maximize cost savings to the program unless otherwise noted. Here is a breakdown of the PDL statuses for these new drugs: atomoxetine (authorized generic), preferred with conditions; Strattera, non-preferred with conditions; buprenorphine patch, non-preferred with conditions; ezetimibe/simvastatin, non-preferred; fluticasone/salmeterol, non-preferred; tazarotene, non-preferred with conditions; Airduo RespiClick, non-preferred; Arymo ER, non-preferred with conditions; Kisqali Pak Femara, recommended with conditions; MorphaBond ER, non-preferred with conditions; Synjardy XR, non-preferred with conditions; and Xatmep, non-preferred. Chuck Wadle motioned to accept the above recommendations. Heidi Price-Eastman seconded the motion, and

all members were in favor. Additonally, Xultophy was recommended to be non-preferred with conditions. Carole Frier motioned to accept this, Jolene Kelly seconded, and Kevin de Regnier abstained. All others were in favor.

XII. Future Meeting Locations: Carol Frier again proposed that future P&T Meetings be held at locations other than the Capitol, as guns are now allowed to be carried on Capitol grounds per recent legislation, and asked about potential liability coverage for the committee members if anything should happen. Erin Halverson and Susan Parker will look into this.

A motion was made by Chuck Wadle to adjourn the meeting. It was seconded by Heidi Price-Eastman, and all in attendance approved. The meeting adjourned at 12:18 p.m. The next scheduled meeting is tentatively set for November 16, 2017.