

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes June 2, 2010

Attendees:

Commission Members

Bruce Alexander, R.Ph., Pharm.D., BCPP; Casey Clor, M.D.; Craig Logemann, R.Ph., Pharm.D., BCPS; Sara Schutte-Schenck, D.O., FAAP; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Rick Rinehart, M.D; Susan Parker, Pharm.D.; and Mark Graber, M.D., FACEP.

Staff

Thomas Kline, D.O.; and Pam Smith, R.Ph.

Guests

Chuck Wadle, D.O., Magellan; Colleen Kacher, IME; Nick Ford, IME; Laura Wiggins, IME; Sandy Pranger, R.Ph., IME; and Melissa Biddle, IME.

Welcome & Introductions

Chairperson Dr. Mark Graber called the meeting to order at 9:31 a.m. at the Learning Resource Center in West Des Moines. Commission members and guests were welcomed and introduced. Bruce Alexander received a letter and certificate of recognition from the Iowa Medicaid Director for his 8 years of service to the DUR Commission.

The minutes from the May 5, 2010 meeting were approved. (Motion by Larry Ambroson, second by Dr. Rick Rinehart, unanimous approval by voice vote.)

Iowa Medicaid Enterprise Updates

Dr. Jason Kessler was recently named the new Iowa Medicaid Medical Director. A Clinical Advisory Committee meeting was held in May; they are currently looking for 3 new members. Beginning July 1, 2010 there will be some new programs at the IME, as well as contract integration and new vendors. Lock-in services will now be operated by Member Services instead of Medical Services. DHS is still working through how much of an impact Healthcare Reform will have on drug rebates. The SSDC pool meeting to discuss rebates for the next calendar year is June 15-16. DHS is also in the process of establishing rules for bringing mental health drugs onto the PDL. Draft rules and timeline were posted on www.iowamedicaidpdl.com under the Rules link, and emailed to the listserv as well. The next P&T Meeting will be September 9th at the Capitol. Informational letter 903 was just sent out, announcing changes brought about from the last P&T Meeting, along with new PA criteria for *Cymbalta*, *Lyrica*, and *Savella*.

Case Studies

Pam Smith presented four intervention case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of \$16,332.65 pre-rebate (state and federal).

Public Comment

Thomas Carattini from Accord Pharmaceuticals spoke about Ampyra. Victoria Lopez from Endo Pharmaceuticals offered to answer any questions about the Lidoderm Patch as it was on the agenda. Karen Loihl from the Iowa Psychiatric Society voiced concerns regarding the proposed prior authorization criteria for Intuniv, along with the fact that it had been referred to the Mental Health Advisory Group but no meeting had been called to discuss it. Nancy Bell congratulated Bruce Alexander on his retirement from the DUR Commission and thanked him for his service.

PA Criteria

Extended Release Formulations: The Commission reviewed the prior authorization criteria as follows:

Payment for a non-preferred extended release formulation will be considered when the following is met:

- *Previous trial with the preferred immediate release product at a therapeutic dose that resulted in a partial response with a documented intolerance to the preferred immediate release product of the same chemical entity and a*
- *Previous trial and therapy failure at a therapeutic dose with a preferred drug of a different chemical entity indicated to treat the submitted diagnosis.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Larry Ambrosion motioned to accept the proposed criteria, and Dr. Rick Rinehart seconded. The motion passed unanimously.

Extended Release Guanfacine (Intuniv): The Commission reviewed a letter from the Iowa Psychiatric Society regarding concerns about the proposed prior authorization criteria for *Intuniv*. The Commission reviewed the prior authorization criteria, as follows, addressing the issues within the letter:

Prior authorization is required for Intuniv. Payment will be considered for patients when the following is met:

- 1) *The patient has a diagnosis of ADHD and is between 6 and 17 years of age; and*
- 2) *Previous trial with immediate release guanfacine at a therapeutic dose that resulted in a partial response with a documented intolerance; and*
- 3) *Previous trial and therapy failure at a therapeutic dose with two of the following: a preferred amphetamine stimulant, a preferred non-amphetamine stimulant, or Strattera.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

A quantity limit of 30 tablets per 30 days for all strengths (1mg, 2mg, 3mg, and 4mg) was also recommended. Craig Logemann motioned to accept the criteria, and Bruce Alexander seconded. The motion passed with no objections or abstentions.

Sodium Oxybate (Xyrem): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for sodium oxybate (Xyrem®). Payment will be considered for patients 16 years of age or older under the following conditions:

- 1. A diagnosis of cataplexy associated with narcolepsy and previous trial and therapy failure at a therapeutic dose with a tricyclic antidepressant or SSRI.*
- 2. A diagnosis of excessive daytime sleepiness associated with narcolepsy and previous trial and therapy failure at a therapeutic dose with a preferred stimulant.*
- 3. Requests for patients with a prior history of substance abuse will not be considered. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.*

This topic was tabled until a future meeting so that information and wording could be clarified regarding the stimulants, making the language consistent with other prior authorizations.

Dalfampridine (Ampyra): The Commission reviewed the prior authorization criteria as follows:

- Prior authorization is required for dalfampridine (Ampyra™).*
- Payment will be considered for patients that have a gait disorder associated with MS.*
- Initial authorizations will be approved for 12 weeks; additional prior authorizations will be considered after assessing the benefit to the patient as measured by an increase in walking speed using the Timed 25-foot Walk assessment.*
- Prior authorizations will not be considered for patients with a seizure diagnosis or in patients with moderate or severe renal impairment.*

A quantity limit of 60 tablets per 30 days was also recommended. Neurologists will be contacted for feedback, and their input will be brought back to the next meeting.

Biologicals for Ankylosing Spondylitis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for ankylosing spondylitis. Payment will be considered following inadequate responses to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum therapeutic doses, unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least three months in duration. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: sulfasalazine and methotrexate.

Payment for non-preferred biologicals for ankylosing spondylitis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents.

Dr. Casey Clor motioned to accept the modified criteria, and Bruce Alexander seconded. The motion passed unanimously.

Biologicals for Arthritis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for rheumatoid arthritis. Payment will be considered following an inadequate response to a preferred disease modifying antirheumatic drug such as hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, or minocycline, and a combination of methotrexate and another preferred disease modifying antirheumatic drug (DMARD) unless contraindicated.

Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents.

This will be brought back to the next meeting with updated wording.

Biologicals for Inflammatory Bowel Disease: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for inflammatory bowel disease. Prior authorization is required for all non-preferred biologicals for inflammatory bowel disease as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. Payment for non-preferred biologicals for Crohn's disease will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred agents.

- *Crohn's Disease – Payment will be considered following an inadequate response to two preferred conventional therapies such as aminosalicylates (mesalamine, sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate.*
- *Ulcerative colitis (moderate to severe) – Payment will be considered following an inadequate response to two preferred conventional therapies such as aminosalicylates, and/or azathioprine/6-mercaptopurine.*

Dr. Mark Graber motioned to accept the proposed criteria, and Dr. Casey Clor seconded. There were no objections.

Biologicals for Plaque Psoriasis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for plaque psoriasis. Payment will be considered following an inadequate response to phototherapy, systemic retinoids (oral isotretinoin), methotrexate, or cyclosporine. Prior authorization is required for all non-

preferred biologicals for plaque psoriasis as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. Payment for non-preferred biologicals for plaque psoriasis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred agents.

Dr. Casey Clor motioned to accept the proposed criteria, and Larry Ambroson seconded. There were no objections.

Lidocaine Patch: At the April 8, 2010 P&T Committee meeting, it was requested the DUR review the language for the Lidocaine Patch PA. It was the P&T Committee's opinion that the language was restrictive and gave the impression that it would only be approved for a diagnosis of pain associated with post-herpetic neuralgia. The Prior Authorization Criteria chart, available online, states at the top of each page "The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity. All required trials must be of appropriate dose and duration for the indication and must be documented by the prescriber on the request for prior authorization form, including dates, dose, and nature of failure." All PA Criteria follows the same format listing only FDA approved indications. The only FDA approved indication for *Lidoderm* is post-herpetic neuralgia. The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for topical lidocaine patches (Lidoderm®). Payment will be considered for a diagnosis of pain associated with post-herpetic neuralgia following a previous treatment failure with two preferred agents at a therapeutic dose from two of the following: tricyclic antidepressant, opioid, gabapentin, carbamazepine, or valproic acid. A maximum of 30 patches may be dispensed with the initial prescription to determine efficacy.

Larry Ambroson motioned to accept the proposed criteria, and Dr. Casey Clor seconded. The decision was unanimous.

Pro-DUR Edits

Quetiapine (Seroquel): Through the process of reviewing regular member profiles, it has been observed that members are receiving multiple tablets of the same strength of quetiapine (*Seroquel*) where there is the potential to consolidate the dose to a higher strength tablet, thus resulting in a cost savings to the State. Quetiapine (*Seroquel*) is the only atypical antipsychotic not subject to quantity limits. Quetiapine (*Seroquel*) is indicated for the treatment of schizophrenia and bipolar disorder. Recommended dosing is either twice to three times daily, depending on the diagnosis, with a maximum dose of 800mg per day. It has also been observed that members are taking low doses of quetiapine (*Seroquel*) without a valid diagnosis in their medical claims history. Non-reversed, paid pharmacy claims were analyzed between 3/1/10 and 4/15/10 looking at the number of tablets per day of quetiapine (*Seroquel*). In addition, members using low dose quetiapine (*Seroquel*) without any other strengths of quetiapine (*Seroquel*) in their

pharmacy claims history were identified. Based on the findings, Dr. Richard Rinehart motioned to adopt the proposed quantity limits and Craig Logemann seconded. All were in favor of this decision. No Pro-DUR edits blocking low dose *Seroquel* will be developed at this time, although this issue may be re-evaluated in January.

Public Comment

There were no speakers in this public comment section.

Focus Studies

Dronabinol (Marinol) Utilization: The purpose of this study was to determine the frequency of off-label dronabinol (*Marinol*) utilization. Dronabinol (*Marinol*) is a synthetic form of delta-9 tetrahydrocannabinol (THC), the active chemical entity in marijuana. It was first approved by the FDA in 1985 and is indicated for the prevention of chemo-induced nausea and vomiting that has been refractory to other antiemetic treatments, as well as anorexia associated with weight loss in AIDS patients. While dronabinol (*Marinol*) has not had a high amount of utilization in the Iowa Medicaid population, its use remains steady when comparing quarters over the last few years. During the first quarter of calendar year 2010, forty-seven prescriptions were filled for 24 unique members with a total paid amount of \$51,044.05 (pre-rebate; state and federal dollars). It has been suspected, through the review of member profiles, that some of this utilization has been for off-label use. Non-reversed, paid pharmacy claims were analyzed between 1/1/10 and 3/31/10. Members with claims for dronabinol (*Marinol*) during this time were identified. The medical claims histories for those members who had claims for dronabinol (*Marinol*) were then analyzed. Of the 12 members who did not have an approved indication in their claim histories, the top 3 most commonly observed ICD-9 codes associated with dronabinol (*Marinol*) use were: malaise and fatigue, lumbago, and pain in limb. A focus study will be developed to contact the prescribers of those members who were identified as using dronabinol (*Marinol*) for what appears to be an off-label use. This issue will also be referred to the P&T Committee with the recommendation to make dronabinol (*Marinol*) non-preferred.

Quetiapine Off-Label Utilization: The purpose of this study was to determine the frequency of off label quetiapine (*Seroquel*) utilization, particularly for the treatment of ADD/ADHD. Through the process of reviewing regular member profiles and monitoring prior authorization requests, the use of quetiapine (*Seroquel*) for off label indications appears to remain high, particularly for the treatment of ADD/ADHD in children and adolescents. Quetiapine (*Seroquel*) was first approved in 1997 and is indicated for the treatment of bipolar disorder, schizophrenia, and as adjunctive therapy for major depressive disorder. The immediate release product is a preferred product on the Iowa Medicaid Preferred Drug List, while the extended release version is non-preferred and requires a prior authorization. Neither formulation is subject to quantity limit edits. The two most common off label uses observed through the PA department are low dose quetiapine (*Seroquel*) for sleep and for children and adolescents for ADD/ADHD. Quetiapine (*Seroquel*) does not have a listing for ADD/ADHD in the compendia as there

is no good data to support its use for the treatment of ADD/ADHD. Non-reversed, paid pharmacy claims from 1/1/10 to 3/31/10 were analyzed. Members who had paid claims for quetiapine (*Seroquel*) during this time were identified. We then reviewed the medical claims histories of those identified as having fills for quetiapine (*Seroquel*). There were 3,243 members with claims for quetiapine (*Seroquel*) between 1/1/10 and 3/31/10, with 1,756 members without an approved diagnosis for use (bipolar disorder, schizophrenia, or depression), including 660 members with a diagnosis of ADHD without a co-existing approved diagnosis. This issue was referred to the Mental Health Advisory Group for further evaluation and additional suggestions to discourage off-label usage.

Duplicate Long-Acting Stimulants: The purpose of this study was to determine the frequency of concurrent use of long acting stimulants. Through the process of regular member profile reviews, the combination of long acting stimulants is frequently observed. Stimulants do not require a PA in members less than 21 years of age, which is where the majority of these duplications occur. For those 21 years of age and older, a prior authorization is required. When prior authorizations are requested for duplicate long acting stimulants, they are denied without proper medical rationale as to why the combination is warranted (most are for severe narcoleptic patients who have failed to control symptoms with a single agent). Using duplicate long acting stimulants can have an additive effect, increasing the risks of tachycardia, hypertension, and other noradrenergic side effects. Additionally, it is more costly to use two products at sub-therapeutic doses when symptoms could be controlled on one agent at a full, therapeutic dose. Available treatment guidelines for ADD/ADHD do not support the use of duplicate long acting stimulants. Non-reversed, paid pharmacy claims were analyzed between 12/1/09 and 3/31/10. Members who were using duplicate long acting stimulants concurrently for two or more months that continued the combination into March 2010 were identified. These members were broken out to those over 21 years of age, and those 21 years of age and under. 170 members continued the combination of long-acting stimulants into March 2010, 165 of them 21 years of age or younger. This was also referred to the Mental Health Advisory Group. The members asked that the number of prescribers for each member and their respective specialties be added to the report.

Multiple Anti-Epileptic Medications: The purpose of this study was to determine the number of Iowa Medicaid members using three or more anticonvulsants for any diagnosis concurrently. It is often noted in member profile reviews that members are on multiple anticonvulsants concurrently. This often receives comments on the member profiles discussed at Commission meetings. Anticonvulsants can be prescribed for the treatment of seizure disorders or for the maintenance of bipolar disorder. When used as maintenance therapy for bipolar disorder, the American Psychiatric Association's Practice Guideline for the Treatment for Patients with Bipolar Disorder recommends the use of lithium as first line therapy followed by valproic acid if lithium is not tolerated or does not produce a response. Lamotrigine and carbamazepine are considered possible

alternatives if a second medication is required. When used to treat epilepsy, approximately half of the patients with a new diagnosis of epilepsy are successfully treated with the first antiepileptic used. If a trial with a second product is required, either due to an inadequate response or side effects, nearly half of these patients will be successful with the second drug. Combination and polypharmacy is only recommended if at least two adequate trials of single agents have failed. It is estimated that only 10-15% of patients achieve seizure remission with two or more products in combination following failure of monotherapy. Another recent phenomenon observed in the Pharmacy Prior Authorization department is an increase in the use of the new antiepileptic drug, *Banzel* (rufinamide). *Banzel* (rufinamide) is FDA-approved for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome. Many of the prior authorization requests that have been received are requesting *Banzel* (rufinamide) for an off-label indication (the efficacy of *Banzel* in treating other seizure types has not been established) and/or it is being requested as an addition to an existing antiepileptic regimen as a fourth or even fifth product. The use of *Banzel* (rufinamide) has slowly increased in the Iowa Medicaid population; in the first quarter of calendar year 2010, there were 121 prescriptions filled for a total cost of \$39,090 (state and federal dollars, pre-rebate). Non-reversed, paid pharmacy claims were analyzed between 1/1/10 and 3/31/10. Members with two or more prescriptions in their claims history for any anticonvulsant were identified (clonazepam and diazepam were not counted as anticonvulsants for this report). Of those identified, those who were using three or more different anticonvulsants concurrently were identified and analyzed. Of the 334 members taking three or more different anticonvulsants concurrently, 27 were identified as having *Banzel* (rufinamide) as part of their regimen. Letters will be sent to the prescribers of *Banzel* to inquire about the diagnosis for use since it is only FDA approved for use in Lennox-Gastaut syndrome and cannot be teased out by looking at ICD-9 codes. Letters will also be sent to the prescribers of the members who had a diagnosis of bipolar disorder or conversion disorder without a coexisting seizure diagnosis who were not on any combinations of carbamazepine, valproate, and lamotrigine. Nineteen members identified as using 3 or more anticonvulsants concurrently without a corresponding diagnosis of epilepsy or bipolar disorder will also receive letters. Letters will also be sent to the prescribers of the members being treated with three or more anticonvulsants with a diagnosis of febril convulsions if they do not have any other seizure diagnosis.

Miscellaneous

DUR Digest: The Commission members offered changes and additions to the draft for DUR Digest Volume 22, Number 3.

SMAC Updates: The Commission members were given a copy of the SMAC changes that had gone into effect in May.

MedWatch: The Commission members received FDA announcements concerning new

Black Box Warnings.

A unanimous vote was made at 12:10 p.m. to adjourn the meeting and move to closed session (1st by Bruce Alexander, 2nd by Dr. Richard Rinehart).

The next meeting will be held at 9:30 a.m. on Wednesday, August 4, 2010 at the Learning Resource Center in West Des Moines.