



MINUTES

Utah Department of Health
Pharmacy and Therapeutics Committee

Thursday, June 16, 2016
7:15 a.m. to 8:45 a.m.
Cannon Health Building
Room 125

Committee Members Present:

Bryan Larson, PharmD
Clinton Sheffield, MD
Jameson Rice, PharmD

Keith Tolman, MD
Abril Atherton, PharmD
Susan Siegfried, MD

Committee Members Excused:

Clayton Grace, RPh

Elizabeth Young, PharmD

Dept. of Health/Div. of Health Care Financing Staff Present:

Alyssa Pitts, RN
Merelynn Berrett, RN
Heather Santacruz, RN

Chad Hope, PharmD
Robyn Seely, PharmD
Megan Schlappi, CPhT

University of Utah Drug Regimen Review Center Staff Present:

Vicki Frydrych, PharmD

Other Individuals Present:

Gary Oderda, PharmD, UofU
Bob Gustafson, Lundbeck
Lori Blackner, Pfizer
Dave Chapman, UCB
Christian Obah, M.D.
Cody Ball, Select Health
Joan Brammer, Valley Behavioral Health

Joanne LaFleur, PharmD, UofU
John Schillo, Lundbeck
Alan Bailey, Pfizer
Aimee Redhair, UCB
Eric Winfree, UCB
Charissa Anne, J+J

Meeting conducted by: Clinton Sheffield, MD

- Welcome & Housekeeping:** Clinton Sheffield opened the meeting, confirmed that there was a quorum, and reminded everyone to sign in.
- Review and Approval of May Minutes:** Clinton Sheffield made a motion to approve the minutes from May. Keith Tolman seconded the motion. All in favor.
- Changes in the Committee and within the Drug Regimen Review Center:** Clinton Sheffield thanked Ellie Brownstein M.D. (in absentia) for her participation in the Committee. Bryan Larson welcomed Abril (“Abby”) Atherton PharmD, psychiatric hospital pharmacist to the Committee. Prof. Gary Oderda PharmD is retiring from the DRRC. Prof. Joanne LaFleur PharmD will

take his place.

4. **Statute Citation:** Chad Hope cited HB 437 (2016) regarding a psychotropic PDL. Education regarding the DAW provision was discussed.
5. **Newer Anticonvulsant Agents:** Vicki Frydrych, PharmD presented a review of brivaracetam, clobazam, eslicarbazepine, ezogabine, felbamate, gabapentin, lacosamide, lamotrigine, levetiracetam, oxcarbazepine, perampanel, pregabalin, rufinamide, tiagabine, topiramate, vigabatrin, and zonisamide. She presented peer-reviewed research regarding the safety and efficacy of each agent, clinical trials, disease-state treatment guidelines, and Utah Medicaid utilization data.
6. **Public Comment:**
 - a. David Chapman Ph.D. of UCB Pharmaceuticals spoke regarding lacosamide (Vimpat®) and brivaracetam (Briviact®).
 - b. Lori Blackner PharmD of Pfizer Pharmaceuticals spoke regarding pregabalin (Lyrica®).
 - c. Tim Grange M.D., physical medicine and rehabilitation specialist, spoke regarding the use of these drugs for indications other than seizures.
 - d. Christian Obah M.D., pain management specialist, also spoke regarding the use of these drugs for indications other than seizures.
7. **Other States Report:** Bryan Larson reported PDL listings for agents in this class in other States' Medicaid programs.
8. **Board Discussion**
 - a. Keith Tolman observed that only six drugs (lamotrigine, levetiracetam, gabapentin, pregabalin, topiramate, and vigabatrin) are needed to cover all seizure indications. He mentioned grandfathering and drug trial and failures.
 - b. Chad Hope reminded the Committee of the DAW provision in HB 437 and of the mechanisms by which the PDL provides cost savings.
 - c. The P&T Committee is charged with establishing the equality or differences in safety and in efficacy of the drugs reviewed. Susan Siegfroid suggested that the drugs were all efficacious for their FDA-approved indications and that each drug has different safety issues. She called attention to vigabatrin (Sabril®, which has a REMS) and felbamate (Felbatol®, which does not have a REMS). Dr. Siegfroid mentioned that the guidance from the various neurological societies include off-label recommendations.
 - d. Keith Tolman agreed that felbamate has major safety issues and suggested that it should be included on the PDL as Non-Preferred. He agreed that vigabatrin has major safety issues but is the drug of choice for infantile seizures.
 - e. Susan Siegfroid noted the extremely low utilization of vigabatrin, suggesting that use is on-label and that safety risks are sufficiently monitored by the REMS (or "SHARE" program).
 - f. Chad Hope again reminded the Committee of the DAW provision in HB 437.
 - g. **MOTION 1:** Keith Tolman motioned that both felbamate and vigabatrin be Non-Preferred, noting the DAW provision in HB 437. Susan Siegfroid seconded the motion. All in favor.
 - h. The Committee discussed the safety and efficacy of the drugs in greater detail,

concluding that vigabatrin's REMS adequately addresses safety concerns.

- i. **Motion 1 stricken in favor of Motion 2**
- j. **MOTION 2:** Clinton Sheffield motioned that felbamate be Non-Preferred. Keith Tolman seconded the motion. All in favor.
- k. **MOTION 3:** Keith Tolman motioned all of the newer anticonvulsants (excluding felbamate) are equally safe and effective for their respective FDA-approved indications. Clinton Sheffield seconded the motion. All in favor.
- l. Clinton Sheffield noted that gabapentin and pregabalin are unique drugs that merit additional discussion but the meeting was already over its allotted time.
- m. **MOTION 4:** Clinton Sheffield moved that each first-line agent for the various indications are equally safe and efficacious and should be considered for inclusion on the PDL. Keith Tolman seconded the motion. All in favor.
- n. Vicki Frydrych agreed to present information regarding gabapentin and pregabalin, including their role in pain management and abuse potential, at a future Committee meeting.

9. **Meeting Adjourned: MOTION 5:** Clinton Sheffield moved to adjourn. Bryan Larson seconded the motion. All in favor.

10. The next meeting is scheduled for July 21, 2016.

Audio recording of all P&T meetings are available online at

<https://medicaid.utah.gov/pharmacy/pt-committee?p=Board%20Meeting%20Audio%20Recordings>