

Thursday, January 21, 2016
7:15 a.m. to 8:45 a.m.
Cannon Health Building
Room 128

Committee Members Present:

Bryan Larson, PharmD
Clinton Sheffield, M.D.
Clayton Grace, RPh
Susan Siegfried, M.D.

Beth Young, PharmD
Keith Tolman, M.D.
Ellie Brownstein, M.D.
Jameson Rice, PharmD

Committee Members Excused:

Beth Johnson, R.Ph

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

Robyn Seely, PharmD
Merelynn Berrett, RN
Megan Schlappi, CPhT

Chad Hope, PharmD
Heather Santacruz, RN

University of Utah Drug Regimen Review Center Staff Present:

Vicki Frydrych, UofU

Other Individuals Present:

Camille Kerr, Amgen
James Gaustad, Purdue
Chris Desimone, Aegerion
Sushma Patel, AstraZeneca

Debbie Drayer, Amgen
Cody Ball, Select Health
Charissa Anne, Johnson & Johnson

Meeting conducted by: Clinton Sheffield, MD

1. **Welcome & Housekeeping:** Clinton Sheffield opened the meeting and reminded all guests to sign the roster.
2. **Review and Approval of December Minutes:** Keith Tolman made a motion to approve the minutes from December. Clinton Sheffield seconded the motion. All in favor.
3. **Drug Utilization Review (DUR) Board update:** The DUR board reviewed Movantik and added PA criteria. They also reviewed the methodologies for determining preferred drug lists from 4 Accountable Care Organizations.
4. **PCSK-9 Inhibitors:** Vicki Frydrych presented a review of PCSK-9 Inhibitors. She presented peer-reviewed research regarding the safety and efficacy of each agent, clinical trials, disease-state treatment guidelines and Utah Medicaid utilization data.

5. **Other States Reports:** Bryan Larson presented information from other States, with their Preferred Drug List listings for PCSK-9 Inhibitors. The States that have reviewed this class of medications have all placed them as non-preferred.
6. **Public Comments:** Debra Drayer, from Amgen, presented. She voiced her concerns about the established PA criteria.
7. **Board Discussion**
 - a) Keith Tolman asked Debra Drayer why the prevalence of neurocognitive effects is stated as 0.9% in the presented documents, but less than 0.2% in the drugs package insert. She told him that those numbers were from two of the different drugs: Alirocumab (0.9%) and Evolocumab (0.2%). This lead Keith Tolman to question whether the drugs were both equally safe and effective.
 - b) Vicki Frydrych said that although those numbers may be statistically significant, the drugs have not been on the market long enough or studied enough to really decide if the difference is clinically significant. In a meta-analysis, the drugs do appear to be equally safe.
 - c) Keith Tolman stated that it appears that these drugs are possibly causing insulin resistance, liver enzymes, fatty liver disease, and neurocognitive problems in patients who are already susceptible to these diseases. He questioned whether we really have enough data to decide if these drugs are safe and effective.
 - d) Clinton Sheffield noted that, with the data presented, you can see that these drugs do what they are intended to do: lower LDL. However, without long-term studies, it is hard to see if they are effective at helping with cardiovascular events, or if they are causing adverse events.
 - e) Elizabeth Young noted that many drugs are approved without long term studies, and with the data presented it would appear that these drugs are both equally safe and efficacious, but PA criteria should be in place.
 - f) Bryan Larson pointed out that there is established PA criteria that will be effective in February 2016.
 - g) Keith Tolman made a motion that both drugs are equally safe and effective. Clinton Sheffield seconded the motion. All in favor.
 - h) Clinton Sheffield reiterated how important the PA criteria are for these drugs. He made a motion to keep the PA criteria in place. Bryan Larson seconded the motion. All in favor.
8. **Meeting Adjourned:** Keith Tolman made a motion to end the meeting. Elizabeth Young seconded the motion. All in favor.
9. The next meeting is scheduled for February 18, 2016. Skeletal Muscle Relaxants will be re-reviewed.