



Thursday, October 8th, 2015
7:30 a.m. to 8:30 a.m.
Cannon Health Building
Room 125

Board Members Present:

Jay Aldus, D.D.S
Ben Berrett, Pharm.D.
Jennifer Brinton, M.D., Board Chair
Neal Catalano, Pharm.D.
Holly Gurgle, Pharm.D.
Steve Lore, M.D.

Kumar Shah, M.Sc., P.Eng.
Susan Siegfroid, M.D.
Katherine Smith, Pharm.D.
Michael Symond, M.D.
Keith Tolman, M.D.

Board Members Excused:

n/a

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

Chad Hope, Pharm.D.
Robyn Seely, Pharm.D.
Bryan Larson, Pharm.D.

Merelynn Berrett, R.N.
Heather Santacruz, R.N.
Alyssa Pitts, R.N.

Other Individuals Present:

Gary Oderda, University of Utah
Joanita Lake, University of Utah
Eliot Brinton, Utah Lipid Center
Cody Ball, Select Health
Mindy Peterson, Healthy U
Laura Britton, Healthy U
Lynsey Spence, State Auditor

Greg Gittus, Alkermes
Paul Skodny, Amgen
Charissa Anne, Johnson & Johnson
Chris DeSimone, Agerion
Lori Howarth, Bayer

Meeting conducted by Robyn Seely, Pharm.D.

- 1. Welcome** – Robyn Seely opened the meeting and welcomed the new Board members; Ben Berrett, Pharm.D., Neal Catalano, Pharm.D., Holly Gurgle, Pharm.D. and Steve Lore, M.D.. Each Board member, as well as Joanita Lake, introduced themselves.
- 2. Election of a New Chair** – Robyn Seely stated that she had received nominations for Mike Symond and Jennifer Brinton and called for other nominations. Keith Tolman recalled that the election should be an open process and that nominees should be called from the floor. Robyn Seely called for nominations again. No one volunteered to be Chair. Jennifer Brinton nominated Susan Siegfroid. Mike Symond nominated Jennifer Brinton. Kumar Shah seconded Jennifer Brinton. All in favor. Jennifer Brinton accepted.

3. **Housekeeping** – Robyn Seely collected Conflict of Interest forms from the new Board members. Robyn Seely reminded Board members and guests to sign in. She also called attention to the printed DUR roles and responsibilities (R414-60A. Health, Health Care Financing, Coverage and Reimbursement Policy), pages 2 and 3 of the meeting packet.

Robyn Seely then called for a review of September’s meeting minutes. Kumar Shah noted a typo under Housekeeping. “Kumar Shah has agreed to serve another *year* on the DUR board” should read “Kumar Shah has agreed to serve another *term* on the DUR board”.

4. **Public Comment** – Paul Skodny, Pharm.D., (of Amgen Pharmaceuticals) presented testimony on behalf of evolocumab (Repatha). This was done before the University’s clinical presentation in order to accommodate Paul Skodny’s scheduled plane flight. Paul Skodny reviewed the FDA-approved prescribing information and mentioned an ongoing study regarding cardiovascular outcomes. Robyn Seely requested that he complete a Conflict of Interest form. Steve Lore briefly discussed the product with Paul Skodny.

5. **Clinical Presentation – Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Inhibitors: Praluent (alirocumab, Sanofi/Regeneron) and Repatha (evolocumab, Amgen)** – Joanita Lake from the University of Utah DRRC presented drug information including disease symptoms, studies, side effects, indications and other information about the agents. Data was also presented about the utilization of the drugs in the Utah Medicaid fee-for-service population.

6. **Public Comment and Board Discussion** – Eliot Brinton, M.D. President of the Utah Lipid Center provided testimony regarding the relationship between LDL cholesterol and cardiovascular outcomes and mentioned various current guidelines, including those which have no specific recommended LDL goal levels. Eliot Brinton’s testimony was cut short at the allowed 3 minutes. Robyn Seely called for questions and discussion. Keith Tolman requested that Eliot Brinton continue his testimony. Eliot Brinton addressed differences in efficacy between alicumab (Praluent) and evolocumab (Repatha), which he believes are minimal.

- a. Eliot Brinton suggested the following prior authorization requirements:
 - i. Failure on HMG-CoA reductase inhibitor (“statin”) therapy: at maximum FDA-approved dose to establish statin insufficiency or at minimum FDA-approved dose to establish patient intolerance.
 - ii. Failure on ezetimibe (Zetia) in addition to a statin
 - iii. Approve a PCSK9 inhibitor based upon the following cholesterol level thresholds:
 - 1. LDL > 100^{mg}/_{dL} or non-HDL > 130^{mg}/_{dL} for secondary prevention of cardiovascular events
 - 2. LDL > 130^{mg}/_{dL} or non-HDL > 160^{mg}/_{dL} for primary prevention of cardiovascular events in high-risk patients

Eliot Brinton opined that a diagnosis of familial heterozygous hypercholesterolemia is irrelevant. He stated that anyone with cholesterol levels described above will benefit from treatment.

Bryan Larson observed that while lipidologists would be most qualified to prescribe PCSK9 inhibitors, many fee-for-service Utah Medicaid patients live in rural areas and do not have access to specialists.

Eliot Brinton also advocated for chest CT scanning for coronary artery calcium scoring. He suggested that if the score is greater than 100 HU a patient may begin therapy when LDL > 130^{mg}/_{dL} or non-HDL > 160^{mg}/_{dL} regardless of prior cardiovascular events.

Ben Berrett recalled that the DUR Board's purview is the whole state of Utah. Steve Lore observed that patients in rural areas or those that are home bound have a difficult time accessing a cardiologist, let alone a lipidologist. Bryan Larson mentioned Utah Medicaid's transportation services, but Utah Medicaid staff were not familiar enough with the program to comment on the reality of improving access to specialists. Susan Siegfried stated that while prior authorization criteria may require consultation with a specialist, the patient may not have to physically visit the specialist. Phone calls, email or use of Telehealth, if documented, could serve as a consultation.

Joanita Lake provided clarification of guidelines cited and recommendations in the clinical presentation.

Robyn Seely called attention to the time and asked if the Board would like to continue this conversation at the next scheduled DUR Board meeting. Mike Symond observed that a consensus seemed to be forming among the Board.

Keith Tolman suggested that prior authorization requirements should not include failure of appropriate diet and exercise, despite their inclusion in the FDA-approved labeling of both drugs.

Robyn Seely suggested that she revise the presented draft criteria to reflect the discussion and present it at next month's meeting. Steve Lore motioned affirmatively and motioned to limit the discussion to 20 minutes. Mike Symond seconded the motion. All in favor.

- 7. Meeting Closure** – Mike Symond made a motion to close the meeting. Neal Catalano seconded the motion. All in favor.

The next DUR Board meeting is scheduled for Thursday, November 12th.

Minutes prepared by Robyn Seely, Pharm.D.

Recording available upon request, send email to medicaidpharmacy@utah.gov