



Thursday, August 13, 2015
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 125

Board Members Present:

Tony Dalpiaz, PharmD.
Susan Siegfroid, M.D
Keith Tolman, M.D.
Mark Balk, PharmD.

Jennifer Brinton, MD
Jay Aldus, DDS
Mr. Kumar Shah

Board Members Excused:

Michael Symond, M.D.

George Hamblin, PharmD

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

Robyn Seely, Pharm.D
Trevor Smith C.Ph.T.
Merelynn Berrett, R.N.
Heather Santacruz, R.N .

Chad Hope, Pharm.D.
Bryan Larson, Pharm.D.
Alyssa Pitts, R.N.

Other Individuals Present:

Joanita Lake, UofU
Gary Oderda, UofU
Ken Love, Bioventus
Sushma Patel, AstraZeneca
Corinne Glock, Relypsa
Lori Howarth, Bayer

Vinod Dasa, Bioventus
Charissa Anne, J&J
Laura Litzenburger, Janssen
Kelly Ponce, AstraZeneca
Clayne Garrett, BI

Meeting conducted by: Tony Dalpiaz, Pharm.D.

- 1. Welcome** – Tony Dalpiaz opened the meeting.
- 2. Housekeeping** – Robyn Seely welcomed everyone to the meeting and reminded everyone to sign in. She also welcomed Bryan Larson, the new Utah Medicaid pharmacy P&T coordinator.
- 3. P&T Committee report** – The next P&T meeting will discuss Antiretroviral, Protease Inhibitor agents.
- 4. Approval of prior meeting minutes** – Keith Tolman made a motion to approve the July meeting minutes. Mark Balk seconded the motion. All in favor.

5. **Proton Pump Inhibitor – 9 month review** – Robyn Seely said that the auto PA set last year on the PPIs is working well and sees no problem with keeping the same criteria for this next year.
6. **Hyaluronic Acid Derivatives (Intra-Articular Preparations)** – Joanita Lake, from the University of Utah DRRC presented drug information including disease symptoms, studies, side effects, indications and other information about the intra-articular Hyaluronic Acid Derivative agents. Data was also presented about the utilization of the drugs in the Utah Medicaid population.

7. Public Comment

- a. Dr. Vinod Dasa, (Bioventus) – He presented information on intra-articular hyaluronic acid derivatives and the benefits of the product. He offered to answer board questions.

8. Board Discussion - Hyaluronic Acid Derivatives (Intra-Articular Preparations)

- a. Keith Tolman asked about the use of this as a primary therapy
- b. Dr Dasa said that it can be better than NSAIDs or opioids because of the potential side effects of those drugs.
- c. Chad Hope asked about safety and efficacy, because these products are considered devices, not drugs.
- d. Dr Dasa said that these products are not held to the same standards as drugs because they are considered devices. He went on to say that with the usage data, there are no significant side effects, with the majority being injection technique. It was explained that these are class three medical devices, which are held to a higher standard than other devices.
- e. Bryan Larson said that in the documentation, the level of efficacy shown was directly related to the entity who sponsored the study.
- f. Keith Tolman said that there is publication bias in many studies and gave examples when it occurred in PPI studies. He then said that placebos are active and can produce results.
- g. Dr Dasa said that in these intra-articular HA preparations, the placebo is even higher, as the placebo injection can affect function in a different way than a traditional placebo would work.
- h. Keith Tolman said that since these products are benign and do not cause side effects, the PA should not be implemented.
- i. Joanita Lake said that while the product does not have side effect issues, it does have the potential to be used off label, for cosmetic uses or may be used in unapproved joints. She said it should only be used in the knee.
- j. Kumar Shah said that it is important to look why there is the need for this HA treatment, and if there is a way to prevent or treat the problem at an earlier step. He also said that it would be important to have these products go through the same testing that drugs must undergo to ensure safety and efficacy.
- k. Mark Balk made a motion to have a PA on the intra-articular HA preparations to ensure it is used only for on label usage in the knee. Keith Tolman seconded the motion. All in favor.

9. Hyaluronic Acid Derivatives (Ophthalmic and Topical Preparations) – Joanita Lake, from the University of Utah DRRC presented drug information including disease symptoms, studies, side effects, indications and other information about the ophthalmic and topical preparations of Hyaluronic Acid Derivative agents. Data was also presented about the utilization of the drugs in the Utah Medicaid population.

10. Public Comment - None

11. Board Discussion - Hyaluronic Acid Derivatives (Ophthalmic and Topical Preparations) -

- a. Mark Balk said that because of the previous motion to put a PA on the other formulation of HA derivatives, it would be good to be consistent with the other formulations.
- b. Keith Tolman said that retinal detachment would need special consideration because it can be an emergency situation that can't wait for a PA approval.
- c. Chad Hope explained that those claims would be a hospital claim, not a regular outpatient claim, so the PA would not apply.
- d. Mark Balk made a motion to have a PA on the ophthalmic and topical preparations of HA products. He specified that the criteria be set at three months for the initial authorization and the reauthorization periods. Keith Tolman seconded the motion. All in favor.

12. Meeting Adjourned – Mark Balk made a motion to close the meeting. Tony Dalpiaz seconded the motion. All in favor.

The next DUR Board meeting is scheduled for Thursday, September 10th. Tentative schedule is to discuss CFTR agents: Orkambi (Lumacaftor and Ivacaftor) & Kalydeco (Ivacaftor).

Minutes prepared by Trevor Smith.

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