Drug Formulary Committee: Minutes of February 12, 2014 Public Meeting

Members in attendance
Monica Brands, RPh., Stacey Ness, Pharm.D., William Korchik, M.D., Kelly Ruby, Pharm.D., Al Heaton, Kathyrn Lombardo, M.D., James Phillips, M.D.

DHS staff present
Adam Pavek, PharmD., Sara Drake, RPh., MPH, MBA, Jeff Schiff M.D., MBA, Mary Beth Reinke,

Others in attendance
Nina Bandali, Pharm.D., Katie Counts, Pharm.D.

Report of the Chair
In respect of time the chair bypassed the report of the chair.

Approval of the minutes
Minutes from the October 2013 meeting were reviewed and approved.

Old Business
None

New Business

Existing Drugs for PA Consideration: buprenorphine/naloxone
The committee discussed the current criteria for buprenorphine+/−naloxone. The Department is looking to ensure that its buprenorphine PA criteria are clinically appropriate. Zubsolv, a new sublingual tablet recently launched and initiated a review. Furthermore an anticipated increase in buprenorphine use, driven by a potential for reduced access to methadone treatment programs and increasing opiate and heroin use, was considered. Currently, the department requires PA, requiring prescribers to have a DEA (X) number to use buprenorphine for the treatment of opioid dependency. The department allows only 2 active PA at a one time and a max daily dose of 32 mg for buprenorphine/naloxone. Buprenorphine is approved for patients that cannot tolerate naloxone and allows only 1 active buprenorphine PA at a time. The Department asked the committee to provide advice for enhancing the clinical appropriateness of the existing prior authorization criteria:

The additional criteria for consideration included:
- Requiring prescriber attestation that they have checked the prescription drug monitoring program prior to prescription authorization
- Limit maintenance dose to max of 16mg per day
- Limit prescription to one pharmacy in order to facilitate coordination of care
- Restrict concomitant use of benzo’s, hypnotics, opioids, and tramadol
- Require documentation of an office visit prior to dispensing of suboxone
- Require reauthorization every 3 months

The committee recommended that the department require documentation of an office visit prior to a script being written, prescriber attestation that the prescription drug monitoring program is actively being monitored, a max daily dose of 24mg, limiting the PA to one pharmacy and 3 month duration for PA approval with reauthorization looking for concomitant use of other opioids or benzodiazepines.
Class Review:

Hepatitis C: The committee discussed Hepatitis C in a class review format. The Department recommended continuing prior authorization on Sovaldi and Olysio, the two new drugs for the treatment of Hepatitis C infection. The committee recommended that the clinical criteria mirror on-label use and to use the definition of interferon ineligible as found in the recently published AASLD guidelines.

Epinephrine auto-injectors: The committee reviewed the epinephrine autoinjector class. Epinephrine has been the mainstay of on-demand treatment of life-threatening anaphylactic shock. There are currently 3 devices approved by the FDA; Epi-Pen, Auvi-Q, and epinephrine injection. All devices deliver a single dose from one unit via auto-injection. The Auvi-Q talks and guides patients and caregivers through the injection process with audio cues. All products come in 2 strengths, 0.3mg dose for patients >66lbs and 0.15 mg dose for patients weighing 33-66 lbs.

The committee recommended to the department that epinephrine auto-injectors be considered therapeutically equivalent and manage the category based on cost. The committee asked the department to ensure that a training device be included for the preferred agent.

New Drugs for Continued PA

The committee discussed BREO ELLIPTA (fluticasone furoate and vilanterol trifenatate) powder [GlaxoSmithKline LLC]. The committee recommended to the department that Breo Ellipta remain on PA by a unanimous vote. The committee recommended that clinical criteria require on-label use and the trial and failure of 2 preferred products.

The committee discussed BRISDELLE (paroxetine) capsule [Noven Therapeutics, LLC]. The committee recommended that criteria include trial and failure of the generic 5mg and 10 mg strengths of paroxetine.

The committee discussed ZUBSOLV (buprenorphine hydrochloride and naloxone hydrochloride) orally disintegrating tablet, [Orexo US, Inc.] The committee recommended to the department that Zubsolv remain on PA by a unanimous vote. The committee considered Zubsolv therapeutically equivalent to alternative buprenorphine/naloxone products.

The committee discussed ZORVOLEX (diclofenac) capsule [Iroko Pharmaceuticals LLC]. The committee recommended to the department that Zorvolex remain on PA by a unanimous vote.

The committee discussed FETZIMA (levomilnacipran hydrochloride) [Forest Pharmaceutical] extended release capsule. The committee recommended to the department that Fetzima remain on PA by a unanimous vote.

The committee discussed BRINTELLIX (vortioxetine) tablet, film coated [Takeda Pharmaceuticals America, Inc.] . The committee recommended to the department that Brintellix remain on PA by a unanimous vote.

New Specialty Drugs for Continued PA

The committee discussed SOVALDI (sofosbuvir) tablet, film coated [Gilead Sciences, Inc.] The committee recommended to the department that Sovaldi remain on PA by a unanimous vote. The committee recommended that clinical criteria follow labeled indications.
The committee discussed OLYSIO (simeprevir) capsule [Janssen Products LP].
The committee recommended to the department that Olysio remain on PA by a unanimous vote. The committee recommended that clinical criteria follow labeled indications.

The committee discussed OPSUMIT (macitentan) tablet, film coated [Actelion Pharmaceuticals US, Inc.]. The committee recommended to the department that Opsumit remain on PA by a unanimous vote.

The committee discussed ADEMPAS (riociguat) tablet, film coated [Bayer HealthCare Pharmaceuticals Inc.]. The committee recommended to the department that Adempas remain on PA by a unanimous vote.

The committee discussed TIVICAY (dolutegravir sodium) tablet, film coated [ViiV Healthcare Company]. The committee recommended to the department that Tivicay remain on PA by a unanimous vote. The committee recommended that Tivicay be re-reviewed in 3 months.

The committee discussed MEKINIST (trametinib) tablet, film coated [GlaxoSmithKline LLC]. The committee recommended to the department that Mekinist remain on PA by a unanimous vote.

The committee discussed GILOTRIF (afatinib) tablet, film coated [Boehringer Ingelheim Pharmaceuticals, Inc.]. The committee recommended to the department that Gilotrif remain on PA by a unanimous vote.

The committee discussed COMETRIQ capsule [Exelixis, Inc.]. The committee recommended to the department that Cometriq remain on PA by a unanimous vote.

The committee discussed ASTAGRAF XL (tacrolimus extended-release capsules) extended release capsule [Astellas Pharma US, Inc.]. The committee recommended that Astagraf XL remain on PA by a unanimous vote.

**Adjournment**
The meeting was adjourned at 9:05 pm CST.