Drug Utilization Review (DUR) Committee

September 19th 2014 Minutes

Members Present
Robin Cooke, PharmD, CGP
Jenny Love, MD
John Pappenheim, MD
Maggi Rader, CNM
Chuck Semling, PharmD
Chad Hope, PharmD (DHSS)
Erin Narus, PharmD (DHSS)

Members Absent/Excused
Greg Salard, MD

Non-Members Present
Tolu Balogun, PharmD (Magellan)
Julie Pritchard, PharmD (Magellan)

Meeting started at approximately 1:00pm; attendance was taken
Teleconference access available

Welcome
Public testimony, Dr. Dion Roberts – Inhaled antibiotics for Cystic Fibrosis
Review of agenda for changes

ProDUR

- Proposed new Prior Authorization Tobi Podhaler (tobramycin dry powder inhalation)
  - Appropriate utilization and access prompted review for prior authorization
  - Committee heard testimony of Dr. Dion Roberts, Pediatric Pulmonologist
  - Product currently on Interim PA list as of 6/26/13 requiring failure of at least one prior therapy
  - Generic tobramycin inhalation now available which averages approximately one-half the cost of the brand Tobi neb and Tobi Podhaler.
  - Initial criteria presented suggested step therapy requirements for individuals who are currently taking nebulized treatments
  - Committee voted to remove step therapy requirement
  - Criteria for use will be in alignment with FDA approved package insert for individuals age 6 years or greater

  APPROVED, UNANIMOUS

- Interim Prior Authorization List Review – Removal
  - The following medications were reviewed for Interim PA list removal and removed due to their HCFA termination:
    Nexiclon XR, Orbivan CF
  - The following medications were reviewed for Interim PA list removal and removed due to not having an NDA or ANDA:
    Aluvea cream, Tropazone cream, Sonafine topical emulsion, ANIMI-3, Neosalu/CP, Lycelle, Hylatopic plus cream, Dologesic, Zithranol shampoo, Aqua Glycolic kit

  APPROVED, UNANIMOUS

- Review of Existing Prior Authorization – Kalydeco® (ivacaftor)
  - Kalydeco had recent FDA indication change which prompted the review
  - Proposed changes to criteria included adding 8 mutations to the approved list of approved mutations in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene eligible for treatment
  - Individuals homozygous for the *F508del* mutation in the CFTR gene were added to the denial criteria

  APPROVED, UNANIMOUS

- Review of Existing Prior Authorization – Ampyra® (dalfampyridine)
    - Ampyra criteria last updated 11/2010; FDA label changes and periodic review of prior authorizations prompted review of this criteria
    - No substantive changes were made to the criteria
    - Package insert references and document layout were updated

    APPROVED, UNANIMOUS

- Review of Existing Prior Authorization – Linzess® (linaclotide)
    - Linzess criteria last updated 11/2013; FDA label changes prompted review of this criteria
    - No substantive changes were made to the criteria
    - Package insert references and document layout were updated

    APPROVED, UNANIMOUS

- Periodic Review of Existing Prior Authorization – Actiq® (fentanyl citrate oral transmucosal lozenge)
    - Actiq criteria last updated 6/2007; periodic review of prior authorizations prompted review of this criteria
    - No substantive changes were made to the criteria
    - Educational reference about the TIRF (transmucosal immediate release fentanyl) REMS Access program was added to the document for educational purposes
    - Package insert references and document layout were updated

    APPROVED, UNANIMOUS

- Periodic Review of Existing Prior Authorization – Adcirca® (tadalafil)
    - Adcirca criteria last updated 3/2010; periodic review of prior authorizations prompted review of this criteria
    - Substantive changes were made to the criteria to require a trial period of step therapy through ANDA approved generic sildenafil (AB rated to Revatio)
    - Quantity limit reference was updated from 60 tablets per 30 days to 2 tablets per day
    - Package insert references and document layout were updated

    APPROVED, UNANIMOUS

- Periodic Review of Existing Prior Authorization – Amrix® (cyclobenzaprine ER)
    - Amrix criteria last updated 5/2009; periodic review of prior authorizations prompted review of this criteria
    - Substantive changes were made to the criteria for safety purposes to deny approval if the individual was concurrently taking an MAOI or if the individual had hyperthryoidism
    - Package insert references and document layout were updated

    APPROVED, UNANIMOUS

- Periodic Review of Existing Prior Authorization – Onfi® (clobazam)
    - Onfi criteria last updated 9/2012; periodic review of prior authorizations prompted review of this criteria
    - Substantive changes were made to the criteria to remove the 5mg tablet which is no longer manufactured and add reference to the oral suspension (2.5mg/mL in 120mL bottles)
    - Clarification of “no more than 34 day supply” not to exceed 40mg per day
    - Package insert references and document layout were updated

    APPROVED, UNANIMOUS

- Periodic Review of Existing Prior Authorization – Bactroban® cream (mupirocin)
  - Bactroban cream criteria last updated 3/2011; periodic review of prior authorizations prompted review of this criteria
  - No substantive changes were made to the criteria
  - Package insert references and document layout were updated

  APPROVED, UNANIMOUS

Past Intervention Updates

- Bisphosphonate – 3 month deployment review
  - A higher percentage of preferred agents were used SFY2014Q4 (94%) as compared to SFY2013Q4 (76%)
  - An overall decrease in the total number of recipients utilizing oral bisphosphonates was observed during SFY2014Q4 (123) as compared to SFY2013Q4 (148)
  - Will review again April 2015
- Medication Assisted Opioid Therapy
  - Letters not able to be sent due to technology constraints; will address next meeting

FDA/DEA Updates – Educational

- Incivek to be discontinued by manufacturer as new Direct Acting Agents for Hepatitis C come on the market.
- Hydrocodone combination products
  - Hydrocodone combination products will be moving from Schedule III to Schedule II on 10/6/14
  - All new Rxs will require a hard-copy Rx
  - Refills for Rxs written prior to change will be honored until 4/8/15; Alaska Medicaid's Pharmacy Point of Sale system will be able to accommodate this interim period
  - Approximately 2,500 Alaska Medicaid recipients filled prescriptions for hydrocodone combination products during July 2014

Retrospective DUR

- FAERS reports – potential signals review
  http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082196.htm

Product	**FAERS Potential Signal** (causal relationship not confirmed by FDA)	**Claims (Utilization) [2013Jul01 – 2014Jun30]**	**Recommendation**
Brentuximab (Adcetris)	Hepatotoxicity	0	No review
Testosterone products [HIC3: F1A]	Potential for abuse, misuse, or dependence	< 500	Review Nov 2014 DUR
Antidepressants, except MAOI	Angle-closure glaucoma	~4000	Await further FDA guidance

- PQA (Pharmacy Quality Alliance) Measures
  - Introduced PQA measures as an opportunity to provide clinical benchmarking between programs; focus on safety and clinical appropriateness
  - Will identify relevant quality measures and incorporate structured retrospective reviews based on PQA measures prior to March 2015 meeting

- Standing Reviews
  - Prescriber shopping – thresholds were determined for reviews and intervention letters

Next Meeting

November 21, 2014 at 1:00pm

Meeting adjourned.