Drug Utilization Review (DUR) Committee

November 15th 2013 Minutes

Members Present:
Dharna Begich, Pharm.D.
Jenny Love, MD
Chuck Semling, Pharm.D.
Greg Salard, MD
C.J. Kim, R.Ph. (DHSS)
Erin Narus, Pharm.D. (Magellan)

Members Absent:
John Pappenheim, MD
Rader, Maggi, CNM

Public attendees:
Shane Hall
Anne Marie Licos
Chris DeSimone
Fred Sego
Lisa Valaika (*Telephonic*)
Nancy Martin (*Telephonic*)
Lori Howarth (*Telephonic*)

- Meeting started at 1:10pm and attendance was taken
- Review of minutes from April 19, 2013 meeting (Approved)
- Welcome back, review the Conflict of Interest (COI) paperwork
- Read aloud from the DUR committee By-Laws, Article II – "Purpose" after starting the proposal for FDA lowering acetaminophen
- Review agenda for additions;
  - Agenda item to be added – PA proposal for Primlev
  - Agenda item to be deleted - PA proposal for Iclusig

ProDUR

- Proposed FDA lowering acetaminophen per dosage units
  - Information summarized from FDA Drug Safety Communication from January 13, 2011 that will be impacting the amount of acetaminophen contained per dosage unit for prescription products only. This is addressing the issue of increased risk of severe liver injury caused by overutilization of acetaminophen. The maximum allowed amount of acetaminophen will be 325mg or less per dosage unit. Manufactures have until January 14, 2014 to limit the amount of acetaminophen or choose to withdraw the drug product. The maximum daily amount is unchanged at four grams per day.
  - To help facilitate these upcoming changes the proposal is requesting:
    - to update quantity limits on any new release products that contains acetaminophen
    - to re-establish quantity limits on reformulated products (Cross over current limits to new products)
    - to establish new quantity limits on products that contain 325mg or less acetaminophen
    - UNANIMOUSLY APPROVED
- Proposed Prior Authorization Relistor syringe, kit, vial
  - General background information presented on medication
  - Claims history is suggesting that the product may not be correctly prescribed as indicated from package insert (such as usage greater than four months, possibly not being used for recipients receiving 'palliative care')
  - Discussion regarding criteria for approval line (5) – committee fine with terminology
    - UNANIMOUSLY APPROVED
- Proposed Prior Authorization Linzess and Amitiza
  - General background information presented on medications with noted differences regarding their mechanism of action
  - Claims history is identifying potential inappropriate dosing, age utilization not indicated for, and a significant amount of claims that do not meet the definition of 'chronic' diagnosis
  - Discussion on possible addition of clinical definition of 'Constipation' to be included as part of the criteria. Committee felt it was not necessary to add a clinical definition
  - Constipation can generally be treated by other regimens: lifestyle modifications, increased water consumption, increased exercise, fiber laxatives, stimulant laxatives, or osmotic laxatives as initial therapy
  - Noted Criteria differences from Relistor PA as the indications are similar but have defined differences
    - UNANIMOUSLY APPROVED

- Proposed New Prior Authorization 'Buckets'; Cancer & Specialty Medications, Medications Reformulated and/or Modified Dosage Form, Topical Combination Kits and New Topical Formulations
  - Advantages to the new 'buckets' – some medications receive new indications, if either an indication is removed or added then the PA criteria does not have to re-reviewed and re-discussed through the committee. An example is for Botox as it has been approved for an additional indication. If necessary items can be removed and more individualized criteria can be designated
  - Items presented are basically mimicking the package insert under "Indications and Usage"
  - Items with Box Warnings have been included in the criteria to be discussed with recipient
  - Items that require lab monitoring (pre and post usage) will require positive documentation
  - The criteria is designed to help maintain on-label utilization and maintain other monitoring parameters (lab work) to help prevent adverse events from the medication
  - These new cancer & specialty medications are extremely disease specific that make them susceptible for non approved indications
  - Many of the new medications have strict distribution policies (REMS) or even pharmacy exclusivity distribution
  - Oral Multiple Sclerosis (MS) agents were discussed as part of the PA bucket. Claims history is starting to see some utilization. Rather than to limit access and considering that the medications are new, drug options are limited to treat MS. The committee decided NOT to add any PA criteria to the sub-class "Multiple Sclerosis Agents". Topic may be re-visited in a future meeting when possibly new guidance may be determined for their place in therapy
  - Medications that may have a new dosage form (capsule versus tablet or others) may require a generic trial or a preferred product to help promote generic utilization
  - New Topical Brand Kits are including various OTC products – generic trial or a preferred product to help promote generic utilization
  - Quantity limits were discussed as part of the criteria. An additional benefit to assigning quantity limits is as a safeguard for overutilization, improper dosing, and accidental claims that may be submitted with incorrect quantities. Pharmacies may benefit as noted from previous audits from inadvertent claims with inappropriate submitted quantities
    - UNANIMOUSLY APPROVED with Noted Deletion of Oral MS drugs
- Proposed PA addition of PRIMLEV to the new 'bucket' – Medications Reformulated and/or Modified Dosage Form
  - Drug manufacture recently became rebate eligible
  - Combination of oxycodone & acetaminophen with three strengths available (5/300,7.5/300.10/300)
  - Single source with no generic equivalent available
  - Criteria proposed – generic trial of oxycodone & acetaminophen with letter of medical necessity
    - UNANIMOUSLY APPROVED
- Proposed Invokana Prior Authorization
  - Discussed new medication, mechanism of action, and side effects
  - Initial drug therapy for type 2 diabetes is metformin along with lifestyle modifications
    - UNANIMOUSLY APPROVED
- Proposed Combine PA Eliquis with Xarelto
  - Xarelto PA approved 3/15/2013
  - Both have same mechanism of action as a factor Xa inhibitor
  - Eliquis only indication is to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation
    - UNANIMOUSLY APPROVED
- Proposed Combination PA for Juxtapid & Kynamro
  - New medications for treating homozygous familial hypercholestolemia (HoFH) which is a rare disease
  - Comments were submitted to members
  - Discussed agents for proper usage, age restrictions and what information can be used to constitute a positive diagnosis other than genetic testing
  - Both medications have REMS program in place
    - UNANIMOUSLY APPROVED

- Proposed Combination PA Vascepa (new) with *updated* Lovaza PA
  - Both medications indicated for as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500mg/dl) hypertriglyceridemia
  - Criteria updated to one laboratory test result with the last 12 months, trial & failure with fibrate or niacin and age restrictions apply, must be 18 years of age or older
    - UNANIMOUSLY APPROVED
- Proposed Interim PA List Removals – Review of Drugs (9)
  - Medications may be under the PDL for class management
  - Medications to be removed: Prepopik powder packet, Ultresa DR, Ilevro drops, Lotemax Opth Gel, Nesina, Kazano, Oseni, Abilify Maintena, Suclear Bowel Prep-Kit
    - UNANIMOUSLY APPROVED
- End of public meeting 2:56pm

Retrospective DUR

- Discuss review criteria
  - The profiles were discussed and evaluated for intervention letters to be sent out to the providers.
    - Interventions discussed on profiles varied from polypharmacy, polyprovider, therapeutic duplication, over-utilization, high-dose, drug-drug interactions, candidates for possible "lock-ins", and unnecessary care/duration.
    - As part of the process, the information is evaluated from different perspectives; viewing as a prescriber or the other end as a pharmacist who dispenses the prescription.
  - Retrospective DUR (FDA warning: Fluoroquinolones may cause permanent nerve damage) – Even though no official meeting was held in September 2013, fifteen (15) medication profiles were sent to members for review. Case profiles were discussed as necessary for potential criteria letters to be sent out to physicians.
  - Retrospective DUR (Medications that increase the risk of falls in the elderly) – Fifteen (15) profiles were reviewed and evaluated per committee member. Profiles discussed and presented based on selected criteria. Letters to be sent out to physicians for criteria and other findings noted by the committee members.
    - During profile reviews, was noted that multiple female profiles had low dose zolpidem (*5mg*) being prescribed
- Comments/Suggestions:
  - Presented information (claims history) on previous implemented edits:
    - PA for Atypical Antipsychotics for Children < 5 years old (June 2012)
    - QL on Low-Dose Seroquel (June 2012)
    - PA for H.Pylori Kits (May 2013)
    - PA/QL Celebrex (May 2013)
    - QL Lyrica (May 2013)
    - PA Marinol (June 2013)
  - Approved edits, quantity limits, and prior authorizations from previous meetings have been put into production except the Bisphosphonate Step-Edit. Additional work and testing are in progress with a date of deployment to be determined
  - Message on intervention cover letter will remove the PDMP reminder and replace with: "Information to report possible Fraud, Waste, and Abuse"; language still to be finalized but with the intent of providing phone numbers and/or website address to providers
  - Greg suggested that fifteen (15) profiles was a good number as he is able to give more attention to detail to a smaller sample size
  - Chuck suggested that a review be done on Cymbalta quantity limits
  - C.Kim suggested to committee members to submit informational websites they use in their practice. Will add websites on intervention letters to pass on educational information to providers about new drugs, therapies, or in general to pass on useful information
- Next meeting is tentatively scheduled for January 17, 2014 and location same as before
- Meeting adjourned 3:45pm