Drug Utilization Review (DUR) Committee

April 17th 2015

Members Present

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

Members Absent

Non-Members Present

Tolu Balogun, PharmD (Magellan)
John Bloomfield (Drug Rep)
Dr Roberts (Provider Specialist)

Meeting started at approximately 1:10pm; Attendance was taken

Welcome
Review of minutes from March 15th meeting
Approved unanimously without modification
Review of agenda
Approved unanimously with modification to defer #6a (CNS Stimulants) to September meeting
Open floor to members for comments, questions, concerns
No issues brought forward
Dr. Roberts commented on Kalyedeco and place in therapy.
Recommendation is that a requirement of sweat test and physiological manifestations of the condition be requested; estimated prevalence is about 60-70 CF patients in AK

ProDUR

- **Review of existing Prior Authorizations, Quantity Limits, Edits**
  - Kalydeco
    - Last reviewed 9/19/14
    - New FDA indication changes prompted review
    - Treatment cost is $300,000 per year per patient
    - Indicated for patients with CF that are 2 years of age and older who have R117H mutation
    - Criteria for approval includes that the prescriber be a specialist or provider who is familiar with CF treatment
    - Documentation of clinical status must be submitted with renewal request
    - Criteria for denial includes patients less than 2years of age per FDA indication and concomitant use with CYP3A4 inducers

    APPROVED; UNANIMOUS

  - Hepatitis C, Direct Acting Agents – fax form update
    - Provider feedback
      - Recommendation to add MF Score of F0 and F1
      - Recommendation that fax form be made mandatory

    APPROVED; UNANIMOUS

  - Botulinium Toxin – fax form, max dose (upper limb spasticity)

- Note current form does not have new indications
- Product is a physician administered drug so product is billed via J codes and not at pharmacy point of sale
- State requested a conditional approval to revise the form, remove gaps and include current FDA approved indications
- Motion made to update form to match criteria

APPROVED; UNANIMOUS

- Botulinium Toxin – fax form, max dose (upper limb spasticity)
  - Pg 3 editing/correcting criteria – max is 360??? Not 400???
  - Pg 5 – removed initial by spodismos
  - Pg 5 - Note that the current fax form (mandatory form)
  - Motion made to accept revision to botox form

APPROVED; UNANIMOUS

- Extended Release Opioids
  - New proposed criteria includes
    - Educational information concerning risks associated with the use of opioids including the risk of overdose with dosage increases
    - Opioid dose calculator is located on the first page
    - Link to REMS program
    - Included information about PDMP (Prescription Drug Monitoring Program)
  - Prior authorization (PA)
    - With the higher costs associated with new products and dosages, need now arises for definition of specific doses that will be approved
    - Quantity Limit – intent is to increase the awareness of prescribers on the patient risk of overdose as well as targeted education for prescribers on the reasoning behind available Quantity Limits.
    - Therapeutic Duplication edit already exists; patients cannot receive more than 1 extended release opioid.
    - Criteria for approval proposed changes include:
      - All PA requests must include calculated MED (morphine equivalent dose) to help prescribers evaluate and determine appropriateness before requesting PAs
      - Move #6 to #3
      - Future analysis will take diagnosis into consideration
      - Definition on Page 3 – remove last sentence in definition paragraph
    - Recommendation made by committee member for provision of form or template for pain contract for prescribers
      - State stated that form will be edited and template for contract will be available to prescribers who want them
  - Motion made to approve PA changes as discussed and move forward and forms as discussed

APPROVED; UNANIMOUS

- **Proposed new Prior Authorizations, Quantity Limits, Edits**
    - Xyrem (tabled from March)
        - Presently is on PA in the form of maximum cost (cost exceeds max) as it falls in category of drugs above $7500 per month.
        - Proposed criteria in order to ensure conformity with FDA safety concerns (sleep apnea, respiratory decline etc) and recommendations with drug
        - Enrollment form
            - For patient and prescriber – attestation that patient has been educated and has received prescriptive material
        - As parts of the REMs program
            - Only one pharmacy in the U.S. has been approved to dispense Xyrem
            - Requires prescriber to enroll and attestation to be completed
            - Patient enrollment form, does not address safety concerns, hence need to be a part of AK criteria
        - Criteria for denial
            - Concomitant use of sedative hypnotic is an absolute contraindication
        - Criteria for approval
            - Sleep specialist or neurologist as prescriber
        - Recommendation made to include comment that lost, stolen destroyed medication will not be replaced
        - Motion made to approve all changes discussed

      APPROVED; UNANIMOUS

Meeting adjourned at 3:27pm
Next Meeting: TBD