October 19, 2016 Meeting Minutes

- Review and Vote
Magellan Class Reviews

Therapeutic Class

• Glucocorticoids, Inhaled
Glucocorticoids, Inhaled

Sarah Martinez, PharmD
Guideline Update:

• The 2016 update to the GINA Global Strategy for Asthma Management and Prevention guidelines did not contain any significant changes to recommendations for first-line drug therapy. (May 2016)
Glucocorticoids, Inhaled

Guideline Update:

• The 2017 update to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines observe that combination bronchodilator use may be more appropriate in patients with less advanced disease, but data does not definitively show LAMA/LABA treatment to be more effective than ICS/LABA. (December 2016)
P&T Public Class Vote for Inhaled Glucocorticoids
Opioid 7-day Quantity Limitation

Sara Salek MD, CMO, AHCCCS
Follow Up – Oral Oncology

Suzi Berman, RPh
Follow Up HIV Drugs

Suzi Berman, RPh
BIOSIMILAR UPDATE

• Inflectra (infliximab-dyyb)
• Biosimilar for Remicade
• Physician administered
• Recommendation is to continue to cover Brand Only Remicade because it is the more cost effective product to the State.
New Drug Reviews

Suzi Berman, RPh
New Products

- Bromsite – Bromfenac Ophthalmic 0.075%
- Byvalson – Nebivolol HCl / Valsartan
- Cuvitru – Immune Globulin SQ
- Otovel - Ciprofloxacin 0.3% / Fluocinolone Otic
- Relistor – MethylNaltrexone Bromide
- Sustol – Granisetron Injection Extended Release
- Yosprala – Aspirin / Omeprazole
- Zurampic – Lesinurad
Bromsite – Bromfenac Ophthalmic

• A non-steroidal anti-inflammatory indicated for treatment of postoperative inflammation and reduction of ocular pain following cataract surgery.
• Bromfenac is currently available as a generic drug.
• Black Box Warning - None
Bromsite – Bromfenac Ophthalmic

• Recommendation is to not add Bromsite to the AHCCCS Drug List because there are other Bromfenac Ophthalmic products available with similar efficacy and they are more cost effective.

• Bromsite is available through prior authorization based on medical necessity.
Byvalson – Nebivolol HCL/ Valsartan

- A beta blocker (BB) / angiotensin II receptor blocker (ARB) combination drug.
- Indicated for hypertension
- Drugs are available as single agents
- Recommendation is to not add Byvalson to the AHCCCS Drug List because it is more cost effective to prescribe the drugs individually.
Cuvitru – Immune Globulin SQ 20%

- Indicated for Primary Humoral Immunodeficiency
- Black Box Warning – Thrombosis
- SubQ injection
- Fee-for-Service and MCOs all require PA approval prior to use.
- Immune Globulins are not listed on the AHCCCS Drug List.
- Recommendation is to not add to the AHCCCS Drug List. It is available through the PA process.
Otovel - Ciprofloxacin 0.3% / Fluocinolone Otic

- Indicated for the treatment of acute otitis media with tympanostomy tubes (AOMT) in pediatric patients aged 6 months and older due to *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, and *Pseudomonas aeruginosa*.

- Otic administration only – 14 single use applications.
Otovel - Ciprofloxacin 0.3% / Fluocinolone Otic

- Dosage- one single-dose vial (0.25 mL) into the affected ear canal twice daily for 7 days.
- Black Box Warning – None
- Clinical Trials –
  - Two phase 3 multicenter, double-blind trials were conducted in 662 pediatric patients aged 6 months to 12 years old with AOMT
• Clinical Trials Continued
  o Compared Otovel to Ciprofloxacin and Fluocinolone in separate arms of the trial.
  o Otovel was superior over these products separately however the comparator should have been Ciprodex.
Otovel - Ciprofloxacin 0.3% / Fluocinolone Otic

- Adverse Reactions
  - Auricular swelling
  - Balance Disorder
  - Ear infection and/or itching
  - Otorrhea
  - Tympanic membrane inflammation
Otovel - Ciprofloxacin 0.3% / Fluocinolone Otic

- Recommendation is to not add Otovel to the AHCCCS Drug List because the products are available separately and there are other combination products available which are more cost effective.
- Otovel is available through prior authorization based on medical necessity.
Relistor – Methylnaltrexone Bromide

- Indicated for opioid-induced constipation with chronic noncancerous pain.
- Dosage - 450 mg tablet once daily
- Use beyond 4 months has not been studied
- Black Box Warning – None
- Clinical Trials- randomized double blinded placebo controlled 4-week study with 401 patients
Relistor – Methylnaltrexone Bromide

- Clinical Trials –
  - 200 Patients given Relistor
  - 201 Patients given Placebo
  - Relistor – 52% responded positively
  - Placebo – 38% responded positively
Relistor – Methylnaltrexone Bromide

• Adverse Reactions occurring in > 10% of the study participants:
  o Abdominal Pain

• Recommendation is to not add this drug to the AHCCCS Drug Lists because there are many products available that are more cost effective.

• Relistor is available through prior authorization based on medical necessity.
Sustol – Granisetron ER

• Is a serotonin-3 (5-HT3) receptor antagonist indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy

• Granisetron Extended Release Injection is administered by a healthcare provider.
**Sustol – Granisetron ER**

- Recommendation is to not add Granisetron ER Injection to the AHCCCS drug list.
- It is physician-administered and not dispensed at the point-of-sale.
- It should be billed using a medical claim.
Yosprala – Aspirin & Omeprazole

• Secondary prevention of cardiovascular and cerebrovascular events:
• Reduction of the risk of aspirin-associated gastric ulcers in patients at risk of developing gastric ulcers due to age (55 years and older)
• Combination of EC Aspirin 81mg or 325mg with Omeprazole 40mg
Yosprala – Aspirin & Omeprazole

• Recommendation is to not add Yosprala to the AHCCCS Drug List because enteric coated aspirin and omeprazole are currently available as individual products.
Zurampic – Lesinurad

- Indicated in combination with a xanthine oxidase inhibitor for the treatment of high serum uric acid associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone.
- Dosage - 200 mg once daily in combination with a xanthine oxidase inhibitor, including allopurinol or Uloric (febuxostat)
Zurampic – Lesinurad

• Black Box Warning
  o Risk of acute renal failure, more common when used without a xanthine oxidase inhibitor.

• Clinical Trials – 3 multicenter, randomized, double-blinded placebo-controlled clinical studies in adult patients with high serum uric acid and gout in combination with allopurinol or Uloric.
Zurampic – Lesinurad

- Patients achieving serum uric acid target:
  - Study 1
    - Allopurinol + Placebo = 28%
    - Zurampic + Allopurinol = 54%
  - Study 2
    - Allopurinol + Placebo = 23%
    - Zurampic + Allopurinol = 54%
Zurampic – Lesinurad

- Contraindicated in patients with:
  - Severe Renal Impairment
  - Tumor Lysis Syndrome

- Adverse Reactions:
  - Renal issue
    - Elevated serum creatinine
  - Cardiovascular events
Zurampic – Lesinurad

- Recommendation is to not add Zurampic to the AHCCCS Drug List because it is a 2nd line therapy.

- Zurampic is available through prior authorization based on medical necessity.
Generic Drug Pricing

Lydia Nesemann, Pharm.D.
Please send agenda items to:

- Robin Davis – Robin.Davis@azahcccs.gov
- Suzi Berman – Suzanne.Berman@azahcccs.gov
- AHCCCS Pharmacy Department Mailbox- AHCCCSPharmacyDept@azahcccs.gov
Thank You.