Washington State Health Care Authority

Apple Health Policies

April Phillips, PharmD
Apple Health PDL/DUR Manager
Health Care Services
February 21st 2018

Washington State Health Care Authority

Antihyperuricemic Agents

(Uloric, Zurampic, Krystexxa)

1. Diagnosis of symptomatic hyperuricemia associated with gout confirmed by **ONE** of the following:
   a) Measurement of blood uric acid levels
   b) Measurement of erythrocyte sedimentation rate
   c) Polarized light microscopy for identification of crystal in synovial fluids obtained from joints or bursas (as well as material aspirated from tophaceous deposits, if any)
   d) Magnetic resonance imaging for gouty tophus
2. Greater than or equal to (≥) 3 gout flares in the previous 18 months that were inadequately controlled by colchicine, corticosteroids or NSAIDs, or at least 1 gout tophus or gouty arthritis
3. Medications known to precipitate gout attacks have been discontinued/changed when possible
4. History of failure (normalize serum uric acid to less than 6 mg/dL), contraindicated or intolerant to ≥ 3 months of allopurinol at maximum tolerated dose

Antihyperuricemic Agents

- For Uloric only
  - NO history of cardiovascular disease (e.g. non-fatal myocardial infarctions (MI), and non-fatal strokes)
- For Zurampic only
  - Used in combination with a allopurinol or uloric
- For Duzallo Only
  - No history of severe renal impairment, CrCl has to be greater than 30ml/min
- For Krystexxa only
  - History of failure, contraindication or intolerance to one of the following: (Allopurinol or Uloric) and Zurampic, or Duzallo
  - NO history of G6PD deficiency (contraindication).

Prostatic Hypertrophy Agents

- Preferred first-line agents do not require prior authorization (e.g. Alpha-1 Adrenergic Blocker, 5-Alpha Reductase Inhibitor)
- Non-preferred agents require a history of failure, contraindication or intolerance to at least **TWO** preferred products
- Brand products with generic available require clinical justification why any generic cannot be used

Prostatic Hypertrophy Agents

- Tadalafil (Cialis)
  - Diagnosis of Benign Prostatic Hyperplasia (BPH)
  - History of failure, contraindication or intolerance to at least one medication from **BOTH** of the following:
    - Greater than or equal to (≥) 4 week trial of an Alpha-1 Adrenergic Blocker *(e.g. alfuzosin, doxazosin, silodosin, terazosin, tamsulosin)*
    - Greater than or equal to (≥) 6 month trial of 5-Alpha Reductase Inhibitor *(e.g. dutasteride, finasteride)*
    - *Dose limit 5mg per day*

Agents for Gaucher Disease

- Documented diagnosis of **type 1 Gaucher disease**
- Members ≥ 18 years of age has **ANY** of the following symptoms:
  - Moderate to severe anemia (hemoglobin ≤ 11.5 g/dL [adult women] or ≤ 12.5 g/dL [adult men] or ≤ 1.0 g/dL or more below the lower limit of normal for age and sex)
  - Significant hepatomegaly (liver size 1.25 or more times normal [1,750 cc in adults]) or splenomegaly (spleen size 5 or more times normal [875 cc in adults])
  - Skeletal disease beyond mild osteopenia and Erlenmeyer flask deformity
  - Symptomatic disease, including abdominal or bone pain, fatigue, exertional limitation, weakness, or cachexia
  - Thrombocytopenia (platelet count less than or equal to 120,000/mm3).
- Zavesca and Cerdelga only: Treatment with enzyme-replacement therapy (i.e. Cerezyme, Elelyso, VPRIV) was ineffective, not tolerated, or is contraindicated
- Cerdelga only: The member has been tested to determine CYP2D6 genotype is one of the following: extensive metabolizer (EM), intermediate metabolize (IM), or poor metabolizer (PM)

Agents for Gaucher Disease

- The member has a documented diagnosis of **type 3 Gaucher disease**
- The member has neurologic findings consistent with type 3 Gaucher disease, including encephalopathy, ophthalmoplegia, progressive myoclonic epilepsy, cerebellar ataxia, spasticity, or dementia
- The member has **ANY** of the following symptoms:
  - Moderate to severe anemia (hemoglobin ≤ 11.5 g/dL [adult women] or ≤ 12.5 g/dL [adult men] or ≤ 1.0 g/dL or more below the lower limit of normal for age and sex)
  - Significant hepatomegaly (liver size 1.25 or more times normal [1,750 cc in adults]) or splenomegaly (spleen size 5 or more times normal [875 cc in adults])
  - Skeletal disease beyond mild osteopenia and Erlenmeyer flask deformity
  - Symptomatic disease, including abdominal or bone pain, fatigue, exertional limitation, weakness, or cachexia; **or** Thrombocytopenia (platelet count less than or equal to 120,000/mm3).

GI Motility, Chronic

(Lotronex, Viberzi)

Diagnosis of severe irritable bowel syndrome with diarrhea (IBS-D)

- Known or suspected GI obstruction has been ruled out
- Greater than or equal to (≥) **ONE** of the following:
  - Frequent and severe abdominal pain/discomfort
  - Frequent bowel urgency or fecal incontinence
  - Disability or restriction of daily activities due to IBS-D
- Greater than or equal to (≥) 18 years of age
- History of failure (at least 2 weeks trial), contraindication or intolerance to **TWO** of the following conventional therapies:
  - Antidiarrheal (e.g. loperamide)
  - Antispasmodics (e.g. dicyclomine, hyoscyamine)
  - Antibiotics
  - Antidepressants (e.g. amitriptyline, sertraline)
  - Bile acid sequestrants (e.g. cholestyramine, colestipol)

GI Motility, Chronic

(Amitiza, Linzess, Trulance)

Diagnosis of chronic constipation

- Diagnosis of **ONE** of the following:
  - Irritable bowel syndrome with constipation (IBS-C)
  - Chronic idiopathic constipation (CIC)
  - Advanced illness (or terminal illness) receiving palliative care
- Greater than or equal to (≥) 18 years of age
- History of failure, contraindication or intolerance to **TWO** of the following conventional therapies:
  - Bulk-forming laxative (e.g. psyllium)
  - Stool softener (e.g. docusate sodium)
  - Osmolar agents (e.g. lactulose)
  - Stimulant laxative (e.g. sennoside)
- Known or suspected GI obstruction has been ruled out

GI Motility, Chronic

(Movantik, Relistor, Symproic)

Diagnosis of opioid-induced constipation (OIC) with chronic non-cancer pain

- Greater than or equal to (≥) 18 years of age
- History of failure (at least 2 weeks trial), contraindication or intolerance to **TWO** of the following conventional therapies:
  - Bulk-forming laxative (e.g. psyllium)
  - Stool softener (e.g. docusate sodium)
  - Osmolar agents (e.g. lactulose)
  - Stimulant laxative (e.g. sennoside)
- Known or suspected GI obstruction has been ruled out
- Patient must be currently taking an opioid

Hereditary Angioedema (HAE) Agents

- Diagnosis of hereditary angioedema (HAE) confirmed by documentation of serum C4 **AND** C1-INH (antigenic or functional level) that are below the lower limits of normal
- History of moderate or severe HAE attacks (i.e. airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion)
- Not used in combination with other approved treatments for HAE attacks
  - For acute attacks (e.g. Berinert, Firazyr, Kalbitor or Ruconest)
  - For prophylaxis of attacks (e.g. Cinryze, Haegarda)
- No evidence of medications used that are known to cause angioedema (e.g. ACE inhibitors, ARBs, estrogen products)
- Prescribed by or in consultation with **ONE** of the following specialists:
  - Allergist
  - Immunologist
  - Hematologist

Immunomodulators, Asthma

(Cinqair, Fasenra, Nucala)

- Diagnosis of severe asthma with an eosinophilic phenotype
- Documentation of blood eosinophil count (in the absence of other potential causes of eosinophilia) of ONE of the following:
  - Greater than or equal to (≥) 150 cells/µL in prior 6 weeks
  - Greater than or equal to (≥) 300 cells/µL in prior 12 months
- Uncontrolled or inadequately controlled severe asthma is defined by at least ONE of the following:
  - FEV_1 less than (<) 80% predicted
  - Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months
  - Poor symptom control (e.g., ACQ score consistently greater than 1.5 or ACT score consistently less than 20)
- History of failure (remains symptomatic after 2-6 weeks), contraindication or intolerance to high-dose inhaled corticosteroid in combination with additional controller(s)
  - Used in combination with additional asthma controller medications
- NOT used in combination with other monoclonal antibodies for the treatment of asthma (e.g. mepolizumab, reslizumab, benralizumab, omalizumab)
- Prescribed by or in consultation with a specialist in allergy, pulmonology, or immunology

Immunomodulators, Asthma

(Nucala Only)

Eosinophilic granulomatosis with polyangiitis (EPGA, formally known as Churg-Strauss syndrome)

- Symptoms that include **TWO** of the following
  - Documentation of blood eosinophil count (in the absence of other potential causes of eosinophilia) of **ONE** of the following:
    - Greater than or equal to (≥) 150 cells/µL in prior 6 weeks
    - Greater than or equal to (≥) 300 cells/µL in prior 12 months
  - White blood cells present outside blood vessels (extravascular eosinophilia)
  - Migratory spots or lesions on a chest X-ray (pulmonary infiltrates)
  - Sinus problems (acute or chronic sinusitis)
  - Damage to one or more nerve groups (mononeuropathy or polyneuropathy)
- History of failure, contraindication or intolerance to **ONE** of the following:
  - Corticosteroids
  - Immunosuppressants (e.g. cyclophosphamide, azathioprine, methotrexate)
- Dose less than or equal to (≥) 300mg every 4 weeks
- Prescribed by or in consultation with a specialist in allergy, cardiology, hematology, pulmonology, or rheumatology

Immunomodulators, Asthma
(Xolair Only)

- Moderate to severe persistent allergic asthma
  - Greater than or equal to (≥) 6 years of age
  - History of failure (remains symptomatic after 2-6 weeks), contraindication or intolerance to medium- to high-dose inhaled corticosteroids (ICS)
  - Positive skin test or in vitro reactivity to a perennial aeroallergen
  - FEV1 is less than (<) 80% predicted
  - Pre-treatment serum IgE level between 30 and 1500 IU/mL
- Chronic idiopathic urticaria
  - Greater than or equal to (≥) 12 years of age
  - History of failure, contraindication or intolerance to H1 antihistamine therapy (e.g. diphenhydramine, hydroxyzine, cetirizine, loratadine)
- NOT used in combination with other monoclonal antibodies for the treatment of asthma (e.g. mepolizumab, reslizumab, benralizumab)
- Prescribed by or in consultation with a specialist in allergy, pulmonology, or immunology

Movement Disorder Agents

(Austedo, Ingrezza, Xenazine)

- Diagnosis of **ONE** of the following:
  - Chorea associated with Huntington's disease
  - Tardive dyskinesia
- Greater than or equal to (≥) 18 years of age
- Not used in combination with another vesicular monoamine transporter 2 (VMAT2) -inhibitor (e.g. tetrabenazine, deutetrabenazine, valbenazine)
- Prescribed by or in consultation with a neurologist or psychiatrist

Movement Disorder Agents

(Austedo, Ingrezza, Xenazine)

Austedo only

- Less than or equal to (≤) 48mg per day
- No hepatic impairment or concurrent use or recent discontinuation of MAOIs or reserpine

Ingrezza only

- Diagnosis of tardive dyskinesia
- Less than or equal to (≤) 80mg per day
- No history of congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval, history of severe renal impairment or concomitant use with MAOIs.

Xenazine Only

- **ONE** of the following dose limits:
  - Diagnosis of Chorea associated with Huntington's disease less than or equal to (≤) 50mg per day. (For doses, greater than 50mg per day genotyping for CYP2D6 is required to determine if client is an intermediate or extensive metabolizer)
  - Diagnosis of tardive dyskinesia less than or equal to (≤) 200mg per day (off-label)
- No hepatic impairment or concurrent use or recent discontinuation of MAOIs or reserpine