Magellan Rx MANAGEMENT℠

Magellan Medicaid Administration

Washington Pharmacy Advisory Committee Meeting

August 15, 2018

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Agenda Topics

- Overview of Disease State
- Indications
- Dosage & Formulations
- Guideline Updates

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Magellan Medicaid Administration

Cough and Cold

Overview of Disease State – Cough and Cold

- The common cold is a viral illness that affects persons of all ages, prompting frequent use of over-the-counter (OTC) and prescription medications and alternative remedies
  - Adults in the United States experience 2 to 4 colds per year
  - Common cold is one of the most common reasons for physician visits, with cough being a common presenting symptom
- At least 200 identified viruses are capable of causing the common cold
  - The viruses often implicated include rhinoviruses, coronaviruses, parainfluenza viruses, respiratory syncytial virus, adenoviruses, and enteroviruses.
  - Although histologic effects on the nasal epithelium may vary, any of the viruses can cause vasodilation and hypersecretion, leading to the common cold syndrome, which includes nasal congestion, nasal discharge, postnasal drip, throat clearing, sneezing, and cough
- Acute cough has been characterized as a cough lasting 3 weeks or less
  - Causes of acute cough include the common cold or other respiratory tract infection, and allergic rhinitis
- Sub-acute cough lasts 3 to 8 weeks
  - Subacute cough remains after the initial cold or respiratory infection is over
- Chronic cough lasts over 8 weeks
  - Causes of chronic cough include asthma, chronic bronchitis, and chronic obstructive pulmonary disease (COPD)
- Cough may also be associated with factors such as gastroesophageal reflux disease (GERD), medication side effects, pulmonary embolism, smoking, and lung cancer; cough due to these conditions will not be addressed in this class review

Overview of Disease State – Cough and Cold

- Cough and cold formulations are available for use in the treatment of the signs and symptoms of the common cold, sinusitis, allergies, and cough
  - They come in various combinations from simple cold formulations, narcotic cough and cold formulations, as well as non-narcotic cough and cold formulations
  - The cold formulations are available as prescription generics which are combined in one of the following manners with several of the available ingredients:
    - Antihistamine-only
    - Antihistamine-decongestant
    - Decongestant-expectorant
    - Expectorant-only
  - There are many narcotic cough and cold formulations available as prescription generics which are combined in one of the following manners with several of the available ingredients:
    - Antitussive-anticholinergic
    - Antitussive-antihistamine-decongestant
    - Antitussive-decongestant-expectorant
    - Antitussive-expectorant
  - Lastly, there are many non-narcotic cough and cold formulations that are available as prescription generics which are combined in one of the following manners with several of the available ingredients:
    - Antitussive-antihistamine
    - Antitussive-antihistamine-decongestant
    - Antitussive-antihistamine-decongestant-expectorant
    - Antitussive-decongestant
    - Antitussive-decongestant-expectorant
    - Antitussive-expectorant

Cough and Cold – Dosing and Availability

Drug (Products containing drug)	Maximum Recommended Daily Dose		Availability
	Adult	Child	
Anticholinergics			
homatropine	9 mg	Ages: 6 to 12 years: 4.5 mg	Tablet and syrup formulations
methscopolamine	12.5 mg	Safe and effective use has not been established	Tablet, chewable tablet, and syrup formulations
scopolamine	2.4 mg	Safe and effective use has not been established	Tablet and solution formulations
Antihistamines			
brompheniramine	48 mg	Ages: 6 to 11 years: 24 mg 2 to 5 years: 12 mg 1 to 2 years: 6 mg 6 to 12 months: 3 mg 3 to 6 months: 2 mg 1 to 3 months: 1 mg	Tablet, capsule, solution, syrup, and suspension formulations
carbinoxamine	32 mg	Ages: > 6 years: 24 mg 3 to 6 years: 16 mg 2 to 3 years: 8 mg	Solution, suspension, syrup formulations
chlorpheniramine	24 mg	Ages: ≥ 6 years: 12 mg 2 to 5 years: 4 mg	Suspensions, solutions, extended-release tablets, chewable tablets Extended release formulations are not recommended for children under age 6 years
clemastine	2 mg	Ages: ≥ 12 years: 2 mg < 12 years: safe and effective use has not been established	Tablet and caplet formulations

Cough and Cold – Dosing and Availability

Drug (Products containing drug)	Maximum Recommended Daily Dose		Availability
	Adult	Child	
Antihistamines			
cyproheptadine	32 mg	Ages: 7 to 14 years: 16 mg 2 to 6 years: 12 mg	Syrup and tablet formulations
dexbrompheniramine	12 mg	Ages: ≥ 12 years: 12 mg < 12 years: safe and effective use has not been established	Tablets, extended-release tablets, and syrup formulations
dexchlorpheniramine	No maximum dosing information available	Available for use in patients ages ≥ 2	Extended release tablet and oral solution formulations Extended release tablets are not recommended for use in children 3 to 5 years of age
diphenhydramine	300 mg	Ages: ≥ 6 years: 300 mg	Tablet and suspension formulations
doxylamine	25 mg	Ages: ≥ 12 years: 25 mg	Suspension and chewable tablet formulations
hydroxyzine	400 mg	Ages: ≥ 6 years: 100 mg < 6 years: 50 mg Infants: safety and efficacy have not been established	Tablets, capsules, and solution formulations
promethazine	100 mg	Ages: Adolescents: 100 mg ≥ 2 years: lesser of 25 mg/dose or 0.5 mg/pound/dose	Tablets and syrup formulations

Cough and Cold – Dosing and Availability

Drug (Products containing drug)	Maximum Recommended Daily Dose		Availability
	Adult	Child	
Antihistamines			
cyproheptadine	32 mg	Ages: 7 to 14 years: 16 mg 2 to 6 years: 12 mg	Syrup and tablet formulations
dexbrompheniramine	12 mg	Ages: ≥ 12 years: 12 mg < 12 years: safe and effective use has not been established	Tablets, extended-release tablets, and syrup formulations
pyrilamine	No maximum dosing information available	Available for use in patients ages ≥ 2 years	Tablet, syrup, suspension, and chewable tablet formulations
triprolidine	10 mg	Ages: 6 to 11 years: 5 mg 4 to 5 years: 3.75 mg 2 to 3 years: 2.5 mg 4 months to 1 year: 1.25 mg	Tablet, solution, and suspension formulations
Antitussives (opiate)			
codeine	360 mg	Use limited to patients > 18 years	Tablet, capsule, syrup, and solution formulations
dihydrocodeine	90 mg	Use limited to patients > 18 years	Syrup and solution formulations
hydrocodone	30 mg (as an antitussive)	Use limited to patients > 18 years	Capsule and syrup formulations

Cough and Cold – Dosing and Availability

Drug (Products containing drug)	Maximum Recommended Daily Dose		Availability
	Adult	Child	
Antitussives (non-opiate)			
carbetapentane	240 mg	Ages: 6 to 12 years: 120 mg 4 to 5 years: 30 mg 2 to 3 years: 15 mg	Tablets, capsules, extended-release capsules, and suspension formulations
chlophedianol	100 mg	Ages: 2 to 12 years: 50 mg	Solution formulations
dextromethorphan	120 mg	Ages: 6 to 11 years: 60 mg 2 to 5 years: 30 mg	Tablet, chewable tablet, suspension, and solution formulations
Decongestants			
phenylephrine	60 mg	Ages: 6 to 12 years: 30 mg 2 to 5 years: 15 mg	Tablet, chewable tablet, solution, and syrup formulations
pseudoephedrine	240 mg	Ages: 6 to 11 years: 120 mg 2 to 5 years: 60 mg	Chewable tablet, capsule, solution, suspension, and syrup formulations
Expectorants			
guaifenesin	2,400 mg	Ages: 6 to 11 years: 1,200 mg 2 to 5 years: 600 mg < 2 years: 300 mg	Extended-release capsule, tablet, solution, suspension, and syrup formulations

Cough and Cold – Guidelines

- American College of Chest Physicians (ACCP) Evidence-Based Clinical Practice Guidelines on the Diagnosis and Management of Cough, 2006
  - Patients with acute cough associated with the common cold can be treated with a first-generation antihistamine and decongestant preparation

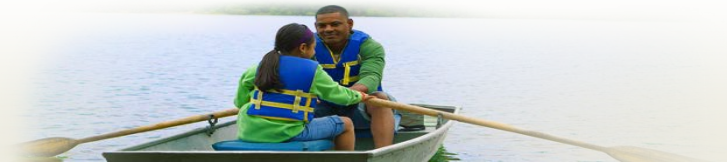
Cough / Cold

- Decongestants – Systemic
- Decongestants – Intranasal
- Antitussives
- Expectorants
- Misc.
- Misc. Combinations

Cough / Cold

Recommendation:

- Continue coverage of cough/cold products in accordance with federal laws.
- All of the products within each sub-class are considered safe and efficacious within that sub-class and are eligible for preferred status and grandfathering at the discretion of HCA.
- All non-preferred products require a trial of two preferred products within that sub-class with the same indication and different active ingredients before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.



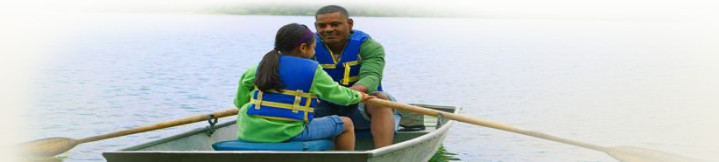
Cough / Cold

Motion:

"I move that the Apple Health Medicaid Program implement the limitations for the Cough/Cold drug class listed on slide 12 as recommended."

Motion: Figueroa

2nd: Chew



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Macular Degeneration Agents
Ophthalmic- Angiogenesis Inhibitors

Overview of Disease State – Macular Degeneration Agents

- Age-related macular degeneration (AMD) is the most common cause of irreversible vision loss in the United States
  - Divided into two subtypes:
    - Dry or nonexudative
      - In dry AMD, drusen (yellow deposits of lipids and fatty protein) form from the deposits of extracellular material beneath the retinal pigment epithelium (RPE)
      - Dry AMD, may progress to wet AMD in approximately 10% to 20% of patients, in which pathologic choroidal neovascular membranes (CNVM) grow under the retina
    - Wet or exudative (neovascular)

- Retinal vein occlusion (RVO) can also cause macular edema
  - The exact pathogenesis of RVO is unknown; multiple factors have an impact on closure of the retinal vein
  - Occlusion of this vein leads to back up of retinal blood flow and increases blood flow resistance, leading to retinal damage
  - VEGF is hypothesized to be increased in retinal damage, stimulating neovascularization and capillary leakage resulting in macular edema

Overview of Disease State – Macular Degeneration Agents

- Macular edema
  - Diabetes is the leading cause of new blindness in the U.S. Without appropriate eye care, diabetics have a 20% to 30% risk of moderate vision loss
  - Thickening of the retina within 2 disc diameters of the center of the macula and is a consequence of microvascular changes to the retina resulting in leakage of plasma constituents and leading to retinal edema

- Degenerative myopia, also referred to as pathologic myopia
  - Seventh leading cause of blindness in the U.S
  - Myopia is common with prevalence in developed countries ranging from 11% to 36%, and approximately 27% to 33% of the myopia population are classified with degenerative myopia
  - Of the patients with degenerative myopia, up to 10% of that population may develop choroidal neovascularization (CNV), a condition where blood vessels begin to grow in the choroid area and into the retina
  - Advanced states CNV can appear as a macular scar where retinal atrophy is present and can lead to vision loss

Macular Degeneration Agents – Indications

Drug	Generic	Indication(s)
aflibercept (Eylea)	---	• Neovascular (wet) age-related macular degeneration (AMD) • Macular edema following retinal vein occlusion (RVO) • Diabetic macular edema (DME) • Diabetic retinopathy (DR) in patients with DME
pegaptanib sodium (Macugen)	---	• Neovascular (wet) age-related macular degeneration (AMD)
ranibizumab (Lucentis)	---	• Neovascular (wet) age-related macular degeneration (AMD) • Macular edema following retinal vein occlusion (RVO) • Diabetic macular edema (DME) • Diabetic retinopathy (DR) • Myopic choroidal neovascularization (mCNV)

Macular Degeneration Agents – Dosing and Availability

Drug	Dose	Administration Comments	Dosage Forms
aflibercept (Eylea)	**Neovascular (wet) AMD:** • 2 mg by intravitreal injection every 4 weeks for the first 12 weeks, followed by 2 mg every 8 weeks • Although, additional efficacy of every 4 week dosing was not demonstrated in most patients, some patients may need every 4 week dosing after the first 12 weeks **Macular edema following RVO:** • 2 mg by intravitreal injection every 4 weeks **DME:** • 2 mg by intravitreal injection every 4 weeks for the first 5 injections, followed by 2 mg every 8 weeks • Although, additional efficacy of every 4 week dosing was not demonstrated in most patients, some patients may need every 4 week dosing after the first 20 weeks **DR in patients with DME:** • 2 mg by intravitreal injection every 4 weeks for the first 5 injections, followed by 2 mg every 8 weeks • Although, additional efficacy of every 4 week dosing was not demonstrated in most patients, some patients may need every 4 week dosing after the first 20 weeks	• Injection procedure should be done in sterile conditions with adequate analgesia and a pre-procedure broad-spectrum microbicide • A new vial should be used for both eyes if treated of both eyes is needed • Patients should be monitored for increased intraocular pressure before and after the procedure	2 mg/0.05 mL in a single-use vial

Macular Degeneration Agents – Dosing and Availability

Drug	Dose	Administration Comments	Dosage Forms
pegaptanib sodium (Macugen)	**Neovascular (wet) AMD:** •0.3 mg every 6 weeks by intravitreous injection	• Injection procedure should be done in sterile conditions with adequate analgesia and a pre-procedure broad-spectrum microbicide • Safety and efficacy of administration to both eyes concurrently have not been evaluated • Patients should be monitored for increased intraocular pressure before and after the procedure	0.3 mg/90 µL solution in a single-use syringe
ranibizumab (Lucentis)	**Neovascular (wet) AMD:** •0.5 mg by intravitreal injection once monthly •Although less effective, patients may also be treated with less frequent injections following the first 3 to 4 months of injections **Macular edema following RVO:** •0.5 mg by intravitreal injection once monthly **DME:** •0.3 mg by intravitreal injection once monthly **DR:** •0.3 mg by intravitreal injection once monthly **mCNV:** •0.5mg by intravitreal injection once monthly for up to 3 months. Retreat as needed	• Injection procedure should be done in sterile conditions with adequate analgesia and a pre-procedure broad-spectrum microbicide; • A new vial should be used for both eyes if treated of both eyes is needed; • Patients should be monitored for increased intraocular pressure before and after the procedure	0.3 mg/0.05 mL and 0.5 mg/0.05 mL in single-use vials 0.5 mg/0.05 mL in single-use prefilled syringe

Macular Degeneration Agents – Guidelines

- Age-Related Macular Degeneration Preferred Practice Pattern, American Academy of Ophthalmology (AAO), 2015
  - State intravitreal vascular endothelial growth factor (VEGF) inhibitors, such as aflibercept, bevacizumab, and ranibizumab, should be used as first-line treatment as they are the most effective agents to manage neovascular AMD (AMD)
- Retinal Vein Occlusion, American Academy of Ophthalmology (AAO), 2015
  - Two years of treatment with an intravitreal VEGF inhibitor was safe and effective in macular edema associated with central or branch RVO
  - Vision-related quality of life was improved at 1 month and 6 months after therapy for branch RVO
  - There is limited data to prefer 1 anti-VEGF agent over another
- Macular Edema, American Academy of Ophthalmology (AAO), 2016
  - Clinically significant macular edema (CSME)
    - Laser surgery has been the traditional treatment
    - Current data indicate that intravitreal anti-VEGF therapy is more effective for center-involving CSME than monotherapy with laser surgery
    - Recommends anti-VEGF therapy as the preferred initial treatment for center-involving macular edema, with or without laser therapy
  - Nonproliferative diabetic retinopathy (NPDR)
    - State that intravitreal anti-VEGF therapy may sometimes be used in patients with NPDR that is mild, moderate, or severe with clinically significant macular edema or in patients with clinically significant macular edema and proliferative diabetic retinopathy (PDR) who are not considered high risk for vision loss
  - Proliferative diabetic retinopathy (PDR)
    - In patients with PDR without macular edema but a high risk for vision loss, they recommend anti-VEGF therapy should be considered
    - They also usually recommend anti-VEGF therapy in patients with any amount macular edema, regardless if it is considered clinically significant, as these treatments have been shown effective in center-involving DME

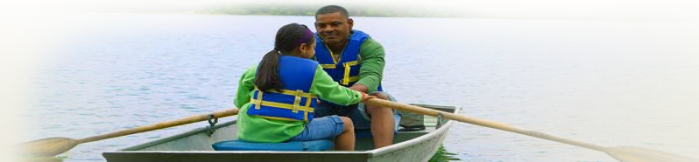
Macular Degeneration Agents – Guidelines

- American Diabetes Association (ADA), 2017
  - Recommend ophthalmic assessment in general for patients with type 2 diabetes at the time of diabetes diagnosis and within 5 years of diabetes onset in adults with type 1 diabetes
    - If exams are negative for 1 or more annual exam, then assessment may occur every 2 years
  - State that intravitreous therapy with anti-VEGF agents is currently the standard of care in the management of central involved DME (CIDME) as monotherapy or in combination with laser therapy
    - Based on their assessment, data suggest Eylea may be most effective at improving visual acuity for eyes with CIDME and acuity levels of 20/50 or worse
    - For eyes with CIDME and visual acuity of 20/40 or better, they found that efficacy of anti-VEGF agents is similar
    - Anti-VEGF therapy may be a suitable alternative to pan retinal laser phototherapy (PRP) in patients with proliferative diabetic retinopathy (PDR) through at least 2 years

Ophthalmic – Angiogenesis Inhibitors

Recommendation:

- All ophthalmic angiogenesis inhibitors are considered safe and efficacious are eligible for preferred status and grandfathering at the discretion of HCA.
- All non-preferred products require a trial of two preferred products with the same indication and different active ingredients before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.



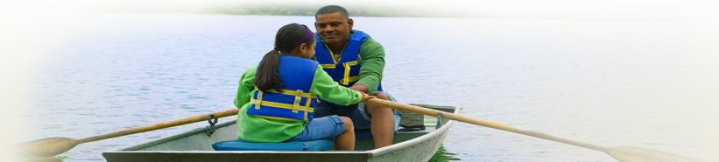
Ophthalmic – Angiogenesis Inhibitors

Motion:

"I move that the Apple Health Medicaid Program implement the limitations for the Ophthalmic – Angiogenesis Inhibitors listed on slide 22 as recommended."

Motion: Sanderson

2nd: Buccola



Anthelmintics

Magellan Medicaid Administration

Overview of Disease State – Anthelmintics

- Helminths are worm-like parasites such as flukes and nematodes (e.g., roundworms, tapeworm, whipworm, hookworm)
- Roundworms (e.g., Trichinella spp. and Anisakis spp.) and Tapeworms (e.g., Diphyllobothrium spp. and Taenia spp)
  - Most common foodborne parasites in the US
  - Symptoms of foodborne helminthic infections include abdominal pain, diarrhea, muscle pain, skin lesions, malnutrition, weight loss
  - Transmitted by water, soil, or person-to-person contact and pets (particularly roundworms and hookworms)
- Roundworm (Strongyloides stercoralis)
  - Prevalent in tropical areas, including the southern U.S
  - Often found in rural areas, institutional settings, and lower socioeconomic groups
  - Larvae in contaminated soil penetrate the skin and migrate to the small intestine by various routes (lungs, connective tissue) where the adult female worms lay eggs
  - Symptomatic cases include gastrointestinal (GI), dermatologic, and pulmonary symptoms
- Pinworm
  - Generally not responsible for serious health concerns
  - Spread easily from one child to another by the transfer of eggs, which are swallowed. Once hatched, the pinworm travels to the anus where it deposits eggs
  - Pinworms infection is characterized by itching around the anal and vaginal area at night

Overview of Disease State – Anthelmintics

- Hookworm (*Ascaris lumbricoides)*
  - Once widespread in the U.S. southeastern region, but improvements in living conditions have greatly reduced infections
  - Mainly acquired by walking barefoot on contaminated soil
  - Larvae penetrates the skin and migrate to the small intestine, then are passed in the feces
  - Most people infected with hookworms have no symptoms, but some may experience GI symptoms
  - Most serious effects are blood loss leading to anemia, in addition to protein loss
- Tapeworm infections (cystic echinococcosis by *Echinococcus granulosus* and alveolar echinococcosis by *Echinococcus multilocularis)*
  - Both parasites are found in dogs; therefore, referred to as dog tapeworm
  - Cystic echinococcosis in humans are asymptomatic; however, harmful, slowly enlarging cysts in the liver, lungs, and other organs can develop unnoticed and untreated for years
  - Alveolar echinococcosis is rare in humans, but if contracted, it can lead to parasitic tumors in the liver, lungs, brain, and other organs
    - If it is left untreated, can be fatal
- Neurocysticercosis
  - Parasitic infection that is targeted by the CDC for public health action
  - There are an estimated 1,000 new hospitalizations for neurocysticercosis in the U.S. each year, most frequently reported in New York, California, Texas, Oregon, and Illinois
  - Caused by the pork tapeworm, *Taenia solium*, which can infect various parts of the body leading to cysticercosis, or larval cysts
  - The most serious form is neurocysticercosis, which affects the brain, and can lead to death
  - It can be transmitted by ingesting contaminated food. It is prevented by proper hand washing, particularly by food handlers

Overview of Disease State – Anthelmintics

- Onchocerciasis (caused by the parasitic worm *Onchocerca volvulus*)
  - "River blindness" because the blackfly that transmits the infection lives near rivers and streams and the infection can result in blindness
  - Onchocercal infections are found in tropical climates, most prevalently in sub-Saharan Africa, and limited in the Americas and Middle East
  - People who become infected are usually long-term travelers to these areas. Once infected, the adult parasites typically reside in nodules in subcutaneous connective tissues for approximately 15 years
  - Symptoms include rash, pruritus, skin nodules, and vision changes
- Schistosomiasis
  - Not typically found in the U.S.
  - It occurs after contact with freshwater contaminated with *Schistosoma* parasites which penetrate the skin, typically when wading, swimming, bathing, or washing
  - Over several weeks, the parasites migrate through host tissue and develop into adult worms inside the blood vessels of the body
  - Parasite eggs that do not pass out of the body can become lodged in the intestine or bladder, causing inflammation or scarring
  - Without treatment, schistosomiasis can last for years and lead to increased risk of bladder cancer
  - Signs and symptoms of chronic schistosomiasis include: abdominal pain, enlarged liver, blood in the stool or urine, and difficulty urinating
- Liver flukes (*Clonorchis* and *Opisthorchis* species)
  - Usually found in Asia or in Asian immigrants
  - Transmitted by eating raw or undercooked freshwater fish
  - Infect the liver, gallbladder, and/or bile duct
  - Symptoms are related to inflammation and intermittent obstruction of the biliary ducts
  - If left untreated, inflammation may lead to cancer

Anthelmintics – Indications

Drugs	Generic	Indications
albendazole (Albenza)		– Treatment of cystic hydatid disease of the liver, lung, and peritoneum caused by the larval form of the dog tapeworm Echinococcus granulosus – Treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm Taenia solium
ivermectin (Stromectol)	**X**	– Treatment of intestinal (nondisseminated) strongyloidiasis due to the nematode parasite Strongyloides stercoralis – Treatment of onchocerciasis due to the nematode parasite Onchocerca volvulus – Note: ivermectin is not effective against adult Onchocerca volvulus parasites
mebendazole (Emverm)		– Treatment of Enterobius vermicularis (pinworm), Trichuris trichiura (whipworm), Ascaris lumbricoides (common roundworm), Ancylostoma duodenale (common hookworm), and Necator americanus (American hookworm) in single or mixed infections
praziquantel (Biltricide)		– Treatment of infections due to all Schistosoma species (e.g., Schistosoma mekongi, Schistosoma japonicum, Schistosoma mansoni and Schistosoma hematobium), – Treatment of infections due to the liver flukes, Clonorchis sinensis/Opisthorchis viverrini
pyrantel pamoate OTC (Pin-X, Reese's Pinworm)		– Treatment of pinworms

Anthelmintics – Dosing and Availability

<table>
<tr><th>Drugs</th><th>Dosage</th><th>Availability</th></tr>
<tr><td>albendazole (Albenza)</td><td>Patients weighing ≥ 60 kg: 400 mg twice daily
Patients weighing < 60 kg: 15 mg/kg/day in divided doses twice daily; maximum 800 mg per day total
Therapy duration:
– Hydatid Disease: 28-day cycle followed by a 14-day albendazole-free interval; repeat for a total of 3 cycles
– Neurocysticercosis: 8 to 30 days

Tablets may be crushed or chewed</td><td>200 mg tablet</td></tr>
<tr><td>ivermectin (Stromectol)</td><td>Strongyloidiasis: a single oral dose designed to provide about 200 mcg/kg of body weight, according to the following:
<table><tr><td>– 15-24 kg: 1 tablet</td><td>– 51-65 kg: 4 tablets</td></tr><tr><td>– 25-35 kg: 2 tablets</td><td>– 66-79 kg: 5 tablets</td></tr><tr><td>– 36-50 kg: 3 tablets</td><td>– ≥ 80 kg: 200 mcg/ kg</td></tr></table>
Onchocerciasis: a single oral dose to provide 150 mcg/kg of body weight
<table><tr><td>– 15-25 kg: 1 tablet</td><td>– 65-84 kg: 4 tablets</td></tr><tr><td>– 26-44 kg: 2 tablets</td><td rowspan="2">– ≥ 85 kg: 150 mcg/kg</td></tr><tr><td>– 45-64 kg: 3 tablets</td></tr></table>
Take on an empty stomach with water</td><td>3 mg tablet</td></tr>
<tr><td>mebendazole (Emverm)</td><td>▪ Pinworm: 1 tablet taken for 1 dose
▪ Common roundworm, hookworm, and whipworm: 1 tablet morning and evening for 3 consecutive days
▪ Repeat course of therapy if patient is not cured 3 weeks after treatment</td><td>100 mg chewable tablet</td></tr>
</table>

Anthelmintics – Dosing and Availability

<table>
<tr><th>Drugs</th><th>Dosage</th><th>Availability</th></tr>
<tr><td>praziquantel (Biltricide)</td><td>Administer weight-based dose 3 times a day as a 1 day treatment, at intervals of not less than 4 hours and not more than 6 hours
– Schistosoma: 20 mg/kg per dose
– Clonorchiasis and opisthorchiasis: 25 mg/kg per dose

• Wash down unchewed tablet with water during meals
• Tablets can produce a bitter taste, resulting in gagging or vomiting, if kept in the mouth</td><td>600 mg tablet</td></tr>
<tr><td>pyrantel pamoate OTC (Pin-X, Reese’s Pinworm)</td><td>Adults and children 2 years to under 12 years of age: 11 mg/kg single dose; do not exceed 1 gram

Body weight/Dosage:
<table>
<tr><td>11-16 kg</td><td>125 mg, given as ½ tablet or 2.5 mL oral susp.</td></tr>
<tr><td>17-28 kg</td><td>250 mg, given as 1 tablet or 5 mL)</td></tr>
<tr><td>29-39 kg</td><td>375 mg, given as 1-1/2 tablets or 7.5 mL</td></tr>
<tr><td>40-50 kg</td><td>500 mg, given as 2 tablets or 10 mL</td></tr>
<tr><td>51-62 kg</td><td>675 mg given as 2-1/2 tablets or 12.5 mL</td></tr>
<tr><td>63-72 kg</td><td>750 mg given as 3 tablets or 15 mL</td></tr>
<tr><td>74-84 kg</td><td>875 mg, given as 3-1/2 tablets or 17.5 mL</td></tr>
<tr><td>> 84 kg</td><td>1,000 mg, given as 4 tablets or 20 mL</td></tr>
</table>
• Do not use in patients < 11 kg or < 2 years of age unless directed by a physician
• May administer at any time of day, without regard to food
• If symptoms persist, consult a physician; Do not repeat course of therapy unless directed by a physician
• Shake oral suspension well before using</td><td>250 mg chewable tablet (Pin-X only)

144 mg/mL (50 mg/mL base) oral suspension</td></tr>
</table>

Anthelmintics – Guidelines

- Albendazole, mebendazole, and ivermectin target parasitic worms that infect the small intestine
  - These types of infection are transmitted through human fecal contamination of soil, which lead to consumption of contaminated plants

- Pyrantel pamoate is available over-the-counter (OTC) to treat pinworm, which is easily spread among children

- Praziquantel, is more limited in its action and is used to treat schistosomiasis. It is not active against nematodes.

- In tropical medicine, mass chemotherapy programs with anthelmintics, (e.g., ivermectin) have played an important role in controlling parasitic infections

Anthelmintics – Guidelines

- Roundworm (Strongyloides stercoralis)
  - According to the Centers for Disease Control and Prevention (CDC)
    - First-line therapy is ivermectin as a single dose for 1 to 2 days
    - An alternative is albendazole daily for 7 days
    - In hyperinfection or disseminated cases, ivermectin is recommended until stool and/or sputum are negative for 2 weeks
- Pinworm
  - Treatment is with mebendazole, pyrantel pamoate, or albendazole (off-label)
  - Pyrantel pamoate does not reliably kill pinworm eggs. It is recommended as 1 dose initially, and then repeated 2 weeks later
  - Physicians may advise treating other family members, as well, to prevent reinfection as well as washing underclothes, bedclothes, and sheets
- Hookworm (*Ascaris lumbricoides)*
  - Albendazole and mebendazole, taken for 1 to 3 days, are the drugs of choice for treatment of hookworm infections

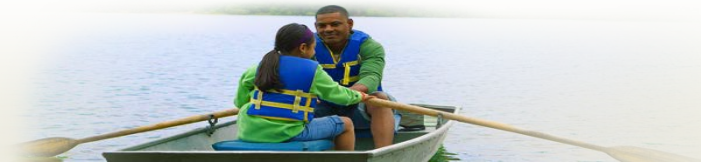
Anthelmintics – Guidelines

- Tapeworm infections (cystic echinococcosis by *Echinococcus granulosus* and alveolar echinococcosis by *Echinococcus multilocularis)*
  - Surgery is the most effective treatment to remove cysts; however, chemotherapy, cyst puncture and percutaneous aspiration, injection of chemicals, and reaspiration have also been used
  - Albendazole is FDA approved to treat cystic hydatid disease of the liver, lung, and peritoneum
- Neurocysticercosis
  - It is prevented by proper hand washing, particularly by food handlers
  - Practice guidelines for cysticercosis are under development by the Infectious Diseases Society of America (IDSA)
- Onchocerciasis (caused by the parasitic worm *Onchocerca volvulus*)
  - The recommended treatment is ivermectin, which kills the larvae, but not adult worms
  - Ivermectin is given every 6 months for the life span of the adult worms or for as long as skin and ocular symptoms persist
- Schistosomiasis
  - The recommended treatment praziquantel, taken for 1 to 2 days
- Liver flukes (*Clonorchis* and *Opisthorchis* species)
  - Per CDC recommendations, raziquantel or albendazole are the drugs of choice to treat *Clonorchis* and *Opisthorchis* infections

Antiparasitics：Antihelmintics

Recommendation:

- All products are considered safe and efficacious and are eligible for preferred status and grandfathering at the discretion of HCA.
- All non-preferred products require a trial of two preferred products with the same indication and different active ingredients before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.



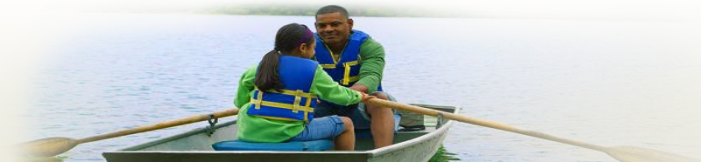
Antiparasitics : Antihelmintics

Motion:

"I move that the Apple Health Medicaid Program implement the limitations for the Antiparasitics : Antihelmintics drug class listed on slide 34 as recommended."

Motion: Figueroa

2nd: Sanderson



Penicillins

Magellan Medicaid Administration

Penicillins - Indications & Dosing/Availability

- See Penicillins Appendix

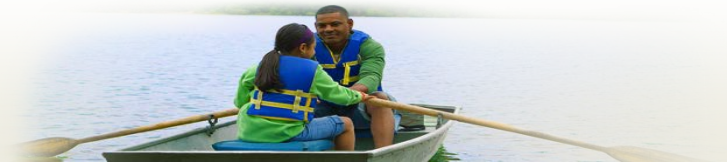
Antibiotics : Penicillins

- Natural Penicillins
- Aminopenicillins
- Penicillinase-Resistant Penicillins
- Penicillin Combinations

Antibiotics : Penicillins

Recommendation:

- All of the products within each sub-class are considered safe and efficacious within that sub-class and are eligible for preferred status and grandfathering at the discretion of HCA.
- All non-preferred products require a trial of two preferred products within that sub-class with the same indication and different active ingredients before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.



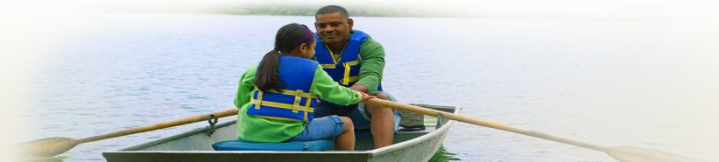
Antibiotics : Penicillins

Motion:

"I move that the Apple Health Medicaid Program implement the limitations for the Antibiotics : Penicillins drug class listed on slide 39 as recommended."

Motion: Sanderson

2nd: Buccola



Macrolides/Ketolides

Magellan Medicaid Administration

Overview of Disease State – Macrolides/Ketolides

- Erythromycin, the first macrolide, was introduced in 1952
- Activity against gram-positive cocci and atypical pathogens made erythromycin a good treatment option for upper and lower respiratory tract infections and soft tissue infections
  - However, erythromycin does have several limitations, such as variable absorption, short elimination half-life, gastrointestinal irritation, and lack of activity against *Hemophilus influenza*
  - Both azithromycin (Zithromax) and clarithromycin (Biaxin) demonstrate better tolerability with more convenient dosing regimens and improved activity against *H. influenza*
  - Macrolides have been shown to be useful agents in the treatment of upper respiratory bacterial infections including community-acquired pneumonia (CAP), acute sinusitis, and acute otitis media (AOM). Antibiotic resistance may limit the overall effectiveness of the agents in this class as multi-drug resistant bacteria become more prevalent
- Telithromycin (Ketek), a ketolide, concentrates inside phagocytes and is effective against intracellular respiratory pathogens
  - Provides effective coverage against many respiratory pathogens in a once daily oral formulation for adults
  - Serious adverse effects, drug interactions, and having only one indication limit the usefulness of telithromycin

Macrolides/Ketolides – Indications

Drugs	Generic	Indications						
		AECB	AOM	CAP	Pharyngitis/Tonsillitis	Skin	Sinusitis	Others
azithromycin (Zithromax)	X	X	X (> six months old)	X (> six months old)	X (> two years old)	X	X (> six months old)	▪ Non-gonococcal urethritis and cervicitis due to Chlamydia trachomatis ▪ Prevention (taken alone or in combination with rifabutin) and treatment (taken in combination with ethambutol) of disseminated MAC in HIV patients
azithromycin ER suspension (Zmax)	--	--	--	X (> six months old)	--	--	X (Adults only)	
clarithromycin (Biaxin)	X	X	X (> six months old)	X (> six months old)	X (> six months old)	X (> six months old)	X (> six months old)	▪ Prevention and treatment of disseminated MAC in HIV patients (> 20 months old) ▪ In combination with other drugs to treat Helicobacter pylori
clarithromycin ER (Biaxin XL)	X	X (Adults only)	--	X (Adults only)	--	--	X (Adults only)	
erythromycin	X	--	X	X	X	X	X	▪ Respiratory tract infections ▪ Pertussis ▪ Diphtheria ▪ Legionnaire's disease ▪ PID ▪ Urethritis and cervicitis ▪ Syphilis ▪ Acne vulgaris ▪ Prevent recurrent attacks of rheumatic fever ▪ Gonorrhea ▪ Surgical infection prophylaxis with bowel preparation
telithromycin (Ketek)	--	--	--	X (including MDRSP; Adults only)	--	--	--	▪ In 2007, the FDA removed the indications for AECB and sinusitis

Macrolides/Ketolides – Dosing and Availability

Drugs	AECB Dosage	Sinusitis Dosage	AOM Dosage	CAP Dosage
azithromycin (Zithromax) 100, 200 mg/5mL suspension 250, 500, 600 mg tablet 1 g powder packet	500 mg for one dose, then 250 mg daily on days 2 – 5 or 500 mg daily for three days **Duration: 3-5 days**	500 mg daily Pediatrics: > six months of age: 10 mg/kg for three days **Duration: 3 days**	Pediatrics: > six months of age: 10 mg/kg for one dose, then 5 mg/kg daily on days 2 – 5 or 30 mg/kg for one dose or 10 mg/kg/day for three days **Duration: 1-5 days**	500 mg for one dose, then 250 mg daily on days 2 – 5 or IV therapy: 500 mg daily IV for ≥ two days then oral 500 mg daily to complete seven to 10 days of therapy Pediatrics: > six months of age: 10mg/kg for one dose, then 5 mg/kg daily on days 2 – 5 **Duration: 5-10 days**
azithromycin ER suspension (Zmax) 2 g/60 mL suspension	--	2 g as one-time dose – take on empty stomach **Duration: 1 day**	--	2 g as one-time dose Pediatrics: > six months of age: 60mg/kg as one-time dose, up to 2 g maximum Take on empty stomach **Duration: 1 day**
clarithromycin (Biaxin) 125, 250 mg/5mL suspension 250, 500 mg tablet	250 – 500 mg every 12 hours **Duration: 7-14 days**	500 mg every 12 hours Pediatrics: > six months of age: 7.5 mg/kg every 12 hours **Duration: 14 days**	Pediatrics: > six months of age: 7.5 mg/kg every 12 hours **Duration: 10 days**	250 mg every 12 hours Pediatrics: > six months of age: 7.5 mg/kg every 12 hours **Duration: 7-14 days**

Macrolides/Ketolides – Dosing and Availability

Drugs	AECB Dosage	Sinusitis Dosage	AOM Dosage	CAP Dosage
clarithromycin ER (Biaxin XL) 500 mg ER tablet	1,000 mg daily **Duration: 7 days**	1,000 mg daily **Duration: 14 days**	--	1,000 mg daily **Duration: 7 days**
erythromycin (many)	--	250 – 500 mg (of base or stearate) every six hours or 400 – 800 mg (ethylsuccinate) every six hours pediatrics: 20 – 50 mg/kg/day in divided doses every six to 12 hours **Duration: 7-14 days**	pediatrics: 20 – 50 mg/kg/day in divided doses every six to 12 hours **Duration: 10 days**	250 – 500 mg (of base or stearate) every six hours or 400 – 800 mg (ethylsuccinate) every six hours pediatrics: 20 – 50 mg/kg/day in divided doses every six to 12 hours **Duration: 7-14 days**
telithromycin (Ketek) 300, 400 mg tablets	--	--	--	800 mg daily **Duration: 7-10 days**

Drug	Prevention of disseminated MAC infections in HIV+ patients		Treatment of disseminated MAC infections in HIV+ patients	
	Adults	Children	Adults	Children
azithromycin (Zithromax)	1,200 mg weekly	--	600 mg daily	--
clarithromycin (Biaxin)	500 mg twice daily	7.5 mg/kg twice daily	500 mg twice daily	7.5 mg/kg twice daily

Macrolides/Ketolides – Guidelines

- Community-acquired pneumonia (CAP) Guidelines, American Thoracic Society (ATS) and Infectious Diseases Society of America (IDSA), 2007
  - Recommend macrolides (e.g., erythromycin, clarithromycin, and azithromycin – strong recommendation) or doxycycline (weak recommendation) for adult patients who are otherwise healthy without risk factors for multi-drug resistant *S. pneumoniae*
  - For adult outpatients with comorbidities including chronic heart, lung, renal, hepatic disorders, diabetes, alcoholism, malignancies, asplenia, immunosuppression, use of any antibiotic within the last three months, or other risk factors for multi-drug resistant *S. pneumoniae*, first line therapy may include a respiratory fluoroquinolone (moxifloxacin, gemifloxacin, or levofloxacin 750 mg) or a beta-lactam plus a macrolide (strong recommendation)
  - For children (school-age and adolescents) evaluated in an outpatient setting, macrolide antibiotics should be prescribed when findings are compatible with CAP caused by atypical pathogens
  - Antibiotics should be used judiciously with appropriate dosing in an effort to avoid antibiotic resistance

- Sexually transmitted diseases (STDs), Centers for Disease Control and Prevention (CDC) , 2010
  - Azithromycin as a recommended regimen for the treatment of chancroid, nongonococcal urethritis, cervicitis, and *Chlamydia* infections
  - Uncomplicated gonorrhea, now recommends azithromycin 1 gram orally as a single dose or doxycycline 100 mg orally twice daily for seven days along with ceftriaxone intramuscularly as recommended combination therapy, due to increased resistance to the oral cephalosporin cefixime
  - Erythromycin base and erythromycin estolate are considered alternative regimens for several infections; however, the gastrointestinal adverse effects of erythromycin may reduce the effectiveness of the therapy if treatment is not completed

Macrolides/Ketolides – Guidelines

- Skin and skin structure infections including impetigo, IDSA, 2014
  - Azithromycin and clarithromycin are indicated for skin and skin structure infections
  - Some strains of *Staphylococcus aureus* and *Streptococcus pyogenes* may be resistant

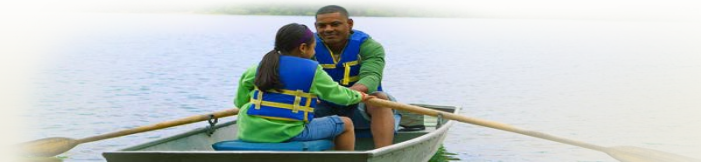
- Pertussis, CDC, 2012
  - Recommend erythromycin, azithromycin, or clarithromycin for the post-exposure prophylaxis or treatment of Pertussis

- *Mycobacterium avium complex* (MAC), CDC, IDSA, and NIH for prevention and treatment of opportunistic infections in HIV-infected adults and adolescents
  - Azithromycin or clarithromycin are the preferred prophylactic agents
  - Initial treatment of MAC disease should consist of two or more antimycobacterial drugs to prevent or delay the emergence of resistance with clarithromycin being a preferred first agent
  - Clarithromycin has been studied more extensively than azithromycin in patients with acquired immunodeficiency syndrome (AIDS) and appears to have a more rapid clearance of MAC from the blood
  - Azithromycin may be used in place of clarithromycin when drug interactions or drug intolerance are a concern

Antibiotics：Macrolides

Recommendation:

- All of the products are considered safe and efficacious and are eligible for preferred status and grandfathering at the discretion of HCA.
- All non-preferred products require a trial of two preferred products with the same indication and different active ingredients before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.



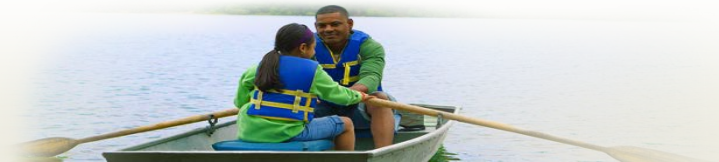
Antibiotics : Macrolides

Motion:

"I move that the Apple Health Medicaid Program implement the limitations for the Antibiotics : Macrolides drug class listed on slide 48 as recommended"

Motion: Schwilke

2nd: Flatebo



Nitrofurantoin Derivatives
Urinary Anti-infectives

Magellan Medicaid Administration

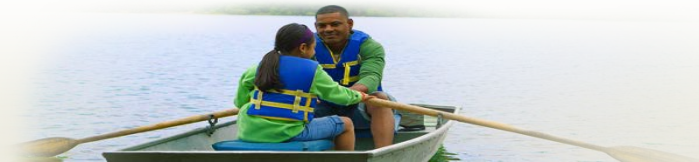
Nitrofurantoin Derivatives – Indications

Label Name	Manufacturer	Brand Name Route
NITROFURANTOIN MCR 100 MG CAP	SUN PHARMACEUTICALS	NITROFURANTOIN MACROCRYSTALS CAPSULES (ORAL)
NITROFURANTOIN MCR 25 MG CAP	SUN PHARMACEUTICALS	NITROFURANTOIN MACROCRYSTALS CAPSULES (ORAL)
NITROFURANTOIN MCR 50 MG CAP	SUN PHARMACEUTICALS	NITROFURANTOIN MACROCRYSTALS CAPSULES (ORAL)
NITROFURANTOIN MONO-MCR 100 MG	SANDOZ	NITROFURANTOIN MONO-MACRO CAPSULES (ORAL)
NITROFURANTOIN 25 MG/5 ML SUSP	NOSTRUM LABORAT	NITROFURANTOIN SUSPENSION (ORAL)

Urinary Anti-infectives

Recommendation:

- All of the products are considered safe and efficacious and are eligible for preferred status and grandfathering at the discretion of HCA.
- All non-preferred products require a trial of two preferred products with the same indication and different active ingredients before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.



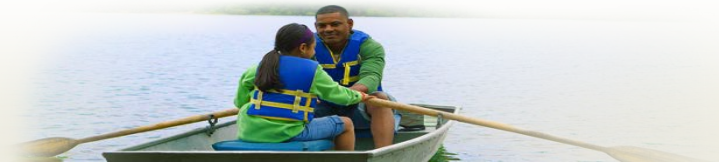
Urinary Anti-infectives

Motion:

"I move that the Apple Health Medicaid Program implement the limitations for the Urinary Anti-infectives drug class listed on slide 52 as recommended"

Motion: Figueroa

2nd: Sanderson



Magellan Rx MANAGEMENT℠

Magellan Medicaid Administration

Contraceptives, Oral

Overview of Disease State – Contraceptives, Oral

- Hormonal oral contraceptives (OCs) are available in various dosage forms for prevention of pregnancy and are available as either a combination of estrogen and progestin (combination OCs) or progestin alone
- Products differ in the specific hormones they contain and how these hormones are dosed throughout the cycle (hormone phases) resulting in several product options
- The various hormone combinations and phases in which they are dosed create products that produce different cycle lengths and physiological effects
- Traditional OCs are administered daily for 21 days, followed by a hormone-free week during which menstruation occurs
- Extended cycle products (e.g., 91 day cycle) delay or completely eliminate the break in hormone use and may be desirable to women who wish to avoid menstruation

Overview of Disease State – Contraceptives, Oral

- Estrogen Component
  - The majority of OCs contain the synthetic estrogen ethinyl estradiol, and the dose varies across products from 20 mcg/day to 50 mcg/day
  - There are products still available that contain mestranol, the estrogen used in many of the original OCs
    - Mestranol is an inactive prodrug of ethinyl estradiol which is metabolized in the liver to ethinyl estradiol
- Progestin Component
  - There are currently 9 different progestins contained in OCs
    - Progestins vary in their progestational, estrogenic, antiestrogenic, and androgenic activity
  - The progestin in an OC is the primary differentiator among different OCs
    - They are commonly referred to as first through fourth generation progestins based on when they were introduced into the market
    - The older first generation agents include norethindrone, norethindrone acetate, and ethynodiol diacetate
      - Generally well tolerated but are associated with spotting and breakthrough bleeding
    - Second generation progestins include norgestrel and its active isomer, levonorgestrel
      - More potent progestins with longer half-lives
      - More androgenic activity compared to the first generation drugs and may be associated with more androgenic side effects, such as hirsutism, acne, or dyslipidemia. The androgenic effect may also translate to improvements in libido
    - Third generation agents are norgestimate and desogestrel
      - Have less androgenic activity; adverse effects, such as acne, may occur less frequently
    - Fourth generation agents are drospirenone and dienogest

Overview of Disease State – Contraceptives, Oral

- Progestin-only OCs
  - Contain 35 mcg of norethindrone
  - They contain active drug in all tablets taken throughout the monthly cycle; there is no hormone-free period
  - Primarily used during lactation and in women who need to avoid estrogen due to tolerance issues or contraindications
  - Progestin only OCs are associated with more breakthrough bleeding and possibly higher failure rates than combination OCs
  - For maximum effectiveness, it is essential that progestin-only tablets be taken at the same time each day

- Combination OCs
  - Combination OCs (estrogen/progestin) are generally grouped based on the dosage regimen strategy used by a specific product
  - Most are based on a 28-day monthly cycle and are available as monophasic, biphasic, triphasic, and 4-phasic products. There are also extended-cycle products and a continuous-cycle product available.
    - Monophasic products contain the same amount of estrogen and progestin in each tablet taken throughout the cycle and are most frequently dosed as a daily active combined pill for 21 days followed by 7 days of no pills or a placebo pill
      - Several monophasic pills vary the duration of active versus inactive pills (e.g., Minastrin® 24 FE has 24 days of active combination pills followed by a 4-day placebo period in each cycle).
  - Multiphasic pills (biphasic, triphasic, and 4-phasic) contain differing doses of 1 or both hormones in the active pills in an attempt to emulate the body's natural menstrual cycle and decrease dose-related adverse effects
    - Many multiphasic products contain a lower total dose of hormones over the course of a cycle

Guidelines – Contraceptives, Oral

- Centers for Disease Control and Prevention (CDC)
  - Recommend combination oral contraceptives and progestin-only oral contraceptives as effective methods of contraception
  - Details on the appropriate selection of an effective contraceptive method (e.g., intrauterine device, implant, injection, oral contraceptives) are described in their published Medical Eligibility Criteria

- American college of Obstetricians and Gynecologists (ACOG)
  - State that long-acting reversible contraceptives (LARC) are safe and have higher rates of efficacy, continuation, and satisfaction compared with short-acting contraceptives; therefore, are excellent contraceptive choices for adolescents

Guidelines – Contraceptives, Oral

- See Oral Contraceptives Appendix

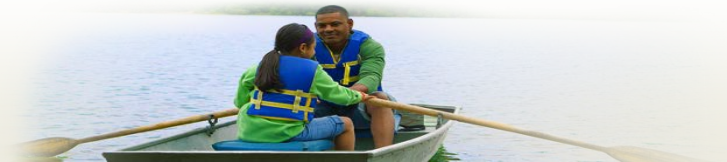
Contraceptives : Oral

- Progestin Contraceptives – Oral
- Combination Contraceptive – Oral
- Combination Contraceptive – Oral, Biphasic
- Combination Contraceptive – Oral, Triphasic
- Combination Contraceptive – Oral, Extended Cycle
- Combination Contraceptive – Oral, Continuous

Contraceptives : Oral

Recommendation:

- All of the products within each sub-class are considered safe and efficacious within that sub-class and are eligible for preferred status and grandfathering at the discretion of HCA.
- All non-preferred products require a trial of two preferred products within that sub-class with the same indication and different active ingredients before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.



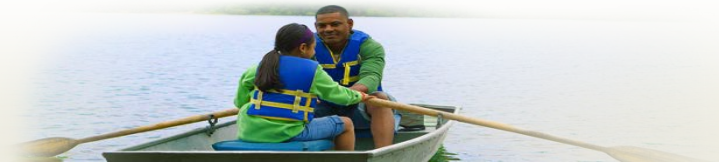
Contraceptives : Oral

Motion:

"I move that the Apple Health Medicaid Program implement the limitations for the Contraceptives : Oral drug class listed on slide 61 as recommended."

Motion: Flatebo

2nd: Storhaug



Magellan Rx MANAGEMENT℠

Magellan Medicaid Administration

Prenatal Vitamins

Overview of Disease State – Prenatal Vitamins

- Prenatal vitamins are approved for nutritional supplementation of females of childbearing potential during pre-conception, pregnancy, or lactation

- Prenatal vitamins provide supplementation for both the mother and fetus. While prenatal supplements contain numerous vitamins and minerals, the folic acid, iron, and calcium content are particularly important

- Current products are listed in Appendix

Prenatal Vitamins – Indications/Dosing

- See Prenatal Vitamins Appendix

Prenatal Vitamins – Guidelines

- Folic Acid
  - American College of Obstetricians and Gynecologists (ACOG), 2017
    - Recommends periconceptional folic acid supplementation as it has shown to reduce the occurrence and recurrence of neural tube defects
    - All women of child-bearing potential should take folic acid supplementation daily
    - For women at low-risk of neural tube defect
      - 400 mcg per day is recommended and supplementation should be initiated at least 1 month prior to pregnancy and continued through the first 12 weeks of pregnancy
    - For women at high-risk of neural tube defect
      - Defined as those who have had a prior neural tube defect pregnancy, who have a neural tube defect themselves, or who have a partner who has a neural tube defect or a child with a neural tube defect
      - 4 mg/day is recommended; initiated at least 3 months prior to pregnancy and continued until 12 weeks of gestational age
      - Higher levels of folic acid supplementation (> 400 mcg/day) should be achieved by taking an additional folic acid supplement and not by taking excess multivitamins, since they may contain vitamin A, which is potentially teratogenic at high doses
  - U.S. Preventive Services Task Force (USPSTF), 2017
    - Recommends that all women planning or capable of pregnancy take a daily supplement 400 mcg to 800 mcg of folic acid
      - Does not apply to women who have had a prior pregnancy affected by neural tube defects or women taking certain anti-epileptic medicines
    - The task force found that most women in the U.S. are not ingesting fortified foods at a level thought to provide optimal benefit

Prenatal Vitamins – Guidelines

- The Centers for Disease Control (CDC) and March of Dimes
  - Iron is recommended to prevent maternal anemia, preterm labor, low birth weight, and aid in maternal/fetal muscle development

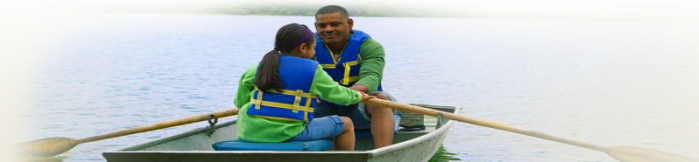
- Calcium and Vitamin D
  - Institute of Medicine (IOM)
    - For pregnant and lactating women ages 14 to 18 years old recommended daily allowance (RDA) is 1,300 mg/day and 600 IU/day of calcium and vitamin D, respectively
    - For pregnant and lactating women ages 19 to 50 years old, the RDA is 1,000 mg and 600 IU daily calcium and vitamin D supplementation, respectively.

- American Dietetic Association
  - Daily vitamin supplementation is not a substitute for a healthy diet
  - Prenatal vitamins should be used along with balanced meals to ensure adequate levels of vitamins and minerals and ensure a healthy pregnancy outcome.

Vitamins : Prenatal Vitamins

Recommendation:

- All products are considered safe and efficacious and are eligible for preferred status and grandfathering at the discretion of HCA.
- All non-preferred products require a trial of two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.



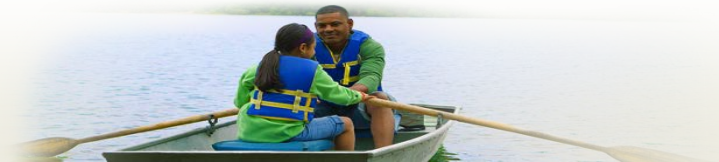
Vitamins : Prenatal Vitamins

Motion:

"I move that the Apple Health Medicaid Program implement the limitations for the Prenatal Vitamins drug class listed on slide 68 as recommended. A chewable product must be preferred."

Motion: Buccola

2nd: Storhaug



Diuretics

Magellan Medicaid Administration

Overview of Disease State – Diuretics

- See Diuretics Appendix

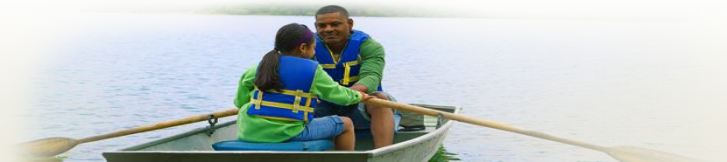
Cardiovascular Agents :
Diuretics

- Carbonic Anhydrase Inhibitors
- Loop Diuretics
- Osmotic Diuretics
- Potassium Sparing Diuretics
- Thiazide and Thiazide-like Diuretics
- Diuretic Combinations

Cardiovascular Agents :
Diuretics

Recommendation:

- All of the products within each sub-class are considered safe and efficacious within that sub-class and are eligible for preferred status and grandfathering at the discretion of HCA.
- All non-preferred products require a trial of two preferred products within that sub-class with the same indication and different active ingredients before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.



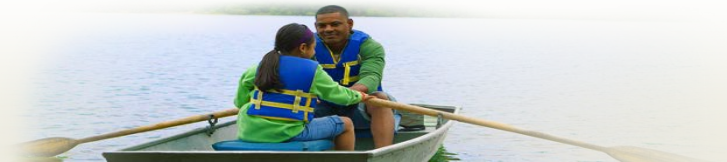
Cardiovascular Agents :
Diuretics

Motion:

"I move that the Apple Health Medicaid Program implement the limitations for the Cardiovascular Agents : Diuretics listed on slide 73 as recommended."

Motion: Schwilke

2nd: Storhaug



Emollients

Magellan Medicaid Administration

Overview of Disease State – Emollients

- Atopic dermatitis (atopic eczema or eczema)
  - A common disease with worldwide prevalence
  - Clinically, eczematous patches and plaques are seen, which favor the face and extensor surfaces in young children and flexor surfaces (including the antecubital and popliteal fossae, ankles, and neck) in older children
  - Management of almost every case of atopic dermatitis will include topical therapy
    - Patients with mild to moderate eczema, topical therapy may be entirely sufficient to control disease activity
      - Emollients should be considered as first-line therapy for mild disease
    - Patients with more severe disease may require more advanced therapy including phototherapy or systemic therapy
      - Other topical therapeutic options for more advanced cases of atopic dermatitis include corticosteroids and calcineurin inhibitors

- Xerosis or dry skin
  - Caused by a loss of water in the upper layer of the skin
  - Emollients work by forming an oily layer on the top of the skin that traps water in the skin
  - These agents are designed to make the stratum corneum softer and more pliant by increasing its hydration
  - A large number of preparations are available, many of which are marketed as cosmetic and therapeutic moisturizers

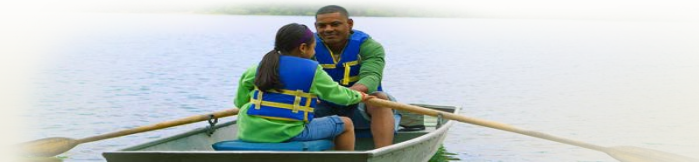
Emollients – Indications & Dosing/Availability

- See Emollient TCR

Dermatologics :
Emollients & Kerolytic Agents

Recommendation:

- All products are considered safe and efficacious and are eligible for preferred status and grandfathering at the discretion of HCA.
- All non-preferred products require a trial of two preferred products before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.



Dermatologics :
Emollients & Kerolytic Agents

Motion:

"I move that the Apple Health Medicaid Program implement the limitations for the Emollients & Kerolytic Agents listed on slide 78 as recommended."

Motion: Sanderson

2nd: Flatebo