Magellan Rx MANAGEMENT℠

Magellan Medicaid Administration

Washington Pharmacy Advisory Committee Meeting

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Agenda Topics

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

Anti-Allergens, Oral

Magellan Medicaid Administration

Overview of Disease State

- Allergic rhinitis, with or without allergic conjunctivitis, affects approximately 30 million people in the U.S.

- Subcutaneous therapy (SCIT) has proven to be effective in the management of allergic rhinitis and asthma since the early 20th Century; however, it requires regular injections and carries the potential of serious systemic allergic reactions

- In 1998, the World Allergy Organization (WAO) stated that cumulative evidence showed sublingual allergen immunotherapy (SLIT) to be an appropriate alternative to SCIT
  - Allergen-specific immunotherapy, including SLIT, may reduce the onset of new sensitizations, and reduce the onset of asthma, although SLIT is not appropriate as monotherapy for the treatment of asthma

Anti-Allergens, Oral – Indications

Drugs	Indications
Short ragweed (*Ambrosia artemisiifolia*) pollen allergen extract (Ragwitek)	Immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for short ragweed pollen in adults 18 years through 65 years of age
Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass mixed pollens allergen extract (Oralair)	Immunotherapy for the treatment of grass pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the 5 grass species contained in this product in persons 10 years through 65 years of age
Timothy grass (*Phleum pratense*) pollen allergen extract (Grastek)	Immunotherapy for the treatment of grass pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens in persons 5 years through 65 years of age
House dust mite (Dermatophagoides farinae and Dermatophagoides pteronyssinus) allergen extract (Odactra)	Immunotherapy for the treatment of house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites, or skin testing to licensed house dust mite allergen extracts in patients 18 to 65 years of age

Anti-Allergens, Oral – Dosing and Availability

Drugs	Dose Range in Adults	Availability
Short ragweed pollen allergen extract (Ragwitek)	1 tablet administered sublingually once daily	Sublingual tablet: Amb a 1-Unit 30 and 90 tablet packages
Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract (Oralair)	**Adults:** 300 index of reactivity (IR) administered sublingually once daily **Pediatrics:** 100 IR once daily on Day 1; 2 x 100 IR once daily on Day 2; then 300 IR once daily thereafter.	Sublingual tablets: 100 IR and 300 IR Adult starter pack: three 300 IR tablets Pediatric starter pack: three 100 IR tablets Commercial pack: thirty 300 IR tablets
Timothy grass pollen allergen extract (Grastek)	1 tablet administered sublingually once daily	Sublingual tablet: 2,800 bioequivalent allergy unit (BAU) 30 tablet package
House dust mite (Dermatophagoides farinae and Dermatophagoides pteronyssinus) allergen extract (Odactra)	1 tablet administered sublingually once daily	Sublingual tablet: 3 blister packages of 10 12 standardized quality house dust mite (SQ-HDM) tablets

Anti-Allergens, Oral – Guidelines

- American Academy of Allergy, Asthma, and Immunology (AAAAI), 2017
  - Recommends SLIT should only be used for FDA-approved uses and advises against off-label use of any other SLIT preparations.
    - FDA-approved SLIT products for allergic rhinitis are Oralair, Grastek, and Ragwitek.
  - Practice parameters on allergen immunotherapy stress the importance of appropriate indications, absence of significant comorbid conditions, and patient's ability to comply with allergen immunotherapy.
  - Stated that SLIT is safe and effective; however, variations in effectiveness have been attributed to the differences in the dose of allergen used.

- Head and Neck Surgery Practice Guidelines, American Academy of Otolaryngology, 2015
  - Offer immunotherapy (SLIT or SCIT) for patients who have an inadequate response to pharmacologic therapy, with or without environmental controls, and that both forms of immunotherapy have been proven effective in reducing symptoms.
  - Indications for considering immunotherapy include patient preference, adherence, adverse effects of other medications, coexisting allergic asthma, and possible prevention of asthma.

Allergenic Extracts (Oral)

(Grastek, Odactra, Oralair, Ragwitek)

- Diagnosis of severe allergen-induced allergic rhinoconjunctivitis or asthma confirmed by a positive skin test or in vitro testing for allergen-specific IgE antibodies
- History of failure of one preferred product in two different classes with a trial of at least 30 days, or contraindication or intolerance to all of the following classes:
  - Intranasal corticosteroids
  - Oral non-sedating antihistamines
  - Intranasal antihistamines
  - Leukotriene modifiers

Allergenic Extracts (Oral)

(Grastek, Odactra, Oralair, Ragwitek)

- Not used in combination with similar immunotherapy
- Currently between the ages of
  - Grastek: 5 and 65 years of age
  - Oralair: 10 and 65 years of age
  - Ragwitek/Odactra: 18 and 65 years of age
- Prescribed by or in consultation with a specialist in allergy or immunology

Allergenic Extracts (Oral)

- **Recommendation:**
  - All oral allergenic extract products are considered safe and efficacious per labeling and are eligible for preferred status at the discretion of HCA.
  - All non-preferred products require a trial of a preferred product with the same indication and different active ingredient before a non-preferred drug will be authorized unless contraindicated, or not clinically appropriate.

Allergenic Extracts (Oral)

- Motion: "I move that the Apple Health Medicaid Program implement the limitations for the oral allergenic agents as recommended on slide 8-10."

Motion: Figueroa

2nd: Storhaug

Cystic Fibrosis

Magellan Medicaid Administration

Overview of Disease State

- Cystic Fibrosis (CF) is a serious autosomal recessive multiorgan disorder
- Affects ~30,000 children and adults in the U.S. and is the most common fatal genetic disease in Caucasians
- Median survival in patients with CF is 36.9 years. With current treatments, children are anticipated to live to ~40 years of age
- Mutations lead to the disease of the exocrine gland function, resulting in the formation of thick mucus that builds up in the lungs, digestive tract, and other parts of the body
  - CF transmembrane conductance regulator (CFTR) functions as a chloride channel
  - Mutations in CFTR results in abnormalities of chloride transport across epithelial cells on mucosal surfaces
- Goals of CF treatment include:
  - Maintaining lung function by controlling infection and clearing mucus in the airway
  - Maintaining appropriate growth by providing nutritional support (e.g., enzyme, mineral, and multivitamin supplements)
  - Managing disease complications (e.g., insulin therapy in patients who develop diabetes)

Cystic Fibrosis- Indications

Drugs	FDA-Approved Indications
ivacaftor (Kalydeco)	• Treatment of cystic fibrosis (CF) in patients age 2 years and older who have one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data.
lumacaftor/ivacaftor (Orkambi)	• Treatment of cystic in patients age 6 years and older who are homozygous for the *F508del* mutation in the *CFTR* gene. • Limitation of use: safety and efficacy have not been established in patients with CF other than those homozygous for the *F508del* mutation
tezacaftor/ivacaftor (Symdeko)	• Treatment of patients with cystic fibrosis (CF) aged 12 years and older who are homozygous for the *F508del* mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence.

Cystic Fibrosis- Dosing and Availability

Drugs	Dose	Availability
ivacaftor (Kalydeco)*+	Adults and children ≥ 6 years of age: 150 mg orally every 12 hours (300 mg daily)	Tablets: 150 mg Oral granules in unit-dose packets: 50 mg and 75 mg Oral granules should be mixed with 5mL (1 tsp) of age-appropriate food or liquid and completely consumed within 1 hour at or below room temperature.
	Children 2 to < 6 years old and ≥ 14 kg: One 75 mg packet (oral granules) every 12 hours (150 mg daily)	
	Children 2 to < 6 years old and < 14 kg: One 50 mg packet (oral granules) every 12 hours (100 mg daily)	
lumacaftor/ivacaftor (Orkambi)*+	Adults and children ≥ 12 years of age: Two 200/125 mg tablets orally every 12 hours (800/500 mg daily)	Tablets: 100/125 mg, 200/125 mg
	Children 6 to 11 years of age: Two 100/125 mg tablets orally every 12 hours (400/500 mg daily)	
tezacaftor/ivacaftor (Symdeko)*	Adults and children ≥ 12 years of age: One tablet containing tezacaftor 100 mg/ivacaftor 150 mg orally in the morning and one tablet containing invafactor 150 mg in the evening (~12 hours apart)	Tablets: 100/150 mg tezacaftor/ivacaftor + 150 mg ivacaftor

*All doses should be administered with fat-containing food.

+Reduce dose to once daily in patients with moderate to severe hepatic impairment and those taking concomitant CYP3A inhibitors; reduce dose to twice weekly in patients taking concomitant strong CYP3A Inhibitors.

Cystic Fibrosis – Guideline

- Cystic Fibrosis Foundation, 2013
  - Inhaled treatments (e.g., tobramycin, dornase alfa, hypertonic saline, corticosteroids) and oral treatments (e.g., antibiotics, corticosteroids) for treatment of symptoms, exacerbations, and/or infections
  - Chronic treatment of ivacaftor for individuals 6 years of age and older with at lease one *G551d CFTR* mutation to improve lung function and quality of life and to reduce exacerbations

- Clinical Pharmacogenetics Implementation Consortium (CPIC), 2014
  - Recommend ivacaftor therapy based on *CFTR* genotype in CF patients ≥ 6 years old who are homozygous or heterozygous for the *G551D CFTR* variant
  - CPIC further states that there are no data regarding whether or not ivacaftor can replace other established therapy.

- Please note: lumacaftor/ivacaftor and tezacaftor/ivacaftor were not approved in 2013/2014 and were not addressed in either guideline

Cystic Fibrosis Agents (Kalydeco)

- Diagnosis of cystic fibrosis
- Documentation of at least **ONE** mutation in the CFTR gene that is responsive to ivacaftor potentiation
- Greater than or equal to (≥) 2 years of age

Cystic Fibrosis Agents (Orkambi))

- Diagnosis of cystic fibrosis
- Confirmation of 2 copies of the *F508del* mutation in the CFTR gene (i.e. the patient is homozygous for the *F508del* mutation)
- Greater than or equal to (≥) 6 years of age

Cystic Fibrosis Agents (Symdeko)

- Diagnosis of cystic fibrosis
- **ONE** of the following:
  - Confirmation of 2 copies of the F508del mutation in the CFTR gene (i.e. the patient is homozygous for the F508del mutation)
  - Documentation of at least **ONE** mutation in the CFTR gene that is responsive to Symdeko
- Greater than or equal to (≥) 12 years of age

Kalydeco			Orkambi	Symdeko		
A1067T c.3199G>A	G1244E c.3731G>A	R352Q c.1055G>A	F508del/F508del c.1521_1523delCTT	F508del/F508del c.1521_1523delCTT	K1060T c.3179A>C	711+3A→G c.579+3A>G
A455E c.1364C>A	G1349D c.4046G>A	R74W c.220C>T		A1067T c.3199G>A	L206W c.617T>G	
D110E c.330C>A	G178R c.532G>A	S1251N c.3752G>A		A455E c.1364C>A	P67L c.200C>T	
D110H c.328G>C	G551D c.1652G>A	S1255P c.3763T>C		D110E c.330C>A	R1070W c.3208C>T	
D1152H c.3454G>C	G551S c.1651G>A	S549N c.1646G>A		D110H c.328G>C	R117C c.349C>T	
D1270N c.3808G>A	K1060T c.3179A>C	S549R c.1645A>C, c.1647T>G		D1152H c.3454G>C	R347H c.1040G>A	
D579G c.1736A>G	L206W c.617T>G	S945L c.2834C>T		D1270N c.3808G>A	R352Q c.1055G>A	
E193K c.577G>A	P67L c.200C>T	S977F c.2930C>T		D579G c.1736A>G	R74W c.220C>T	
E56K c.166G>A	R1070Q c.3209G>A	2789+5G→A c.2657+5G>A		E193K c.577G>A	S945L c.2834C>T	
E831X c.2491G>T	R1070W c.3208C>T	3272-26A→G c.3140-26A>G		E56K c.166G>A	S977F c.2930C>T	
F1052V c.3154T>G	R117C c.349C>T	3849+10kbC→T c.3718-2477C>T		E831X c.2491G>T	2789+5G→A c.2657+5G>A	
F1074L c.3222T>A	R117H c.350G>A	711+3A→G c.579+3A>G		F1052V c.3154T>G	3272-26A→G c.3140-26A>G	
G1069R c.3205G>A	R347H c.1040G>A			F1074L c.3222T>A	3849+10kbC→T c.3718-2477C>T	

Cystic Fibrosis Agents

- **Recommendation:**
  - All cystic fibrosis agents are considered safe and efficacious and are eligible for preferred status at the discretion of HCA.
  - All non-preferred products require a trial of a preferred product with the same indication before a non-preferred drug will be authorized unless contraindicated, or not clinically appropriate.

Cystic Fibrosis Agents

- Motion: "I move that the Apple Health Medicaid Program implement the limitations for the cystic fibrosis agents as recommended on slides 17-21."

Motion: Schwilke

2nd: Flatebo

Pituitary Suppressive Agents, LHRH

Magellan Medicaid Administration

Overview of Disease State

- Central Precocious Puberty (CPP)
  - Refers to the appearance of hormonal and physical characteristics of pubertal development at an earlier age than is considered normal, before age 8 in girls and before age 9 in boys
  - Gonadotropin-dependent in where the premature activation of the hypothalamic-pituitary gonadal (HPG) axis occurs
  - ~1 in 5,000 to 10,000 children
  - Can result in premature rapid development of secondary sexual characteristics
  - Treatment goal is management (suppression) of puberty

- Endometriosis
  - Characterized by the abnormal growth of endometrial cells similar to those that form the inside of the uterus, but in a location outside of the uterus (e.g., pelvic cavity, fallopian tube, and ovaries)
  - ~10% of women are affected; typical age that women are diagnosed with endometriosis is in their 30s or 40s
  - Management goals include pain relief and/or enhancement of fertility
  - The 2010 Management of Endometriosis guidelines (reaffirmed in 2016) recommend initial medical treatment; surgical treatment is recommended when there has been an inadequate response to medical treatment

Overview of Disease State

- Prostate Cancer
  - Estimated number of new prostate cancer in the U.S. in 2017 is 161,360 with estimated deaths at 26,730
  - Treatment decisions are multifactorial depending on assigned risk group at time of initial diagnosis and patient's projected survival based on age and comorbidities
  - Hormonal therapy, also called androgen deprivation therapy (ADT), is the mainstay of treatment for metastatic prostate cancer
    - Lowers androgen (testosterone and dihydrotestosterone) levels which causes the prostate tumor to shrink or grow more slowly
    - Luteinizing hormone-releasing hormone (LHRH) agonists prevent signaling of the testicles to make testosterone, therefore decreasing circulating testosterone levels

- Uterine Leiomyomata
  - AKA fibroids are benign tumors that develop in the smooth muscle of the uterus
  - True incidence and prevalence in the general female population are unknown because the condition is frequently asymptomatic and therefore not identified
  - Most women affected by uterine leiomyomata are asymptomatic and require no treatment unless rapid growth is observed or there are any reasons to suspect pelvic malignancy

Pituitary Suppressive Agents, LHRH- Indications

Drugs	FDA-Approved Indications			
	Endometriosis	Central Precocious Puberty	Prostate Cancer	Uterine Leiomyomata (Fibroids)
goserelin† (Zoladex 1 month implant)	X		X	
goserelin (Zoladex 3 month implant)			X	
histrelin subcutaneous implant (Supprelin LA)		X		
histrelin subcutaneous implant (Vantas)			X	
leuprolide acetate solution			X	
leuprolide acetate suspension (Eligard)			X	
leuprolide acetate suspension (Lupron Depot)	X		X	X‡
leuprolide acetate suspension (Lupron Depot-Ped 1-month and 3-month)		X		
leuprolide acetate suspension and norethindrone tablets (Lupaneta Pack)	X			
nafarelin nasal solution (Synarel)	X	X		
triptorelin (Trelstar)			X	
triptorelin (Triptodur)		X		

† Goserelin (Zoladex) 3.6 mg formulation is also approved for use as an endometrial thinning agent before endometrial ablation for dysfunctional uterine bleeding and in the palliative treatment of advanced breast cancer.

‡ Lupron Depot-3 Month (11.25 mg) in combination with iron therapy is indicated for the preoperative hematologic improvement of anemia caused by uterine leiomyomata; it is indicated only for women for whom 3 months of hormonal suppression is deemed necessary. Recommended therapy is a single Lupron Depot -3 Month injection.

Pituitary Suppressive Agents, LHRH- Dosing and Availability

Drugs	FDA-Approved Indications				Availability
	Endometriosis	Central Precocious Puberty	Prostate Cancer	Uterine Leiomyomata (Fibroids)	
goserelin implant (Zoladex)	3.6 mg SC into the upper abdominal wall every 28 days	--	Prostate cancer: 3.6 mg SC into the upper abdominal wall once every 28 days or 10.8 mg SC into the upper abdominal wall once every 12 weeks For prostate cancer Stage B2-C: Start with 3.6 mg SC implant into the upper abdominal wall 8 weeks prior to initiating radiation therapy, followed in 28 days by 10.8 mg SC implant; Alternatively, 4 injections of 3.6 mg depot can be administered SC at 28 day intervals, 2 depot injections preceding radiotherapy and 2 during radiotherapy	--	Goserelin acetate, equivalent to 3.6 mg or 10.8 mg goserelin in a d,l-lactic and glycolic acids copolymer implant
histrelin subcutaneous implant (Supprelin LA)	--	50 mg histrelin acetate inserted SC in the inner upper arm every 12 months	--	--	Vial (containing implant) for SC implantation: 50 mg
histrelin subcutaneous implant (Vantas)	--	--	50 mg histrelin acetate inserted SC in the inner upper arm every 12 months	--	Vial (containing implant) for SC implantation: 50 mg
leuprolide acetate, solution	--	--	1 mg SC once daily	--	Solution for injection 1 mg/0.2 mL in 2.8 mL vials
leuprolide acetate (Eligard)	--	--	7.5 mg SC once a month 22.5 mg SC every 3 months 30 mg SC every 4 months 45 mg SC every 6 months	--	7.5 mg, 22.5 mg, 30 mg, 45 mg suspension for injection syringe (SD)

SD = single-dose, IM = intramuscular, SC = subcutaneous

Pituitary Suppressive Agents, LHRH- Dosing and Availability

Drugs	FDA-Approved Indications				Availability
	Endometriosis	Central Precocious Puberty	Prostate Cancer	Uterine Leiomyomata (Fibroids)	
leuprolide acetate 1 (3.75 mg) and 3 (11.25 mg) month formulation (Lupron Depot)	Initial treatment: 3.75 mg IM once a month or 11.25 mg IM once every 3 months, with or without norethindrone, for 6 months Retreatment: 3.75 mg IM once a month or 11.25 mg IM once every 3 months with norethindrone for 6 months	--	--	3.75 mg IM once a month up to 3 months or 11.25 mg IM once	3.75 mg, 11.25 mg prefilled dual chamber syringe (SD) in a kit
leuprolide acetate 1 month (7.5 mg), 3 month (22.5 mg), 4 month (30 mg) and 6 month (45 mg) formulations (Lupron Depot)	--	--	7.5 mg IM every 4 weeks, 22.5 mg IM every 12 weeks, 30 mg IM every 16 weeks, or 45 mg IM every 24 weeks for the palliative treatment of advanced prostatic cancer	--	7.5 mg, 22.5 mg, 30 mg, 45 mg prefilled dual chamber syringe (SD) in a kit
leuprolide acetate 1 and 3 month formulations (Lupron Depot-Ped)	--	The initial dose is based on body weight and is administered IM every 4 weeks: ≤ 25 kg: 7.5 mg (1 month form); > 25 kg to 37.5 kg: 11.25 mg (1 month form); > 37.5 kg: 15 mg (1 month form); Dosage is individualized based on hormonal suppression with increases to the next higher dose at the next monthly injection; dosage may be adjusted with changes in body weight 11.25 mg or 30 mg (3 month form) IM every 3 months (12 weeks) based on monthly dosage	--	--	7.5 mg, 11.25 mg, 15 mg for once monthly administration; 11.25, 30 mg for administration every 3 months; administration in prefilled dual chamber syringe (SD)

Pituitary Suppressive Agents, LHRH- Dosing and Availability

Drugs	FDA-Approved Indications				Availability
	Endometriosis	Central Precocious Puberty	Prostate Cancer	Uterine Leiomyomata (Fibroids)	
leuprolide acetate/ norethindrone (Lupaneta Pack)	Leuprolide 3.75 mg IM every month or 11.25 mg IM every 3 months for up to 6 months and norethindrone 5 mg orally daily for up to 6 months	--	--	--	Copackaged kits: 1-month kit: 3.75 mg leuprolide depot and 30 norethindrone 5 mg tablets 3-month kit: 11.25 mg leuprolide injection and 90 norethindrone 5 mg tablets
nafarelin nasal solution (Synarel)	Start treatment on day 2 to 4 of menstrual cycle; 200 mcg/spray into one nostril twice daily alternating nostrils for morning and evening dose; Total dose of 400 mcg/day	2 sprays (400 mcg) into each nostril in the morning and 2 sprays (400 mcg) into each nostril in the evening. Total dose of 1,600 mcg (8 sprays)/day If inadequate response, dose may be increased to 1,800 mcg/day (3 sprays/600 mcg in alternating nostrils 3 times a day)	--	--	8 mL bottle (2 mg/mL) with metered spray pump
triptorelin (Trelstar)	--	--	3.75 mg IM (buttocks) every 4 weeks 11.25 mg IM (buttocks) every 12 weeks 22.5 mg IM (buttocks) every 24 weeks	--	3.75 mg, 11.25 mg, and 22.5 mg depot powder for suspension for injection (SD)
triptorelin (Triptodur)	--	22.5 mg IM every 24 weeks, under supervision of a physician	--	--	22.5 mg depot powder for suspension for injection (SD)

Pituitary Suppressive Agents, LHRH- Guidelines

- Consensus statement from Lawson Wilkins Pediatric Endocrine Society and European Society for Endocrinology, 2009
  - Concludes that all available GnRH agonists are effective despite their different routes of administration, dosing, and duration of action.
  - Favors depot products due to improved compliance.

- Management of Endometriosis Guidelines- American College of Obstetricians and Gynecologists, 2010
  - Recommend initial medical treatment
    - NSAIDs
    - Oral Contraceptives
    - GnRH agonists
    - Progestins
  - Surgical treatment is recommended when there has been inadequate response to medical treatment.
    - Conservative surgery (uterus and ovaries are preserved)
    - Definitive surgery (removal of the uterus with or without the ovaries)

Pituitary Suppressive Agents, LHRH- Guidelines

- Treatment of Prostate Cancer, National Comprehensive Cancer Network (NCCN), 2017
  - Treatment options consist of
    - Active surveillance
    - Radiation therapy
    - Hormonal therapy
    - Chemotherapy
    - Surgery
    - Combination of 2 or more
  - Androgen deprivation therapy (ADT) is the mainstay of treatment of metastatic prostate cancer
  - Recommend administering anti-androgens in conjunction with LHRH agonists to prevent testosterone from reaching cancer cells

- American College of Obstetricians and Gynecologists, 2008
  - Management of symptoms
    - Oral contraceptives and progestin-releasing intrauterine devices (IUDs) to help reduce menorrhagia
    - Non-steroidal anti-inflammatory drugs (NSAIDs) for pain management
    - Mifepristone and GnRH agonists to shrink fibroids
  - Treatment selection based on woman's preference and desire for uterine preservation and future fertility

Pituitary Suppressive Agents

- True (central) precocious puberty
  - Diagnosed with central precocious puberty (idiopathic or neurogenic), defined as sexual maturation before age 8 in girls and age 9 in boys
  - Clinical diagnosis is confirmed with:
    - bone age advanced one year or more beyond chronologic age
    - pubertal response to a GnRH stimulation test
    - Intracranial tumor has been ruled out by CT, MRI, or ultrasound
  - Baseline laboratory investigations have been performed:
    - height and weight
    - sex steroid levels
    - adrenal steroid level to exclude congenital adrenal hyperplasia
    - beta human chorionic gonadotropin to rule out chorionic gonadotropin-secreting tumor
    - pelvic/adrenal/testicular ultrasound to rule out a steroid-secreting tumor
    - Discontinuation for central precocious puberty should be considered at age 11 for girls and age 12 for boys

Pituitary Suppressive Agents

- Stimulation test for diagnosing hypogonadism and central precocious puberty
  - pubertal response has been defined as an luteinizing hormone level after leuprolide stimulation greater than 8 IU/L
- To suppress onset of puberty in adolescents with early onset of puberty on growth hormone therapy
  - Diagnosis of early onset of puberty
  - Currently on growth hormone supplementation
  - Not within target growth range (within 1 standard deviation of mean height for age and sex)
- To suppress changes that would occur during puberty for gender dysphoria/transgender adolescents with age of discontinuation up to provider discretion

Pituitary Suppressive Agents

- Treatment of endometriosis up to 12 months when conventional therapies (e.g. analgesics and hormonal contraceptives), have been unsuccessful
- Treatment of dysmenorrhea that is refractory to oral contraceptives
- Treatment of women with chronic refractory pelvic pain or dysfunctional uterine bleeding when pharmacotherapies (e.g. analgesics, hormonal contraceptives), have been unsuccessful
- To decrease endometrial thickness or fibroid size prior to surgery
- For prevention of heavy uterine bleeding in pre-menopausal women during chemotherapy

Pituitary Suppressive Agents

- For treatment of men and pre-menopausal women with hormone-receptor positive cancer
- Hormonal therapy for clinical relapse following initial treatment in persons with stage II to IV granulosa cell tumors of the ovary
- For treatment-resistant paraphilias

Pituitary Suppressive Agents

- **Recommendation:**
  - All pituitary suppressive agents are considered safe and efficacious and are eligible for preferred status 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 when there is only one preferred product. Nasal administration should be available for children.

Pituitary Suppressive Agents

- Motion: "I move that the Apple Health Medicaid Program implement the limitations for the pituitary suppressive agents as recommended in slides 32-36."

Motion: Buccola

2nd: Storhaug

Androgenic Agents, Topical

Magellan Medicaid Administration

Overview of Disease State

- Male hypogonadism is caused by insufficient production of testosterone and characterized by low serum concentrations and may present as testosterone deficiency, infertility, or both
- Approximately 20% of men ages 60 to 69 years old and 30% of men ages 70 to 79 years old have serum testosterone levels below the normal range
- Symptoms at presentation will primarily depend on the patient's age at the time of disease onset and can include
  - Impotence
  - Decreased libido
  - Fatigue
  - Loss of energy
  - Mood Depression
  - Regression of secondary sex characteristics
- Potential risks due to male hypogonadism include
  - Osteoporosis
  - Sexual dysfunction
  - Depression
  - Cardiovascular disease

Androgenic Agents - Indications

Drugs	FDA-Approved Indications
testosterone gel (AndroGel)	Testosterone replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone, such as primary or secondary hypogonadism (congenital or acquired)
testosterone gel (Fortesta)	
testosterone gel (Testim)	
testosterone gel (Vogelxo)	
testosterone nasal gel (Natesto)	
testosterone solution (Axiron)	
testosterone transdermal system (Androderm)	

Androgenic Agents - Dosing and Availability

Drugs	Generic	Dosing	Administration	Availability
testosterone 1% gel (Androgel 1%)	X	5 g daily, preferably in the morning (delivers 5 mg systemically) Dosing may be increased to 10 mg (by 2.5 mg increments)	Apply to clean, dry, intact skin of the shoulders and upper arms Do not apply to the genitals	2.5, 5 g packets (contains 25 mg or 50 mg testosterone, respectively; 30 packets); 75 g pump with 60 pump actuations delivering 12.5 mg of testosterone per actuation (1.25 g of gel)
testosterone 1.62% gel (Androgel 1.62%)	X	40.5 mg (1.25 g of gel) once daily Dosing may be adjusted between 20.25 mg and 81 mg based on levels drawn at 14 and 28 days after start of therapy	Apply to clean, dry, intact skin of the shoulders and upper arms Do not apply to the genitals	1.25, 2.5 g packets (contains 20.25 mg or 40.5 mg testosterone, respectively; 30 packets) 75 g pump with 60 pump actuations delivering 20.25 mg of testosterone per actuation (1.25 g of gel)
testosterone gel (Fortesta)	X	Initiate at 40 mg once every morning Dosing may be adjusted from 10 mg to 70 mg based on levels 2 hours after application at days 14 and 35 after start of last adjustment	Apply to clean, dry, intact skin of the front and inner thighs Do not apply to genitals or other parts of the body	In a 60 g canister with metered dose pump delivering 10 mg testosterone in 0.5 g gel per actuation
testosterone gel (Testim)	X	5 g daily, preferably in the morning (delivers 5 mg systemically)	Apply to clean, dry, intact skin of the shoulders and/or upper arms Do not apply to genitals or abdomen	5 g tubes (30 per package)

Androgenic Agents - Dosing and Availability

Drugs	Generic	Dosing	Administration	Availability
testosterone gel (Vogelxo)	X	50 mg applied topically once daily at approximately the same time each day Dosing may be adjusted to 100 mg once daily based on levels drawn at 14 days after start of therapy; Maximum dose is 100 mg daily	Apply to clean, dry, intact skin of the shoulders and/or upper arms Do not apply to genitals or abdomen	In unit-dose tubes or packets containing 50 mg testosterone in 5 g of gel; multiple-dose metered pumps delivering 12.5 mg of testosterone in 1.25 g of gel per actuation
testosterone nasal gel (Natesto)		11 mg total, or 1 pump actuation in each nostril, 3 times a day (once in the morning, once in the afternoon, and once in the evening, about 6 to 8 hours apart) Maximum total daily dose is 33 mg intranasally	Patients should blow nose prior to administration Actuator should be tipped toward lateral wall of nostril to ensure gel is applied appropriately prior to pressing the pump Refrain from blowing nose or sniffing for 1 hour following administration Do not apply to genitals or abdomen	Metered dose pump containing 11 g of gel dispensed as 60 metered pump actuations; each actuation delivers 5.5 mg of testosterone
testosterone solution (Axiron)	X	Initiate at 60 mg once a day Dosing may be adjusted 30 mg based on levels drawn 2 to 8 hours after application at days 14 after start or last adjustment	Apply to clean, dry, intact skin of the axilla preferably at the same time every morning Do not apply to the genitals or other parts of the body	110 mL of topical solution in a metered dose pump; each pump delivers 30 mg of testosterone in 1.5 mL of solution; each bottle has an applicator top
testosterone transdermal system (Androderm)		4 mg daily (nightly)	Apply to clean, dry skin of the back, abdomen, upper arms, or thighs; do not apply to genitals, bony prominences, or parts of the body that may be subject to prolonged pressure due to sitting or sleeping; rotate sites every 7 days	2 mg patches (60 per carton); 4 mg patches (30 per carton) Patches contain 9.7 mg testosterone (delivering 2 mg/day) or 19.5 mg (delivering 4 mg/day)

Androgenic Agents – Guideline

- American Association of Clinical Endocrinologist, 2010
  - Recommend testosterone therapy for symptomatic men with classical androgen deficiency syndromes aimed at inducing and maintaining secondary sex characteristics and at improving their sexual function, sense of well-being, and bone mineral density
  - Initiating testosterone therapy using testosterone options on the basis of the patient's preference, treatment burden, and cost
  - The guidelines recommend against testosterone therapy in patients with:
    - Breast or prostate cancer
    - Palpable prostate nodule or induration or prostate specific antigen (PSA) 4 ng/mL or PSA 3 ng/mL in men at high risk of prostate cancer
    - Hematocrit greater than 50%, untreated severe obstructive sleep apnea, severe lower urinary tract symptoms associated with benign prostatic hypertrophy, and uncontrolled or poorly controlled congestive heart failure
  - Treatment goals are continuation of normal activities of daily living and decreased risk of secondary complications such as infertility, osteoporosis, fatigue, and mood disturbances

Androgenic Agents

- **Recommendation:**
  - All androgenic agent are considered safe and efficacious and are eligible for preferred status at the discretion of HCA.
  - All non-preferred products require a trial of two preferred topical products with the same indication before a non-preferred drug will be authorized unless contraindicated, or not clinically appropriate.

Androgenic Agents

- Motion: "I move that the Apple Health Medicaid Program implement the limitations for the androgenic agents as recommended on slide 44."

Motion: Lee

2nd: Flatebo

Enzyme Replacement, Gaucher Disease

Magellan Medicaid Administration

Overview of Disease State

- Gaucher disease
  - Hereditary metabolic disorder that is the most common lysosomal storage disorder
  - Affecting approximately up to 1 in 40,000 live births
- It is an autosomal recessive condition caused by deficiency of glucocerebrosidase, an endogenous lysosomal enzyme and component of the cell membrane. This deficiency results in abnormal accumulation of glycolipids in cell lysosomes
- Patients can suffer from skeletal disease (including but not limited to osteopenia, fractures, and bone crisis), anemia, hemorrhage, thrombocytopenia, splenomegaly, and hepatomegaly, and growth retardation, which is of particular concern in the pediatric population
- Type 1 GD is non-neuronopathic in nature and is the most prevalent type
  - It is most frequently encountered in those of Ashkenazi Jewish descent, occurring in approximately 1 in 450 in this ethnic group
- Goals of therapy:
  - Improving/eliminating symptoms
  - Preventing irreversible damage
  - Improvement in patient quality of life

Enzyme Replacement, Gaucher Disease- Indications

Drugs	FDA-Approved Indications
	Enzyme Replacement Therapy (ERT)
imiglucerase (Cerezyme)	Long-term enzyme replacement therapy for pediatric and adults with confirmed type 1 Gaucher disease that results in 1 or more of the following conditions: ▪ anemia ▪ thrombocytopenia ▪ bone disease ▪ hepatomegaly or splenomegaly
taliglucerase alfa (Elelyso)	Long-term enzyme replacement therapy for adults and pediatric patients with confirmed type 1 Gaucher disease
velaglucerase alfa (Vpriv)	Long-term enzyme replacement therapy for pediatric (4 years of age or older) and adults with type 1 Gaucher disease

Enzyme Replacement, Gaucher Disease- Indications

Drugs	FDA-Approved Indications
	Substrate Reduction Therapy
eliglustat (Cerdelga)	Treatment of adult patients with type 1 Gaucher disease who are CYP2D6 extensive metabolizers, intermediate metabolizers, or poor metabolizers as detected by an FDA-approved test
miglustat (Zavesca)	Treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g., due to constraints such as allergy, hypersensitivity, or poor venous access)

Enzyme Replacement, Gaucher Disease - Dosing and Availability

Drugs	Dosing	Availability
	Enzyme Replacement Therapy (ERT)	
imiglucerase (Cerezyme)	Intravenous (IV) infusion; individualized dosing; 2.5 units/kg of body weight 3 times/week up to 60 units/kg every 2 weeks; Initial dosages range from 2.5 units/kg of body weight 3 times a week to 60 units/kg once every 2 weeks Most data available with 60 units/kg every 2 weeks	Lyophilized powder for injection (single-use): 200 units/vial 400 units/vial
taliglucerase alfa (Elelyso)	Treatment-naïve adult and pediatric patients 4 years of age and older: 60 units/kg every other week as a 60-120 minute IV infusion. For patients switching from imiglucerase, start taliglucerase at the same unit/kg dose as the patient's previous imiglucerase dose. Dosage adjustments can be made based on patient achieving as well as maintaining individual therapeutic goals.	Lyophilized powder for injection (single-use): 200 units/vial Mix gently. Do not shake
velaglucerase alfa (Vpriv)	IV infusion: individualized dosing; 60 units/kg administered every 2 weeks; trials have evaluated doses from 15 units/kg to 60 units/kg every other week Patients being treated with stable imiglucerase dosages for Gaucher disease can switch to velaglucerase at previous imiglucerase dose 2 weeks after last imiglucerase dose	Lyophilized powder for injection (single-use): 400 units/vial

Enzyme Replacement, Gaucher Disease - Dosing and Availability

Drugs	Dosing	Availability
	Substrate Reduction Therapy	
eliglustat (Cerdelga)	Oral capsule: Extensive or intermediate CYP2D6 metabolizers: 84 mg twice daily; Poor CYP2D6 metabolizers: 84 mg once daily	84 mg capsule
miglustat (Zavesca)	Oral capsule: 100 mg three times daily. Reduce frequency to once or twice daily if adverse effects (diarrhea or tremor) become problematic	100 mg capsule

Enzyme Replacement, Gaucher Disease – Guideline

- International Collaborative Gaucher Group (ICGG), 2004
  - Recommend Enzyme Replacement Therapy (ERT) for symptomatic pediatric patients as well as for patients with severe disease
    - Velaglucerase (Vpriv) appears to have comparable efficacy to imiglucerase (Cerezyme)
    - Taliglucerase (Elelyso) is only indicated in adults
    - Eliglustat (Cerdelga) is also FDA approved for first-line use
  - Depending on CYP2D6 metabolizer status, eliglustat offers an oral option in type 1 GD compared to the current standard therapy of intravenous ERT
  - If ERT or oral eliglustat is not possible, miglustat (Zavesca), another oral option, can be used as an alternative for the management of adults with mild to moderate type 1 Gaucher Disease

Agents for Gaucher's Disease

- **Recommendation:**
  - All agents for Gaucher's disease are considered safe and efficacious and are eligible for preferred status 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.
  - Preferred products must include at least one intravenous and one oral route of administration

Agents for Gaucher's Disease

- Motion: "I move that the Apple Health Medicaid Program implement the limitations for the agents for Gaucher's disease as recommended on slide 53."

Motion: Chew

2nd: Sanderson

Hereditary Angioedema

Magellan Medicaid Administration

Overview of Disease State

- Hereditary angioedema (HAE) is a rare dominant, autosomal genetic disorder that affects between 6,000 and 30,000 individuals in the United States
- Characterized by recurrent episodes of nonpruritic, nonpitting, subcutaneous or submucosal edema involving the skin or mucosal tissues of the upper respiratory and gastrointestinal (GI) tracts
- Although swelling can resolve spontaneously in several days, without treatment, laryngeal edema may be fatal and the pain of GI attacks can be incapacitating
- Symptoms can begin as early as 2 years of age and persist throughout life with unpredictable severity and frequency of attacks
  - It is thought that minor trauma and stress can lead to an attack; however, many attacks can occur without any apparent trigger
- HAE prophylaxis is needed to reduce potential edema caused by a stressor or procedure likely to precipitate an attack (short-term prophylaxis) or decrease the number of severity of angioedema attacks (long-term prophylaxis)

Hereditary Angioedema - Indications

Drugs	FDA-Approved Indications
Ecallantide (Kalbitor)	Treatment of acute HAE attacks in ages ≥ 12 years
icatibant (Firazyr)	Treatment of acute HAE attacks in ages ≥ 18 years
C1-esterase inhibitor [human] (Berinert)	Treatment of acute HAE facial, laryngeal, or abdominal attacks in adult and pediatric patients Safety and efficacy for prophylactic therapy have not been established
pdC1-INH [human] (Cinryze)	Routine prophylaxis against angioedema attacks in adolescents and adult with HAE
rhC1-INH [recombinant] (Ruconest)	Treatment of acute attacks in adult and adolescent patients with HAE Limitation of use: effectiveness has not been established in HAE patients with laryngeal attacks

Hereditary Angioedema - Dosing and Availability

Drugs	Dosing	Availability
ecallantide (Kalbitor)	30 mg SC administered as 10 mg/mL at 3 anatomical sites: abdomen, thigh, upper arm (site rotation not necessary) May repeat dose within a 24 hour period if attack persists HCP-administered	10 mg/mL solution single-use vial (3 per carton)
icatibant (Firazyr)	30 mg SC abdominally over at least 30 seconds; Additional doses may be administered at interval of at least 6 hours if inadequate response or symptoms recur; No > 3 injections should be administered in 24 hours May be self-administered with proper training	30 mg/3 mL prefilled syringe
pdC1-INH (Berinert)	20 IU/kg IV at a rate of 4 mL/min Lower doses than 20 IU/kg should not be given May be self-administered with proper training A silicone-free syringe should be used for reconstitution and administration of Berinert	Lyophilized powder for reconstitution; 500 IU/10 mL single-use vial
pdC1-INH (Cinryze)	1,000 units IV every 3 to 4 days at a rate of 1 mL/min (10 minutes) If no response to the above routine prophylaxis dosing: doses up to 2,500 units [U] (not exceeding 100 U/kg) every 3 to 4 days may be considered based on individual response May be self-administered with proper training	Lyophilized powder for reconstitution; 500 units/5 mL single-use vial
rhC1-INH (Ruconest)	50 IU/kg IV over 5 minutes; May repeat dose if attack symptoms persist; Do not exceed 4,200 IU per dose; Do not exceed 2 doses in a 24 hour period Body weight < 84 kg: 50 IU/kg Body weight ≥ 84 kg: 4,200 IU (2 vials) May be self-administered with proper training	Lyophilized powder for reconstitution; 2,100 IU/25 mL single-use vial

Hereditary Angioedema - Guideline

- Hereditary Angioedema International Working Group (HAWK) and World Allergy Organization, 2012
  - No 1 agent is recommended over another
  - Consider C1-INH (Berinert, Cinryze, Ruconest), ecallantide (Kalbitor), or icatibant (Firazyr) all first-line agents in HAE treatment
  - Antihistamines, corticosteroids, or epinephrine have little or no clinical benefit for treatment of HAE

- U.S. Hereditary Angioedema Association (HAEA), 2016
  - Recommends short-term prophylaxis prior to medical, dental, or surgical procedures
  - Need for long-term prophylaxis should be made on attack frequency, attack frequency, comorbid conditions, access to treatment, and patient experience and preference
  - Treatment strategies should be individualized based primarily on patient specific factors
  - Berinert is currently the only agent FDA-approved to treat all pediatric ages and is preferred treatment of choice for short-term prophylaxis prior to medical, surgical and dental procedures

Hereditary Angioedema (HAE) Agents

- **Recommendation:**
  - All HAE agents are considered safe and efficacious and are eligible for preferred status 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.
  - Preferred products must include at least one intravenous and one subcutaneous route of administration

Hereditary Angioedema (HAE) Agents

- Motion: "I move that the Apple Health Medicaid Program implement the limitations for the HAE agents as recommended on slide 60."

Motion: Figueroa

2nd: Sanderson

Movement Disorders

Magellan Medicaid Administration

Overview of Disease State

- Huntington's Disease (HD)
  - Rare and fatal genetic disorder resulting in neurodegeneration of the brain, which affects over 35,000 people in the United States
  - As chorea, an abnormal involuntary twisting or writhing movement, becomes more severe, it can interfere with patients' function. As the disease progresses, chorea is replaced by dystonia and parkinsonism
  - Chorea affects approximately 90% of people with HD. It often develops early, gradually worsens, and plateaus in late stages

- Tardive Dyskinesia (TD)
  - Involuntary movements of the tongue, lips, face, trunk, and extremities that occur in patients treated with medications with dopamine antagonist properties
  - The epidemiology of TD is not well defined as prevalence evaluations are often done in differing settings
  - TD can occur in all ages, but the risk increases with age
  - It may consist of movements classified as bradykinesia and/or hyperkinesia
  - Dopamine transporter dysfunction and chronic central dopamine blockade have been hypothesized to play a role in the development of TD, although multiple other pathophysiologic mechanisms have been proposed

Movement Disorders - Indications

Drugs	FDA-Approved Indications
deutetrabenazine (Austedo)	Treatment of chorea associated with Huntington's disease Treatment of tardive dyskinesia
tetrabenazine (Xenazine)	Treatment of chorea associated with Huntington's disease
valbenazine (Ingrezza)	Treatment of tardive dyskinesia

Movement Disorders - Dosing and Availability

<table>
<tr><th>Drugs</th><th>Dosing</th><th>Availability</th></tr>
<tr><td>deutetrabenazine (Austedo)</td><td>Tardive dyskinesia: 6 mg twice daily, titrated at weekly intervals by 6 mg per day to a tolerated dose that reduces dyskinesia (maximum dose, 48 mg/day)

Administer total daily dosages of ≥ 12 mg in 2 divided doses; take with food; swallow whole

Assess the QT interval before and after increasing total dosage above 24 mg/day

Dosage of deutetrabenazine should be adjusted to no more than 18 mg as a maximum single dose and a maximum total daily dose of 36 mg in patients taking concomitant strong CYP2D6 inhibitors or CYP2D6 poor metabolizers
Deutetrabenazine may be discontinued without tapering; if treatment is interrupted for > 1 week, treatment should be re-titrated when resumed; interruptions of < 1 week do not require retitration

Huntington’s chorea: 6 mg once daily (in those not being switched from tetrabenazine), titrated at weekly intervals by 6 mg per day to a tolerated dose that reduces chorea (maximum dose, 48 mg/day)

When switching from tetrabenazine, initiate deutetrabenazine 1 day after the last dose of tetrabenazine and use the following dosage conversion table</td><td>Tablets:
6 mg, 9 mg, 12 mg

<table><tr><th>Current tetrabenazine daily dosage</th><th>Initial deutetrabenazine dose</th></tr><tr><td>12.5 mg</td><td>6 mg once daily</td></tr><tr><td>25 mg</td><td>6 mg twice daily</td></tr><tr><td>37.5 mg</td><td>9 mg twice daily</td></tr><tr><td>50 mg</td><td>12 mg twice daily</td></tr><tr><td>62.5 mg</td><td>15 mg twice daily</td></tr><tr><td>75 mg</td><td>18 mg twice daily</td></tr><tr><td>87.5 mg</td><td>21 mg twice daily</td></tr><tr><td>100 mg</td><td>24 mg twice daily</td></tr></table></td></tr>
</table>

Movement Disorders - Dosing and Availability

Drugs	Dosing	Availability
tetrabenazine (Xenazine)	**Huntington's chorea:** dosing should be individualized and titrated slowly over several weeks **Dosing ≤ 50 mg/day**: 12.5 mg once daily in the morning; after 1 week, increase to 25 mg/day, given as 12.5 mg twice daily Titrate up at weekly intervals by 12.5 mg/day to identify a tolerate dose that reduces chorea Doses of 37.5 to 50 mg should be divided into 3 doses; the maximum single dose is 25 mg **Dosing > 50 mg/day**: patients requiring dosing above 50 mg/day should be first evaluated for CYP2D6 metabolizer status Those qualifying for doses above 50 mg/day (intermediate to extensive CYP2D6 metabolizers) should be titrated slowly by 12.5 mg/day at weekly intervals Doses exceeding 50 mg/day should be given in 3 divided doses; the maximum daily dose is 100 mg and the maximum single dose is 37.5 mg Dosage of tetrabenazine should be adjusted to no more than 25 mg as a maximum single dose and a maximum total daily dose of 50 mg in patients taking concomitant strong CYP2D6 inhibitors or CYP2D6 poor metabolizers Tetrabenazine may be discontinued without tapering; re-emergence of chorea may occur within 12 to 18 hours following the last tetrabenazine dose; if treatment is interrupted for > 5 days, treatment should be re-titrated when resumed; interruptions of < 5 days does not require retitration	Tablets (scored): 12.5 mg, 25 mg
valbenazine (Ingrezza)	**Tardive dyskinesia:** 40 mg once daily with or without food; dose can be increased to 80 mg once daily after 1 week of treatment Moderate to severe hepatic impairment (Child-Pugh, 7 to 15) or co-administered with a strong CYP3A4 inhibitor: 40 mg once daily CYP2D6 poor metabolizer or co-administered with a strong CYP2D6 inhibitor: Reduce valbenazine dose based on tolerability	Capsules: 40 mg, 80 mg

Movement Disorders – Guideline

- American Academy of Neurology (AAN), 2012
  - Huntington's Disease (HD)
    - Recommend tetrabenazine (up to 100 mg daily) for chorea associated with HD
    - Austedo and Ingrezza approved in 2017
  - Tardive Dyskinesia
    - If possible, a potential offending agent should be switched to an alternative with a lower TD risk, the dose should be reduced, and the duration of use should be limited to prevent TD onset
    - Deutetrabenazine and valbenazine have not been addressed in clinical practice guidelines

Movement Disorder Agents

- **Recommendation:**
  - All movement disorder agents are considered safe and efficacious and are eligible for preferred status 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 when there is only one preferred product.

Movement Disorder Agents

- Motion: "I move that the Apple Health Medicaid Program implement the limitations for the movement disorder agents as recommended on slide 68."

Motion: Buccola

2nd: Sanderson