Magellan Rx MANAGEMENT℠

Magellan Medicaid Administration

Washington Pharmacy Advisory Committee Meeting

February 21, 2018

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Agenda Topics

Anticonvulsants

Magellan Medicaid Administration

Anticonvulsants – Indications

Drug Class	Drugs	FDA-Approved Indications (*Pediatric, †Adjunct Only)							
		Absence Seizures	Myoclonic Seizures	Partial Seizures	Tonic-Clonic Seizures	Neuropathic Pain	Lennox-Gastaut Syndrome	Migraine Prophylaxis	Bipolar Disorder
Barbiturates	primidone (Mysoline)			X*	X*				
	phenobarbital		X	X*	X*				
Hydantoins	ethotoin (Peganone)			X*	X*				
	phenytoin ER (Dilantin, Phenytek)			X*	X*				
Succinimides	ethosuximide (Zarontin)	X*							
	methsuximide (Celontin)	X*							
Benzodiazepines	clobazam (Onfi)						X*†		
	clonazepam (Klonopin)	X*	X*				X*		
	diazepam rectal gel (Diastat)			X*†	X*†				
Valproic Acid Derivatives	valproic acid (Depakene)	X*	X*	X*	X*				
	divalproex delayed-release (Depakote)	X*	X	X	X			X	X
	divalproex sodium extended-release (Depakote ER)	X*		X*					

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		Absence Seizures	Myoclonic Seizures	Partial Seizures	Tonic-Clonic Seizures	Neuropathic Pain	Lennox-Gastaut Syndrome	Migraine Prophylaxis	Bipolar Disorder
Carbamazepine Derivatives	carbamazepine (Tegretol)			X*	X*	X			
	carbamazepine extended-release (Tegretol XR)			X*	X*	X			
	carbamazepine extended-release (Carbatrol)			X*	X*	X			
	carbamazepine extended-release (Equetro)			X*	X*	X			X
	eslicarbazepine (Aptiom)			X*					
	oxcarbazepine (Trileptal)			X*					
	oxcarbazepine extended-release (Oxtellar XR)			X†					
Other	brivaracetam (Briviact)			X†					
	felbamate (Felbatol)			X* (2^{nd} line)					
	gabapentin (Neurontin)			X*†		X			
	lacosamide (Vimpat)			X*					

Anticonvulsants – Indications

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		Absence Seizures	Myoclonic Seizures	Partial Seizures	Tonic-Clonic Seizures	Neuropathic Pain	Lennox-Gastaut Syndrome	Migraine Prophylaxis	Bipolar Disorder
Other	lamotrigine (Lamictal)			X	X*†		X*†		X
	lamotrigine XR (Lamictal XR)			X*†	X*				
	levetiracetam (Keppra, Spritam)		X*†	X*†	X*†				
	levetiracetam XR (Keppra XR)			X*†					
	perampanel (Fycompa)			X*	X*†				
	pregabalin (Lyrica)			X†		X			
	rufinamide (Banzel)						X*†		
	tiagabine (Gabitril)			X*†					
	topiramate (Topamax)			X*	X*		X*†	X*	
	topiramate XR (Qudexy XR)			X*†	X*†		X†	X*	
	topiramate XR (Trokendi XR)			X*	X*		X*†	X*	
	vigabatrin (Sabril)			X*†					
	zonisamide (Zonegran)			X*†					

Anticonvulsants – Dosing and Availability

Drugs	Generic	DEA Schedule	Dose Range in Adults	Availability
primidone (Mysoline)	X	C-IV	100-2,000 mg per day (3 divided doses)	Tablets: 50, 250 mg
phenobarbital	X	C-IV	180-300 mg per day (1-2 divided doses)	Elixir: 20 mg/5 mL Tablets:15, 16.2, 30, 32.4, 60, 64.8, 97.2, 100 mg
ethotoin (Peganone)			1,000-3,000 mg per day (4-6 divided doses)	Tablets: 250 mg
phenytoin ER (Dilantin, Phenytek)	X		300-600 mg per day	Capsule: 30, 100, 200, 300 mg Chew tab: 50 mg; Oral suspension: 125 mg/5 mL
ethosuximide (Zarontin)	X		250-1,500 mg per day (2 divided doses)	Capsule: 250 mg; Oral solution: 250 mg/5 mL
methsuximide (Celontin)			300-1,200 mg per day (2-4 divided doses)	Capsule: 300 mg
clobazam (Onfi)		C-IV	5-40 mg per day	Tablets: 10, 20 mg; Oral suspension: 2.5 mg/mL
clonazepam (Klonopin)	X	C-IV	1.5-20 mg per day (3 divided doses)	Tablets: 0.5, 1, 2 mg ODT: 0.125, 0.25, 0.5, 1, 2 mg
diazepam rectal gel (Diastat)	X	C-IV	Rescue therapy up to 5 times per month	Rectal gel system: 2.5, 10, 20 mg
valproic acid (Depakene)	X		Up to 60 mg/kg/day in divided doses	Capsules: 250 mg; Syrup: 250 mg/5mL
divalproex delayed-release (Depakote)	X		Up to 60 mg/kg/day in divided doses	Tablets: 125, 250, 500 mg Sprinkle capsules: 125 mg
divalproex sodium extended-release (Depakote ER)	X		Up to 60 mg/kg/day dosed once daily	Tablets: 250, 500 mg

Anticonvulsants – Dosing and Availability

Drugs	Generic	DEA Schedule	Dose Range in Adults	Availability
carbamazepine (Tegretol)	X		400-1,600 mg per day (3-4 divided doses)	Tablets: 200 mg; Chew tabs: 100 mg Oral suspension: 100 mg/5 mL
carbamazepine extended-release (Tegretol XR)	X		400-1,600 mg per day (2 divided doses)	Tablets: 100, 200, 400 mg
carbamazepine extended-release (Carbatrol)	X		400-1,600 mg per day (2 divided doses)	Capsules: 100, 200, 300 mg
carbamazepine extended-release (Equetro)			400-1,600 mg per day (2 divided doses)	Capsules: 100, 200, 300 mg
eslicarbazepine (Aptiom)			400-1,200 mg once daily	Tablets: 200, 400, 600, 800 mg
oxcarbazepine (Trileptal)	X		600-2,400 mg per day (2 divided doses)	Tablets: 150, 300, 600 mg Oral suspension: 300 mg/5 mL
oxcarbazepine extended-release (Oxtellar XR)			600-2,400 mg once daily	Tablets: 150, 300, 600 mg
brivaracetam (Briviact)		C-V	25-100 mg twice daily	Tablets: 10, 25, 50, 75, 100 mg Oral solution: 10 mg/mL
felbamate (Felbatol)	X		1,200-3,600 mg per day (3-4 divided doses)	Tablets: 400, 600 mg; Oral suspension: 600 mg/5 mL
gabapentin (Neurontin)	X		900-3,600 mg per day (3 divided doses)	Capsules: 100, 300, 400 mg; Tablets: 600, 800 mg Oral solution: 250 mg/5 mL
lacosamide (Vimpat)		C-V	100-400 mg per day (2 divided doses)	Tablets: 50, 100, 150, 200 mg Oral solution: 10 mg/mL

Anticonvulsants – Dosing and Availability

Drugs	Generic	DEA Schedule	Dose Range in Adults	Availability
lamotrigine (Lamictal)	X		25-500 mg per day	Tablets: 25, 100, 150, 200; Chew tabs: 5, 25 mg ODT: 25, 50, 100, 200 mg
lamotrigine XR (Lamictal XR)	X		25-500 mg per day	Tablets: 25, 50, 100, 200, 250, 300 mg
levetiracetam (Keppra)	X		500-1,500 mg twice daily	Tablets: 250, 500, 750, 1000 mg Oral solution: 100 mg/mL
levetiracetam (Spritam)			500-1,500 mg twice daily	ODT: 250, 500, 750, 1000 mg
levetiracetam XR (Keppra XR)	X		1,000-3,000 mg once daily	Tablets: 500, 750 mg
perampanel (Fycompa)		C-III	2-12 mg once daily at bedtime	Tablets: 2, 4, 6, 8, 10, 12 mg Oral suspension: 0.5 mg/mL
pregabalin (Lyrica)		C-V	150-600 mg per day (2-3 divided doses)	Capsules: 25, 50, 75, 100, 150, 200, 225, 300 mg Oral solution: 20 mg/mL
rufinamide (Banzel)			400-3,200 mg per day (2 divided doses)	Tablets: 200, 400 mg; Oral suspension: 40 mg/mL
tiagabine (Gabitril)	2, 4 mg		4-56 mg per day (2-4 divided doses)	Tablets: 2, 4, 12, 16 mg
topiramate (Topamax)	X		50-400 mg per day (2 divided doses)	Capsules: 15, 25 mg Tablets: 25, 50, 100, 200 mg
topiramate XR (Qudexy XR)			50-400 mg once daily	Capsules: 25, 50, 100, 150, 200 mg
topiramate XR (Trokendi XR)			50-400 mg once daily	Capsules: 25, 50, 100, 200 mg

Anticonvulsants – Dosing and Availability

Drugs	Generic	DEA Schedule	Dose Range in Adults	Availability
vigabatrin (Sabril)	Powder only		500-1,500 mg twice daily	Tablets: 500 mg Powder for oral solution: 500 mg
zonisamide (Zonegran)	X		100-600 mg per day (1-2 doses)	Capsules: 25, 50, 100 mg

Anticonvulsants – Guidelines

- Epilepsy, 2004 American Epilepsy Society (AES) and American Academy of Neurology (AAN)
  - Guidelines do not differentiate superiority of 1 agent over another
  - Seek to help healthcare professionals understand published research on anticonvulsants
  - Suggest that gabapentin (Neurontin), lamotrigine (Lamictal), topiramate (Topamax), and oxcarbazepine (Trileptal) have enough supporting evidence to be used as monotherapy in adolescents and adult patients newly diagnosed with partial or mixed seizures
- Epilepsy, 2017 International League Against Epilepsy (ILAE)
  - Revised seizure classifications
- Sudden Unexpected Death in Epilepsy, 2017 American Academy of Neurology (AAN) and American Epilepsy Society (AES)
  - New Guideline

Anxiolytics

Magellan Medicaid Administration

Anxiolytics - Indications

Class/Mechanism	Drug	FDA-Approved Indications (for Oral Dosage Forms)	DEA Schedule
Benzodiazepine	alprazolam (Xanax)	• Anxiety disorders • Panic disorder	C-IV
Serotonin 1A partial agonist	buspirone (Buspar)	• Anxiety disorders	
Benzodiazepines	chlordiazepoxide	• Alcohol withdrawal • Anxiety disorders • Preoperative anxiety	C-IV
	clorazepate (Tranxene-T)	• Alcohol withdrawal • Anxiety disorders • Partial seizures	C-IV
	diazepam (Valium)	• Alcohol withdrawal • Anxiety disorders • Muscle relaxant • Preoperative sedation • Seizures	C-IV
	lorazepam (Ativan)	• Anxiety disorders • Insomnia	C-IV
Unknown	meprobamate	• Anxiety disorders	C-IV
Benzodiazepine	oxazepam	• Alcohol withdrawal • Anxiety disorders	C-IV

Anxiolytics – Dosing and Availability

Drugs	Generic	Dose Range in Adults	Availability
alprazolam (Xanax)	X	ER tablet: 0.5-6 mg once daily Solution, tablet/ODT: 0.25-2 mg 3 times daily	ER tablets: 0.5, 1 , 2, 3 mg Oral Intensol Solution: 1 mg/mL Tablets & ODT: 0.25, 0.5, 1, 2 mg
buspirone (Buspar)	X	15-60 mg per day (2-3 divided doses)	Tablets: 5, 7.5, 10, 15, 30 mg
chlordiazepoxide	X	Alcohol withdrawal: up to 300 mg/day initially Anxiety: 5-25 mg up to 4 times daily	Capsule: 5, 10, 25 mg
clorazepate (Tranxene-T)	X	Alcohol withdrawal: up to 90 mg/day initially Anxiety: 15-60 mg per day (2-3 divided doses)	Tablets: 3.75, 7.5, 15 mg
diazepam (Valium)	X	2-10 mg up to 4 times daily	Oral Solution: 5 mg/5 mL, Oral Intensol Solution: 5 mg/mL Tablets: 2, 5, 10 mg
lorazepam (Ativan)	X	Anxiety: 1-3 mg per day (2-3 divided doses) Insomnia: 1-4 mg at bedtime	Tablets: 0.5, 1, 2 mg Oral “Intensol” Solution: 2 mg/mL
meprobamate	X	1,200-1,600 mg per day (3-4 divided doses)	Tablets: 200, 400 mg
oxazepam	X	Alcohol withdrawal: 15-30 mg up to 4 times daily Anxiety: 10-30 mg up to 4 times daily	Capsules: 10, 15, 30 mg

Anxiolytics – Guideline

- Generalized Anxiety Disorder and Panic Disorder in Adults, 2015 American Academy of Family Physicians (AAFP)
- Major Depressive Disorder, 2010 American Psychiatric Association (APA)
- Panic Disorder, 2009 APA

- Guidelines suggest that benzodiazepines should be reserved as add-on treatment for cases where the benefits of rapid-onset and/or short term relief outweigh risks (e.g., sedation, dependency)
  - Useful adjunct for depression where significant anxiety and/or insomnia is present
  - May speed recovery of anxiety-related symptoms when combined with antidepressants
- Longer-acting benzodiazepines (e.g., clonazepam, diazepam) may offer less risk of abuse than short-acting (e.g., alprazolam, lorazepam)
- Buspirone considered first-line for anxiety and is not associated with dependency
- Antidepressants (including SSRIs, SNRIs, bupropion and mirtazapine) also considered first line for anxiety but the onset of effect is long (4-8 weeks for maximum benefit)

Drug Classes

- Anticonvulsants
- Anxiolytics

Recommendation

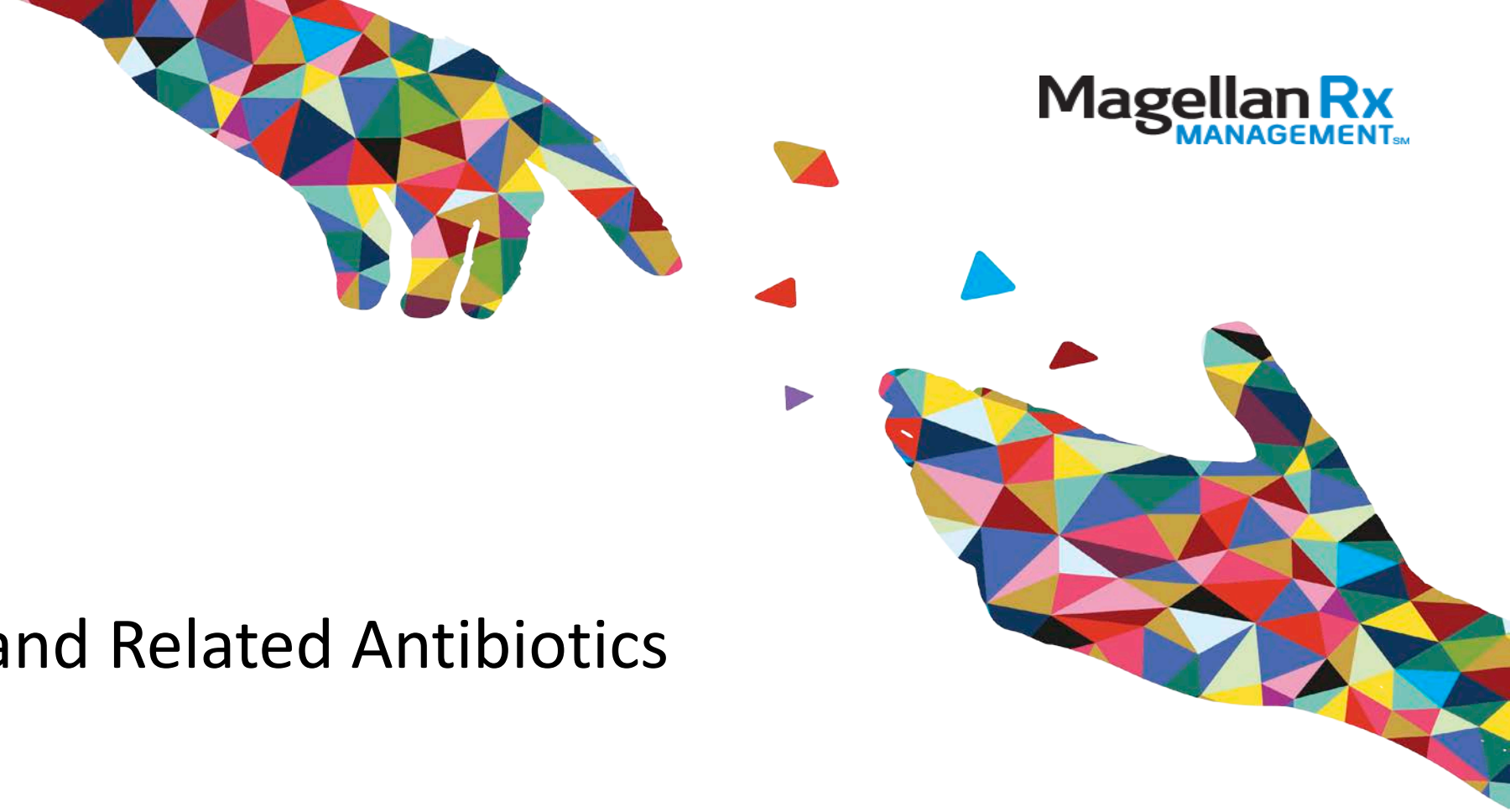
- All of the products within each drug class or sub-class are considered safe and efficacious within that class or sub-class and are eligible for preferred status at the discretion of HCA.
- All non-preferred products require a trial of two preferred products within that class or sub-class with the same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

Motion

- I move that the Apple Health Medicaid Program implement the limitations listed on slide 17 for each drug class listed on slide 16 amended to grandfather patients already on medications with the exception of the benzodiazepines subclass.

- Motion: Storhaug

2nd: Flatebo



Cephalosporins and Related Antibiotics

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Cephalosporins and Related Antibiotics – Indications

Class	Drug	CAP	AECB	AOM	Pharyngitis /Tonsilitis	Gonorrhea	Skin	UTI	Sinusitis	Lyme disease	Impetigo
First Generation Cephalosporins	cefadroxil				X		X	X			X
	cephalexin (Keflex, Daxbia)	X		X	X		X	X	X		X
Second Generation Cephalosporins	cefaclor	X	X	X	X		X	X			
	cefprozil		X	X	X		X		X		
	cefuroxime axetil suspension		X	X	X	X	X	X		X	X
	cefuroxime axetil tablets		X	X	X	X	X	X	X	X	
Third Generation Cephalosporins	cefdinir	X	X	X	X		X		X		
	cefditoren pivoxil (Spectracef)	X	X		X		X				
	cefixime (Suprax)		X	X	X	X		X			
	cefpodoxime proxetil	X	X	X	X	X	X	X	X		
	ceftibuten (Cedax)		X	X	X						
Penicillin/Beta-Lactamase Inhibitor Combinations	amoxicillin/clavulanate (Augmentin)			X			X	X	X		
	amoxicillin/clavulanate ER (Augmentin XR)	X							X		

(AECB = Acute Exacerbation of Chronic Bronchitis; AOM = Acute Otitis Media;
CAP= Community Acquired Pneumonia; UTI = Urinary Tract Infection)

Cephalosporins and Related Antibiotics – Dosing and Availability

Drugs	Generic	Dose Range in Adults	Availability
cefadroxil	X	1,000 mg per day (1 or 2 doses)	Capsules: 500 mg Tablets: 1 g Suspension: 250, 500 mg/5 mL
cephalexin (Keflex)	X	250-500 mg up to 4 times daily	Capsules: 250, 500, 750 mg Tablets: 250, 500 mg Suspension: 125, 250 mg/5 mL
cephalexin (Daxbia)		1-4 g per day (2-4 divided doses)	Capsules: 333 mg
cefaclor	X	Capsule/suspension: 250-500 mg 3 times daily ER tablet: 500 mg twice daily	Capsules: 250, 500 mg Suspension: 125, 250, 375 mg/5 mL ER tablets: 500 mg
cefprozil	X	250-500 mg twice daily	Tablets: 250, 500 mg Suspension: 125, 250 mg/5 mL
cefuroxime axetil (Ceftin) suspension		250-500 mg twice daily	Suspension: 125, 250 mg/5 mL
cefuroxime axetil (Ceftin) tablets	X	250-500 mg twice daily	Tablets: 250, 500 mg
cefdinir	X	600 mg per day (1 or 2 doses)	Capsules: 300 mg Suspension: 125, 250 mg/5 mL
cefditoren pivoxil (Spectracef)	X	200-400 mg twice daily	Tablets: 200 mg, 400 mg

Cephalosporins and Related Antibiotics – Dosing and Availability

Drugs	Generic	Dose Range in Adults	Availability
cefixime (Suprax)	Suspension only	400 mg per day (1-2 doses)	Tablets: 200 mg, 400 mg
cefpodoxime proxetil	X	100-400 mg twice daily	Tablets: 100 mg, 200 mg Suspension: 50, 100 mg/5 mL
ceftibuten (Cedax)	X	400 mg daily	Capsules: 400 mg Suspension: 180 mg/5 mL
amoxicillin/clavulanate (Augmentin)	X	250-500 mg 3 times daily OR 875 mg twice daily	Tablets: 250/125 mg, 500/125 mg, 875/125 mg Chewable tablets: 200/28.5 mg, 400/57 mg Suspension: 125/31.25 mg/5 mL, 200/28.5 mg/5 mL, 250/62.5 mg/5 mL, 400/57 mg/5 mL, 600/42.9 mg/5 mL
amoxicillin/clavulanate ER (Augmentin XR)	X	2 tablets twice daily	Tablets: 1,000/62.5 mg

Cephalosporins and Related Antibiotics – Guideline

- **Respiratory Infections**
  - CAP, 2007 American Thoracic Society (ATS) and Infectious Diseases Society of America (IDSA)
    - Amoxicillin/clavulanate; indicated, with a macrolide, in patients with comorbidities
    - Cefpodoxime and cefuroxime listed as alternative beta-lactam selections to amoxicillin or amox/clav
  - Childhood CAP, 2014 World Health Organization (WHO)
    - Amoxicillin/clavulanate is listed as 2nd line (alone or with a macrolide)
  - Acute Bacterial Rhinosinusitis (ABRS), 2015 American Academy of Otolaryngology
    - Amoxicillin or amox/clav considered 1st line
  - Acute Pharyngitis, 2015 IDSA
    - First-generation cephalosporins listed as alternative to 1st line (penicillin)
- **Genitourinary Infections**
  - Acute Cystitis, 2011 IDSA
    - Recommend amox/clav, cefdinir, cefaclor, cefpodoxime when other agents cannot be used
- **Skin/Skin Structure Infections**
  - Impetigo, 2014 IDSA
    - Cephalexin 1st line in susceptible *S. aureus*

Fluoroquinolones, Oral

Magellan Medicaid Administration

Fluoroquinolones, Oral – Indications

Drug	Abdominal	AECB	Acute sinusitis	Bone and Joint	CAP	Nosocomial Pneumonia	Inhalational Anthrax	Infectious Diarrhea	Gonorrhea	LRTI	PID	Plague	Prostatitis	Skin	Typhoid fever	UTI
ciprofloxacin (Cipro)	X	X	X	X	-	-	X	X	X	X	-	-	X	X	X	X
ciprofloxacin ER (Cipro XR)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	X
delafloxacin (Baxdela)	-	-	-	-	-	-	-	-	-	-	-	-	-	X	-	-
levofloxacin (Levaquin)	-	X	X	-	X	X	X	-	-	-	-	X	X	X	-	X
moxifloxacin (Avelox)	X	X	X	-	X	-	-	-	-	-	-	-	-	X	-	-
ofloxacin	-	X	-	-	X	-	-	-	X	-	X	-	X	X	-	X

Abdominal = Intra-abdominal infections, AECB = Acute exacerbation of chronic bronchitis,
CAP = Community acquired pneumonia, LRTI = Lower respiratory tract infections,
PID = Pelvic inflammatory disease, UTI = Urinary tract infection

Fluoroquinolones, Oral – Dosing and Availability

Drugs	Generic	Dose Range in Adults	Availability
ciprofloxacin (Cipro)	X	250-750 mg twice daily	Tablets: 250, 500, 750 mg Oral Suspension: 250, 500 mg/5 mL
ciprofloxacin ER (Cipro XR)	X	500 or 1,000 mg daily	Tablets: 500, 1000 mg
delafloxacin (Baxdela)		450 mg twice daily	Tablets: 450 mg
levofloxacin (Levaquin)	X	250-750 mg daily	Tablets: 250, 500, 750 mg Oral Solution: 25 mg/mL
moxifloxacin (Avelox)	X	400 mg daily	Tablets: 400 mg
ofloxacin	X	200-400 mg twice daily	Tablets: 200, 300, 400 mg

Fluoroquinolones, Oral – Guideline

- CAP, 2007 American Thoracic Society (ATS) and Infectious Diseases Society of America (IDSA)
  - Levofloxacin, moxifloxacin considered 1st line in CAP with comorbidities
- Anthrax, 2014 CDC
  - Ciprofloxacin and levofloxacin are recommended for initial treatment
  - Ciprofloxacin 1st line for cutaneous anthrax
- Acute Bacterial Rhinosinusitis (ABRS), 2015 American Academy of Otolaryngology
  - Recommended for multidrug-resistant and beta-lactamase producing organisms
  - Recommended for patients, including children, with penicillin allergy
- Acute Cystitis, 2011 IDSA
  - Fluoroquinolones are efficacious but use has been linked to MRSA

Lincosamides, Oxazolidinones, and Streptogramins

Magellan Medicaid Administration

Lincosamides, Oxazolidinones, and Streptogramins– Indications

Drug	FDA-Approved Indications
clindamycin HCl (Cleocin) clindamycin palmitate HCl (Cleocin Pediatric)	• Treatment of serious infections caused by susceptible anaerobic bacteria • Treatment of serious infections due to susceptible strains of streptococci, pneumococci, and staphylococci; its use should be reserved for penicillin-allergic patients or other patients for whom a penicillin is inappropriate.
linezolid (Zyvox)	Treatment of the following infections caused by susceptible Gram-positive bacteria: • Community-acquired pneumonia (CAP) • Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis • Nosocomial pneumonia • Uncomplicated skin and skin structure infections • Vancomycin-resistant *Enterococcus faecium* infections
tedizolid (Sivextro)	• Treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria.

Lincosamides, Oxazolidinones, and Streptogramins – Dosing and Availability

Drugs	Generic	Dose Range in Adults	Availability
clindamycin (Cleocin)	X	150-450 mg 4 times daily	Capsules: 75, 150, 300 mg
clindamycin palmitate HCl (Cleocin Pediatric)	X	150-450 mg 4 times daily	Granules for Oral Suspension: 75 mg/5 mL
linezolid (Zyvox)	X	600 mg twice daily	Tablets: 600 mg Oral Suspension: 100 mg/5 mL
tedizolid (Sivextro)		450 mg twice daily	Tablets: 450 mg

Lincosamides, Oxazolidinones, and Streptogramins– Guidelines

- Skin and Soft Tissue Infections (SSTIs), 2014 IDSA
  - Clindamycin recommended for MRSA in impetigo as well as MSSA/MRSA SSTIs
  - Linezolid listed as alternative to vancomycin

- CAP, 2007 IDSA and American Thoracic Society (ATS)
  - Guideline update in progress
  - Linezolid or vancomycin for MRSA; limit use to patients with confirmed infection
  - Clindamycin and linezolid may inhibit bacterial toxin production

- HAP/VAP, 2016 IDSA and ATS
  - Linezolid or vancomycin are preferred for MRSA empiric coverage/treatment
  - Choice may be guided by patient specific factors and/or cost

- Diabetic Foot Infections, 2012 IDSA
  - Clindamycin usually active against MRSA but check sensitivity
  - Clindamycin may be used with levofloxacin or ciprofloxacin in moderate infections
  - Linezolid FDA-approved for MRSA diabetic foot infections; note risk of use beyond 2 weeks

Tetracyclines

Magellan Medicaid Administration

Tetracyclines – Indications

- Tetracycline antibiotics, with the exception of doxycycline hyclate 20 mg, doxycycline monohydrate delayed-release 40 mg (Oracea), and minocycline extended-release (Solodyn ER), are indicated for many infections, including:
  - Ophthalmic infections caused by *Chlamydia trachomatis*
  - Rickettsial infections (Rocky Mountain spotted fever, typhus fever, Q fever, rickettsialpox, and tick fevers)
  - Respiratory tract infections caused by *Mycoplasma pneumoniae* and, when susceptible, *H. influenza, Kebsiella* and *Streptococcus pneumoniae*
  - Sexually transmitted infections caused by *Chlamydia trachomatis*
  - Anthrax due to *Bacillus anthracis*
  - Other specific bacterial infections such as plague (*Yersinia pestis*) and cholera (*Vibrio cholerae)*
  - Can be used as an alternative to pencillin for some organisms
  - Adjunctive therapy for severe acne and acute intestinal amebiasis

- Demeclocycline primarily used for Syndrome of Inappropriate Antidiuretic Hormone (SIADH)

Tetracyclines – Indications (continued)

Drug	Additional FDA-Approved Indications
demeclocycline	• Skin and skin structure infections caused by S. aureus (Note: not the drug of choice) • Off label: Syndrome of Inappropriate Antidiuretic Hormone (SIADH)
doxycycline (Vibramycin)	Prophylaxis of malaria due to Plasmodium falciparum in short-term travelers (< 4 months) to areas with chloroquine and/or pyrimethamine-sulfadoxine resistant strains
doxycycline hyclate	20 mg tablets: Adjunct to scaling and root planing to promote attachment level gain and to reduce pocket depth in patients with adult periodontitis
doxycicline hyclate delayed-release (DR) tablets (Doryx, Doryx MPC, Morgidox, Targadox)	Prophylaxis of malaria due to *Plasmodium falciparum* in short-term travelers (< 4 months) to areas with chloroquine and/or pyrimethamine-sulfadoxine resistant strains
doxycycline monohydrate capsules (Adoxa, Monodox)	Adoxa: Skin and skin structure infections caused by S. aureus (Note: not the drug of choice)
doxycycline monohydrate delayed release (DR) (Oracea)	Treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients
minocycline (Minocin)	• Treatment of meningococcal infection • Treatment of symptomatic carriers of *Neisseria meningitidis* to eliminate the meningococci from the nasopharynx • Skin and skin structure infections caused by S. aureus (Note: not the drug of choice)
minocycline extended-release (ER) (Solodyn)	Treatment of only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients > 12 years of age
tetracycline	• Respiratory tract infections due to *Streptococcus pyogenes* • Lower respiratory tract infections due to *Streptococcus pyogenes* or *S. pneumoniae* • Skin and skin structure infections caused by *S. pyogenes* or *S. aureus* (Note: not the drug of choice) • Infections caused by *N. gonorrhoeae*

Tetracyclines – Dosing and Availability

Drugs	Generic	Dose Range in Adults	Availability
demeclocycline	X	600 mg per day (2 or 4 doses)	Tablets: 150, 300 mg
doxycycline calcium (Vibramycin)		Most infections: 100 mg twice daily Dental: 20 mg twice daily	Syrup: 50 mg/5 mL
doxycycline hyclate	X		Capsules: 20, 50, 100 mg Tablets: 20, 50, 75, 100, 150 mg
doxycycline hyclate delayed-release (DR) tablets (Doryx, Doryx MPC, Morgidox, Targadox)	X		DR Capsules: 50, 75, 100, 200 mg DR Tablets: 50, 75, 100, 150, 200 mg
doxycycline monohydrate capsules (Adoxa, Monodox)	X		Capsules: 50, 75, 100, 150 mg Tablets: 50, 75, 100, 150 mg Oral Suspension: 25 mg/5 mL
doxycycline monohydrate delayed release (DR) (Oracea)	X	1 capsule daily	Capsules: 40 mg
minocycline (Minocin)	X	200 mg per day (2 or 4 doses)	Capsules: 50, 75, 100 mg Tablets: 50, 75, 100 mg
minocycline extended-release (ER) (Solodyn)	X	1 mg/kg daily	Solodyn ER Tablets: 55, 65, 80, 105, 115 mg Generic ER Tablets: 45, 90, 135 mg
tetracycline	X	1,000-2,000 mg per day (2 or 4 doses)	Capsules: 250, 500 mg

Tetracyclines – Guidelines

- Sexually Transmitted Diseases (STD), 2015 CDC
  - Doxycycline preferred drug for lymphogranuloma venereum, cervicitis, and infections due to Chlamydia; part of the treatment regimen for acute epididymitis and proctitis and STD rectal infections when gonococcal and/or *Chlamydia* infections are presumed
  - Doxycycline preferred over tetracycline (GI intolerance)
- Pneumonia, 2007 American Thoracic Society (ATS) & Infectious Disease Society of America (IDSA)
  - Doxycycline can be used as an alternative to macrolides (1st line alternative)
- Anthrax, 2014 CDC
  - Doxycycline considered 1st line for inhalation anthrax treatment and prophylaxis in adults
  - Doxycycline considered 1st line for cutaneous anthrax treatment in adults and children
- Acne Vulgaris, 2016 American Academy of Dermatology
  - Tetracyclines are a standard of care for moderate/severe acne as well as inflammatory acne
  - Doxycycline and minocycline more effective than tetracycline

Antifungals, Oral

Magellan Medicaid Administration

Antifungals, Oral – Indications

Drugs	FDA-Approved Indication(s)
clotrimazole lozenge	▪ Treatment of oropharyngeal candidiasis ▪ To prophylactically reduce the incidence of oropharyngeal candidiasis in patients immunocompromised by conditions that include chemotherapy, radiotherapy, or steroid therapy utilized in the treatment of leukemia, solid tumors, or renal transplantation
fluconazole (Diflucan)	▪ Treatment of oropharyngeal, esophageal, and vaginal candidiasis ▪ Treatment of *Candida* urinary tract infections, peritonitis, candida systemic infections including candidemia, disseminated candidiasis, and pneumonia ▪ Cryptococcal meningitis ▪ Prevention of candidiasis in patients undergoing bone marrow transplantation receiving cytotoxic chemotherapy and/or radiation
flucytosine (Ancobon)	Used in combination with amphotericin B for the treatment of serious infections caused by susceptible strains of *Candida* or *Cryptococcus*
griseofulvin suspension	Ringworm infections of the body, skin, hair, and nails, namely tinea corporis, tinea pedis, tinea cruris, tinea barbae, tinea capitis, and tinea unguium (onychomycosis)
griseofulvin, microsized	
griseofulvin, ultramicrosized (Gris-PEG)	
isavuconazonium (Cresemba)	Azole antifungal for use in the treatment of invasive aspergillosis, and invasive mucormycosis in patients 18 years and older
itraconazole (Onmel)	Treatment of onychomycosis of the toenail caused by *Trichophyton rubrum*, or *T. mentagrophytes*

Antifungals, Oral – Indications

Drugs	FDA-Approved Indication(s)
itraconazole (Sporanox)	▪ Onychomycosis of the fingernail and/or toenail due to dermatophytes (tinea unguium) in non-immunocompromised patients ▪ Treatment in immunocompromised and non-immunocompromised patients with pulmonary and extrapulmonary blastomycosis, histoplasmosis; or patients with aspergillosis intolerant of amphotericin B; or aspergillosis refractory to amphotericin B
ketoconazole	Blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, paracoccidioidomycosis, only in patients who are intolerant to, or who have failed, other agents*
miconazole (Oravig)	Local treatment of oropharyngeal candidiasis in adults
nystatin	Gastrointestinal and oral candidiasis caused by *Candida albicans*
posaconazole (Noxafil)	▪ Delayed-release tablet and oral suspension: Prophylaxis of invasive *Aspergillus* and *Candida* infections in patients 13 years and older who are at high risk of developing these infections due to being severely immunocompromised (e.g., hematopoietic stem cell transplant recipient with graft versus host disease [GVHD] or those with hematologic malignancies with prolonged neutropenia from chemotherapy) ▪ Oral suspension: Treatment of oropharyngeal candidiasis, including oropharyngeal candidiasis refractory to itraconazole and/or fluconazole
terbinafine (Lamisil)	Onychomycosis of the toenail or fingernail due to dermatophytes (tinea unguium)
terbinafine (Lamisil Granules)	Treatment of tinea capitis in patients 4 years of age and older
voriconazole (Vfend)	Treatment of the following infections in those 12 years of age and older: ▪ Invasive aspergillosis ▪ Serious infections caused by Scedosporium apiospermum and Fusarium species including Fusarium solani, in patients intolerant of, or refractory to, other therapy ▪ Esophageal candidiasis ▪ Candidemia in non-neutropenic patients and disseminated candidiasis in skin, abdomen, kidney, bladder wall, and wounds

Antifungals, Oral – Dosing and Availability

Drugs	Generic	Dose Range in Adults	Availability
clotrimazole	X	Treatment: 10 mg 5 times daily x 14 days Prophylaxis: 10 mg 3 times daily	Troche (lozenge): 10 mg
fluconazole (Diflucan)	X	50-200 mg daily; duration based on indication	Tablets: 50, 100, 150, 200 mg Oral suspension: 10, 40 mg/mL
flucytosine (Ancobon)	X	50-150 mg/kg per day (divided into 4 doses)	Capsules: 250, 500 mg
griseofulvin suspension	X	500-1,000 mg once daily; duration based on indication	Oral suspension: 125 mg/5 mL
griseofulvin, microsized	X		Tablets: 500 mg
griseofulvin, ultramicrosized (Gris-PEG)	X	375-750 mg once daily; duration based on indication	Tablets: 125, 250 mg
isavuconazonium (Cresemba)		2 capsules every 8 hours for 2 days, then 2 capsules once daily	Capsule: 186 mg
itraconazole (Onmel)		200 mg once daily x 12 weeks	Tablets: 200 mg
itraconazole (Sporanox)	X	200-400 mg daily; duration based on indication	Capsules: 100 mg Oral solution: 10 mg/mL
ketoconazole	X	200-400 mg daily	Tablets: 200 mg
miconazole (Oravig)		50 mg once daily x 14 days	Buccal tablets: 50 mg
nystatin	X	1.5-3 million units per day (3-4 divided doses)	Capsules, Lozenges, Tablets, Suspension

Antifungals, Oral – Dosing and Availability

Drugs	Generic	Dose Range in Adults	Availability
posaconazole (Noxafil)		100-400 mg up to 3 times daily; dosing and duration based on indication	Tablets: 100 mg Oral suspension: 40 mg/mL
terbinafine (Lamisil)	X	250 mg daily for 6-12 weeks	Tablets: 250 mg
terbinafine (Lamisil Granules)		250 mg daily for 6-12 weeks	Granules: 125, 187.5 mg
voriconazole (Vfend)	X	100-300 mg every 12 hours	Tablets: 50, 200 mg Oral suspension: 40 mg/mL

Antifungals, Oral – Guidelines

- Candidiasis, 2016 Infectious Diseases Society of America (IDSA)
  - Antifungal agents have different spectrums of activity and are approved for a variety of infections
  - Clotrimazole, miconazole, and nystatin can be used in mild-to-moderate oropharyngeal disease
  - Fluconazole is first line for moderate-to-severe oropharyngeal and esophogeal disease
  - Itraconazole, posaconazole, or voriconazole can be utilized for fluconazole-resistant disease
  - Ketoconazole is no longer recommended as first-line therapy
- Onychomycosis can be managed with topical antifungals for mild-to-moderate disease; more involved/advanced cases require systemic treatment with griseofulvin, itraconazole or terbinafine.
  - Comparative trials have showed higher success rates with terbinafine compared to itraconazole
  - Griseofulvin utility has decreased since the emergence of azole antifungals and terbinafine

Antifungals, Topical

Magellan Medicaid Administration

Antifungals, Topical – Indications

Drugs	FDA-Approved Indications					
	Tinea pedis	Tinea cruris	Tinea versicolor	Tinea corporis	Cutaneous candidiasis	Other
benzoic acid/salicylic acid (Bensal HP)						• Inflammation and irritation associated with common forms of dermatitis including certain eczematoid conditions and complications associated with pyodermas • Treatment of insect bites, burns, and fungal infections
butenafine (Lotrimin Ultra OTC, Mentax)	X	X	X	X		
ciclopirox (Loprox)	X	X	X	X	X	Seborrheic scalp dermatitis (shampoo)
ciclopirox (Ciclodan cream/kit)	X	X	X	X	X	
ciclopirox (Ciclodan solution, CNL-8, Penlac)						Topical treatment in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails due to *Trichophyton rubrum*
ciclopirox/urea (Pedipak)						
clotrimazole (Alevazol [OTC], Lotrimin)	X	X	X	X	X	
clotrimazole / betamethasone (Dermacinrx Therazole Pak)	X	X		X		Caused by the organism *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum*
clotrimazole / betamethasone (Lotrisone)	X	X		X		
econazole cream	X	X	X	X	X	
econazole foam (Ecoza)	X					

Antifungals, Topical – Indications

Drugs	FDA-Approved Indications					
	Tinea pedis	Tinea cruris	Tinea versicolor	Tinea corporis	Cutaneous candidiasis	Other
efinaconazole (Jublia)						Topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*
ketoconazole	X	X	X	X	X	Seborrheic dermatitis
ketoconazole (Extina)						Seborrheic dermatitis
ketoconazole (Nizoral Shampoo)			X			
ketoconazole (Xolegel)						Seborrheic dermatitis
luliconazole (Luzu)	X	X		X		Caused by the organism *Trichophyton rubrum* and *Epidermophyton floccosum*
miconazole	X	X	X	X	X	
miconazole (Azolen, Fungoid)	X			X		
miconazole (Zeasorb)	X	X				
miconazole/zinc oxide/ white petrolatum (Vusion)						Diaper dermatitis (adjunctive treatment)
naftifine (Naftin)	X	X		X		
nystatin (Pediaderm AF)					X	
nystatin/triamcinolone					X	

Antifungals, Topical – Indications

Drugs	FDA-Approved Indications					
	Tinea pedis	Tinea cruris	Tinea versicolor	Tinea corporis	Cutaneous candidiasis	Other
oxiconazole (Oxistat)	X	X	X	X		
sertaconazole (Ertaczo)	X					
sulconazole (Exelderm)	X	X	X	X		
tavaborole (Kerydin)						Topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*
terbinafine (Lamisil)	X	X	X	X		
tolnaftate (Fungoid-D)	X					
tolnaftate (Tinactin)	X	X	X	X		
undecylenic acid (Hongo Cura)	X	X		X		Relief of itching, burning, and cracking
undecylenic acid/zinc undecylenate (Fungi Nail)	X			X		Relief of itching, burning, and cracking
undecylenic acid/zinc undecylenate (Hongo Cura)	X			X		Relief of itching, burning, and cracking

Antifungals, Topical – Dosing and Availability

Drugs	Generic	OTC	Instructions for Use	Availability
benzoic acid/salicylic acid (Bensal HP)			Twice daily for 7 days	6%/3% ointment
butenafine (Lotrimin Ultra OTC, Mentax)		X	1-2 times daily for 1-4 weeks	1% cream
ciclopirox (Loprox)	X		Cream/gel/suspension: Twice daily for 4 weeks Shampoo: twice weekly Lacquer: daily for 48 weeks	0.77% cream, gel, topical suspension 1% shampoo; 8% nail lacquer
ciclopirox (Ciclodan)				0.77% cream; 8% nail lacquer
ciclopirox (CNL-8)				8% nail lacquer
ciclopirox (Penlac)	X			8% nail lacquer
ciclopirox/urea (Pedipak)			Lacquer: once daily; cream: twice daily or as directed	8% nail lacquer and 20% urea cream
clotrimazole (Alevazol [OTC], Lotrimin)	X	X	2-4 times daily for up to 4 weeks	1% cream, solution
clotrimazole / betamethasone (Dermacinrx Therazole Pak)			Twice daily for 1-4 weeks	1/0.05% cream; includes zinc oxide 20% paste
clotrimazole / betamethasone (Lotrisone)	X		Twice daily for 1-4 weeks	1/0.05% cream, lotion
econazole cream	X		1-2 times daily for 2-4 weeks	1% cream
econazole foam (Ecoza)			Once daily for 4 weeks	1% foam
efinaconazole (Jublia)			Once daily for 48 weeks	10% solution

Antifungals, Topical – Dosing and Availability

Drugs	Generic	OTC	Instructions for Use	Availability
ketoconazole	X		Cream: 1-2 times daily for 2-6 weeks Foam: twice daily for 4 weeks Shampoo: twice weekly for 4 weeks	2% cream, foam, shampoo
ketoconazole (Extina)			Twice daily for 4 weeks	2% foam
ketoconazole (Nizoral Shampoo)	X	X	Shampoo 2%: as directed twice weekly for 4 weeks Shampoo 1%: use every 3-4 days for up to 8 weeks	Rx: 2% shampoo OTC: 1% shampoo
ketoconazole (Xolegel)			Daily for 2 weeks	2% gel
luliconazole (Luzu)			Once daily for 1-2 weeks	1% cream
miconazole	X	X	Twice daily for 2-4 weeks	Rx: 2% cream OTC: 2% aerosol powder, cream, ointment, powder, spray
miconazole (Azolen, Fungoid)		X	Twice daily	2% tincure; Fungoid: includes nail scrub lotion
miconazole/zinc oxide/ white petrolatum (Vusion)			Apply at each diaper change for 7 days	0.25%/15%/81.35% ointment
naftifine (Naftin)	cream		1% cream: once daily for 4 weeks; 1% gel: twice daily for 4 weeks 2% cream, gel: once daily for 2 weeks	Generic: 1%, 2% cream Brand: 2% cream, 1%, 2% gel
nystatin	X		Cream/ointment: twice daily until healed Powder: 2-3 times daily until healed	100,000 units/gm cream, ointment, powder
nystatin (Pediaderm AF)			Twice daily until healing complete	100,000 units/gm cream

Antifungals, Topical – Dosing and Availability

Drugs	Generic	OTC	Instructions for Use	Availability
nystatin / triamcinolone	X		Twice daily	100,000 units/gm/0.1% cream, ointment
oxiconazole	cream		1-2 times daily for 2-4 weeks	1% cream, lotion
sertaconazole (Ertaczo)			Twice daily for 4 weeks	2% cream
sulconazole (Exelderm)			1-2 times daily for 2-4 weeks	1% cream; 1% solution
tavaborole (Kerydin)			Once daily for 48 weeks	5% solution
terbinafine (Lamisil)	X	X	Cream: twice daily for 1-2 weeks Gel: once daily for 1 week Spray: 1-2 times daily for 1 week	1% cream, gel, spray
tolnaftate (Tinactin)	X	X	Twice daily for 2-4 weeks	1% aerosol powder, cream, powder, solution, spray
Tolnaftate (Fungoid-D)			Apply 1-2 times daily	1% cream
undecylenic acid (Hongo Cura)			Twice daily for 2-4 weeks	25% spray
undecylenic acid (Fungi-Nail)			Twice daily for 2-4 weeks	25% solution
undecylenic acid/zinc undecylenate (Fungi Nail, Hongo Cura)			Twice daily for 4 weeks	5%/20% ointment

Antifungals, Topical – Guidelines

- Several agents indicated to treat superficial fungal skin infections (Tinea pedis, Tinea cruris, Tinea corporis) as well as cutaneous candidiasis
  - Newer agents (e.g., econazole, luliconazole) may offer shorter treatment duration
  - Several agents available over-the-counter (OTC) including clotrimazole, miconazole, terbinafine, and tolnaftate
  - Combination products that include a corticosteroid can be considered when inflammation is present
- Lack of comparative data in onychomycosis
  - Treatment courses are long with topical agents (e.g., 48 weeks) with failure rate around 20%
  - Oral antifungal agents may offer higher success rates

Antivirals, Oral

Magellan Medicaid Administration

Antivirals, Oral – Indications

Disease	Drugs	FDA-Approved Indication(s)
Herpes	acyclovir (Zovirax)	▪ Treatment of herpes zoster (shingles) ▪ Treatment of varicella (chickenpox) in patients > 2 years old ▪ Treatment of genital herpes simplex (initial and recurrent episodes)
	buccal acyclovir (Sitavig)	Treatment of recurrent herpes labialis (cold sores) in immunocompetent adults
	famciclovir	▪ Treatment of herpes zoster (shingles) ▪ Treatment and suppression of recurrent genital herpes in immunocompetent adults ▪ Treatment of recurrent episodes of orolabial or genital herpes infections in HIV-infected patients ▪ Treatment of recurrent herpes simplex labialis (cold sores) in immunocompetent adults
	valacyclovir (Valtrex)	▪ Treatment of herpes zoster (shingles) ▪ Treatment of genital herpes: ▪ Treatment of herpes labialis (cold sores) in patients ≥ 12 years old) ▪ Treatment of varicella (chickenpox) in immunocompetent patients 2 to 18 years old

Influenza	oseltamivir (Tamiflu)	▪ Treatment of acute, uncomplicated illness due to influenza infection in patients 2 weeks of age and older who have been symptomatic for no more than 2 days
		▪ Prophylaxis of influenza in patients older than 1 year of age
		  ▪ There is no evidence for efficacy of oseltamivir in any illness caused by agents other than influenza virus A and B.
		  ▪ Efficacy of oseltamivir in patients who begin treatment after more than 48 hours of symptoms has not been established.

	rimantadine (Flumadine)	▪ Prophylaxis and treatment of illness caused by influenza A virus in adults (≥ 17 years older) ▪ Prophylaxis of influenza A virus in patients older than 1 year of age (ages 1 to 16 years)
	zanamivir (Relenza) *Powder for Inhalation*	▪ Treatment of uncomplicated acute illness due to influenza A or B virus in adults and pediatric patients 7 years and older who have been symptomatic for no more than 2 days ▪ Prophylaxis of influenza in patients older than 5 years of age

Antivirals, Oral – Dosing and Availability

Drugs	Generic	Dose Range in Adults	Availability
acyclovir (Zovirax)	X	1,000-1,200 mg per day (in 3-5 divided doses)	Capsules: 200, 400, 800 mg Suspension: 200 mg/5 mL
buccal acyclovir (Sitavig)		50 mg daily	Buccal tablet: 50 mg
famciclovir	X	250 mg 2-3 times daily	Tablets: 125, 250, 500 mg
valacyclovir (Valtrex)	X	500-1,000 mg 1-2 times daily	Tablets: 500, 1000 mg
oseltamivir (Tamiflu)	X	Prophylaxis: 75 mg daily for 10 days Treatment: 75 mg twice daily for 5 days	Capsules: 30 mg, 45 mg, 75 mg Oral Suspension: 6 mg/mL
rimantadine (Flumadine)	X	100 mg twice daily Note: Not recommended in US	Tablets: 100 mg Syrup: 50 mg/5 mL
zanamivir (Relenza) *Powder for Inhalation*		Prophylaxis: 10 mg twice daily for 10 days Treatment: 10 mg twice daily for 5 days	Diskhaler: 5 mg per inhalation

Antivirals, Oral – Guidelines

Herpes Antivirals: acyclovir, famciclovir, valacyclovir

- Centers for Disease Control and Prevention (CDC) sexually transmitted disease (STD) treatment guidelines (2015)
  - All 3 agents are similar in efficacy and side effects
  - Do not recommend one agent over another for genital herpes or herpes zoster
  - Acyclovir and valacyclovir are approved for treatment of varicella (chickenpox)

Influenza Antivirals: amantadine, oseltamivir, rimantidine, zanamavir

- CDC monitors influenza viral resistance and publishes recommendations for each season
- Vaccination is the primary recommended means of preventing infection
- Rimantidine is not recommended for use in the US due to viral resistance and lack of Influenza B coverage
- Relenza (zanamavir) utilizes a complex inhalation device and is not recommended in patients with respiratory disorders
- Therapy should be initiated within 48 hours of exposure (prophylaxis) or symptoms (treatment) for best results

Hepatitis B Agents

Magellan Medicaid Administration

Hepatitis B Agents – Indications

Drug	Additional FDA-Approved Indications
adefovir dipivoxil (Hepsera)	Chronic hepatitis B virus (HBV) infection in patients ≥ 12 years of age with active viral replication and evidence of persistent elevation of alanine aminotransferase (ALT) or histologically active disease
entecavir (Baraclude)	Chronic hepatitis B virus (HBV) infection in patients ≥ 12 years of age with active viral replication and evidence of persistent elevation of alanine aminotransferase (ALT) or histologically active disease
lamivudine HBV (Epivir HBV)	Chronic HBV infection in adults and children 2 years and older with active viral replication and active liver inflammation
telbivudine (Tyzeka) *Product discontinued DEC 2016*	Chronic HBV infection in adults and adolescents (≥ 16 years) with evidence of active viral replication and either persistent elevations of ALT or AST or histologically active disease
tenofovir alafenamide fumarate (TAF) (Vemlidy)	Chronic HBV infection in adults with compensated liver disease
tenofovir disoproxil fumarate (TDF) (Viread) ***Reviewed in HIV/AIDS Class***	• Chronic HBV infection in adults and in pediatric patients 12 years of age and older • Combination therapy with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 2 years of age and older

Hepatitis B Agents – Dosing and Availability

Drugs	Generic	Dose Range in Adults	Availability
adefovir dipivoxil (Hepsera)	X	10 mg daily	Tablets: 10 mg
entecavir tablets (Baraclude)	X	0.5-1 mg daily	Tablets: 0.5, 1 mg
entecavir solution (Baraclude)		0.15 – 1 mg daily	Oral Solution: 0.05 mg/mL
lamivudine HBV tablets (Epivir HBV)	X	100 mg daily	Tablets: 100 mg
lamivudine HBV solution (Epivir HBV)		3 mg/kg daily (up to 100 mg)	Oral Solution: 5 mg/mL
telbivudine (Tyzeka)		600 mg daily	Product discontinued DEC 2016
tenofovir alafenamide fumarate (TAF) (Vemlidy)		25 mg daily with food	Tablets: 25 mg

Hepatitis B Agents – Guidelines

- Chronic Hepatitis B Infection, 2015 World Health Organization (WHO)
  - Recommend entecavir or tenofovir in adults and children ≥12; entecavir for children under 12
  - Do not recommend lamivudine, adefovir, or telbivudine as 1st line therapy
- Chronic Hepatitis B Infection, 2015 American Gastroenterological Association (AGA)
  - Entecavir and tenofovir disoproxil fumarate (TDF) are 1st line oral options
  - No longer recommend adefovir due to lower efficacy/higher resistance
  - Do not recommend lamivudine HBV unless other agents are inappropriate due to high resistance
- Chronic Hepatitis B Infection, 2016 American Association for the Study of Liver Diseases (AASLD)
  - Entecavir and tenofovir disoproxil fumarate (TDF) are 1st line oral options
  - Tenofovir alafenamide fumarate (TAF) has not yet been addressed in guidelines

Immunosuppressants, Oral

Magellan Medicaid Administration

Immunosuppressants, Oral – Indications

Class/Mechanism	Drug	Prophylaxis Against Organ Rejection			Rheumatoid Arthritis (RA)	Refractory Plaque Psoriasis
		Heart	Kidney	Liver		
Antiproliferative	azathioprine (Azasan, Imuran)		X adjunctive		X	
Calcineurin Inhibitors	cyclosporine (Sandimmune)	X adjunctive	X adjunctive	X adjunctive		
	cyclosporine, modified (Gengraf, Neoral)	X adjunctive	X adjunctive	X adjunctive	X refractory	X
mTOR Inhibitor	Everolimus (Zortress)		X adjunctive	X adjunctive		
Antiproliferative	mycophenolate mofetil (CellCept)	X adjunctive	X adjunctive	X adjunctive		
	mycophenolate sodium (Myfortic)		X adjunctive			
mTOR Inhibitor	sirolimus (Rapamune)		X adjunctive			
Calcineurin Inhibitors	tacrolimus (Prograf)	X adjunctive	X adjunctive	X adjunctive		
	tacrolimus extended- release (Astagraf XL)		X adjunctive			
	tacrolimus extended-release (Envarsus XR)		X adjunctive			

Immunosuppressants, Oral – Dosing and Availability

Drugs	Generic	Dose Range in Adults	Availability
azathioprine (Azasan, Imuran)	X	Transplant: 1-3 mg/kg daily RA: 1-2.5 mg/kg once or twice daily	Tablets: 50, 75, 100 mg
cyclosporine (Sandimmune)	X	5-10 mg/kg once daily	Capsule: 25, 100 mg Oral Solution: 100 mg/mL
cyclosporine, modified (Gengraf, Neoral)	X	Transplant: 5-10 mg/kg once daily Psoriasis/RA: 2.5-4 mg/kg/day in 2 doses	Capsule: 25, 50, 100 mg Oral Solution: 100 mg/mL
Everolimus (Zortress)		0.75-3 mg twice daily; dose based on blood levels	Tablets: 0.25, 0.5, 0.75 mg
mycophenolate mofetil (CellCept)	X	1,000-1,500 mg twice daily	Capsule: 250 mg Tablet: 500 mg Powder for Suspension: 200 mg/mL
mycophenolate sodium (Myfortic)	X	180-720 mg twice daily	DR Tablets: 180, 360 mg
Sirolimus (Rapamune)	X	0.5-2 mg daily; dose based on blood levels	Tablets: 0.5, 1, 2 mg Oral Solution: 1 mg/mL
tacrolimus (Prograf)	X	Dose based on weight, drug regimen, and blood levels. Typical range of 1-7 mg per day.	Capsules: 0.5, 1, 5 mg
tacrolimus extended- release (Astagraf XL)			XR Capsules: 0.5, 1, 5 mg
tacrolimus extended-release (Envarsus XR)			XR Tablets: 0.75, 1, 4 mg

Immunosuppressants, Oral – Guidelines

- Kidney Transplant, 2009 Kidney Disease Improving Global Outcomes
  - Recommend initial maintenance immunosuppression with: antiproliferative AND calcineurin inhibitor with or without corticosteroids.
  - Suggest myophenolate (antiproliferative) and tacrolimus (calcineurin inhibitor) as 1st line in their respective classes
  - Caution against use of mTOR inhibitors until graft function is established and surgical wounds are healed
- Liver Transplant, 2012 AASLD
  - No standard-of-care designation for liver transplant patients; acknowledge that drug selection and dosing are individualized
- Rheumatoid Arthritis, 2015 American College of Rheumatology (ACR)
  - Azathioprine and cyclosporine not included in this update due to lack of new data since 2012; less relevant due to biologics
- Plaque Psoriasis, 2009 American Academy of Dermatology (AAD)
  - Cyclosporine should be considered only in adult that are not immunocompromised with failure of another systemic therapy

Drug Classes

- Cephalosporins and Related Antibiotics
- Fluoroquinolones, Oral
- Lincosamides/Oxazolidinones/Streptogramins
- Tetracyclines
- Antifungals, Oral
- Antifungals, Topical
- Antivirals, Oral
- Hepatitis B Agents
- Immunosuppressives, Oral

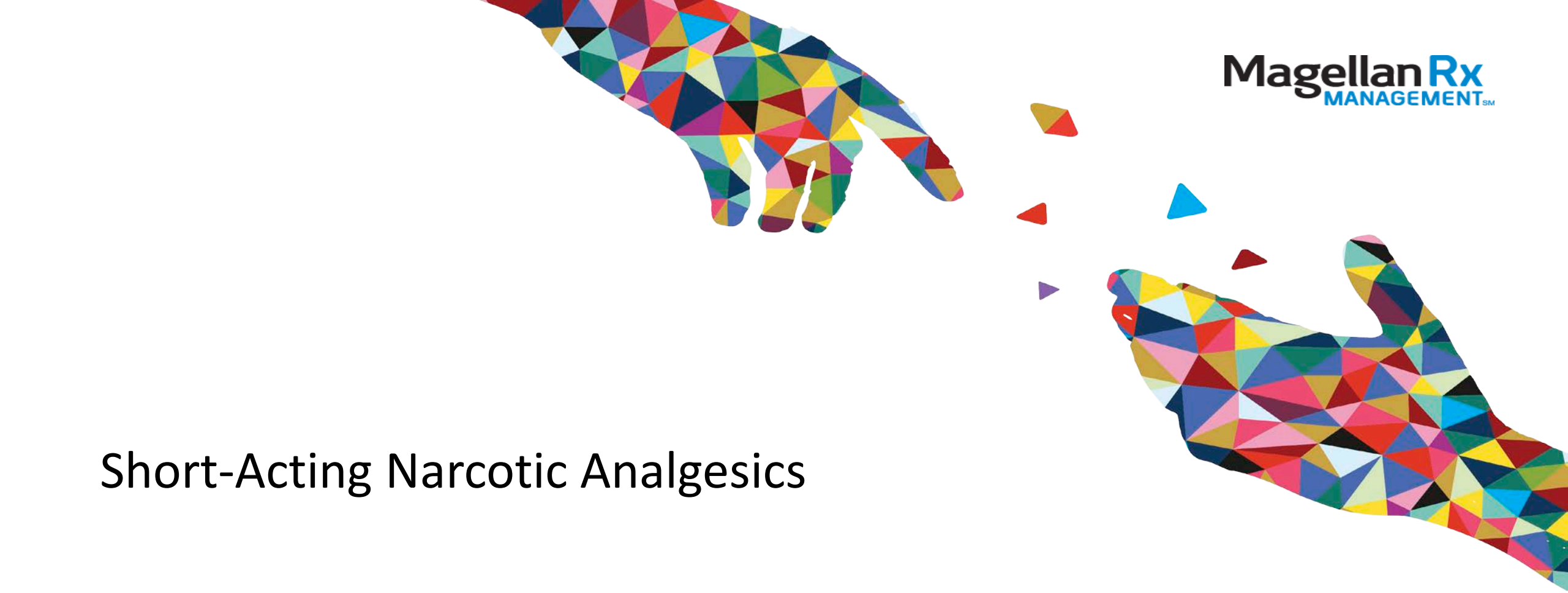
Recommendation

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

Motion

- “I move that the Apple Health Medicaid Program implement the limitations listed on slide 64 for each drug class listed on slide 63.
- delafloxacin and demeclocycline should be non-preferred with the PA criteria
- Immunosuppressive agents and Hepatitis B drugs should be grandfathered
- Motion: Sanderson

2nd: Flatebo



Short-Acting Narcotic Analgesics

Short-Acting Narcotic Analgesics- Indications

Drug	Federal Schedule	Generic	Indication
butorphanol nasal spray	CIV	X	Management of pain when the use of an opioid analgesic is appropriate
codeine sulfate	CII	X	Mild to moderately severe pain
codeine/acetaminophen (Tylenol #3, Tylenol #4, Capital)	CIII	X	Mild to moderate pain
codeine/butalbital/apap/caffeine (Fioricet with codeine)	CIII	X	Tension or muscle contraction headache
codeine/butalbital/aspirin/caffeine (Fiorinal with codeine)	CIII	X	Tension or muscle contraction headache
codeine/carisoprodol/aspirin	CIII	X	Moderate pain and muscle spasm associated with acute, painful musculoskeletal conditions
dihydrocodeine bitartrate/ APAP/caffeine (Trezix)	CIII	X	Moderate to moderately severe pain
dihydrocodeine bitartrate/ASA/caffeine (Synalgos DC)	CIII	X	Moderate to moderately severe pain
fentanyl buccal (Fentora); nasal (Lazanda); sublingual spray (Subsys); sublingual tablet (Abstral); transmucosal oral lozenge (Actiq)	CII	X (oral lozenge)	Breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain
hydrocodone/APAP solution (Hycet, Lortab, Zamicet); tablet (Lorcet, Lortab, Norco, Verdrocet, Vicodin, Xodol)	CII	X	Moderate to moderately severe pain
hydrocodone/IBU (Ibudone, Reprexain, Vicoprofen, Xylon)	CII	X	Short-term management of acute pain

Short-Acting Narcotic Analgesics- Indications

Drug	Federal Schedule	Generic	Indication
hydromorphone (Dilaudid)	CII	X	Management of pain in patients where an opioid analgesic is appropriate
levorphanol	CII	X	Moderate to severe pain
meperidine (Demerol)	CII	X	Moderate to severe pain
morphine IR	CII	X	Moderate to severe acute and chronic pain
oxycodone IR (Oxaydo)	CII		Moderate to severe acute and chronic pain
Oxycodone IR (Roxicodone)	CII	X	Moderate to severe pain
oxycodone/APAP (Endocet, Percocet, Primlev, Roxicet)	CII	X	Moderate to severe pain
oxycodone/APAP (Xartemis XR)	CII		Management of acute pain severe enough to require opioid treatment
oxycodone/aspirin (Endodan, Percodan)	CII	X	Moderate to severe pain
oxycodone/ibuprofen	CII	X	Short-term (7 days or less) treatment of acute, moderate to severe pain
oxymorphone IR (Opana)	CII	X	Moderate to severe acute pain
pentazocine/naloxone	CIV	X	Moderate to severe pain
tapentadol (Nucynta)	CII		Relief of moderate to severe acute pain
tramadol (Ultram)	CIV	X	Management of moderate to moderately severe pain in adults
tramadol/APAP (Ultracet)	CIV	X	Short-term (5 days or less) treatment of acute pain

Short-Acting Narcotic Analgesics- Dosage and Availability

Drug	Starting Dose	Dosing Instructions	Availability
butorphanol nasal spray	1 spray into 1 or both nostrils; may repeat after 3 to 4 hours	If 1 spray is administered and adequate pain relief is not achieved within 60 to 90 minutes, an additional 1 mg dose may be given; The initial 2-dose sequence may be repeated in 3 to 4 hours, as required, after the second dose of the sequence	Solution: 10 mg/mL
codeine sulfate	15 to 60 mg every 4 to 6 hours, as needed	Do not exceed 360 mg in 24 hours	Tablets: 15 mg, 30 mg, 60 mg
codeine/APAP (Tylenol #3, Tylenol #4, Capital)	Tablet: 1 to 2 every 4 hours, as needed Elixir: 15 mL every 4 hours	Do not exceed codeine 60 mg per dose and 360 mg per day or acetaminophen 4 g per day	Tablets: 15/300 mg, 30/300 mg, and 60/300 mg Elixir: 12/120 mg per 5 mL Suspension (Capital): 12/120 mg per 5 mL
codeine/butalbital/APAP/ caffeine (Fioricet with codeine)	1 to 2 capsules every 4 hours as needed for pain	Do not exceed 6 capsules per day	Capsule: codeine 30 mg/butalbital 50 mg/APAP 300 mg/caffeine 40 mg
codeine/butalbital/ASA/caffeine (Fiorinal with codeine)	1 to 2 capsules every 4 hours as needed for pain	Do not exceed 6 capsules per day	Capsule: codeine 30 mg/butalbital 50 mg/aspirin 325 mg/caffeine 40 mg
codeine/carisoprodol/ASA	1 to 2 tablets, 4 times daily	Do not exceed 8 tablets per day	Tablet: codeine 16 mg/carisoprodol 200 mg/aspirin 325 mg
dihydrocodeine bitartrate/ APAP/ caffeine (Trezix)	2 capsules every 4 hours, as needed	Do not exceed 10 capsules per 24 hours	Capsule: APAP 320.5 mg/caffeine 30 mg/ dihydrocodeine 16 mg
dihydrocodeine bitartrate aspirin/caffeine (Synalgos DC)	2 capsules every 4 hours, as needed	Do not exceed 10 capsules per 24 hours	Capsule: aspirin 356.4 mg/caffeine 30 mg/dihydrocodeine 16mg

Short-Acting Narcotic Analgesics- Dosage and Availability

Drug	Starting Dose	Dosing Instructions	Availability
fentanyl buccal (Fentora)	100 mcg, as needed	Until the appropriate dose is reached, patients may find it necessary to use an additional unit during a single episode of breakthrough pain not relieved in 30 minutes; 1 tablet of the same dose may be taken; If pain is not relieved, patients must wait 4 hours before treating another episode of breakthrough pain; If treatment of several consecutive breakthrough cancer pain episodes requires more than 1 unit per episode, an increase in dose to the next higher available strength should be considered; If patient is currently on fentanyl transmucosal lozenges (Actiq), see prescribing information for additional dosing recommendations	Tablets: 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg
fentanyl nasal spray (Lazanda)	100 mcg, as needed	Individually titrate to an effective dose, from 100 mcg to 200 mcg to 400 mcg, and up to a maximum of 800 mcg, that provides adequate analgesia with tolerable side effects; Dose is a single spray into 1 nostril, a single spray into each nostril (2 sprays), or 2 sprays into each nostril (4 sprays); no more than 4 doses per 24 hours; Wait at least 2 hours before treating another episode of breakthrough pain with fentanyl nasal spray	Nasal sprays: 100 mcg, 300 mcg, 400 mcg
Fentanyl sublingual spray (Subsys)	100 mcg, as needed	Titrated as tolerated to an effective dose; 1 dose of Subsys should be used per breakthrough pain episode; in cases where the pain may not be relieved within 30 minutes of the dose, 1 additional dose of the same strength may be used for that breakthrough episode; At least 4 hours must elapse prior to initiating treatment for another episode of pain; Maintenance dosing should not exceed 4 doses per 24 hours; Dose increase should be considered when several consecutive attempts to control breakthrough pain have failed	Sublingual sprays: 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,200 mcg, 1,600 mcg
fentanyl sublingual tablet (Abstral)	100 mcg, as needed	Doses may be supplemented 1 time after 30 minutes; do not use > 2 doses per episode of breakthrough pain; wait 2 hours before treating another episode; Titrate to a successful dose and limit use to 4 episodes per day	Tablets: 100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, 800 mcg
fentanyl transmucosal oral lozenge (Actiq)	200 mcg, as needed	Until the appropriate dose is reached, patients may find it necessary to use an additional unit during a single episode; patients must wait at least 4 hours before treating another episode of breakthrough pain; If treatment of several consecutive breakthrough cancer pain episodes requires >1 unit per episode, an increase in dose to the next higher available strength should be considered	Transmucosal oral lozenges: 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,200 mcg, 1,600 mcg

Short-Acting Narcotic Analgesics- Dosage and Availability

Drug	Starting Dose	Dosing Instructions	Availability
hydrocodone/ APAP solution (Hycet, Lortab, Zamicet)	15 mL every 4 to 6 hours	Not to exceed 90 mL/24 hours; See dosing chart in prescribing information for initial doses for children	Solution: 7.5/325 mg per 15 mL (Hycet), 10/300 mg per 15 mL (Lortab), 10/325 mg per 15 mL (Zamicet)
hydrocodone/ APAP tablet (Lorcet, Lortab, Norco, Verdrocet, Vicodin, Xodol)	1 to 2 tablets every 4 to 6 hours	Not to exceed 6 tablets or capsules in 24 hrs; for tablets or capsules that contain 8 mg hydrocodone, may take up to 8 tablets per 24 hrs; for tablets that contain 7.5 or 10 mg hydrocodone, take 1 tablet or capsule every 4 to 6 hrs	Tablets: 2.5/325 mg (Verdrocet), 5/300 mg (Vicodin, Xodol), 5/325 mg (Lorcet, Lortab, Norco), 7.5/300 mg (Vicodin ES, Xodol), 7.5/325 mg (Lorcet Plus, Lortab, Norco), 10/300 mg (Vicodin HP, Xodol), 10/325 mg (Lorcet HD, Lortab, Norco)
hydrocodone/ IBU (Ibudone, Reprexain, Vicoprofen, Xylon)	1 tablet every 4 to 6 hours	Not to exceed a maximum of 5 tablets/24 hours	Tablets: 2.5/200 mg (Reprexain), 5/200 mg (Ibudone, Reprexain), 7.5/200 mg (Vicoprofen), 10/200 mg (Ibudone, Reprexain, Xylon)
hydromorphone (Dilaudid)	Tablets: 2 to 8 mg every 4 to 6 hours Liquid: 2.5 to 10 mg every 3 to 6 hours	Dose should be adjusted so that at least 3 to 4 hours of pain relief may be achieved; dose should be increased, as needed, according to patient's response	Tablets: 2 mg, 4 mg, 8 mg Liquid: 5 mg/5 mL Suppository: 3 mg (generic only)
levorphanol	2 mg every 6 to 8 hours	Total oral daily doses of > 6 to 12 mg/24 hours are generally not recommended as starting doses	Tablet: 2 mg
meperidine (Demerol)	Adult: 50 to 150 mg every 3 to 4 hours Pediatric: 1.1 to 1.8 mg/kg every 3 to 4 hours	Not for chronic use	Tablets: 50 mg, 100 mg Solution: 50 mg/5 mL (generic only)
Morphine IR	Tablets: 15 to 30 mg every 4 hours, as needed Solution: 10 to 20 mg every 4 hours, as needed	The dose should be titrated based upon the individual patient's response	Tablets: 15 mg, 30 mg Solution: 10 mg/5 mL, 20 mg/5 mL, 100 mg/5 mL Suppository: 5 mg, 10 mg, 20 mg, 30 mg

Short-Acting Narcotic Analgesics- Dosage and Availability

Drug	Starting Dose	Dosing Instructions	Availability
oxycodone IR (Oxaydo)	Opioid-naïve: 5 to 15 mg every 4 to 6 hours, as needed	The dose must be swallowed whole and is not amenable to crushing and dissolution; Do not use for administration via nasogastric, gastric, or other feeding tubes as it may cause obstruction of the feeding tube	Tablet: 5 mg, 7.5 mg (contains abuse-deterrent properties; resistant to crushing, chewing, snorting, and injection related abuse)
oxycodone IR (Roxicodone)	5 to 15 mg every 4 to 6 hours, as needed	The dose should be titrated based upon the individual patient's response	Capsule: 5 mg Tablets: 5 mg (Roxicodone), 10 mg, 15 mg (Roxicodone), 20 mg, 30 mg (Roxicodone) Solution: 5 mg/5 mL, 20 mg/mL
oxycodone/APAP (Endocet, Percocet, Primlev, Roxicet)	1 to 2 tablets or capsules every 6 hours	Do not exceed oxycodone 60 mg or acetaminophen 4 g per day in adults Children: < 45 kg body weight – do not exceed 90 mg/kg per day based on the acetaminophen component; > 45 kg body weight – do not exceed 4 g per day based on the acetaminophen component	Percocet and Endocet (tablets): 2.5/325 mg, 5/325 mg, 7.5/325 mg, 10/325 mg Primlev (tablets): 5/300 mg, 7.5/300 mg, 10/300 mg Roxicet (tablet): 5/325 mg Roxicet (solution): 5/325 mg per 5 mL
oxycodone/ APAP (Xartemis XR)	2 tablets every 12 hours	Swallow whole (do not crush, break, chew, cut, dissolve, or split) due to biphasic release system; swallow immediately; Dose may be administered as early as 8 hours following the initial dose	Tablet: 7.5/325 mg
oxycodone/ASA (Endodan, Percodan)	1 tablet every 6 hours	The maximum daily dose of aspirin should not exceed 4 grams or 12 tablets	Tablet: 4.8355/325 mg
oxycodone/IBU	1 tablet per dose	Not to exceed a maximum of 4 tablets in 24 hours; do not exceed 7 days of therapy	Tablet: 5/400 mg
oxymorphone IR	10 to 20 mg every 4	Administer on an empty stomach, at least 1 hour prior to or 2 hours after	Tablet: 5 mg, 10 mg

Short-Acting Narcotic Analgesics- Dosage and Availability

Drug	Starting Dose	Dosing Instructions	Availability
pentazocine/ naloxone	1 to 2 tablets every 3 or 4 hours	Do not exceed 600 mg pentazocine per day	Tablet: 50/0.5 mg
tapentadol (Nucynta)	1 tablet every 4 hours	Doses > 700 mg on the first day and doses of > 600 mg on subsequent days are not recommended	Tablets: 50 mg, 75 mg, 100 mg
tramadol (Ultram)	50 mg to 100 mg every 4 to 6 hours	Initiate at 25 mg every morning; titrate in 25 mg increments as separate doses every 3 days to reach 100 mg/day (25 mg 4 times daily), then the total daily dose may be increased by 50 mg as tolerated every 3 days to reach 200 mg/day (50 mg 4 times daily); After titration, tramadol 50 to 100 mg can be administered as needed for pain relief every 4 to 6 hours (not to exceed 400 mg per day)	Tablet: 50 mg
tramadol/ APAP (Ultracet)	2 tablets every 4 to 6 hours	Not to exceed a maximum of 8 tablets/24 hours; for the short-term (≤ 5 days) management of acute pain; The elimination half-life of tramadol is increased in patients with severe renal impairment (CrCl < 30 mL/min), cirrhosis of the liver, or > 75 years, so the dosing interval should be extended	Tablets: 37.5/325 mg

Short-Acting Narcotic Analgesics- Guidelines

- Centers for Disease Control and Prevention (CDC), 2016
  - Guidelines for prescribing opioids for chronic pain (other than active cancer, palliative, and end-of-life care)
    - Prefer nonpharmacologic and nonopioid pharmacologic therapy
    - Prior to prescribing opioids a full individual assessment is recommended
    - Recommend initial therapy with IR opioids instead of ER opioids and at lowest effective dose (chronic pain)
    - IR products should be used at the lowest effective dose; quantity should not exceed the expected duration of pain severe enough to require opioids (typically 3 days, > 7 days rarely needed) (acute pain)
    - Doses of ≥ 50 morphine milligram equivalents (MME)/day should prompt reassessment of benefits vs risks; use of ≥ 90 MME/day should be avoided without justification
    - Tapering patients off the opioid is recommended with routine monitoring
    - Recommend avoiding concurrent use of benzodiazepines and recommend risk management (e.g. naloxone in high-risk individuals)
- American College of Physicians (ACP), 2017
  - Guidelines on noninvasive treatments for acute, subacute, and chronic low back pain
    - Recommend nonpharmacologic treatment in most patients with acute, subacute, and chronic low back pain
    - NSAID or skeletal muscle relaxant is recommended as first line (acute/subacute pain)
    - NSAID as first-line therapy and tramadol or duloxetine as second-line therapy (chronic pain)
    - Opioids should only be considered in those who have failed first-line therapies
- American Society of Interventional Pain Physicians (ASIPP), 2017
  - Management of patients with chronic, non-cancer pain
    - Necessity of opioids based on an average moderate to severe pain (pain or disability level ≥ 4 on a 0 to 10 point scale)
    - Recommends initiation with short-acting opioids at low doses (≤ 40 morphine MME daily)
    - Recommend methadone only after failure of other opioid therapy
    - Long-acting opioids should be avoided during opioid initiation; use when there is severe, intractable pain

Analgesics, Narcotics Short

- **Recommendation:**
  - All Analgesics, Narcotics Short products are considered efficacious when used appropriately 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, or not clinically appropriate.

Analgesics, Narcotics Short acting

- Motion: “I move that the Apple Health Medicaid Program implement the limitations for the Analgesics, Narcotics Short acting listed on slide 75 as recommended.
- Make codeine/carisoprodol/aspirin non-preferred with PA criteria

Motion: Schwilke

2nd: Storhaug

Lipotropics, Other

Lipotropics, Other- Indications

Drug	Generic	Indications
Apolipoprotein B Synthesis Inhibitors		
lomitapide (Juxtapid)		Reduction of LDL-C, total cholesterol, apolipoprotein B (Apo B), and non-HDL-C in patients with homozygous familial hypercholesterolemia (HoFH), as an adjunct to a low-fat diet and other lipid-lowering treatments
mipomersen (Kynamro)		Reduction of LDL-C, total cholesterol, apolipoprotein B (Apo B), and non-HDL-C in patients with homozygous familial hypercholesterolemia (HoFH), as an adjunct to diet and lipid-lowering medications
Bile Acid Sequestrants		
cholestyramine (Questran, Questran Light)	X	• Primary hypercholesterolemia • Relief of pruritus associated with partial biliary obstruction
colesevelam (WelChol)		• Hypercholesterolemia, Fredrickson type IIa (monotherapy or in combination with a statin) • Reduction of LDL-C levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia (HeFH) after failing an adequate trial of diet therapy • Glycemic control in adults with type 2 diabetes mellitus
colestipol (Colestid)	X	Primary hypercholesterolemia
Cholesterol Absorption Inhibitors		
ezetimibe (Zetia)	X	• Primary hypercholesterolemia (monotherapy or in combination with a statin) • Mixed hyperlipidemia (in combination with fenofibrate) • Homozygous familial hypercholesterolemia (HoFH) (adjunctive therapy in combination with atorvastatin or simvastatin) • Homozygous familial sitosterolemia

Lipotropics, Other- Indications

Drug	Generic	Indications
		Fibric Acids
fenofibrate (Antara, Fenoglide, Lipofen, Lofibra, Tricor, Triglide)	X (except Triglide)	As an adjunct to diet: • To reduce elevated LDL-C, Total-C, TG, and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia or mixed dyslipidemia. • To treat adult patients with severe hypertriglyceridemia
fenofibric acid (Fibricor, Trilipix)	X	• Primary hyperlipidemia or mixed dyslipidemia in adults • Severe hypertriglyceridemia in adults
gemfibrozil (Lopid)	X	• Hypercholesterolemia, Fredrickson type IIb (in patients without history of or symptoms of existing CHD) • Hypertriglyceridemia, Fredrickson types IV and V hyperlipidemia
		Niacin
niacin ER (Niaspan)	X	• Primary hyperlipidemia or mixed dyslipidemia • Primary hyperlipidemia or patients with a history of Coronary Artery Disease (CAD) and hyperlipidemia (in combination with a bile acid sequestrant) • Severe hypertriglyceridemia as adjunct in patients at risk for pancreatitis • Patients with a history of myocardial infarction (MI) and hyperlipidemia
niacin IR (Niacor)		• Primary hypercholesterolemia (monotherapy or in combination with bile-acid binding resin) • Hypertriglyceridemia, types IV and V hyperlipidemia for those who present with a risk of pancreatitis (adjunctive therapy)
		Omega-3 Fatty Acids
icosapent ethyl (Vascepa)		Treatment of hypertriglyceridemia in adults with severe triglycerides (TG) ≥ 500 mg/dL, as adjunct to diet
omega-3-acid ethyl esters (Lovaza)	X	Treatment of hypertriglyceridemia in adults with triglycerides (TG) ≥ 500 mg/dL

Lipotropics, Other- Indications

Drug	Generic	Indications
Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors		
alirocumab (Praluent)		Treatment of adults with HeFH or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-C as an adjunct to diet and maximally-tolerated statin therapy
evolocumab (Repatha)		• Treatment of adults with HeFH or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-C as an adjunct to diet and maximally-tolerated statin therapy • Treatment of patients with HoFH who require additional lowering of LDL-C as an adjunct to diet and other LDL-lowering therapies

Lipotropics, Other- Dosage and Availability

Drug	Dose	Availability
Apolipoprotein B Synthesis Inhibitors		
lomitapide (Juxtapid)	Initiate with 5 mg daily; Titrate to 10 mg daily after ≥ 2 weeks, then 4-week intervals to 20 mg, 40 mg, 60 mg; Do not exceed 60 mg per day	5 mg, 10 mg, 20 mg, 30 mg, 40 mg, 60 mg capsules
mipomersen (Kynamro)	200 mg once weekly as a subcutaneous injection	200 mg/1 mL solution in single-use vial and prefilled syringe
Bile Acid Sequestrants		
Cholestyramine (Questran, Questran Light)	1 to 2 packets or scoopfuls twice daily	powder for oral suspension
colesevelam (WelChol)	Hyperlipidemia or Type 2 DM: 3,750 mg daily in 1 or 2 divided doses	625 mg tablets 3,750 mg packet powder for oral suspension
colestipol (Colestid)	2 g once or twice daily (tablets); 5 g to 30 g daily (granules)	1 g tablets; 5 g and 7.5 g granule packets
Cholesterol Absorption Inhibitors		
ezetimibe (Zetia)	10 mg daily	10 mg tablets

Lipotropics, Other- Dosage and Availability

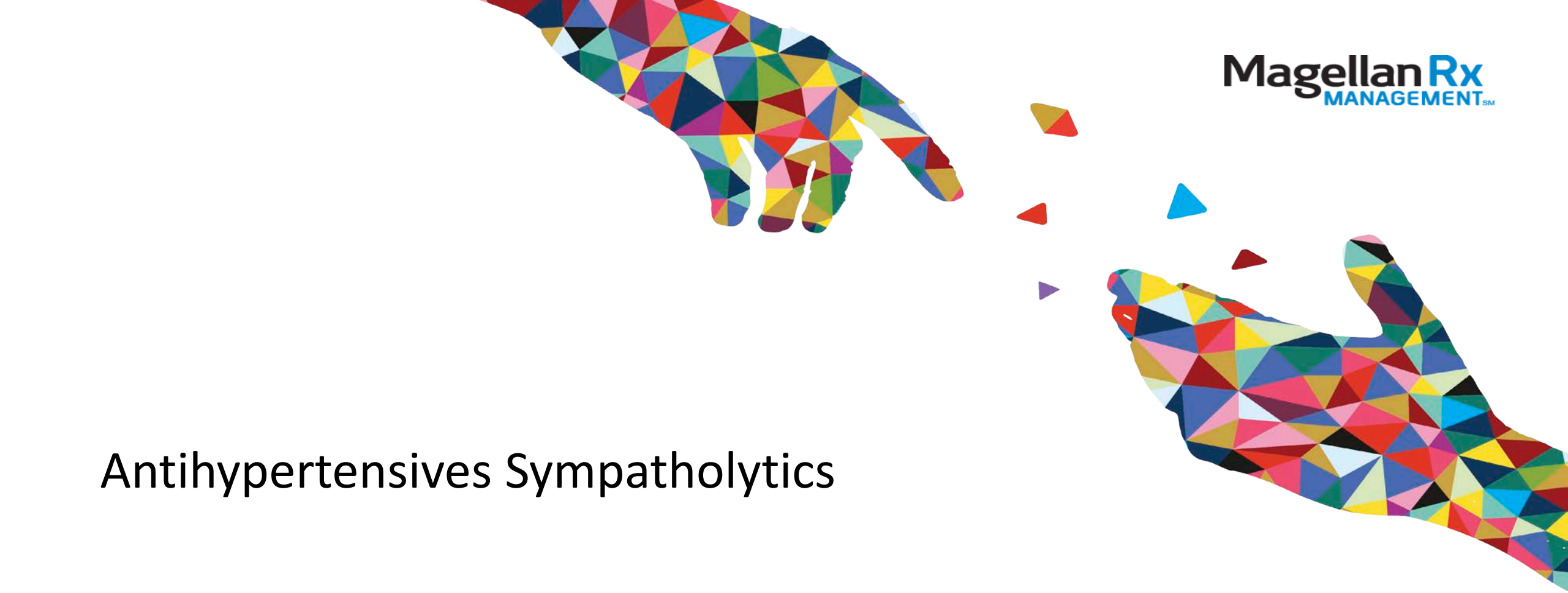
Drug	Dose	Availability
Fibric Acids		
fenofibrate (Lofibra)	67 mg to 200 mg daily	67 mg, 134 mg, 200 mg capsules
	54 mg to 160 mg daily	54 mg, 160 mg tablets
fenofibrate (Antara)	30 mg to130 mg daily	30 mg, 90 mg capsule (brand only) 43 mg, 130 mg capsules (generic only)
fenofibrate (Fenoglide)	40 mg to 120 mg daily	40 mg, 120 mg tablets
fenofibrate (Lipofen)	50 mg to 150 mg daily	50 mg, 150 mg capsules
fenofibrate (Tricor)	48 mg to 145 mg daily	48 mg, 145 mg tablets
fenofibrate (Triglide)	50 mg to 160 mg daily	160 mg tablets
fenofibric acid (Fibricor)	35 mg to 105 mg daily	35 mg, 105 mg tablets
fenofibric acid (Trilipix)	45 mg to 135 mg daily	45 mg, 135 mg delayed release capsules
gemfibrozil (Lopid)	600 mg twice daily	600 mg tablets
Niacin		
niacin ER (Niaspan)	500 mg to 2,000 mg at bedtime	500 mg, 750 mg, 1,000 mg tablets Starter pack
niacin IR (Niacor)	1 g to 2 g twice or 3 times daily	500 mg tablets

Lipotropics, Other- Dosage and Availability

Drug	Dose	Availability
Omega-3 Fatty Acids		
icosapent ethyl (Vascepa)	2 g twice daily	0.5 g and 1 g capsules
omega-3-acid ethyl esters (Lovaza)	4 g daily in 1 or 2 divided doses	1 g capsules
Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors		
alirocumab (Praluent)	75 mg or 150 mg subcutaneously once every 2 weeks; may be increased to a maximum of 150 mg administered every 2 weeks; and alternative starting dose is 300 mg (2 x 150 mg SC injections) may be given once monthly	75 mg/1 mL and 150 mg/1 mL single-use prefilled pen
evolocumab (Repatha)	HeFH or with primary hyperlipidemia: 140 mg subcutaneously once every 2 weeks or 420 mg once monthly; HoFH: 420 mg once monthly	140 mg/1 mL prefilled autoinjector or syringe; 420 mg/3.5 mL single-use Pushtronex system (on-body infusor with prefilled cartridge)

Lipotropics, Other- Guidelines

- American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE), 2017
  - Guidelines for the management of dyslipidemia and prevention of cardiovascular disease
    - Adults ≥ 20 years of age should be assessed annually for dyslipidemia
    - Children should be screened who are at risk for familial hypercholesterolemia
    - Recommend fibrates for treatment of TG > 500 mg/dL
    - Omega-3 fish oil (2 g to 4 g) can be used, as adjunct to fibrates or niacin, to achieve satisfactory TG levels
    - Recommends bile acid sequestrants for reducing LDL-C and apo B and modestly increasing HDL-C
    - Ezetimibe is effective monotherapy in reducing LDL-C and apo B (particularly in statin-intolerant patients)
    - Maintain statins as primary therapy and recommend ezetimibe in addition to statins for addition LDL-C reduction
    - PCSK9 inhibitors may be considered in patients with clinical CVD who are not at goal with maximally tolerated statin or in those with familial hypercholesterolemia
- American Diabetes Association (ADA), 2017
  - Recommends moderate- or high-intensity statin therapy in patients with diabetes bases on patient age and presence of ASCVD or ASCVD risk factors
  - Recommend ezetimibe as add-on to moderate-intensity statin therapy in patients with ACS and LDL-C ≥ 50 mg/dL or in patients with history of ASCVD who cannot tolerate high-dose statins
  - PCSK9 inhibitor to maximally tolerated statin doses may be considered in those at high risk for ASCVD events who require additional LDL-C reduction or who are intolerant to high-intensity statin therapy
  - The ADA does not recommend niacin therapy added onto statin therapy in diabetic patients



Antihypertensives Sympatholytics

Antihypertensives Sympatholytics- Indications, Dosage, and Availability

Drug	Generic	Indication	Initial Dosage	Maintenance and Maximum Daily Dose	Availability
clonidine immediate-release tablet (Catapres)	X	Hypertension	0.1 mg twice daily (morning and bedtime)	0.2 mg to 0.6 mg daily in divided doses; Maximum daily dose is 2.4 mg	0.1 mg , 0.2 mg, and 0.3 mg immediate-release tablets
clonidine transdermal (Catapres-TTS)	X	Hypertension	Apply one 0.1 mg/24 hr transdermal patch every 7 days to a hairless area of intact skin on the upper outer arm or chest	If the desired blood pressure reduction does not occur within the first 2 weeks, an additional TTS-1 patch may be applied or a larger system may be used. More than 2 of the TTS-3 transdermal patches have not been associated with increased efficacy	0.1 mg/24 hr transdermal; 0.2 mg/24 hr transdermal; 0.3 mg/24 hr transdermal
clonidine/ chlorthalidone (Clorpres)		Hypertension	Minimum of 1 tablet (0.1 mg clonidine/15 mg chlorthalidone) once or twice daily	Titrate dosage of clonidine by 0.1 mg/day as needed up to a maximum of 1 tablet (0.3 mg clonidine/15 mg chlorthalidone) twice daily (maximum of 0.6 mg/day clonidine with 30 mg/day chlorthalidone)	0.1 mg/15 mg tablet; 0.2 mg/15 mg tablet; 0.3 mg/15 mg tablet
guanfacine (Tenex)	X	Hypertension	1 mg once daily at bedtime	Maximum dose is 3 mg to 4 mg daily. Increase dose after first 3 to 4 weeks to 2 mg once daily then further increases up to 3 mg once daily if needed	1 mg, 2 mg tablet

Antihypertensives Sympatholytics-Indications, Dosage, and Availability

Drug	Generic	Indication	Initial Dosage	Maintenance and Maximum Daily Dose	Availability
methyldopa	X	Hypertension	Adults: 250 mg 2 to 3 times daily Pediatrics: 10 mg/kg/day or 300 mg/m^2/day in 2 to 4 divided doses Neonates: 5 mg to 10 mg per kg daily in divided doses every 6 to 8 hours	500 mg to 2000 mg daily in 2 to 4 divided doses. Maximum adult dose is 3,000 mg daily. Maximum geriatric dose is 1,000 mg daily. Maximum pediatric daily dose is 65 mg per kg per day or 3,000 mg daily, or whichever is less	250 mg, 500 mg tablets
methyldopa/ HCT	X	Hypertension	One 250 mg/15 mg tablet 2 or 3 times daily or one 250 mg/25 mg tablet twice daily or one 500 mg/30 mg or 500 mg/50 mg tablet once daily (30 and 50 mg formulation not available)	Maximum recommended dose of methyldopa component is 750 mg daily and HCTZ component is 50 mg daily. Additional methyldopa doses may be necessary. Do not exceed maximum dosage for each individual drug.	250 mg/15 mg, 250 mg/25 mg tablet
reserpine	X	Hypertension	0.05 mg to 0.1 mg once daily	0.1 mg to 0.25 mg once daily as maintenance dose; maximum adult daily dose is 0.5 mg and maximum geriatric daily dose is 0.25 mg	0.1 mg, 0.25 mg tablets

Antihypertensives Sympatholytics- Guidelines

- Evidence-Based Guideline for the Management of High Blood Pressure in Adults- Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8), 2014
  - Initial therapy: thiazide-type diuretic, CCB, ACEI, or ARB (nonblack population +/- diabetes)
  - Initial therapy: thiazide-type diuretic or CCB (black population +/- diabetes)
  - If goal blood pressure cannot be reached using thiazide-type diuretic, CCB, ACEI, or ARB (mono or combination therapy) because of a contraindication or the need to use > 3 drugs to reach goal blood pressure, antihypertensive drugs from other classes can be used
- ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA, 2017
  - Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults
    - Initial therapy: thiazide diuretics, CCBs, and ACE inhibitors or ARBs
    - Initiation of antihypertensive drug therapy with a single antihypertensive drug is reasonable in adults with stage 1 HTN and blood pressure goal <130/80 mm Hg; dose titration and sequential addition of other agents may be needed
    - Initiation of antihypertensive drug therapy with 2 first-line agents of different classes is recommended in adults with stage 2 hypertension and an average BP > 20/10 mm Hg above blood pressure target
    - Central alpha1- agonist and other centrally acting drugs (e.g. clonidine, methyldopa, guanfacine) are generally reserved as last-line because of significant CNS adverse effects

Sinus Node Inhibitors

Magellan Medicaid Administration

Sinus Node Inhibitors-Indication, Dosing, and Availability

Drug	Indication	Dosing	Availability
Ivabradine (Corlanor)	Reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤ 35% who are in sinus rhythm with resting heart rate ≥ 70 beats per minute (bpm) and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use	5 mg twice daily with meals; titrate to maximum of 7.5 mg twice daily	5 mg, 7.5 mg tablet

Sinus Node Inhibitors-Guidelines

- American College of Cardiology (ACC), American Heart Association (AHA), and Heart Failure Society of American (HFSA), 2017
  - Can be beneficial to reduce heart failure hospitalization in patients with symptomatic (NYHA class II-III) stable chronic HFrEF (LVEF ≤ 35%) who are receiving guideline-directed evaluation and management, including beta blocker at maximum tolerated dose, and with a heart rate of ≥ 70 bpm at rest and who are in sinus rhythm

Vasodilators, Coronary

Magellan Medicaid Administration

Vasodilators, Coronary- Indication, Dosage, and Availability

Drug	Generic	Indication	Dosage	Availability
isosorbide dinitrate (Isordil)	X	Prevention of angina pectoris due to coronary artery disease	Initial: Take 5 to 20 mg 2 to 3 times daily Maintenance: 10 to 60 mg 2 to 3 times daily; Do not exceed 480 mg/day	Tablets: 5, 10, 20, 30 mg Isordil Titradose tablets: 5, 40 mg
Isosorbide dinitrate ER (Isochron, IsoDitrate ER, Dilatrate-SR)	X	Prevention of angina pectoris due to coronary artery disease	Take 40 mg by mouth twice daily; at least 18 hours apart; Do not exceed 160 mg/day	ER tablets and capsules: 40 mg
isosorbide mononitrate	X	Prevention of angina pectoris due to coronary artery disease	20 mg twice daily, with doses given 7 hours apart; 5 mg may be given to patients with small stature; Do not exceed 40 mg/day	Tablets: 10, 20 mg
isosorbide mononitrate ER	X	Prevention of angina pectoris due to coronary artery disease	30 to 60 mg once daily, preferably in the morning upon awakening; increased to 120 mg; Do not exceed 240 mg/day	ER tablets: 30, 60, 120 mg
nitroglycerin ER (Nitro-Time)	X	Prevention of angina pectoris due to coronary artery disease	Take 2.5 to 6.5 mg 3 to 4 times daily; titrate to clinical response and adverse reactions as needed	ER capsules: 2.5, 6.5, 9 mg
nitroglycerin lingual (NitroMist, Nitrostat, Nitrolingual Pumpspray)	X	Acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease	**Acute relief:** • Translingual spray: 1 to 2 sprays on or under the tongue, may repeat as needed every 5 minutes up to 3 sprays in 15 minutes • Sublingual tablets: 1 tablet dissolved under the tongue or in the buccal pouch immediately following indication of anginal attack, may repeat every 5 minutes up to 3 doses in 15 minutes **Prophylaxis of angina pectoris:** Use 5 to 10 minutes prior to engaging in activities that might precipitate an acute attack	Translingual aerosol spray: 400 mcg/spray in packages containing 90 or 230 doses Lingual metered pumpspray: 400 mcg/spray in packages containing 60 or 200 doses Sublingual tablets: 0.3, 0.4, 0.6 mg

Vasodilators, Coronary- Indication, Dosage, and Availability

Drug	Generic	Indication	Dosage	Availability
nitroglycerin ointment (Nitro-Bid)		Prevention of angina pectoris due to coronary artery disease	Apply 7.5 mg (1/2 inch) to 30 mg (2 inches) twice a day, onto 36 square inches of hairless area of skin (chest, abdomen, thighs); applied on rising in the morning and 6 hours later; The dose may be doubled, and even doubled again, if tolerance occurs	Nitro-Bid 2% topical ointment: 30 gram, 60 gram ; 48 x 1 gram unit dose packets
nitroglycerin transdermal (Minitran, Nitro-Dur)	X	Prevention of angina pectoris due to coronary artery disease	Apply 1 patch topically every 24 hours; leave the patch on for 12 to 14 hours, then remove for 10 to 12 hours prior to applying the next patch	Patch: 0.1, 0.2, 0.3, 0.4, 0.6, 0.8 mg/hr

Vasodilators, Coronary- Guidelines

- American College of Physicians/American College of Cardiology Foundation/American Heart Association/American Association for Thoracic Surgery/Preventive Cardiovascular Nurses Association/Society of Thoracic Surgeons, 2012
  - Relief of symptoms in patients with stable IHD
    - β-blockers should be prescribed as initial therapy
    - Calcium-channel blockers or long-acting nitrates should be prescribed when β-blockers are contraindicated or cause unacceptable side effects
    - Calcium-channel blockers or long-acting nitrates, in combination with β-blockers, should be prescribed when initial treatment with β-blockers is unsuccessful
    - The organizations recommend that sublingual nitroglycerin or nitroglycerin spray should be used for immediate relief of angina
  - Sublingual nitroglycerin tablets or translingual spray are drugs of choice to abort acute anginal attacks and prophylactically to prevent angina due to activity.

Drug Classes

- Lipotropics, Other
- Antihypertensives, Sympatholytics
- Sinus Node Inhibitors
- Vasodilators, Coronary

Recommendation

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

Motion

- “I move that the Apple Health Medicaid Program implement the limitations listed on slide 97 for each drug class listed on slide 96 as recommended.”
- Apo B Synthesis inhibitors and PCSK9 inhibitors should be on PA.
- Corlanor should be on PA

Motion: Figueroa

2nd: Brown

Bone Resorption Suppression and Related Agents

Magellan Medicaid Administration

Bone Resorption Suppression and Related Agents- Indications

Drug	Generic	Indication
Bisphosphonates		
alendronate (Binosto)		Treatment and prevention of osteoporosis in postmenopausal women Treatment to increase bone mass in men with osteoporosis
alendronate (Fosamax)	X	Treatment and prevention of osteoporosis in postmenopausal women Treatment to increase bone mass in men with osteoporosis Treatment of glucocorticoid-induced osteoporosis in men and women receiving glucocorticoids in a daily dosage equivalent of 7.5 mg or greater of prednisone and who have low bone mineral density Treatment of Paget's disease of bone in men and women
alendronate/ vitamin D (Fosamax Plus D)		Treatment of osteoporosis in postmenopausal women Treatment to increase bone mass in men with osteoporosis
etidronate (Didronel)	X	Treatment of Paget's disease of bone Prevention and treatment of heterotopic ossification following total hip replacement or spinal cord injury
ibandronate (Boniva)	X	Treatment and prevention of osteoporosis in postmenopausal women
risedronate (Actonel)	X	Treatment and prevention of osteoporosis in postmenopausal women Treatment to increase bone mass in men with osteoporosis Prevention and treatment of glucocorticoid-induced osteoporosis in men and women who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent of 7.5 mg or greater of prednisone for chronic diseases Treatment of Paget's disease of bone in men and women
risedronate delayed-release (Atelvia)	X	Treatment of osteoporosis in postmenopausal women

Bone Resorption Suppression and Related Agents- Indications

Drug	Generic	Indication
Calcitonins		
calcitonin-salmon (Miacalcin)	X	Treatment of postmenopausal osteoporosis in females greater than 5 years postmenopause with low bone mass. It should be reserved for patients who refuse or cannot tolerate estrogens or in whom estrogens are contraindicated
calcitonin-salmon (Fortical)		Treatment of postmenopausal osteoporosis in females greater than 5 years postmenopause with low bone mass
Others		
denosumab (Prolia)		Treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture, or in patients who have failed or are intolerant to other available osteoporosis therapy Treatment of bone loss in men with prostate cancer on androgen deprivation therapy Treatment of bone loss in women undergoing breast cancer therapy with adjuvant aromatase therapy Treatment to increase bone mass in men diagnosed with osteoporosis and a high fracture risk who have failed or are intolerant to other potential therapies
raloxifene (Evista)	X	Treatment and prevention of osteoporosis in postmenopausal women Reduction in risk of invasive breast cancer in postmenopausal women who either have osteoporosis or are at high risk for invasive breast cancer
teriparatide (Forteo)		Treatment of osteoporosis in postmenopausal women who are at high risk for fractures Increase of bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fractures Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture
abaloparatide (Tymlos)		Treatment of osteoporosis in postmenopausal women who are at high risk for fractures

Bone Resorption Suppression and Related Agents- Dosage and Availability

Drug	Treatment of osteoporosis in postmenopausal women	Prevention of osteoporosis in postmenopausal women	Treatment to increase bone mass in men with osteoporosis	Treatment of glucocorticoid-induced osteoporosis	Paget's disease	Availability
Bisphosphonates						
alendronate (Binosto)	70 mg once/ week	---	70 mg once/week	---	---	70 mg effervescent tablets
alendronate (Fosamax)	10 mg/day or 70 mg once/week	5 mg /day or 35 mg once/week	10 mg per day or 70 mg once/week	5 mg/day, For post-menopausal women not receiving estrogen: 10 mg once daily	40 mg per day for 6 months; May retreat if relapse occurs following a 6-month post-treatment evaluation	5, 10, 35, 40, 70 mg tablets; generic only: 70 mg/75 mL oral solution
alendronate/vitamin D (Fosamax Plus D)	70 mg/2,800 IU or 70 mg/5,600 IU weekly	---	70 mg/2,800 IU or 70 mg/5,600 IU weekly	---	---	70 mg/ 2,800 IU, 70 mg/ 5,600 IU tablets
etidronate (Didronel)	---	---	---	---	5-10 mg/kg/day up to 6 months or 11-20 mg/kg/day up to 3 months; May retreat if relapse occurs following a 90 day post-treatment evaluation	200, 400 mg tablets
ibandronate (Boniva)	2.5 mg/day or 150 mg/month	2.5 mg/day or 150 mg/month	---	---	---	2.5 mg tablets (brand only), 150 mg tablets (brand and generic)

Bone Resorption Suppression and Related Agents- Dosage and Availability

Drug	Treatment of osteoporosis in postmenopausal women	Prevention of osteoporosis in postmenopausal women	Treatment to increase bone mass in men with osteoporosis	Treatment of glucocorticoid-induced osteoporosis	Paget's disease	Availability
Bisphosphonates conti						
risedronate (Actonel)	5 mg/day or 35 mg once/week or 75 mg for 2 consecutive days every month or 150 mg once a month	5 mg/day or 35 mg once/week or 75 mg for 2 consecutive days every month or 150 mg once a month	35 mg once/week	5 mg/day	30 mg/day for 2 months May retreat if relapse occurs, after a 2-month post-treatment observation	5, 30, 35, 75, 150 mg tablets
risedronate delayed-release (Atelvia)	35 mg once weekly	---	---	---	---	35 mg delayed-release tablets
Calcitonins						
calcitonin-salmon (Miacalcin)	200 IU intranasally per day, alternating nostrils daily	---	---	---	---	7 mL (30 dose) bottles
calcitonin-salmon (Fortical)	200 IU intranasally per day, alternating nostrils daily	---	---	---	---	3.7 mL (30 dose) bottle

Bone Resorption Suppression and Related Agents- Dosage and Availability

Drug	Treatment of osteoporosis in postmenopausal women	Prevention of osteoporosis in postmenopausal women	Treatment to increase bone mass in men with osteoporosis	Treatment of glucocorticoid-induced osteoporosis	Paget's disease	Availability
Other						
denosumab (Prolia)	60 mg SC every 6 months; administered by a healthcare professional	---	60 mg SC every 6 months; administered by a healthcare professional	---	---	60 mg/ 1 mL single use pre-filled syringe; 60 mg/ 1 mL single use vial
raloxifene (Evista)	60 mg per day	60 mg per day	---	---	---	60 mg tablets
teriparatide (Forteo)	20 mcg SC per day	---	20 mcg SC per day	20 mcg SC per day	---	750 mcg/3 mL prefilled pen
abaloparatide (Tymlos)	80 mcg SC per day	---	---	---	---	3,120 mcg/1.56 mL prefilled pen

Bone Resorption Suppression and Related Agents- Guidelines

- The American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE), 2016
  - Guidelines for the diagnosis and treatment of postmenopausal osteoporosis
    - Patients at high risk of fracture, initial therapy: alendronate, risedronate, zoledronic acid, or denosumab
    - Patients unable to use oral therapy and patients at especially high risk for fracture, initial therapy: teriparatide, denosumab, or zoledronic acid
    - Patients requiring drugs with spine-specific efficacy: raloxifene or ibandronate
- The American College of Physicians (ACP), 2017
  - Guidelines for treatment of low bone density or osteoporosis to prevent fractures in men and women
    - Offer treatment with alendronate, risedronate, zoledronic acid, or denosumab to reduce the risk for hip/vertebral fractures in women with known osteoporosis
    - Recommend osteoporotic women be treated with pharmacologic therapy for 5 years
    - Offer treatment with bisphosphonates to men who have clinically recognized osteoporosis to reduce the risk of vertebral fracture
    - Recommends against using menopausal estrogen therapy +/- progestogen therapy or raloxifene for the treatment of osteoporosis in women
- American College of Rheumatology (ACR), 2017
  - Guidance on managing glucocorticoid-induced osteoporosis in adults and children
    - Patients with moderate to high risk of fracture- oral bisphosphonates are first-line therapy
    - Subsequent treatments are based on individual characteristics- IV bisphosphonates, teriparatide, denosumab, or raloxifene

Thyroid Hormones, Oral

Magellan Medicaid Administration

Thyroid Hormones – Indications

Drug	FDA-Approved Indication(s)
levothyroxine (Levoxyl, Synthroid, Tirosint, Unithroid)	• Replacement or supplemental therapy in congenital or acquired hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis. • As pituitary TSH suppressants, in the treatment or prevention of various types of euthyroid goiters, including thyroid nodules, subacute or chronic lymphocytic thyroiditis (Hashimoto's), multinodular goiter, and in the management of thyroid cancer.
levothyroxine/liothyronine (Thyrolar)	
liothyronine (Cytomel)	
thyroid, porcine (Armour Thyroid, NP Thyroid)	

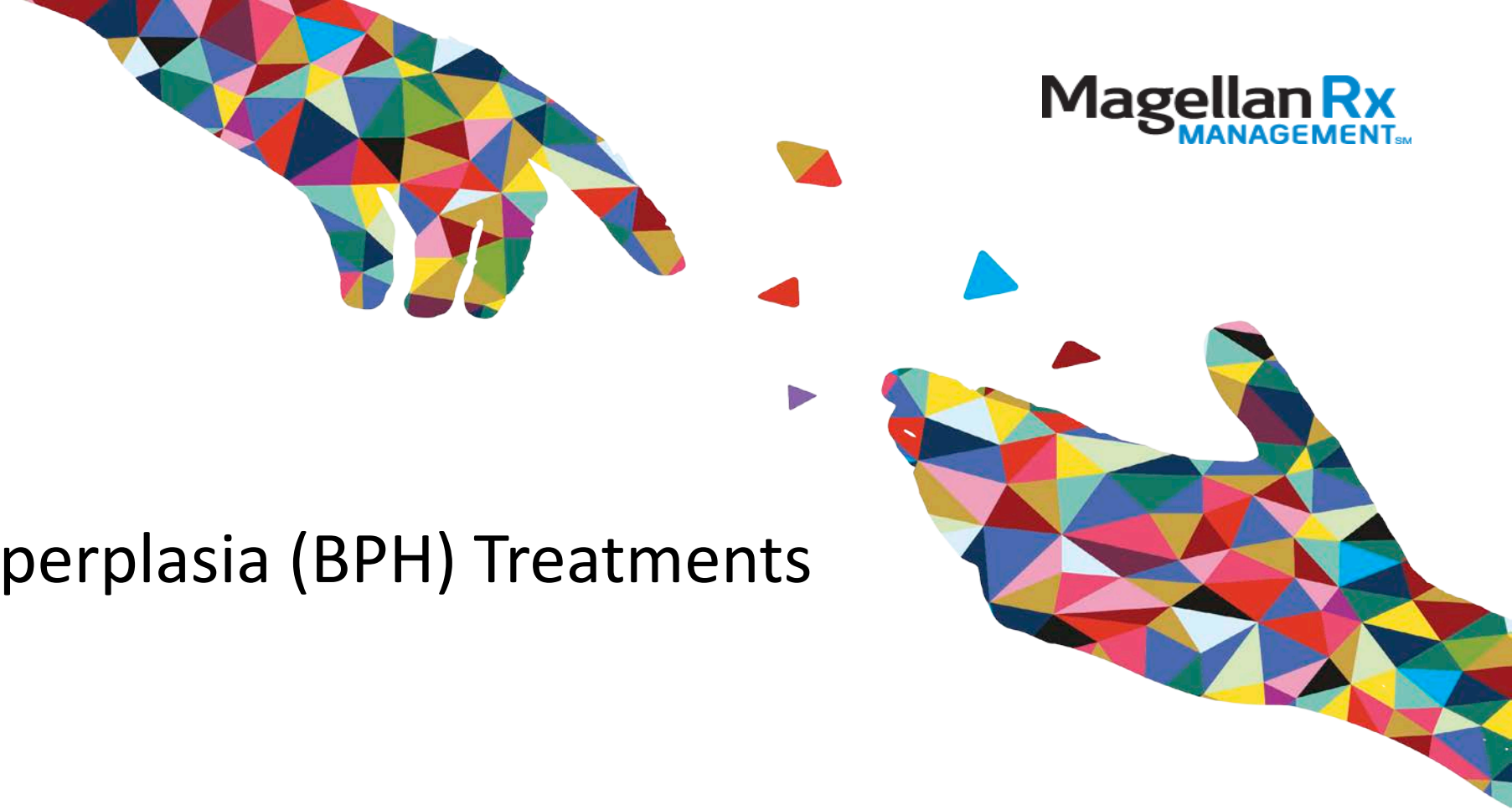
Thyroid Hormone– Dosing and Availability

Drugs	Generic	Dose Range in Adults	Availability
levothyroxine (Levoxyl, Synthroid, Unithroid)	X	12.5-200 mcg daily	Tablets: 25, 50, 75 88, 100, 112, 125, 137, 150, 175, 200, 300 mcg
levothyroxine (Tirosint)		13-200 mcg daily	Capsules: 13, 25, 50, 75, 88, 100, 112, 125, 137, 150 mcg
levothyroxine/liothyronine (Thyrolar)		3.1/12.5 – 37.5/150 mcg daily	Tablets: ¼ (3.1/12.5 mcg), ½ (6.25/25 mcg), 1 (12.5/60 mcg), 2 (25/100 mcg), 3 (37.5/150 mcg)
liothyronine (Cytomel)	X	25-100 mcg daily	Tablets: 5, 25, 50 mcg
thyroid, porcine (Armour Thyroid, NP Thyroid)	X	15-120 mg daily	Tablets: 15, 30, 60, 90, 120 mg Armour Thyroid tablets: above plus 180, 240, 300 mg

Thyroid Hormones – Guidelines

- Hypothyroidism, 2012 American Association of Clinical Endocrinologists (AACE)/ American Thyroid Association (ATA)
  - Recommend levothyroxine monotherapy
  - Evidence does not support combination therapy with levothyroxine and liothyronine; some subpopulations may benefit
  - Expert opinion that desiccated thyroid hormone should not be used for hypothyroidism

- Thyroid Nodules, 2016 AACE/American College of Endocrinology (ACE)
  - Levothyroxine suppressive therapy not recommended for benign nodules
  - Levothyroxine replacement recommended for young patients with subclinical hypothyroidism due to autoimmune thyroiditis
  - Levothyroxine therapy not recommended for preventing recurrence when TSH is normal



Benign Prostatic Hyperplasia (BPH) Treatments

Magellan Medicaid Administration

BPH Treatments- Indications

Drug	Generic	Hypertension	BPH
Alpha-Blockers			
alfuzosin ER (Uroxatral)	X		X
doxazosin (Cardura)	X	X	X
doxazosin ER (Cardura XL)			X
silodosin (Rapaflo)			X
tamsulosin (Flomax)	X		X
terazosin	X	X	X
5-Alpha Reductase (5AR) Inhibitors			
dutasteride (Avodart)	X		• Treatment of symptomatic BPH in men with enlarged prostate to improve symptoms, reduce the risk of acute urinary retention, and reduce the risk of the need for BPH-related surgery • Treatment of symptomatic BPH in combination with the alpha-blocker, tamsulosin, in men with an enlarged prostate • Limitations of use: Not approved for the prevention of prostate cancer
finasteride (Proscar)	X		• Treatment of symptomatic BPH in men with enlarged prostate to improve symptoms, reduce the risk of acute urinary retention, and reduce the risk of the need for BPH-related surgery including transurethral resection of the prostate (TURP) or prostatectomy • Treatment of symptomatic BPH in combination with the alpha-blocker, doxazosin, to reduce the risk of symptomatic progression of BPH • Limitations of use: Not approved for the prevention of prostate cancer

BPH Treatments- Indications

Drug	Generic	Hypertension	BPH
5-Alpha Reductase (5AR) Inhibitors / Alpha-Blocker Combinations			
dutasteride/ tamsulosin (Jalyn)	X		Treatment of symptomatic BPH in men with enlarged prostate Limitations of use: Not approved for the prevention of prostate cancer
Phosphodiesterase 5 (PDE5) Inhibitors			
tadalafil (Cialis)			• Treatment of signs and symptoms of BPH • Note: tadalafil is also indicated for the treatment of erectile dysfunction, with or without BPH • Limitations of use: If tadalafil is used with finasteride to begin BPH treatment, its use is recommended for up to 26 weeks • The incremental benefit of tadalafil decreases from 4 weeks until 26 weeks, and the incremental benefit of tadalafil beyond 26 weeks is unknown

BPH Treatments- Dosage and Availability

Drug	Initial Dose for BPH	Maintenance Dose for BPH	Availability
Alpha-Blockers			
alfuzosin ER (Uroxatral)	10 mg daily	10 mg daily	10 mg extended-release tablets
doxazosin (Cardura)	1 mg daily	1 – 8 mg daily	1 mg, 2 mg, 4 mg, 8 mg tablets
doxazosin ER (Cardura XL)	4 mg daily	4 – 8 mg daily taken with breakfast	4 mg, 8 mg extended-release tablets
silodosin (Rapaflo)	8 mg daily Moderate renal impairment: 4 mg daily	8 mg daily Moderate renal impairment: 4 mg daily	4 mg, 8 mg capsules
tamsulosin (Flomax)	0.4 mg daily	0.4 – 0.8 mg daily	0.4 mg capsules
terazosin	1 mg daily	2 – 20 mg daily	1 mg, 2 mg, 5 mg, 10 mg capsules
5-Alpha Reductase (5AR) Inhibitors			
dutasteride (Avodart)	0.5 mg daily	0.5 mg daily	0.5 mg capsules
finasteride (Proscar)	5 mg daily	5 mg daily	5 mg tablets
5-Alpha Reductase (5AR) Inhibitors / Alpha-Blocker Combinations			
dutasteride/ tamsulosin (Jalyn)	1 capsule daily	1 capsule daily	0.5 mg dutasteride/ 0.4 mg tamsulosin per capsule
Phosphodiesterase 5 (PDE5) Inhibitors			
tadalafil (Cialis)	5 mg daily CrCl 30 – 50 mL/min: 2.5 mg daily	5 mg daily CrCl 30 – 50 mL/min: may increase to 5 mg daily based on individual response	2.5 mg, 5 mg, 10 mg, 20 mg tablets (10 mg and 20 mg strengths are not used in BPH)

BPH Treatments- Guidelines

- No new updates
- American Urological Association (AUA), 2010 and 2014
  - Mild symptoms of BPH (AUA Symptom Score < 8) and patients with moderate or severe symptoms (AUA Symptom Score > 8) who are not bothered by their symptoms → monitor
  - Moderate to severe lower urinary tract symptoms secondary to BPH → Alpha-adrenergic blocker
  - Lower urinary tract symptoms associated with demonstrable prostatic enlargement → 5α-reductase inhibitors are appropriate and effective
  - Lower urinary tract symptoms and definitive prostatic enlargement → α-adrenergic receptor blocker and a 5α-reductase inhibitor combination therapy is appropriate and effective

Contraceptives, Other

Contraceptives, Other- Indications, Dosage, and Availability

Drug	Generic	Indication	Dosage	Availability
Ethinyl Estradiol; Etonogestrel (Nuvaring)		Contraception	Insert 1 NuvaRing on or before day 5 of cycle even if the patient has not finished bleeding. During the first cycle use an additional method of contraception for the first 7 days after insertion of ring. Remove ring after 3 weeks, followed by a one-week rest. Then insert new ring.	Vaginal Insert: ethinyl estradiol 0.015mg/24h, etonogestrel 0.12mg/24h
Ethinyl Estradiol; Norelgestromin (Xulane)		Contraception	Apply 1 patch to the skin. The patch is removed and reapplied once weekly (every 7 days) for 3 weeks, followed by a patch-free period of 1 week before resuming the dosage cycle	Transdermal patch: norelgestromin 0.15mg/24h, ethinyl estradiol 0.035mg/24h
Etonogestrel (Nexplanon)		Contraception	Insert 1 etonogestrel implant (68 mg) subdermally at the inner side of the non-dominant upper arm as per device instructions every 3 years	Implant 68 mg
Intrauterine Copper Contraceptive (Paragard)		Contraception	May be placed at any time during the cycle when the clinician is reasonably certain the patient is not pregnant ; remove on or before 10 years from the date of insertion	Sterile unit
Levonorgestrel (Kyleena, Liletta, Mirena, Skyla)		Contraception; Treatment of menorrhagia (Mirena)	Contraception: insert 1 IUD into the uterus as per device instructions every 3 (Skyla), 4 (Liletta), or 5 years (Mirena, Kyleena)	Vaginal insert: 19.5mg/1U (Kyleena); 52mg/1U (Liletta, Mirena); 13.5mg/1U (Skyla)
Medroxyprogesterone (Depo-Provera)	X (150mg/ mL)	Contraception; Treatment of endometriosis-associated pain	Contraception: IM: 150 mg every 3 months; SQ: 104 mg into the anterior thigh or abdomen every 3 months Endometriosis-associated pain: SQ: 104 mg every 3 months	Depo-Provera/generic: 150 mg/mL Depo-subQ Provera: 104mg/0.65mL

Contraceptives, Other- Guidelines

- **U.S. Selected Practice Recommendations for Contraceptive Use, 2016**
  - Most women can start most contraceptive methods at any time
  - Intrauterine Contraception: <1 woman out of 100 becomes pregnant in the first year
  - Implants: <1 woman out of 100 becomes pregnant in the first year
  - Injectables: ~6 out of 100 women will become pregnant in the first year
  - Combined Hormonal Contraceptives: ~9 out of 100 women become pregnant in the first year

- **U.S. Medical Eligibility Criteria for Contraceptive Use, 2016**
  - Safety, effectiveness, availability, and acceptability should be assessed
  - Uses eligibility categories when assessing the safety of contraceptive method, 1-4
  - The effectiveness of contraceptive methods depends both on inherent effectiveness of the method and on consistent and correct use
  - IUDs and implants are long-acting, reversible contraception (LARC) and are highly effective
  - LARC methods are appropriate for most women, including adolescents and nulliparous women

H.Pylori Treatment

Magellan Medicaid Administration

H. Pylori Treatment- Indications

Drug	Generic	Indication
bismuth subsalicylate, metronidazole, tetracycline (Helidac)		Components are indicated in combination with a histamine type 2-receptor (H2) antagonist for the treatment of patients with *Helicobacter pylori (H. pylori)* infection and duodenal ulcer disease to eradicate *H. pylori*
omeprazole, amoxicillin, clarithromycin (Omeclamox-Pak)		Components are indicated for the treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or up to 1-year history) to eradicate *H. pylori*
lansoprazole, amoxicillin, clarithromycin (Prevpac)	X	Components are indicated for the treatment of patients with *H. pylori* infection and duodenal ulcer disease to eradicate *H. pylori*
bismuth subcitrate potassium, metronidazole, tetracycline (Pylera)		Components are indicated in combination with omeprazole for the treatment of patients with *H. pylori* infection and duodenal ulcer disease to eradicate *H. pylori*; omeprazole should be taken with the breakfast dose and dinner dose of Pylera

H. Pylori Treatment-Dosage and Availability

Drug	Dosage	Additional Medications Required	Duration (days)	Availability
Helidac	metronidazole 250 mg + tetracycline 500 mg + bismuth subsalicylate 525 mg, each given 4 times a day	H2 receptor antagonist	14	14 blister cards, each containing: • 8 bismuth subsalicylate 262.4 mg chewable tablets • 4 metronidazole 250 mg tablets • 4 tetracycline 500 mg capsules
Omeclamox-Pak	omeprazole 20 mg + amoxicillin 1 gm + clarithromycin 500 mg, each given twice a day	omeprazole 20 mg once daily for 18 days if active ulcer is present	10	Individual daily administration pack containing: • 2 omeprazole 20 mg capsules • 4 amoxicillin 500 mg capsules • 2 clarithromycin 500 mg tablets
Prevpac	lansoprazole 30 mg + amoxicillin 1 gm + clarithromycin 500 mg, each given twice a day	---	10 or 14	Individual daily administration pack containing: • 2 lansoprazole 30 mg capsules • 4 amoxicillin 500 mg capsules • 2 clarithromycin 500 mg tablets
Pylera	Each capsule contains: bismuth subcitrate potassium 140 mg + metronidazole 125 mg + tetracycline HCl 125 mg; 3 capsules given 4 times a day	omeprazole 20 mg twice a day	10	The daily dosing pack (10-day therapy pack) is designed to hold: • Twelve 3-in-1 capsules of Pylera each containing: 140 mg bismuth subcitrate potassium, 125 mg metronidazole in outer capsule and 125 mg tetracycline HCl in inner capsule • 2 omeprazole 20 mg capsules

H. Pylori Treatment-Dosage and Availability

Drug	Dosage	Additional Medications Required	Duration (days)	Availability
esomeprazole (Nexium)	esomeprazole magnesium 40 mg daily	clarithromycin 500 mg + amoxicillin 1,000 mg, each given twice a day	10	esomeprazole magnesium: 20 mg, 40 mg delayed-release capsules 2.5 mg, 5 mg, 10 mg, 20 mg, 40 mg delayed-release powder for oral suspension esomeprazole strontium: 24.65 mg and 49.3 mg delayed-release capsules of esomeprazole strontium (equivalent to 20 mg and 40 mg of esomeprazole, respectively)
lansoprazole (Prevacid)	lansoprazole 30 mg twice a day	clarithromycin 500 mg + amoxicillin 1,000 mg, each given twice a day	10 to 14	15 mg, 30 mg delayed-release capsules 15 mg, 30 mg delayed-release orally disintegrating tablets
	lansoprazole 30 mg 3 times a day	amoxicillin 1,000 mg 3 times a day	14	
omeprazole (Prilosec)	omeprazole 20 mg twice a day	clarithromycin 500 mg + amoxicillin 1,000 mg, each given twice a day	10 (14 days recommended by ACG)	10 mg, 20 mg, 40 mg delayed-release capsules 2.5 mg, 10 mg packets for oral suspension Continue with omeprazole 20 mg daily for 14 days in patients with active ulcer
	omeprazole 40 mg daily	clarithromycin 500 mg 3 times a day	14	
rabeprazole (Aciphex)	rabeprazole 20 mg twice a day	clarithromycin 500 mg + amoxicillin 1,000 mg, each given twice a day	7	20 mg delayed-release tablets

H. Pylori Treatment-Guidelines

- American College of Gastroenterology (ACG) guidelines, 2017
  - Patients with a positive test of active infection with *H. pylori* should be offered treatment
  - Therapy with a PPI, clarithromycin, amoxicillin, and a nitroimidazole or sequential therapy with a PPI and amoxicillin followed by a PPI, clarithromycin, and a nitroimidazole are also recommended as first-line treatment options
  - A PPI and amoxicillin followed by a PPI, amoxicillin, clarithromycin, and a nitroimidazole is also a first-line recommendation
  - Fluoroquinolone as a component of the treatment regimen is recommended as first-line treatment option using 1 of the following 2 regimens
    - levofloxacin, PPI, and amoxicillin
    - PPI and amoxicillin followed by a PPI, fluoroquinolone, and nitroimidazole
  - Testing to confirm eradication should be performed

Phosphate Binders

Magellan Medicaid Administration

Phosphate Binders- Indications

Drug	Generic	Reduce Serum Phosphorus in Adults with ESRD	Control Serum Phosphorus Levels in Adults with CKD on Dialysis	Iron Deficiency Anemia in Adults with CKD Not on Dialysis
calcium acetate (Eliphos)	X	X		
calcium acetate	X	X		
calcium acetate (Phoslyra)		X		
ferric citrate (Auryxia)			X	X
lanthanum carbonate (Fosrenol)	X	X		
sevelamer carbonate (Renvela)	X		X (≥ 6 years old)	
sevelamer hydrochloride (Renagel)			X	
sucroferric oxyhydroxide (Velphoro)			X	

Phosphate Binders- Dosage and Availability

Drug	Initial Dosing	Maintenance Dosing	Availability
calcium acetate (Eliphos)	1,334 mg with each meal	2,001 mg to 2,668 mg with each meal	667 mg tablet
calcium acetate	1,334 mg with each meal	2,001 mg to 2,668 mg with each meal; dose may be titrated every 2 to 3 weeks	667 mg gelcap (capsule)
calcium acetate (Phoslyra)	10 mL with each meal	15 mL to 20 mL with each meal; dose may be titrated every 2 to 3 weeks	667 mg per 5 mL solution
ferric citrate (Auryxia)	Hyperphosphatemia: 2 tablets orally 3 times per day with meals Iron deficiency anemia: 1 tablet orally 3 times per day with meals	Hyperphosphatemia: 8 to 9 tablets per day, up to a maximum of 12 tablets daily; dose may be increased or decreased by 1 to 2 tablets daily over 1 week or longer intervals Iron deficiency anemia: Adjust dose as needed to maintain hemoglobin goal; maximum of 12 tablets per day	210 mg ferric iron (equivalent to 1 g ferric citrate) tablet
lanthanum carbonate (Fosrenol)	1,500 mg in divided doses daily given with or immediately after meals	1,500 mg to 3,000 mg in divided doses daily given with or immediately after meals; doses can be titrated in increments of 750 mg daily every 2 to 3 weeks; doses up to 4,500 mg were evaluated	500 mg, 750 mg, and 1,000 mg chewable tablets 750 mg, 1,000 mg oral powder (brand only) Tablets should be chewed completely; do not swallow intact tablet; Oral powder should be sprinkled in applesauce or other similar food and taken immediately; do not attempt to dissolve in liquid

Phosphate Binders- Dosage and Availability

Drug	Initial Dosing	Maintenance Dosing	Availability
sevelamer carbonate (Renvela)	Adults: 800 to 1,600 mg 3 times daily with each meal based on serum phosphorus level Pediatrics ≥ 6 years: 800 mg to 1,600 mg 3 times daily with each meal based on body surface area (BSA)	Adults: 1,600 mg to 2,400 mg 3 times daily with each meal; titrate dose by 800 mg 3 times per day with meals at 2-week intervals; the maximum daily dose is 14 grams Pediatrics ≥ 6 years: titrate dose by 400 mg to 800 mg (increment based on BSA) 3 times per day with meals at 2-week intervals	800 mg tablets 800 mg, 2,400 mg powder packets Powder does not dissolve in water and requires vigorous stirring prior to drinking and should be consumed within 30 minute, resuspend right before drinking
sevelamer hydrochloride (Renagel)	800 mg to 1,600 mg 3 times daily with each meal based on serum phosphorus level	800 mg to 1,600 mg with each meal; dose may be increased or decreased by 1 tablet per meal at 2-week intervals based on serum phosphorus levels; the maximum daily dose is 13 grams	400 mg, 800 mg tablets
sucroferric oxyhydroxide (Velphoro)	500 mg 3 times daily with meals (1,500 mg daily)	1,500 mg to 3,000 mg daily; titrate dose by 500 mg per day with meals at 1-week intervals	500 mg chewable tablet Tablets must be administered with meals and chewed completely and not swallowed whole; the tablets may be crushed to aid with chewing and swallowing

Phosphate Binders- Guidelines

- National Kidney Foundation, 2017
  - Treatment of hyperphosphatemia includes the reduction of dietary phosphorus, phosphate binding therapy, and removal of phosphorus by dialysis
  - Recommend basing decisions on phosphate-lowering treatment on progressively or persistently elevated serum phosphate rather than to prevent hyperphosphatemia
  - Recommend restricting the dose of calcium-based phosphate binders adults with CKD stages 3a through 5D
  - Choice of phosphate-lowering therapy should be based on serum calcium levels in children with CKD stages 3a through 5D
- The Kidney Disease: Improving Global Outcomes (KDIGO) foundation, 2012 & 2014
  - Recommend patients with CKD stages 3 to 5/5D use phosphate-binding agents for the treatment of hyperphosphatemia
  - All phosphate lowering medications are effective in lowering serum phosphorus levels
  - Restrict dose of calcium-based phosphate binders in the presence of persistent/recurrent hypercalcemia, arterial calcification, adynamic bone disease, and serum PTH levels
  - Recommend avoiding the long-term use of aluminum containing phosphate binders
  - Guidelines do not endorse the use or superiority of 1 phosphate binder medication over another

Methotrexate

Magellan Medicaid Administration

Methotrexate– Indications, Dosage, Availability

Drug	Generic	Indications	Dosage	Availability
methotrexate (Otrexup)		• Patients with severe, active rheumatoid arthritis (RA) and polyarticular juvenile idiopathic arthritis (pJIA), who are intolerant of or had an inadequate response to first-line therapy; • Symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy ***Limitation of Use*:** Not indicated for the treatment of neoplastic diseases	Adjust dose gradually to achieve an optimal response following initial dosing: • **RA:** 7.5 mg SC once weekly; • **pJIA:** 10 mg/m^2 SC once weekly; • **Psoriasis:** 10 to 25 mg SC once weekly Injections should be administered to the abdomen or thigh; Doses < 7.5 mg/week or > 25 mg/week or dose adjustments <5 mg should be administered using alternative therapy (e.g., oral therapy); Administer in the abdomen or thigh; May be self-administered	Solution for injection within an auto-injector: 7.5 mg/0.4 mL, 10 mg/0.4 mL, 12.5 mg/0.4 mL, 15 mg/0.4 mL, 17.5 mg/0.4 mL, 20 mg/0.4 mL, 22.5 mg/0.4 mL, and 25 mg/0.4 mL
methotrexate (Rasuvo)		• Patients with severe active RA and pJIA, who are intolerant of or had an inadequate response to first-line therapy; • Symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy ***Limitation of Use*:** Not indicated for the treatment of neoplastic diseases	Adjust dose gradually to achieve an optimal response following initial dosing: • **RA:** 7.5 mg SC once weekly; • **pJIA:** 10 mg/m^2 SC once weekly; • **Psoriasis:** 10 to 25 mg SC once weekly Injections should be administered to the abdomen or thigh; Doses < 7.5 mg/week or > 30 mg/week or dose adjustments <2.5 mg should be administered using alternative therapy (e.g., oral therapy); Administer in the abdomen or thigh; May be self-administered	Solution for injection within an auto-injector: 7.5 mg/0.15 mL, 10 mg/0.2 mL, 12.5 mg/0.25 mL, 15 mg/0.3 mL, 17.5 mg/0.35 mL, 20 mg/0.4 mL, 22.5 mg/0.45 mL, 25 mg/0.5 mL, 27.5 mg/0.55 mL, 30 mg/0.6 mL

Methotrexate– Indications, Dosage, Availability

Drug	Generic	Indications	Dosage	Availability
methotrexate (Xatmep)		• Pediatric patients with acute lymphoblastic leukemia (ALL) as part of a multi-phase, combination chemotherapy maintenance regimen • Pediatric patients with active pJIA who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs)	• **ALL:** initial dose is 20 mg/m^2 given once weekly; base continued dosing on periodic monitoring of absolute neutrophil count (ANC) and platelet count to assure sufficient drug exposure and to adjust for excessive hematological toxicity • **pJIA:** starting dose of 10 mg/m^2 given once weekly; dosages should be tailored to the individual patient and adjusted gradually to achieve an optimal response Methotrexate oral solution should be measured in an accurate measuring device; do not use household teaspoons.	Oral solution: 2.5 mg/mL
methotrexate sodium (Trexall)	X	• Symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy; • Severe, active RA and pJIA, who are intolerant of or had an inadequate response to first-line therapy, including full dose nonsteroidal anti-inflammatory drugs (NSAIDs); • Neoplastic conditions: ALL, disorders of meninges related to leukemia, breast cancer, gestational trophoblastic neoplasia, head and neck cancer, lung cancer, mycosis fungoides, advanced non-Hodgkin's lymphoma, and osteosarcoma	• **Psoriasis:** 10 to 25 mg orally, IM, or IV once weekly; alternative dosing includes 2.5 mg orally every 12 hours for 3 doses once weekly • **RA:** 7.5 mg orally once weekly, adjusted to effect; alternative dosing includes 2.5 mg every 12 hours for 3 doses once weekly • **pJIA:** 10 mg/m^2 orally or IM once weekly, adjusted to effect • Neoplastic conditions: dosage in neoplastic conditions depends on indication, route (IV, intrathecal, intraarterial, IM, SC, or oral), concomitant medications, and regimen; IV, intrathecal, intraarterial, and IM routes are administered by a healthcare professional; Although methotrexate can be self-administered SC, it is not FDA approved for this route of administration and requires patient ability to draw solution from a vial into a syringe and administer correctly	Powder for injection: 1 g; Solution for injection: 50 mg/2 mL, 100 mg/4 mL, 200 mg/8 mL, 250 mg/10 mL, 1 g/40 mL; Oral tablet: 2.5 mg; Trexall oral tablets: 5 mg, 7.5 mg, 10 mg, 15 mg

Methotrexate– Guidelines

- No new updates
- Psoriasis, 2009 American Academy of Dermatology
  - Systemic therapy is usually reserved for patients with moderate to severe disease or those with psoriatic arthritis
  - Methotrexate has been used for treatment of psoriasis with good to excellent results
- Rheumatoid arthritis, 2015 America College of Rheumatology
  - Early rheumatoid arthritis
    - Recommend DMARD monotherapy over double or triple DMARD therapy in patients with low disease activity
    - Conditionally recommend DMARD monotherapy over double or triple DMARD therapy in patients with moderate or high disease activity
    - Methotrexate is the preferred agent of choice for most patients
  - Established rheumatoid arthritis
    - Recommend using DMARD monotherapy over a TNFi for DMARD-naïve patients with low disease activity
    - Conditionally recommend DMARD monotherapy over double or triple DMARD therapy and DMARD monotherapy over Xeljanz for DMARD-naïve patients with moderate or high disease activity
    - Methotrexate should be the preferred initial therapy for most patients
- Juvenile idiopathic arthritis, 2013 America College of Rheumatology
  - Recommend NSAID monotherapy or intra-articular glucocorticoid injections in patients with an AJC ≤ 4
  - Recommends methotrexate, leflunomide, or NSAID monotherapy in patients without active systemic features with an active joint count (AJC) > 4

Drug Classes

- Bone Resorption Suppression and Related Agents
- Thyroid Hormones
- BPH Treatments
- Contraceptives, Other
- H. Pylori Treatment
- Phosphate Binders
- Methotrexate

Recommendation

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

Motion

- “I move that the Apple Health Medicaid Program implement the limitations listed on slide 133 for each drug class listed on slide 132 as recommended.
- Armour Thyroid should be non-preferred
- Cialis and Silodosin should be on PA

Motion: Flatebo

2nd: Brown