



# AHCCS Pharmacy and Therapeutics Committee

November 17, 2015



# Magellan Class Reviews

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Epinephrine, Self-injected  
Cytokine and CAM Antagonists  
Growth Hormone  
Antibiotics, Inhaled  
New Hepatitis C Medications

# Epinephrine, Self-injected



# Epinephrine, Self-injected

## *Class Overview*

- Product Indications:
  - Emergency treatment of Type I allergic reactions (e.g. anaphylaxis to insect bites, foods, drugs)
  - Emergency treatment of idiopathic anaphylaxis
  - Emergency treatment of exercise-induced anaphylaxis
- Epinephrine is injected IM or SC in the anterolateral aspect of the thigh, through clothing if necessary
- All products are available with two devices included, as 0.15 mg/0.15 mL or 0.3 mg/0.3 mL
- Auvi-Q has audio instructions while others have only visual
  - Recently recalled due to inaccurate dosage delivery

# Epinephrine, Self-injected

## *PDL Recommendations:*

- Epipen
- Epipen Jr.
- Epinephrine (generic Adrenaclick)

# Cytokine and CAM Antagonists



# Cytokine and CAM Antagonists

## *Class Overview*

- Cytokines and cell-adhesion molecules (CAMs) are chemical mediators involved in inflammatory processes throughout the body
- Product indications: Rheumatoid Arthritis, Ulcerative Colitis, Crohn's Disease, Juvenile Idiopathic Arthritis, Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Cryopyrin-Associated Periodic Syndromes, Hidradenitis Suppurativa
- Products are administered orally (Otezla, Xeljanz), subcutaneously or intravenously

# Cytokine and CAM Antagonists

## *New Product in Class: Cosentyx (secukinumab)*

- Indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
- Warnings include serious infections in patients with chronic infection or history of recurrent infection, tuberculosis, and exacerbations of Crohn's disease.
- Live vaccines should not be administered with Cosentyx.
- Nasopharyngitis, diarrhea, and upper respiratory tract infection are the most common adverse effects.
- It is in pregnancy category B.

# Cytokine and CAM Antagonists

## *New Product in Class: Cosentyx (secukinumab)*

- Cosentyx is given as two 150 mg subcutaneous injections at weeks 0, 1, 2, 3, and 4 and then every four weeks.
- It is available as a 150 mg/mL solution for injection and a reconstitutable vial.
- The CLEAR study was a manufacturer-funded 52-week comparison of Cosentyx and Stelara in patients with plaque psoriasis. Cosentyx treatment resulted in a statistically significant improvement in PASI 90 response compared to Stelara treatment at week 16.
- FIXTURE studied Cosentyx vs. placebo and Enbrel in plaque psoriasis. Cosentyx was found to be superior to Enbrel as a secondary endpoint in this manufacturer-sponsored, active-control study.

# Cytokine and CAM Antagonists

## *Product Updates:*

- Enbrel prescribing information for psoriatic arthritis has been changed to allow use with or without methotrexate (previously approved for use in combination with methotrexate). (March 2015)
- Humira is now indicated for moderate-to-severe hidradenitis suppurativa. (September 2015)

# Cytokine and CAM Antagonists

## *PDL Recommendations:*

- Enbrel
- Humira

# Growth Hormone



# Growth Hormone

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## *Class Overview*

- Human growth hormone (hGH, somatropin) is secreted by the anterior pituitary gland
- Exogenous growth hormone is used to treat a variety of disorders in which endogenous growth hormone is insufficient to meet the needs of the patient
- The 2009 American Association of Clinical Endocrinologists Guidelines for Clinical Practice indicates that no evidence exists to support any specific growth hormone product over another
- Most growth hormone products are given six or seven times weekly. Saizen and Zomacton can be given to pediatric patients as few as three times per week, as can Nutropin when treating Turner syndrome

# Growth Hormone

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## *Class Overview*

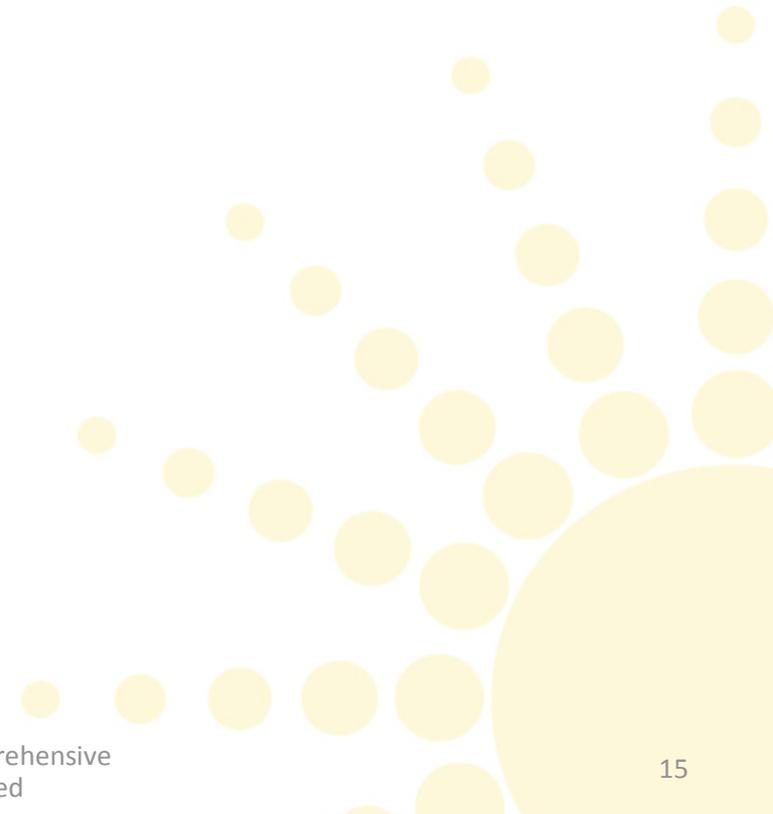
- Product Indications:
  - Growth hormone deficiency (pediatric and adult)
  - Idiopathic short stature
  - Short stature homeobox gene
  - Short bowel syndrome
  - HIV wasting or cachexia
  - Prader-Willi Syndrome
  - Chronic renal insufficiency
  - Small for gestational age
  - Noonan Syndrome

# Growth Hormone

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## *Product Updates*

- Zomacton is the new brand name for Tev-Tropin (April 2015)

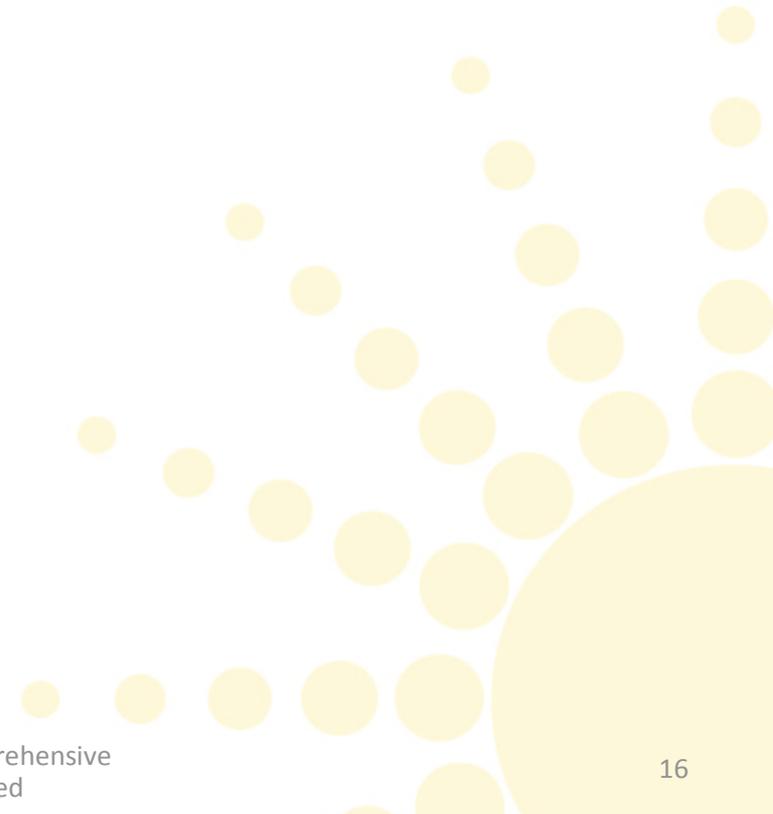


# Growth Hormone

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## *PDL Recommendations:*

- Nutropin
- Norditropin
- Genotropin



# Antibiotics, Inhaled



# Antibiotics, Inhaled

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## *Class Overview:*

- Cystic Fibrosis (CF) is the most common lethal genetic disease among Caucasians, affecting approximately 30,000 individuals residing in the United States
- The typical manifestation of CF involves progressive obstructive lung disease that has been associated with impaired mucous clearance, difficulty clearing pathogens, and risk of chronic pulmonary infection and inflammation. As a result, respiratory failure is the common cause of death in patients with CF with the median expected survival age of 36 years.
- Aztreonam or tobramycin are taken chronically to suppress the growth of *P. aeruginosa* and reduce the risk of CF exacerbation.

# Antibiotics, Inhaled

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## *Class Overview:*

- Products are administered via a nebulizer system or Podhaler device via the TOBI Podhaler (uses dry powder)
- The 2013 CF Pulmonary Guidelines, recommend inhaled tobramycin (Bethkis, Kitabis Pak, TOBI, TOBI Podhaler) and inhaled aztreonam (Cayston) at the same rating to reduce exacerbation for patients who are 6 years of age and older with persistent *P. aeruginosa* culture in the airways.

# Antibiotics, Inhaled

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## *New Product: Kitabis (tobramycin)*

- Indicated for the management of cystic fibrosis patients six years and older with *P. aeruginosa*
- Contraindications, warnings, adverse effects, and drug interactions are similar to those for other tobramycin products
- It is administered as 300 mg twice daily via nebulizer over a 15-minute period in alternating periods of 28 days on drug, followed by 28 days off drug

# Antibiotics, Inhaled

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## *New Product: Kitabis (tobramycin)*

- Kitabis Pak is a co-packaging of tobramycin inhalation solution (a 28-day supply of 56 Single-Use Ampules (300 mg /5 mL)) and a PARI LC PLUS® Reusable Nebulizer
- Kitabis is the only tobramycin inhalation solution available which is also co-packaged with a nebulizer

# Antibiotics, Inhaled

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## *PDL Recommendations:*

- Kitabis Pak
- Bethkis

# Hepatitis C (New Agents)



# Hepatitis C (New Agents)

- **DAKLINZA (daclatasvir)**: Approved genotype: 3 (with Sovaldi)
- **HARVONI (ledipasvir/sofosbuvir)**: Approved genotype: 1 (PDUFA date November for genotype 4, 6)
- **OLYSIO (simeprevir)**: Approved genotype: 1, 4 (with peginterferon and ribavirin, or with Sovaldi)
- **SOVALDI (sofosbuvir)**: Approved genotype: 1,2,3,4 (with ribavirin alone or peginterferon and ribavirin)
- **TECHNIVIE (ombitasvir, paritaprevir, ritonavir)**: Approved genotype: 4 without cirrhosis (with ribavirin)
- **VIEKIRA PAK (dasabuvir, ombitasvir, paritaprevir, ritonavir)**: Approved genotype: 1 (with ribavirin for genotype 1a and 1b (with cirrhosis))

# Hepatitis C (New Agents)

## *Harvoni (ledipasvir/sofosbuvir)*

- Indicated for treatment of chronic hepatitis C infection (genotype 1) in adults (PDUFA date November for genotype 4, 6)
- There are no contraindications
- Warnings include concurrent administration of amiodarone (causing bradycardia) and use with other sofosbuvir-containing products
- Fatigue and headache are the most common adverse effects
- It is in pregnancy category B
- It is available in 90 mg/400 mg tablets
- It is taken once daily

# Hepatitis C (New Agents)

## *Viekira Pak (ombitasvir, paritaprevir, ritonavir, dasabuvir)*

- Indicated with or without ribavirin for treatment of chronic hepatitis C infection (genotype 1) in adults, including those with compensated cirrhosis
- Contraindications include moderate to severe hepatic impairment (Child-Pugh B and C) and co-administration with drugs highly dependent on CYP3A for clearance, strong inducers of CYP3A and CYP2C8, and strong inhibitors of CYP2C8, and known hypersensitivity to ritonavir

# Hepatitis C (New Agents)

*Viekira Pak (ombitasvir, paritaprevir, ritonavir, dasabuvir)*

- Warnings include ALT elevations (perform hepatic laboratory testing on all patients during the first 4 weeks of treatment)
- New warning: *Hepatic decompensation and hepatic failure, including liver transplantation or fatal outcomes, have been reported mostly in patients with advanced cirrhosis. Monitor for clinical signs and symptoms of hepatic decompensation.*
- *Testing Prior to Initiation - Assess for laboratory and clinical evidence of hepatic decompensation.*
- Fatigue, nausea, pruritus, and insomnia are the most common adverse effects
- It is in pregnancy category B

# Hepatitis C (New Agents)

## *Viekira Pak (ombitasvir, paritaprevir, ritonavir, dasabuvir)*

- Viekira Pak is composed of two tablets, ombitasvir 12.5 mg, paritaprevir 75 mg, ritonavir 50 mg combination tablets and dasabuvir 250 mg tablets
- The combination tablet is given once daily with a meal and the dasabuvir tablets twice daily with a meal
- Viekira Pak must be administered with weight-based ribavirin when treating genotype 1a, genotype 1b if patient is cirrhotic, and treatment experienced patients (failure of PEG/RBV)
- If given with ribavirin, all contraindications, warnings, adverse events, and drug interactions for ribavirin should be considered

# Hepatitis C (New Agents)

## *New Product: Daklinza (daclatasvir)*

- Indicated for the treatment of chronic hepatitis C genotype 3 infection in combination with Sovaldi
  - Limitation: SVR rates are reduced in patients with cirrhosis
- Contraindicated with concurrent use of strong CYP3A inducers (dose should be reduced with strong CYP3A inhibitors and increased with moderate CYP3A inducers)
- Warnings include bradycardia when co-administered with Sovaldi and amiodarone
- Headache and fatigue are the most common adverse effects.

# Hepatitis C (New Agents)

## *New Product: Daklinza (daclatasvir)*

- There are no data in pregnant women to inform a drug-associated risk.
- Daklinza is given once daily in combination with Sovaldi for 12 weeks.
- It is available in 30 and 60 mg tablets.

# Hepatitis C (New Agents)

*New Product: Technivie (ombitasvir, paritaprevir, ritonavir)*

- Is indicated for the treatment of chronic hepatitis C genotype 4 infection without cirrhosis in combination with ribavirin.
- Contraindications include moderate to severe hepatic impairment (Child-Pugh B and C) and co-administration with drugs highly dependent on CYP3A for clearance or moderate or strong inducers of CYP3A.
- Warnings include ALT elevations and risks associated with ribavirin therapy
- New warning: *Hepatic decompensation and hepatic failure, including liver transplantation or fatal outcomes, have been reported mostly in patients with advanced cirrhosis. Discontinue treatment in patients who develop evidence of hepatic decompensation.*

# Hepatitis C (New Agents)

*New Product: Technivie (ombitasvir, paritaprevir, ritonavir)*

- *Testing Prior to Initiation: Assess baseline hepatic laboratory and clinical parameters*
- Asthenia, fatigue, nausea, and insomnia are the most common adverse effects.
- It is in pregnancy category B.
- It is available as ombitasvir 12.5 mg, paritaprevir 75 mg, and ritonavir 50 mg combination tablets.
- Given as two tablets once daily in the morning with a meal in combination with weight-based ribavirin for 12 weeks.
- Omitting the ribavirin component may be considered for treatment-naïve patients who cannot take or tolerate it.

# Hepatitis C (New Agents)

## AASLD/IDSA Guidelines Recommendations\*

### Genotype 1a

- Harvoni for 8/12 weeks (12 weeks with cirrhosis)
- Viekira + ribavirin for 12 weeks (24 weeks with cirrhosis)
- Sovaldi + Olysio + ribavirin for 12 weeks (24 weeks with cirrhosis)
- Daklinza + Sovaldi for 12 weeks (24 weeks with or without ribavirin with cirrhosis)

\*Treatment Naïve, August 2015

# Hepatitis C (New Agents)

## AASLD/IDSA Guidelines Recommendations\*

### Genotype 1b

- Harvoni for 8/12 weeks (12 weeks with cirrhosis)
- Viekira for 12 weeks (with ribavirin with cirrhosis)
- Sovaldi + Olysio for 12 weeks (24 weeks with cirrhosis)
- Daklinza + Sovaldi for 12 weeks (24 weeks with or without ribavirin with cirrhosis)

### Genotype 2

- Sovaldi + ribavirin for 12 weeks
- Daklinza + Sovaldi for 12 weeks

\*Treatment Naïve, August 2015

# Hepatitis C (New Agents)

## AASLD/IDSA Guidelines Recommendations\*

### Genotype 3

- Sovaldi + ribavirin for 24 weeks
- Sovaldi + ribavirin + peginterferon for 12 weeks
- Daklinza + Sovaldi for 12 weeks (optimal duration for patients with cirrhosis not established)

### Genotype 4

- Harvoni for 12 weeks
- Viekira + ribavirin for 12 weeks
- Sovaldi + ribavirin for 12 weeks
- Technivie + ribavirin for 12 weeks

\*Treatment Naive, August 2015

Thank You.

