New Parenteral Drugs and Biologics 2010

Thursday, April 7
12:30 to 2:15 p.m.
Hilton Orlando—Orange Ballroom D
New Parenteral Drugs and Biologics 2010

Thursday, April 7, 12:30 to 2:15 p.m.
07-S. New Parenteral Drugs and Biologics 2010
Hilton Orlando – Orange Ballroom D
Pharmacist, Pharmacy Technician and Nurse Continuing Education Contact Hours: 1.5
ACPE Pharmacist and Pharmacy Technician Program #: 207-999-11-241-L01-P&T
Knowledge-Based Learning Activity

Education Overview:
Since January of 2010, the U.S Food and Drug Administration (FDA) has approved a number of new pharmacological entities to treat acute and chronic conditions. This popular session, returning for its 9th consecutive year, is the most highly attended session at the conference. Designed for all members of the home, ambulatory care, and specialty pharmacy team, content will include a review of all new parenteral and specialty drugs approved in 2010, addressing the following for each drug:

- Role of the drug in disease management
- Clinical application in the alternate care setting
- Reimbursement considerations including cost, recognition by private and government payers, and alternative treatment options

Clinicians attending this session will gain insight into the application of each new drug, including administration and patient clinical monitoring considerations. Reimbursement specialists will gain valuable insight regarding cost and third-party payer coverage considerations for the new agents. Sales professionals will gain an understanding of the role each new drug plays in disease management, including its position in the larger treatment landscape for specific medical conditions. All attendees will benefit from a brief overview of FDA approval trends and select pipeline drugs that can influence the field of alternate-site infusion in 2011 and beyond. The New Parenteral Drugs and Biologics 2010 Program will effectively update every member of the team, providing the foundation needed to develop and service new referrals.

Faculty: Anna Nowobilski-Vasilios, PharmD, MBA, FASHP, CNSC, BCNSP, Principal, Anovation Inc., Chicago, IL

Anna Nowobilski-Vasilios is the Principal at Anovation, Inc., an Adjunct Assistant Professor of Pharmacy Practice at Midwestern University, and a Surveyor for the Accreditation Council for Health Care (ACHC). She has held various management and clinical positions at Option Care, Inc., In Home Health, New England Critical Care, Caremark, Travacare, American ContinueCare, St. Mary of Nazareth Hospital (Chicago IL), and Holy Family Hospital (Des Plaines IL). Anna is a Fellow of the American Society of Health-System Pharmacists (FASHP) and an active member of NHIA, American Society of Health-System Pharmacists (ASHP), American Society for Parenteral and Enteral Nutrition (ASPEN), American College of Clinical Pharmacy (ACCP), the Illinois Council of Health-System Pharmacists (ICHP), and the Polish American Pharmacists’ Association (PAPA). She has delivered numerous presentations, and has published articles on the subjects of home infusion therapy, specialty pharmacy, nutrition support, and interdisciplinary collaboration. Her experience includes more than 30 years of pharmacy practice and 25 years in home infusion and specialty pharmacy services. Anna received her Bachelor’s Degree in Pharmacy in 1979 from the University of Illinois, a Masters of Business Administration (MBA) in 1993 from the Keller Graduate School of Management, and a Doctor of Pharmacy (PharmD) in 2000 from Midwestern University. She is a Rho Chi Scholar and board certified in nutrition support (CNSC) and nutrition support pharmacy (BSNPC). Most recently, she was honored as the 2009 University of Illinois, Chicago College of Pharmacy Alumni of the Year in recognition of individual excellence and outstanding service to the profession of pharmacy.

Pharmacist and Nurse Education Objectives:
1. Explain the pathophysiology and therapeutic goals for each disease state that corresponds to new parenteral drugs released in 2010.
2. Discuss the indications and appropriate role of each new agent.
3. Discuss patient education and monitoring interventions that would lead to achievement of therapeutic goals.
4. Describe the major adverse effects, contraindications, and precautions for each new agent.
5. List the reimbursement implications for each new agent.

Pharmacy Technician Education Objectives:
1. Review the disease states for which new drug treatments have been approved in 2010.
2. Discuss the indications and appropriate role of each new agent.
3. List the reimbursement implications for each new agent.
Learning Assessment Questions:

1. Liraglutide results in clinically significant A1C lowering and weight loss than does exenatide.
   a. True  
   b. False

2. In HIV-associated lipodystrophy, tesamorelin has been shown to:
   a. Decrease cardiovascular risk  
   b. Redistribute fat  
   c. Improve adherence to antiretroviral drugs  
   D. All of the above

3. Which of the following statements about acetaminophen IV is FALSE?
   a. Dosing adjustment is not needed when converting from oral to IV acetaminophen  
   b. The IV route reduces liver exposure to acetaminophen  
   c. IV acetaminophen requires further dilution  
   d. IV acetaminophen is physically incompatible with diazepam and chlorpromazine

4. Subcutaneous human immune globulin is indicated for the treatment of:
   a. Primary immune deficiency  
   b. Multifocal motor neuropathy  
   c. Chronic inflammatory demyelinating polyneuropathy  
   d. All of the above

5. Which of the following statements is FALSE?
   a. Ceftaroline is a 5th generation cephalosporin indicated for skin and skin structure infections  
   b. Ceftaroline has better multi-drug resistant gram-positive coverage than ceftriaxone  
   c. Ceftaroline dosing is adjusted in renal dysfunction  
   d. Ceftaroline is indicated for community-acquired pneumonia caused by MRSA

6. Last year’s alglucosidase approval is indicated for the treatment of which Pompe Disease variant?
   a. Infantile onset  
   b. Juvenile onset  
   c. Adult onset  
   d. A and B  
   e. B and C

7. Which of the following statements about velaglucerase is TRUE?
   a. Velaglucerase is indicated in Type 2 and 3 Gaucher disease  
   b. Valglucerase is indicated in Gaucher disease with neurological involvement  
   c. Velaglucerase replaces glycocerebrosidase that is absent in patients with Gaucher disease  
   d. Velaglucerase administration does NOT result in infusion-related reactions

8. Cabazitaxel requires:
   a. Two dilutions prior to infusion  
   b. Premedication with an antihistamine, corticosteroid, and H2 antagonist  
   c. Use of PVC-free and polyurethane-free administration sets  
   d. All of the above

9. Eribulin for late-stage refractory breast cancer is incompatible with:
   a. Normal Saline  
   b. Lactated Ringers  
   c. Dextrose  
   d. Ethanol

10. Of the four commercially available alpha-1 proteinase inhibitors, which requires the longest infusion time?
    a. GLASSIA™  
    b. ZEMAIRA®  
    c. ARALAST™  
    d. PROLASTIN®

Answers can be found on the last page of this booklet.
Top 5 Things to Know for CE:

- Make sure your BADGE IS SCANNED each time you enter a session, to record your attendance.
- Carry the Evaluation Packet you received on registration with you to EVERY session. If you’re not applying for CE, we still want to hear from you! Your opinions about our conference are very valuable.
- Pharmacists, Pharmacy Technicians and Nurses need to track their hours on the Statement of Continuing Education Certificate form as they go.
- FOR CE: At your last session, total the hours and sign both pages of your Statement of Continuing Education Certificate form.
  - Keep the PINK copy for your records.
  - Place the YELLOW and WHITE copies in your Evaluation packet.
  - Make sure an evaluation form from each session you attended is completed and in your Evaluation packet (Forgot to pick up an evaluation form of a session? Ballots are available in an accordion file near the registration desk.)
- Pull your name and unique member ID number (six digit number on the bottom of your badge) on the outside of the packet, seal it, and drop it in the drop boxes in the NHIA registration area at the convention center.

Disclosures

- Anna Nowobilski-Vasilios is Principal for Anovation, Inc. The conflict of interest was resolved by peer review of slide content.
- The speaker holds less than 100 shares of Amgen stock and declares no other financial interest in any service or product mentioned in this program.
- Clinical trials and off-label uses may be discussed but in a fair and unbiased manner.
Learning Objectives

- Explain the pathophysiology and therapeutic goals for disease states treated by each new agent.
- Discuss the indications, dosing, administration, and appropriate role of each new agent.
- Discuss patient education and monitoring interventions that would lead to achievement of therapeutic goals.
- Describe the major adverse effects, contraindications, and precautions for each new agent.
- List the reimbursement implications for each new agent.

New Drug Approvals, 2001-2010

New Drug Approvals 2010

Jan: tocolizumab, dalfampridine, liraglutide
Feb: collagenase, meningitis vaccine, pneumococcal vaccine, verapiloximase
Mar: SCIG, carglumic acid, polidocanol
Apr: everolimus, sipuleucel-T
May: satralizumab, alfaferon-T, hexamethoxyurate

Jun: denosumab, cabazitaxel
Jul: alcofamide, inebotumumab-A
Aug: ipililart
Sep: pegylasem, fangirin, cetuximab, darbazine
Oct: lurasidone, ceftaroline, dabigatran
Nov: tesmorelin, eribulin
Dec: leuprolrelin, eribulin

20 New Approvals
20 New Molecular Entities
9 New Biologicals
13 New Parenterals
New Parenteral Drugs and Biologics 2010

Review of Systems 2010

<table>
<thead>
<tr>
<th>General Medicine</th>
<th>Dermatology</th>
<th>Ophthalmology</th>
<th>Neurology</th>
<th>Obstetrics/Gynecology</th>
<th>Cardiology</th>
<th>Pulmonology</th>
<th>Gastroenterology</th>
<th>Urology</th>
<th>Hematology</th>
<th>Infectious Disease</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ph-Related</td>
<td>AATD (alpha-1 proteinase inhibitor)</td>
<td>RA (tumor necrosis factor)</td>
<td>Osteoporosis (denosumab SQ)</td>
<td>Gout (pegolactate IV)</td>
<td>RD (SCID)</td>
<td>DM (fragile X)</td>
<td>HIV (palvatiserine in SQ)</td>
<td>Prostate CA (cabazitaxel IV &amp; abouce-T IV)</td>
<td>Bone metastases (denosumab SQ)</td>
<td>Breast CA (etanercept)</td>
<td>PDCA (celor or dexamethasone IV)</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Infectious Disease

- Acute Skin & Skin Structure Infections
- Community-Acquired Pneumonia

Infectious Disease

Acute Skin & Skin Structure Infections:
- Pathophysiology
- Bacterial: Staphylococcus aureus, Streptococcus pyogenes, H. influenzae
- Fungal: M. furfur
- Viral: Herpes simplex
- Therapy: Antibiotics
- Prevention: Hygiene
- Treatment: Antibiotics
- Newer: methicillin-resistant S. aureus

Community-Acquired Pneumonia:
- Pathophysiology
- Infection or aspiration of pathogens
- Clinical presentation: cough, fever, chest pain
- Treatment: Antibiotics
- Prevention: Vaccines

Further reading:
- Cellulitis, 6/7/10, www.emedicine.com
- MRSA, 6/2010
- S. aureus, 6/8/10
- H. influenzae, 6/10/10
- Treatment: Antibiotics
- Prevention: Vaccines

References:
- (a) Cellulitis, 6/7/10. www.emedicine.com
- (b) Impetigo. 5/20/10. www.emedicine.com
- (c) Guidance for.
- (d) Review of Systems 2010, 6/9/10; accessed 1/1/11.
### ceftaroline fosamil

**Approved 10/25/2010**

<table>
<thead>
<tr>
<th>Category</th>
<th>IV</th>
</tr>
</thead>
</table>

- **5th generation IV bactericidal cephalosporin for ABSSSI & CABP**
  - MRSA coverage: ABSSSI only
  - Not active against *Actinomyces* or *H. influenzae*
  - Similar to ceftaroline fosamil: doripenem coverage
  - Similar to imipenem (bactericidal) with Gm(+) and endocarditis coverage
  - Activity against MRSA, including resistant to clindamycin & linezolid
  - Further studies needed in MRSA endocarditis & MRSA pneumonia
- Hypersensitivity, CDAD, drug-induced hemolytic anemia
- Diabetes, infusion
- Reconstitute with SWI (pH 4.8-6.5), dilute in NSS, D5W, LR
- Stability 70°C, 24 hrs refrigerated
- Dosing: 900 mg IV gid, 12 hr, >15 kg
- Storage: based on delivery, weight, condition
- Storage adjusted CVs ±20 mL/hr and hemodialysis
- Similar to ceftriaxone w/ better Gm(+) coverage
- 50 mL/hr and hemodialysis

<table>
<thead>
<tr>
<th>Category</th>
<th>IV</th>
</tr>
</thead>
</table>

**Clinical Trials**
- **ABSSSI:** CANVAS 1 & CANVAS 2 (N = 1,376)
  - Comparable to vancomycin + clindamycin
  - **CABP:** FOCUS 1 & FOCUS 2 (N = 128)
  - Noninferior to ceftriaxone in intracerebral abscess or CAP
- **12 to 70 yr:** dosing study
- **3 Cane Plan High**
  - Patient Education: "Hypersensitivity: administer diamines" or "Monitor for adverse reactions"
  - Reimbursement issues:
    - AHRP 5/22 (less than most MRSA ABSS)
    - Firefocus on hospital pathogens
    - NOC 545/5400 (1:1000:400 mg/mL $1.10
    - NOC 54550 (1:1000:400 mg/mL $1.10

**NDC 0456-0600-01; 10:** 600 mg vial #1; 10

**New Parenteral Drugs and Biologics 2010**

### General Wellbeing

- Pain
- Fever

**2011 NHIA Annual Conference & Exposition**
New Parenteral Drugs and Biologics 2010

acetaminophen

Approved 11/2/2010

- Fever reduction, mild to moderate pain, severe pain w/opioids
- Hypersensitivity, hepatic impairment, acute hepatic disease, alcoholism, severe renal impairment
- Do not use in conjunction with MA, meperidine, pentazocine, propoxyphene
- DI's CYP2E1; chronic doses & INR

Dosage & Administration
- Children
  - >2yr (>9kg):
    - 100 mg q8h or 850 mg q 4h IV over 15 min to max 4g/day
    - 3-12 yr: 1/2 adult dose (≤50 kg)
    - >12 yr & >15 kg: adult dose (max 75 mg/kg/day)
  - Ventral IV set into 100 mL vial; administer with 8 hr puncture
  - IV route no first pass effect
- Physically incompatible with diazepam and chlorpromazine

Immunology

- Primary Immune Deficiency (PID)

2011 NHIA Annual Conference & Exposition
New Parenteral Drugs and Biologics 2010

---

**immune globulin G**

- Replacement IgG for Primary Immune Deficiency
- Anaphylaxis, IgA deficiency, renal dysfunction, thrombotic events, ABO, hemolysis, HAT/HJV exposure
- Injection site reactions, HA, vomiting, pain, fatigue
- RT storage, RTU
- Self-administered ≤ 4 simultaneous SQ sites
  - Initial dose based on previous IVIG dose & interval
  - Subsequent weekly doses based on response & IgG trough
  - Initial for infants, MMN

---

**immune globulin G**

- Clinical Trial: 38 patients
- Care Plan Highlights
  - Patient Education: administration, diary/log, warnings, ADR’s
  - Monitor: s/s infection, periodic sIgG, s/s ADR
- Reimbursement Issues
  - Variable coverage
  - Supplies needed: pump, admixture, SQ cath, Y-sites, wipes, syringes, needles, dressing, sharps container

---

**Pulmonology**

- Alpha1 Antitrypsin Deficiency (AATD)
**AATD**

- Inherited genetic disorder
- Defect alters prevents AAT release from hepatocytes
- Protease excess emphysema
- US Prevalence: 1/3000-5000
- NIH: death 1.5x higher for those not receiving enzyme replacement
- Treatment Options: smoking cessation, bronchodilation, pulmonary vaccinations, pulmonary rehabilitation, enzyme replacement

**alpha-1 proteinase inhibitor, human**

- First RTU alpha-1 proteinase inhibitor; inhibits protease
- Anaphylaxis; IgA deficiency w/ IgA antibodies; risk of CJD
- HA; dizziness
- 60 mg/kg IV weekly
- Give at rate 0.04 mL/kg/min (60-80 minutes)

**Dosage Form**

- IV

**Approved 7/1/2010**

- Pregnancy Category C
- Use in Patients with History of CJD
- Use in HIV
- Latex Free
- No Preservatives

**Care Plan Highlights**

- Patient Education: hypersensitivity risks, vaccinations, patient support group
- Monitor: VS, slow/stop for infusion related reactions

**Reimbursement issues**

- NDC 0944-2894-01 1g/mL RTU SDV
- Supply needs: vented V administration set w/ 6 micron filter, 5 micron in-line filter
- Restricted distribution
- Variable reimbursement
- Pricing: 70% higher than originally approved product
Pompe Disease

- Acid alpha-glucosidase (AAG) deficiency
- Glycogenosis Type II
- Without AAG, heart & muscle tissue weaken from glycogen builds up
  - 1:40,000-300,000 births, M:F
- Autosomal recessive disorder
  - Infantile onset – late in first year of life
  - Juvenile onset – slower progress, may survive into 20-30s
  - Adult onset – longer survivor, AAG is effective
- Sleep apnea, death from respiratory failure
- Treatment Options: Symptomatic treatment, anecdotal high-protein diet, ERT since 2006

Enzyme replacement for non-infantile Pompe Disease in patients > 8 yrs with cardiac hypertrophy
- Manifesting process is different from product previously approved for infantile Pompe Disease
- Anaphylaxis, severe allergic reactions, immune-mediated reactions
- Infusion-related reactions (50%), diarrhea, vomiting, partial hearing loss, extremity pain - check compliance
- Preparation by HCP: Sensitivity to air-liquid interfaces
- Do not shake
- Rate 25-30 mg/kg over 2 hrs by IV infusion
- Initiate rate 1 mg/kg/hr, then + 2 mg/kg/hr every 30 minutes to max 1 mg/kg/hr to 3 mg/kg/hr over 2 min infusion
- VS after each step.
**Gaucher Disease**

- Lysosomal glucosylceramide-specific enzyme
- Alternative to imiglucerase that has been in short supply
- Hypersensitivity, infusion-related reactions
- HA, diarrhea, abdominal pain, nausea, back pain, joint pain, UNL
- Reconstitute w/ SWI to 100 mg/mL
- Use w/ 24 hours if refrigerated
- 90 mg IV q2wk, infuse over 1 h
- Adjust based on response

**velaglucerase alfa**

- Lysosomal glucosylceramide-specific enzyme
- Alternative to imiglucerase that has been in short supply
- Hypersensitivity, infusion-related reactions
- HA, diarrhea, abdominal pain, nausea, back pain, joint pain, UNL
- Reconstitute w/ SWI to 100 mg/mL
- Use w/ 24 hours if refrigerated
- 90 mg IV q2wk, infuse over 1 h
- Adjust based on response
- Administer under supervision of HCP, via 0.2 micron filter
- 3 trials, 99 patients w/ Type 1 Gaucher disease ≥ 4 yo

---

**REM**

- alglucosidase alfa
- Approved 5/24/2010
- Pregnancy Category C
- IV
- Shaker C
- No Preservative

---

**New Parenteral Drugs and Biologics 2010**

- Clinical Trials: 90 patients. 6 minute walk test (+) 25 m
- Preclinical trials of gene therapy
- Care Plan Highlights
  - AAEC program, Pompe Registry, Infusion reactions
  - Monitor IVs during infuser. Infusion reaction: IgG antibodies formation q 3 mo x 2 yrs, then q yr
- Reimbursement Issues
  - NDC 584641501: 50mg powder in 20ml SDV
  - REMS with distribution: requires enrollment of physician, patient, family/physician, dispense, administer
  - Variable reimbursement
  - Cost for adults $500,000-$100,000/year

---

References:

(a) FDA News Release, 5/25/10.
(b) Prescribing information, LUMIZYME® (alglucosidase alfa). Cambridge MA: Genzyme; May 2010.
(c) Cambridge MA: Shire Human Genetic Therapies, Company; February 2010.
(e) www.epocrates.com
velaglucerase alfa

- Care Plan Highlights
  - Monitor infusion related reactions
  - Staphart: pre-treat with dexamethasone and acetaminophen
  - Monitor high: HT, platelets, liver & spleen size
- Reimbursement issues
  - NDC 54092-701-02: 300y vialized powder SDV
  - NDC 54092-701-04: 400y vialized powder SDV
  - Restricted distribution
  - Variable coverage
  - Cost expected 15% less than imiglucerase

Rheumatology

- Rheumatoid Arthritis
- Gout
- Osteoporosis

Rheumatoid Arthritis

- Systemic inflammatory disease
- Symmetrical affects peripheral joints
- Pain, swelling, redness
- Incidence: 1.3M in 2005; F: M 2:1
- Morbidity, disability, mortality

- Goals:
  - ↓ pain
  - Prevent long term damage
- Treatment Options
  - Physical & occupational therapy
  - Pharmacotherapy
    - Corticosteroids
    - NSAIDs
    - DMARDs
    - bDMAs

### tocolizumab

**REMS**
- Humanized mAb, infliximab-3 (IL-6) inhibitor
  - Adult rheumatoid arthritis refractory rheumatoid arthritis
  - Monotherapy or in combination with MTX or minb DMARD
- Asthma, severe disease, TBI healing, neutrophils x 2000 mm^3 /
  - platelets x 100,000 mm^3 /ALT or AST > 1.5 x ULN. GI perforation, live vaccine, major surgery
- Infection-esam prostate, HIV, sepsis, sepsis, pyelonephritis, H A, H influenza
- Anticancer dose: CYP450 suppression (imatinib, ribavirin, CCB, ketoacidosis, TDM)
- Prophylactic to DMARDs
- 4 mg/kg, up to 8 mg/kg. V over 1 h every 4 weeks
  - NMT 800 mg per infusion
  - HDN dose 1 h before or after

### Care Plan Highlights
- **REMS**
  - Medication guide
    - WNT management plan
  - Education to infection, hepatic safety
  - Hyper sensitivity, anti-tumor necrosis
  - Pregnancy registry, GI pain, lower half, skin, manifestations
  - Myelosuppression, HIV, RBC, platelets,引用，及}

### Reimbursement & Access Issues
- Cost $13,000 to $26,000/yr
- Lower dose similar to etanercept or adalimumab
- ICD-9-CM: 714.0
- HCPCS J3590
- Administration procedures CPT 96365
- Varied coverage
  - NDC 50242-135-01, 04: 80mg/4mL vial #1,4
  - NDC 50242-135-01, 04: 200mg/10mL vial #1,4
  - NDC 52042-137-01, 04: 400mg/20mL vial #1,4

---

**References**
(a) FDA News Release, Jan 11, 2010.
(b) Prescribing information, ACTEMRA (tocilizumab). South San Francisco CA: Genentech; January 2010.
(c) Pharmacists Letter, March 2010.
(d) www.epocrates.com

---

**New Parenteral Drugs and Biologics 2010**

---

**2011 NHIA Annual Conference & Exposition**
Gout

- Uric acid metabolism disorder
- 1% US population
  - Men 13/1000, Women 6/1000
- Considerable morbidity
  - Severe joint destruction if untreated
  - Chronic renal nephropathy from MSU
- GI: joints red, hot, extremely tender
- Therapeutic Goals
  - Treat acute attack
  - NSAIDS, anti-inflammatory, corticosteroids
- Prevent gout
  - Probenecid, allopurinol, biweekly pegloticase

PEGylated urate oxidase for chronic refractory gout

PEGylated urate oxidase for chronic refractory gout

References:
(a) www.emedicine.com
(b) FDA News Release, 9/14/2010.
(c) Pharmacists Letter CE course 110201.
(d) The Medical Letter, 2/7/2011.
(e) www.epocrates.com

Pt Ed: MedGuide b/4 each infusion, CHF & G6PD warnings

New Parenteral Drugs and Biologics 2010
Bone Fracture Prevention

Pathophysiology
- Decreased bone mass
- Decreased bone strength
- Decrease in fracture risk

Prevention
- Increased calcium intake
- Vitamin D intake

Morbidity & Mortality
- Vertebral fractures
- Non-vertebral fractures

Therapeutic Goals
- Decrease the risk of fractures
- Improve bone density
- Improve bone quality

Pathology
- Hypocalcemia
- Hypophosphatemia

New Parenteral Drugs and Biologics 2010

Denosumab

**Indicated For**
- Skeletal disease associated with bone metastases from solid tumors

**Not Indicated For**
- Prevention or treatment of osteoporosis
- Prevention or treatment of Paget's disease

**Contraindications**
- Hypersensitivity to denosumab
- Hypocalcemia

**Warnings**
- Renal impairment
- Hypocalcemia

**Precautions**
- Hypercalcemia
- Hypophosphatemia

**Adverse Reactions**
- Myalgia
- Arthralgia

**Dosing & Administration**
- Denosumab 120 mg subcutaneous injection

**Special Populations**
- Older adults
- Patients with renal impairment

**DRUGS TO AVOID**
- Calcitonin

**DO NOT SHARE**
- Denosumab

**REMS**
- Risk Evaluation and Mitigation Strategy

**Acknowledgments**
- Kathleen F. Kavanagh, MD, PhD, Associate Director, Department of Medical Affairs, Amgen
- Amgen, Thousand Oaks, CA, USA

**References**
- Bone Fracture Prevention: New Parenteral Drugs and Biologics 2010
- www.emedicine.com
- The Medical Letter 2010;1349:81
New Parenteral Drugs and Biologics 2010

Denosumab

Reimbursement & Access issues:
- Cost: $1500/60mg vs $1150/oral bisphosphonate
- Multiple distributors
- NDC 55513-710-01: 60mg/mL SD syringe #1
- NDC 55513-720-01: 60mg/mL SD vial #1

Oncology

- Bone metastases
- Breast CA
- Prostate CA

Breast Cancer

- 2nd leading cause of cancer related death among women
- 192,370 new cases (910,200), 2009 estimate
- 40,510 deaths (40,170, 44,090), 2009 estimate
- Diagnosis increasing
- Deaths decreasing
- US lifetime risk of breast CA 12.7%
- Treatment options for refractory breast cancer:
  - Capecitabine, resistance to paclitaxel & anthracycline
  - Ixabepilone failure with anthracycline & taxane & capecitabine
  - Capecitabine with ixabepilone, failure of anthracycline & taxane
  - New agents
eribulin

- Late-stage refractory breast cancer
  - 17 of 22 patients with anthracycline-taxane treatments
  - Non-anthracycline anthracycline
    - Synthetic analogue of halichondrin B, isolated from sea sponge
    - Neuropathy, peripheral neuropathy, QT prolongation
  - Amenorrhea, insomnia, fatigue, myalgia, weakness, constipation
- 14 mg/m² IV over 2-5 minutes on Days 1 and 8 (21-day cycle)
- Reduce dose
  - 10 mg/m² if grade 3 or 4 neutropenia, neuropathy
  - Grade 4 neutropenia
  - Incompatible with cisplatin

Prostate Cancer

- Second most common cancer among men in the US
- 1:10 men develop prostate cancer in lifetime
- > 2 million men in the US are alive after diagnosis
- Morbidity & Mortality
  - 2006: 203,415 diagnosed with prostate CA; 28,372 died of prostate CA
  - 2009: 192,000 new cases; 27,000 died of prostate cancer (NCI)
- Treatment Options
  - Advanced Prostate cancer
  - Androgen suppression, radiation, surgery
  - Chemotherapy, hormone therapy
  - Chemotherapy, hormone therapy
**cabazitaxel**

- Taxane microtubule inhibitor
  - advanced hormone-refractory prostate cancer
  - with prednisone
- Severe hypersensitivity (polyethylene 80)
- Neutropenia (6%), anemia, leukopenia, thrombocytopenia, dextran, electrolyte imbalance, fatigue, nausea, vomiting, constipation, weakness, renal failure
- Caution with renal and hepatic impairment
  - caution with strong CYP3A inhibitors or inducers
- Preparation: requires two dilutions

- Dosing: 25 mg/m² IV over 1 h q 3 wks w/ prednisone 10 mg po QD
  - Premedicate w/ IV antihistamine, corticosteroid, H2 antagonist
  - No PVC containers. No polyethylene infusion sets.
  - Use 0.22 micron filter

- Monitoring: med profile, baseline Cr, LFTs, CBC w/ Plts

- Reimbursement Issues

- 755 patients, all previously treated with docetaxel
  - cabazitaxel/prednisone (15.1 month survival) vs. mitoxantrone/prednisone (12.7 month survival)

- Care Plan Highlights
  - Education: ADR reporting, temperature monitoring, compliance with prednisone
  - Monitor: med profile, baseline Cr, LFTs, CBC, w/ Plts
  - Premedicate 1 h prior to each cycle start

- Reimbursement issues
  - NDC 0034-8824-11: 80 mg/15 mL Polysorbate80 0.9% with 0.7 mL 13% ethanol diluent 0.9%
  - Cost $9,800 per cycle
  - Coverage available

---

**sipuleucel-T**

- Administration: intravenous

- Monitoring: fever, chills, nausea, vomiting, diarrhea, electrolyte imbalance, fatigue, neutropenia, thrombocytopenia

- Reimbursement Issues

- 48/59 patients

---

*New Parenteral Drugs and Biologics 2010*
New Parenteral Drugs and Biologics 2010

Endocrinology

- Diabetes Mellitus
- HIV lipodystrophy

liraglutide

Approved 10/23/2010

SQ

- GLP-1 agonist to improve glucose control in Type 2 DM
- Risk of luteal tumors, Cushing’s, or MEN2 in pancreas
- MA, nausea, diarrhea, anti-liraglutide antibodies
- Refractile until first use, then RT for 30 days
- Monitor: IGF-1, glucose, eye exams if diabetes
- Do not reconstitute: 2 mL vial, 1 mg/mL
- Refrigerate until first use, then RT for 30 days
- 1.2 mg inadequate, then 1.8 mg.

Tesamorelin acetate

Approved 11/13/2010

SQ

- Growth hormone releasing factor (GRF) for HIV lipodystrophy
- Weight loss, pre-existing neoplasms, fluid retention
- GI: hypereosinophilic syndrome
- ADR: joint pain, injection site reactions, headache
- On-line pt training video (15 min)
- Dose: 2 mg SQ QO
- CARE Plan Highlights
  - LM Education: regular safety training
  - Weight loss: properly monitor all
  - Ophthalmology: baseline exam
- Reimbursement issues
  - Cost $3500/year
  - NDC 0169-4060-12: multidose pen 6 mg/mL, 3mL, #2
  - NDC 44087-2010-3: 1 mg lyophilized powder #60, SWI 10mL #30

References

(a) Prescribing information, EGRIFTA™ (tesamorelin). Rockland MA: EMD Serono; November 2010.
(b) FDA News Release, 11/10/10.
(c) http://www.pharmacytimes.com
Infectious Disease

- Pneumococcal vaccine
- Meningitis vaccine

Immunizations 0-6yo

Recommended Immunization Schedule for Persons Aged 0 Through 18 Years (Revised 2011)

- Influenza vaccine
- Meningococcal vaccine
- Hepatitis B vaccine
- Haemophilus influenzae type b (Hib) vaccine
- Pneumococcal vaccine

New Parenteral Drugs and Biologics 2010

- Streptococcus pneumoniae 13-valent vaccine for infants and young children ages 6 weeks through 5 years
- This is a latex-free product
- Apnea in premature infants, anaphylaxis (including diphtheria toxoid)
- Expire on date printed
- Suspension, shake well
- For multiple vaccinations, use different syringes and injection sites
- Dosing & Administration: 0.5 mL IM at 2, 4, 6, 12-15 months old
- Category C: Pregnancy
- REIMBURSEMENT ISSUES:
  - NDC: 0235-1871-02 - single dose pre-filled syringe
  - Cost: $105.75

2011 NHIA Annual Conference & Exposition
Immunizations 7-18yo

Immunizations Adult

meningococcal vaccine

• 3rd vaccine against Neisseria meningitidis, 2-55 yo
• 1000-3000 US annually; falls 10-40% 20% disabilities
• Arthropiugynosis
• Injection site reactions: HA, myalgia, malaise, headache
• 0.5ml IM; 2nd dose in 2-5 yo A/C/P
• Clinical Trial: 2183 adolescents 11-18 yo & 1359 adults 19-55 yo

- Headache/tenderness with Menecest; Statistically superior immune response
- No induction of reactivity

Care Plan Highlights

• VFS (vaccine information statement); benefits & risks: pregnancy safety
• VAERS (Vaccine Adverse Event Reporting System)
• Reimbursement issues

NO: 402926-2296-16: 60 ml vials; RACOY and liquid W-15
Variable coverage

New Parenteral Drugs and Biologics 2010

Approved 01/09/10

IM
Parenteral Drug Pipeline 2011-12

- Factor XIII (2/17/11)

Stay tuned for “New Drugs X” in 2012?

Questions?

annanv@anovation.us
Answers:
1. B. False. While liraglutide drops A1c by 1.1%, it is only slightly more effective than exenatide which drops A1C by 0.8%. This difference is not necessarily significant. Both drugs result in similar weight loss.
2. B
3. C. IV acetaminophen requires no further dilution.
4. A. Primary immune deficiency only.
5. D
6. E. MYOZYME® is indicated in infantile onset Pompe Disease, while LUMIZYME® is indicated in non-infantile onset Pompe Disease.
7. C
8. D
9. C
10. A. GLASSIA™ requires 60-80 minutes, while all others are infused over 15 minutes.