Advanced Considerations for Home Administration of Immunoglobulin Therapy

Wednesday, April 6
7:00-8:45 a.m.
Hilton Orlando—Florida Ballroom 4

Supported by an unrestricted educational grant from Baxter Healthcare Corporation, Bio Products Laboratory, and McKesson

A Symposium Held in Conjunction with the 2011 NHIA Annual Conference & Exposition

NHIA 20th Annual Conference & Exposition

Shaping Our Horizon
Advanced Considerations for Home Administration of Immunoglobulin Therapy

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03-S. Advanced Considerations for Home Administration of Immunoglobulin Therapy

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Pharmacist, Pharmacy Technician and Nurse Continuing Education Contact Hours: 1.5

ACPE Pharmacist and Pharmacy Technician Program #: 207-999-11-219-L01-P&T

Knowledge-Based Learning Activity

Education Overview:

Immunoglobulin therapy is used in the treatment of primary and secondary immunodeficiency disorders, and a growing list of more than 100 immune-mediated disease states, despite having formal approval from the U.S. Food and Drug Administration (FDA) for only five diagnoses. As ongoing research continues to demonstrate new applications and administration methods for this therapy, home infusion clinicians must stay abreast of changes to ensure the most efficacious delivery of these drugs to their patients. Join Dr. Alan Huber as he takes you on a journey through the immune system, connecting science to treatment options for patients with immune system-based disorders. Gain new insights into administration methods of the available immunoglobulin drugs, including how to choose the best treatment option for each of your patients.

Faculty: Alan Huber, PharmD., Vice President of Operations, Biofusion Inc., Torrance, CA

Alan Huber, PharmD, is the Vice President of Operations for Biofusion Inc., and an Adjunct Assistant Professor of Pharmacy Practice for the University of Southern California School Of Pharmacy where he lectures on immunoglobulin therapy. After completing a two-year internship in IV therapy at the National Institutes of Health in Bethesda, Maryland, he spent 15 years working in the home infusion field, serving in various positions throughout the industry including managing several nationally accredited home infusion companies. Alan was educated as a clinical pharmacist with Bachelor’s Degrees in Pharmacy and Zoology from the University of Maryland and a Doctor of Pharmacy Degree from Shenandoah University.

Pharmacist and Nurse Education Objectives:

1. Describe the role of IgG therapy in relation to what we know today about immune system function.
2. Explain the difference between primary and secondary immunodeficiencies and how they are acquired.
3. Describe the different types of autoimmune disorders and their status regarding FDA IgG indications for use.
4. Discuss the advantages and disadvantages of subcutaneous immune globulin therapy.
5. Describe post-infusion and rate-related adverse effects of IVIG.
6. Describe strategies to minimize the serious adverse events related to IVIG therapy.
7. List the reimbursement challenges associated with IgG therapy provided in the home.

Pharmacy Technician Education Objectives:

1. Describe the role of IgG therapy in relation to what we know today about immune system function.
2. Review the difference between primary and secondary immunodeficiencies and how they are acquired.
3. Describe the different types of autoimmune disorders and their status regarding FDA IgG indications for use.
4. Discuss the advantages and disadvantages of subcutaneous immune globulin therapy.
5. Describe post-infusion and rate-related adverse effects of IVIG.
6. Describe strategies to minimize the serious adverse events related to IVIG therapy.
7. List the reimbursement challenges associated with IgG therapy provided in the home.
Learning Assessment Questions:

1. Which of the following statements is true regarding reimbursement of IVIG therapy:
   a. When provided for an FDA-approved indication, IVIG is always reimbursed
   b. When provided for an off-label indication, IVIG therapy is always initially denied by the payer requiring appeal by the infusion provider.
   c. When provided for an FDA-approved indication, IVIG therapy may still be denied by the payer if insufficient laboratory or diagnostic results are provided to validate the diagnosis and need for therapy
   d. None of the above.

2. Many off-label indications for IVIG will be covered by insurance if sufficient documentation is provided to justify the medical necessity of the treatment.
   a. True
   b. False

3. Medicare does not cover IVIG therapy in the home.
   a. True
   b. False

4. Before accepting an IVIG referral with a primary insurance of Medicare, which of the following steps should be taken?
   a. Determine your cost of product and compare to the rate of Medicare reimbursement.
   b. Determine if there is coverage for the supplies and equipment through Medicare or another payer.
   c. Determine if there is coverage for the nursing services.
   d. All of the above

5. Obtaining prior authorization for IVIG treatment can reduce the likelihood that therapy will be denied after it has been initiated.
   a. True
   b. False

6. Which Primary Immune Deficiency Disease is not covered by Medicare B for IVIG and SQ reimbursement at home.
   a. Hyper IgM Syndrome
   b. CVID
   c. Hypogammaglobulinemia
   d. Bruton’s XLA
   e. Severe Combined Immune Deficiency (SCID)

7. The FDA has not approved IVIG for which indication?
   a. CIDP
   b. Primary Immune Deficiency
   c. Myasthenia Gravis
   d. Immune Thrombocytopenia
   e. Kawasaki’s Disease

8. What factor is not used when assessing a patient for product choice
   a. Hypertension
   b. Diabetes
   c. Age
   d. Gender
   e. IgA deficiency

Answers can be found on the last page of this booklet.
"If you tell the truth, you don’t have to remember anything."

-Mark Twain

Advanced Considerations for Home Administration of Immunoglobulin Therapy

Alan Huber BS Pharm, PharmD
Senior Vice President Operations
BioFusion Inc
Adjunct Assistant Professor of Pharmacy Practice
University of Southern California School of Pharmacy

Presenter Disclosure Information

• No disclosures to declare
• There will be off-label discussion in this presentation
By the end of the session, the audience will be able to:

- List the most common warning signs for patients with Primary Immune Deficiency
- Understand the basic immunology process and how IVIG is manufactured
- Explain the difference between Primary and Secondary immune deficiencies and how they are acquired
- Describe the different types of Autoimmune Disorders and which disorders are FDA approved for IVIG treatment
- Discuss the advantages and disadvantages of subcutaneous immunoglobulin therapy
- Discuss parameters for clinically assessing a patient prior to infusing IVIG
- Understand the difference between AWP and ASP pricing and how it affects Specialty Pharmacies
- Understand the advantages and disadvantages of the various IVIG products on the market
- Understand Part B and the 2 different LCD’s we use for IVIG/SCIG

Clinical Review

Immune System Essentials

- Innate Immunity
  - Physical Barriers
  - Complement System
  - White Blood Cells
    - Macrophages
    - Neutrophils
    - Eosinophils
    - Monocytes
    - Lymphocytes
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Immune System Essentials

- Adaptive Immunity
  - Humoral Response
  - B Lymphocytes
  - Cell Mediated
    - T Lymphocytes
      - CD4+ (Helper)
      - CD8+ (Cytotoxic)
  - Active Immunity
  - Passive Immunity

Antibody Structure

- Variable region on heavy chain
- Variable region on light chain
- Constant region on heavy chain
- Constant region on light chain
- Disulfide bridges
- Light chain
- Heavy chain
- Antigen binding sites

Composition of Blood

- Red Blood Cells
- White Blood Cells
- Platelets
- Plasma
  - Water (92%)
  - Protein (8%)
    - Albumin
    - Immunoglobulin
    - Wilco Clumping Factor
    - Alpha-1 Antitrypsin Inhibitor

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Plasmapheresis

The process of separating plasma from whole blood by a cell separator.

- **Collection Phase**: Plasma and cells are separated into 2 compartments.
- **Re-infusion Phase**: Blood cells are returned to the donor.
- May donate up to 800mls twice a week with a 48hr waiting period.
- Whole blood donations may only be limited up to 250mls 1.5 times per year.

Autopheresis-C Baxter

Fractionation
Plasma Therapies

- IVIG
- SCIG
- Hemophilia
  - Factor VIII
  - Factor IX
  - vWD
- Alpha-1 AntiTrypsin Deficiency
- Albumin

Viral Inactivation Process

- Solvent Detergent
- Nano Filtration
- Caprylate Chromatography
- Pasteurization
- Low pH treatment
- Cohn-Oncley Fractionation

FDA Approved Indications for IVIG

- Primary Immune Deficiency
- Immune Thrombocytopenia Purpura (ITP)
- Chronic Lymphocytic Leukemia (B-CLL)
- Kawasaki’s Disease
- CIDP
Immune Deficiency

- Primary Immune Deficiency
  - Typically caused by a genetic defect
  - Over 150 types of Primary Immune Deficiency Diseases
  - Many patients are not diagnosed until later in life.

- Secondary Immune Deficiency
  - Occurs when outside factors damage the immune system
  - Radiation, chemotherapy, malnutrition, AIDS, leukemia

Primary Immune Deficiency

- X-Linked Recessive
  - Passed on by mother to son

- Autosomal Recessive
  - Passed on by mother or father to child
10 Warning Signs of Primary Immune Deficiency

1. Eight or more ear or sinus infections within 1 year
2. Recurrent, deep skin or organ infections
3. Two or more serious skin infections within 1 year
4. Persistent thrush in mouth or other infections on skin after age 1 year
5. Two or more episodes of pneumonia with little effect
6. Need for antibiotics for infections with little effect
7. Two or more hospitalizations for infections
8. Failure of an attempt to gain weight or growth normally

Primary Immune Deficiency Diseases

- Hypogammaglobulinemia 279.00
- Agammaglobulinemia (Bruton’s XLA) 279.04
- Hyper IgM Syndrome 279.05
- Common Variable Immune Deficiency (CVID) 279.06
- IgG Subclass Deficiency 279.03
- Severe Combined Immune Deficiency (SCID) 279.2
  - “Boy in Bubble”

Ig Subclasses

- IgG
  - Most abundant immunoglobulin found in tissue and blood
  - Makes up 70% of serum immunoglobulin
- IgA
  - Primarily found in mucus, tears, saliva, respiratory and GI tract
- IgM
  - First antibody produced early in the infection phase
- IgD
  - Main function not determined
- IgE
  - Involved in release of histamine
IgG Subclass

- IgG1 (250-930mg/dl)
  - Often seeningly with decreased levels of total IgG
  - Most important subclass associated with recurrent lower airway infections
- IgG2 (89-625mg/dl)
  - Seen in 1% of all subclass deficiencies
  - Pts show recurrent upper respiratory tract infections (sinusitis, otitis)
  - Low concentrations of IgG2 often occur with IgA deficient patients
- IgG3 (15-135mg/dl)
  - Associated with a history of recurrent infections, leading to chronic lung infection
- IgG4 (1-210mg/dl)
  - Common in young children
- IgG Total Serum (694-1618mg/dl)

Auto Immune Diseases

- The body reacts against its own body and produces antibodies to attack itself
- 75% of all autoimmune diseases occur in females
- Many theories on causes of autoimmune diseases but high correlation between gender, environment and genetic factors

Female Male Ratios in Autoimmune Diseases

<table>
<thead>
<tr>
<th>Disease</th>
<th>Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hashimoto's disease/hypothyroiditis</td>
<td>58:1</td>
</tr>
<tr>
<td>Systemic lupus erythematosus</td>
<td>9:1</td>
</tr>
<tr>
<td>Sjogren's syndrome</td>
<td>9:1</td>
</tr>
<tr>
<td>Antiphospholipid syndrome</td>
<td>9:1</td>
</tr>
<tr>
<td>Primary biliary cirrhosis</td>
<td>9:1</td>
</tr>
<tr>
<td>Mixed connective tissue disease</td>
<td>8:1</td>
</tr>
<tr>
<td>Chronic active hepatitis</td>
<td>8:1</td>
</tr>
<tr>
<td>Graves' disease/hyperthyroiditis</td>
<td>7:1</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>4:1</td>
</tr>
<tr>
<td>Scleroderma</td>
<td>3:1</td>
</tr>
<tr>
<td>Myasthenia gravis</td>
<td>2:1</td>
</tr>
<tr>
<td>Multiple sclerosis</td>
<td>2:1</td>
</tr>
<tr>
<td>Chronic idiopathic thrombocytopenic purpura</td>
<td>2:1</td>
</tr>
</tbody>
</table>
Off Label Indications For IVIG

- Guillain–Barré Syndrome (AIDP)
- Pemphigus Vulgaris
- Myasthenia Gravis (with exacerbation)
- Dermatomyositis
- Polymyositis
- Multiple Sclerosis
- Scleroderma
- NMO (Devic's Disease)
- Stiff Persons Syndrome
- Multi Focal Motor Neuropathy
- PANDAS
- Renal Transplantation
- Infertility
- Susac's Syndrome
- Allogenic BMT

Neurological

- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) 358.71
- Guillain–Barré Syndrome (AIDP) 357.0
- Multiple Sclerosis 340
- Multi Focal Motor Neuropathy 357.9
- Myasthenia Gravis w/Exacerbation 358.01
- Stiff Person's Syndrome 333.91
- Neuromyelitis Optica (Devic's Disease) 341.0
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Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- Progressive weakness and impaired sensory function of the legs and arms
- Myelin of the peripheral nervous system are attacked by antibodies
- ICE Trial (Gamunex®)
  - Improved functional ability and grip strength
  - Lengthen the time to relapse during the 5 month to 1yr period of the study

Myasthenia Gravis

- Latin for “Serious Muscle Weakness”
- 200-400 cases per million
- ACH Receptors blocked
- Mestinon/Cellcept®
- Thymectomy
- Myelin of the peripheral nervous system
- Exacerbation
  - Respiratory failure
  - Difficulty to Speak

Renal Transplant

- 2004: FDA approved the use of IVIG based on the Cedars Sinai protocol
  - Panel Reactive Antibody Test (PRA)
  - 120 gms-140 gms over 8hr
  - Pre/Post Transplant
- 2008: IVG/Rituximab Protocol
  - IVG 2 g/kg on day 0 & 30
  - Rituximab 1g on day 7 & 22

Conditions for Renal Failure

- Diabetes
- Hypertension
- Interstitial Nephritis
- Glomerulonephritis
- Polycystic Kidney Disease
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**Dermatology**

- **Pemphigus Vulgaris**
  - Antibodies attack the desmoglein proteins of the skin cells which cause skin cells to separate
  - Blistering and raw sores will develop as a result
  - 2 gms/kg over 3 to 5 days every month
  - Positive Nikolsky's sign
  - Prednisone/Immunosuppressants

**Anti Phospholipid Syndrome**

- Pts tend to have multiple spontaneous abortions
- Dose: 1gm/kg over 2-3 days
- Dosing starts at 16wks gestation
- Inhibits the APL antibodies which create clotting.

**Connective Tissue Disorder**

- **Myositis** - Inflammation of the voluntary skeletal muscles

  - Autoimmune disease that cause inflammation and muscle weakness (especially in the trunk)

  - **EXAMPLES:**
    - Diffuse (affects the whole body)
    - Limited (affects the arms, hands, legs, and feet)

  - Chronic illness with periods of remissions and exacerbations

  - **Dermatomyositis** - Polymyositis + skin rash
    - Rashes can be surrounded by a subtle discoloration with swelling
    - Stay within 6" of the trunk
    - Rash on the face, neck, and upper chest
    - Gottron's Papules
    - Positive ANA Test/Muscle Biopsy

Adapted from presentation by Sherry Pham, PharmD 2007
Dosing Protocols

<table>
<thead>
<tr>
<th>Disease State</th>
<th>Dosing Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Immune Deficiency IVIG</td>
<td>300-600mg/kg q month</td>
</tr>
<tr>
<td>Primary Immune Deficiency</td>
<td>100-200mg/kg q week</td>
</tr>
<tr>
<td>SCIG</td>
<td></td>
</tr>
<tr>
<td>Chronic Lymphocytic Leukemia</td>
<td>400mg/kg q 3 to 4 weeks</td>
</tr>
<tr>
<td>ITP</td>
<td>400mg/kg daily for 5 days or 1gm/kg for 2 days</td>
</tr>
<tr>
<td>CIDP</td>
<td>2gm/kg over 3-5 days then 1gm/kg every 3 weeks</td>
</tr>
<tr>
<td>Dermatomyositis</td>
<td>2gm/kg over 5 days q month</td>
</tr>
<tr>
<td>Kidney Transplant</td>
<td>120gms to 140gms over 1 day q month up to 4 months then 1 dose post transplant</td>
</tr>
</tbody>
</table>

IVIG Products

- Gammagard® Liquid 10% (Baxter) J1569
- Gammagard® SD Powder (Baxter) J1566
- Gammaplex Liquid® 5% (BPL) J3490
- Gamunex-C Liquid® 10% (Talecris) J1561
- Flebogamma DIF® 5% Liquid (Grifols) J1572
- Privigen Liquid® 10% (CSL Behring) J1459
- Carimune Powder® (CSL Behring) J1563
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Factors to Determine Product Choice

Pre Screening
- Age
- Renal Function
- Hx of Diabetes
- Cardiac Disease
- IgA Deficiency
- Hx of Hypertension
- Volume of dosage
- Cost
- Time of infusion

Adverse Effects

Rate Related
- Headache
- Chills
- Nausea
- Dizziness
- Flushing
- Back Pain

Post Infusion ADR
- Renal Failure
- Thrombosis
- Hemolytic Anemia
- Aseptic Meningitis
- IgA Reaction

Prions

- Infectious Agent (No Nucleus)
  - Bovine Spongiform Encephalopathy (BSE) Mad Cow Disease
  - Creutzfeld-Jakob Disease (Humans)
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Subcutaneous IgG Infusion

- Vivaglobin® J1562
- Hizentra® J1559
- Gamunex-C® J1561

- FDA approved for subcutaneous infusion for treatment of PID
- Steady State IgG levels
- Less adverse effects
- Once a week dosing
- Available in multiple concentrations (10%, 16% and 20%)

Syringe Pump approved by Medicare for SCIG delivery

Advantages of IVIG and SubQ Usage

- **IVIG**
  - Once a month
  - Familiarity with IVIG
  - FDA approved for multiple disease states
  - Long term data available

- **Subcutaneous**
  - Steady state levels
  - Short infusion
  - Lifestyle improvement
  - Less ADRs
  - Medicare B coverage
  - No IV Line
  - Minimal nursing costs
Reimbursement

Types of Payors

• Medicare B
  – Supplemental Coverage
  – Secondary Coverage
• Medicare D
  – Donut Hole
• Commercial Plans (UHC, BC, Aetna, Cigna etc)
• Medicaid
• HMO/IPA (Full, Shared, No Risk Plans)
• PBM

Medicare Act 2003

• This legislation included sweeping changes to the Medicare program. It provided Medicare beneficiaries with some limited assistance paying for prescription drugs.
• The Medicare Act of 2003 also included major restructuring of the traditional Medicare program, relying heavily on private insurance for the delivery of benefits. In addition, it increased beneficiary cost sharing responsibilities.
• Reimbursement for all Physicians and Hospitals went from AWP-5% to ASP +6 in 2004.
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DMERC

- Under the Medicare statute, section 1842(o)(1)(D) of the Social Security Act, infusion drugs and biologicals furnished through an item of DME are not reimbursed by Medicare through the Average Sales Price (ASP) reimbursement model.
- Instead, they are paid at 95% of the average wholesale price (AWP) for the product in effect on October 1, 2003.
- CMS has said that for new DME infusion drugs, the payment rate would be set at 95% of the first available AWP.
- Only health care providers with DME supplier numbers are to bill the DME MAC or DMERC. Coverage through DME MAC/DMERC includes Vivaglobin®, Hizentra® and Gamunex-C® reimbursement as well as reimbursement for the pump, tubing and ancillaries.

Medicare B IgG Coverage

- Drugs Covered
  - Vivaglobin® J1562
  - Hizentra® J1559
  - Gamunex-C® J1561
- Pump
  - Freedom 60 E0779
- Supplies
  - A4221-Supplies for maintenance bill on a week (alcohol wipes, etc)
  - A4222-Supplies used for infusion of med (tubing, syringe, etc)

Medicare B Reimbursement via LCD's

<table>
<thead>
<tr>
<th>LCD L5044</th>
<th>LCD L77260</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCIG</td>
<td>IVIG</td>
</tr>
<tr>
<td>External Infusion Pump</td>
<td>Supplies not covered</td>
</tr>
<tr>
<td>Supplies Covered</td>
<td>Pump not covered</td>
</tr>
<tr>
<td>Pump Covered</td>
<td>Only Reimbursed for Primary Immune Deficiency</td>
</tr>
<tr>
<td>Only Reimbursed for Primary Immune Deficiency</td>
<td>Covered at AWP-5%</td>
</tr>
<tr>
<td>Covered at AWP-5%</td>
<td>Covered at ASP-4%</td>
</tr>
<tr>
<td>Viva/Hizentra/Gmex-C</td>
<td>Modifier J8</td>
</tr>
<tr>
<td>Modifier J8</td>
<td>Only Reimbursed for Primary Immune Deficiency</td>
</tr>
</tbody>
</table>

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Part B versus Part D Coverage

**Part B**
- Congenital Hypogammaglobulinemia
- Hyper IgM Syndrome
- CVID
- Wiskott-Aldrich Syndrome
- SCID

**Part D**
- CIDP
- Myasthenia Gravis
- Stiff Person’s Syndrome
- Polymyositis
- Dermatomyositis
- Pemphigus Vulgaris
- Multiple Sclerosis
- Guillain-Barré Syndrome
- Kidney Transplant

Medicare Part D Appeals Board

- Maximus Federal Services (QIC)
  - Arbitrator of Part D denials.
- Part D Plan denials may be overturned by the Maximus Federal Services

REIMBURSEMENT TABLE

<table>
<thead>
<tr>
<th>Product</th>
<th>Medicare B</th>
<th>COM/PPM/1BM</th>
<th>Medicare D</th>
<th>AWP Q1 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gammagard®</td>
<td>ASP+4%</td>
<td>Per Contract</td>
<td>AWP-15%</td>
<td>$137.92/gm</td>
</tr>
<tr>
<td>Gammagard 50%</td>
<td>ASP+4%</td>
<td>Per Contract</td>
<td>AWP-15%</td>
<td>$128.69/gm</td>
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<tr>
<td>Gammaplex®</td>
<td>ASP+4%</td>
<td>Per Contract</td>
<td>AWP-15%</td>
<td>$136.80/gm</td>
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<tr>
<td>Privigen®</td>
<td>ASP+4%</td>
<td>Per Contract</td>
<td>AWP-15%</td>
<td>$133.20/gm</td>
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<tr>
<td>Gamunex C®</td>
<td>ASP+4% or</td>
<td>Per Contract</td>
<td>AWP-15%</td>
<td>$115.92/gm</td>
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<tr>
<td></td>
<td>AWP-5%</td>
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<tr>
<td>Caritune®</td>
<td>ASP+4%</td>
<td>Per Contract</td>
<td>AWP-15%</td>
<td>$101.01/gm</td>
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<tr>
<td>PlebGam®</td>
<td>ASP+4%</td>
<td>Per Contract</td>
<td>AWP-15%</td>
<td>$96.77/gm</td>
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<tr>
<td>Vivaglobin®</td>
<td>AWP-5%</td>
<td>Per Contract</td>
<td>N/A</td>
<td>$144/gm</td>
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<tr>
<td>Hizanta®</td>
<td>AWP-5%</td>
<td>Per Contract</td>
<td>N/A</td>
<td>$151.20/gm</td>
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</table>
Reimbursement Bullet Points

- Always obtain authorization first!
- Know your contracts!
- Must have a strong clinical team who understands the disease management process.
- Use a team approach. Clinical/Billing must work closely together...literally.
- Understand Medicare B ICD L5044 vs L27260
- Understand what is covered under B vs D
- All products have same therapeutic efficacy however all are different in adverse effect profiles and have different reimbursement models.

Questions?

Selected References

- All products have same therapeutic efficacy however all
- Understand what is covered under B vs D
- Understood...literally.
Answers:
1. c
2. a
3. b
4. d
5. a
6. c
7. e
8. d
SHAPING OUR HORIZON

Maximizing 20 Years of Achievement to Craft a Future of Possibilities