What’s so Special about Specialty Pharmacy?

What Makes a Drug “Special”

enoxaparin is classified as a specialty drug?
- A. True
- B. False

Specialty Drugs
- No universally accepted definition
- The FDA does not have a definition or a list
- The same drug may or may not be considered a specialty drug by insurer, drug manufacturer, pharmacy, hospital, etc.

Specialty Drugs: Potential Characteristics
- Expensive
- Used to treat complex and/or rare condition
- Require special handling
- Unique administration
- Require high patient touch - counseling, monitoring, support, etc.

Specialty Drugs: Expensive
- CMS definition of a specialty drug is one with a cost of $600 or more per month.
- For 2015, All Drugs with Annual Per-User Spending >$10K for Medicare part D was $37.9B, 28% of total program spending
- Total part D spending in 2015 for ledipasvir/sofosbuvir was $7,030,633,485.80, $92,846.74 per user
- Total part D spending in 2015 for enoxaparin was $316,414,099.85, $777.64 per user
Specialty Drugs: Treat Complex and Rare Conditions
- nusinersen
- Infantile spinal muscular atrophy
- 1 in 6,000 to 1 in 10,000 live births

Specialty Drugs: Require Special Handling
- Refrigeration
- Narrow dispensing window from prescription written date

Specialty Drugs: Unique Administration
- Pushtronex™ System for Repatha® (evolocumab)

Specialty Drugs: Require High Patient Touch
- Tacrolimus
  - May have frequent dose changes based on trough values
  - Frequent monitoring for side effects to ensure compliance
  - Complex billing to Medicare part B
- Changes in manufacturer strongly discouraged

For your Consideration
- Should we have a standardized definition of a specialty drug?

HapEpil is a new drug on the market. Which of the following would NOT make it a specialty drug?
- A. It must be kept below 45 degrees at all times
- B. It costs $150 per month
- C. It treats a very rare condition
- D. Drug is administered by injection
What makes a pharmacy a specialty pharmacy?

In order to be a specialty pharmacy, a pharmacy must be accredited by:

- A. The Joint Commission
- B. Utilization Review Accreditation Commission (URAC)
- C. Accreditation commission for Health Care (ACHC)
- D. None of the Above

Specialty Pharmacies

- Dispense Specialty Drugs
  - Specialty Pharmacies dispense specialty drugs.....
  - .....wait didn't we say there was no definition of a specialty drug?
  - May also dispense non-specialty drugs
  - May be low volume - Walgreens local specialty averaged about 50 scripts a day at one point
  - May be high volume - Frisco central fill averages around 700 scripts per day

Specialty Pharmacies - Equipped to handle complex billing

- Prior Authorization
- Medical billing
- Billing multiple payers
- Securing financial assistance

Specialty Pharmacies - Staff may have specialized training

- Clinicians
- Viroligy, HIV training
- Administration training
- Specialty billing training
Specialized Pharmacies - Support Programs
- May have special programs to support patients and increase adherence
- Allow the pharmacy staff to closely monitor the patient
- Proactive care, often calling patient when refills are due
- May offer special services aiming to increase adherence such as delivery of medication to patient’s home or doctor’s office.

Specialized Pharmacies - Reporting
- Many specialty drugs require comprehensive reporting and the pharmacy must be equipped to handle this
- Reporting may be required by the manufacturer, the FDA, the patient’s private insurance, medicare/medicaid, or an accrediting third party
- Near 0% deviation is expected in reporting completion and accuracy
- Revlimid® only allows 3 deviations per year before suspending access

Drug Access Restrictions and Limitations
Susie Q presents to the pharmacy with a prescription for sofosbuvir/velpatasvir. You order the drug and receive it the next day but when you bill Susie’s insurance the claim is rejected with the following message: “Pharmacy not in network. Must be filled by Hptom Mail Order Pharmacy. Call 888-888-8888 to transfer prescription.” sofosbuvir/velpatasvir is an example of:
- A. A Payer Restricted Access Drug
- B. A Limited Distribution Drug
- C. Both A and B

Payer Restricted Drug Access
- Insurance companies may restrict access by only covering specialty medication if it is filled at a specialty pharmacy of their designation
- Sometimes payers will allow first fill or an emergency fill outside the network
- This allows the payer to more tightly control costs and negotiate prices

Limited Distribution Drugs
- The manufacturer limits the number of pharmacies that can obtain the drug
- The FDA may mandate that a drug be LDD
- Manufactures may autonomously decide to limit access to certain pharmacies that can provide things like:
  - Risk evaluations
  - Outcomes data
  - Special documentation
  - Clinical expertise
  - Support for Patients
  - Compliance/side effect monitoring
LDD’s in the Retail Setting - Who has access?

- Local Access is limited:
  - Presbyterian Specialty Pharmacy - Adeglo
  - Walgreens at Lovelace Hospital (Flowers) - Daraprim, Iressa, Lynparza, Tagrisso
  - Walgreens at Lovelace (Lovelace Center) - Cosentyx, Nucala
  - Walgreens at Presbyterian Hospital Downtown - Iressa, Lynparza, Tagrisso
- Most local pharmacies refer specialty scripts to a central fill or specialty partner:
  - Costco - Diplomat Specialty
  - CVS - CVS specialty
  - Walgreens - Walgreens specialty
  - Wal-Mart/Sams Club - Wal-mart specialty

How does a pharmacy get LDD access?

- For new drugs - pharmacies work with manufactures well before drugs are even approved
- Negotiations for access are often started while the drug is still undergoing clinical trials
- A drug may come to market with limited access and then move to regular distribution
- To gain access to LDDs already on the market, accreditation by a 3rd party is often required
- Contact the drug manufacturer directly to get information on their application process

Specialty Drug Billing

- High Cost
- Prior Authorization usually required
- May require billing multiple payers
- Medicare part B may be payer
- Additional Financial Assistance

Prior Authorization

- Drug companies may have "drug access specialist" to facilitate the PA process
- CoventryMeds - "A free system that automates prior authorization requests, saving countless administrative hours on the phone and sending faxes to health plans." - CoventryMeds.com
- Doctor's office's often have their own workflow/personnel to handle prior auths

Medicare Part B - Coverage

- Medicare Part B provides coverage for certain durable medical equipment supplies, prescriptions that can’t be self-administered, and certain self-administered anti-cancer drugs
Medicare Part B - Requirements

In order to use Medicare Part B benefits, the following requirements must be met:

- The patient must have Medicare Part B coverage
- The item must be a Medicare Part B approved item
- The item must be a medical necessity as defined by Medicare (verify ICD-10 code is a covered diagnosis code)

Medicare Part B - Deductible and Co-Pays

- The patient must pay all costs until he/she meets the yearly Part B deductible ($166.00 for 2016). Then Medicare pays its share and the patient pays the copay, which is typically 20% of the Medicare-approved amount for prescriptions.
- If the patient has a supplemental insurance or Medicaid, the deductible and copay are 0.
- If the patient has ONLY Medicare Part B coverage, the following copay applies: Medical and Other Services; 20% of the Medicare-approved amount for most preventative services and durable medical equipment.

Insulin

- Humalog
- Humulin
- Novolog

Medication must be administered in a pump

- The Infusion pump make/model and date of purchase (mm/yyyy) on claim
- Medicare must have paid for the pump

Antiemetic: Oral

- Anzemet 100mg
- Atarax 25mg, 50mg
- Benadryl 25mg
- Compazine 10mg
- Decadron 5mg
- Kyrlot 10mg
- meperidine 50mg, 100mg
- meperidine 25mg
- Tigan 25mg
- Torecan 10mg
- Trilafon 4mg, 8mg
- Zofran (Ondansetron) 8mg

Medication must be used for treatment of Cancer

- Initial dose of medication must be administered 2 hours before or 48 hours after administration of chemotherapy drug
- Patient must be on chemotherapy and have a cancer diagnosis.

Anti-Cancer: Oral

- Alkeran (Melphalan)
- Cytoxan (Cyclophosphamide)
- Hycurtin (Topotecan)
- Methotrexate (Trexall)
- Hybran (Busulfan)
- Temdodar (Temozolomid)
- Vepilid (Etoposide)
- Xeloda (Capecitabine)

Medication must have been ordered as a full therapeutic replacement of IV drugs.

- Patient must have had a covered organ transplant
- Patient must have been enrolled in Medicare Part A when transplant occurred

Immunosuppressive

- Cellcept 250mg (Mycophenolate)
- Imuran (Azathioprine) 50mg, 100mg
- Methyprednisolone (Medrol) 4mg
- Myfortic (Mycophenolics)
- Neoral (Sandimune/Gengraf/Cyclosporin) 25mg, 100mg
- Prednisone 5mg, 10mg
- Prednisolone 4mg
- Prograf 1mg (Tacrolimus)
- Rapamune 1mg (Sirolimus)

Patient must have had a covered organ transplant
Inhalation
- Albuterol 0.083%, 0.5%
- Alupent 0.4%, 0.6%, 5%
- Atrovent
- Broncho Saline
- Cibacryl Sodium
- Biakril
- Halerol
- Ipratropium
- Metaprost 1%, 2%
- Nebupent
- Perforomist
- Proventil 0.083%, 0.5%
- Pulmicort
- Pulmozyme
- Tobramycin 6%
- Ventolin 0.083%, 0.5%
- Xopenex

Medication must be administered in a nebulizer.

Patient must be diagnosed with a chronic pulmonary condition. [Conditions such as pneumonia, bronchitis, shortness of breath and cough are not covered by Medicare Part B]

Copay Assistance for Specialty Medications

Copay Assistance Cards
- Most copay cards are not valid for prescriptions covered by Medicare, Medicaid, or any federal/state funded program
- Check individual offer to verify if it can be used for patients with federal/state funded insurance
- You may get a paid claim, but you put yourself at risk for a chargeback
- Consider developing a consent form that allows you to complete enrolment on behalf of the patient. The following information should be included on the form as it is often requested to complete enrolment:
  - Total number of people residing in the home
  - Total combined annual income of the household

Copay Assistance Cards - Examples

<table>
<thead>
<tr>
<th>Drug Description</th>
<th>Contact</th>
<th>Limits</th>
<th>Patient Activation</th>
</tr>
</thead>
<tbody>
<tr>
<td>INCIVEK (Hep C)</td>
<td>855-837-8394</td>
<td>Up to $10,000/year</td>
<td>Required</td>
</tr>
<tr>
<td>CellCept (Transplant)</td>
<td>877-509-2235</td>
<td>Up to $100</td>
<td>Not Required</td>
</tr>
<tr>
<td>Nexavar (Oncology)</td>
<td>866-639-2827</td>
<td>Up to 95% of copay</td>
<td>Required</td>
</tr>
<tr>
<td>Ampyra (MS)</td>
<td>888-881-1918</td>
<td>Up to $500</td>
<td>Required</td>
</tr>
</tbody>
</table>

Grants
- HealthWell Foundation: 1-888-475-0414
  https://healthwellfoundation.org
- Patient Access Network: 1-866-616-7263
  https://www.patientaccessnetwork.org
- Patient Advocate Foundation: 1-888-532-1274
  http://www.patientadvocate.org
- CancerCare Copayment Assistance Foundation: 1-866-55-0598
  https://cancercarecopay.org
- Good Days Fund: 1-877-809-7233
  https://portal.mygooddays.org