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Defining Concern

The goal of this paper is to provide plan sponsors with an understanding of what specialty pharmacy is and the various approaches that may mitigate the double-digit growth of these high cost drugs. We are finding that traditional management strategies are not adequate, nor are simply looking at the pharmacy benefit. For traditional drugs, pressure on the price paid for the drug provided the most savings. This means that we primarily focus on the member cost share and the network discount. In the specialty pharmacy world—because there are often only one or two drugs for a given category and they are only made by one or two manufacturers—the pressure on price is not possible. For specialty drugs and the diseases they treat, getting the best patient outcomes, avoiding hospitalizations, and minimizing emergency room visits is where the savings are typically found.

Because this drug class is growing so rapidly, it is important to have a specialty pharmacy strategy that balances cost control and patient care. For most employers and health plans, picking a specialty pharmacy program (SPP) that provides the following services is necessary:

- Distribution process with comprehensive cost containment.
- Clinical services designed to optimize patient outcomes and minimize negative consequences.
- Sophisticated data reporting and analysis.
- Acknowledgement and accountability for rebates received by the plan, employer, or the PBM.

### WHY IT IS IMPORTANT TO FOCUS ON SPECIALTY PHARMACY

Initially, specialty drugs were developed for use in treating rare diseases affecting a much lower number of patients. Clinically, the advent of these agents has changed the way the diseases are treated from merely treating the symptoms to treating the underlying pathology.

Traditional pharmacy was carved away from medical in the 1980s.

Retailers and pharmacy benefit managers (PBM)s) developed specific rule sets governing the process of routing a prescription through a system that assured payment, reporting, and safety.

Specialty pharmacy has, until recently, remained integrated with medical due to three factors:

1. The medications are expensive compared to oral solids.
2. The medications often require refrigeration.
3. The medications often require administration and follow-up by a trained team of professionals to assure safety and effectiveness.

Development of specific rule sets for governing the process of routing specialty medications though systems sophisticated enough to deal with the aforementioned factors added complexity and is still a work in progress.

Now, with the growth of biotechnology and advanced methods of drug delivery, the specialty marketplace is increasing. The 2007 Drug Trend Report, produced by Express Scripts, Inc (ESI), quoted that specialty drugs would increase from the 2007 expenditures of $54 billion to more than $99 billion in 2010 (Express Scripts, Inc, 2007). For 2008, the three largest PBMs reported that their drug trend for specialty drugs was 11.7% to 15.8% for 2008. This compares to their reported trends for traditional drugs of between 1.5% and 2.8% (CVS Caremark, 2009) (Express Scripts, Inc., 2008) (Medco Health, 2008). Accredo, an SPP, estimates that by 2013, specialty drugs will account for 25-30% of total pharmacy costs (Medco Health, 2009).

The key drivers of specialty trend are broken into two parts: high cost per patient and increasing utilization (FIGURE 1 Stern, 2008).

<table>
<thead>
<tr>
<th>HIGH COST PER PATIENT</th>
<th>INCREASING UTILIZATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accounts for 15% of pharmaceutical spending in the US</td>
<td>Flourishing pipeline</td>
</tr>
<tr>
<td>Annual growth at 15-20%</td>
<td>New indications for existing drugs</td>
</tr>
<tr>
<td>Annual drug cost ranges from $15,000 - $250,000+ per patient</td>
<td>Earlier use of biologics in treatment regimen</td>
</tr>
<tr>
<td>Manufacturer price increases for existing drugs</td>
<td>Move from rare diseases to more common chronic diseases</td>
</tr>
<tr>
<td>No generics available as products mature</td>
<td>Episodic vs. chronic treatment</td>
</tr>
</tbody>
</table>

*FIGURE 1*
To further elaborate on the specialty pipeline, we currently know that there are over 250 specialty drugs that have been approved by the Food and Drug Administration (FDA) and it is expected that over the next several years, biologic approvals will outnumber the approvals of traditional agents. These drugs will be used to treat the following diseases **FIGURE 2**: 

**NUMBER OF PREFERRED PRODUCTS BY THERAPEUTIC CATEGORY**
Indicates the number of preferred products for each of the following therapeutic classes/products.

<table>
<thead>
<tr>
<th>Therapeutic Category</th>
<th>DOLLARS (IN MILLIONS)</th>
<th>SHARE %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer / Related Conditions</td>
<td>$10,075.7</td>
<td>21%</td>
</tr>
<tr>
<td>Infectious Diseases</td>
<td>$1,159.9</td>
<td>2.4%</td>
</tr>
<tr>
<td>Autoimmune Disorders</td>
<td>$95.3</td>
<td>0.2%</td>
</tr>
<tr>
<td>Other</td>
<td>$796.5</td>
<td>1.7%</td>
</tr>
<tr>
<td>HIV / AIDS Infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiovascular Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes / Related Conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurologic Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Digestive Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genetic Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transplantation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eye Conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Growth Disorders</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Drugs may appear in more than one category. PhRMA 2008 Report: Medicines in Development. Available at www.phrma.org/medicines_in_development_for_biotechnology

We also know that manufacturers are focusing their research and development activities on specialty drugs. According to the 2009 Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, in 2007, 25.3% of the total research and development (R&D) dollars were going to biologics or biotechnology agents (**FIGURE 3** Pharmaceutical Research and Manufacturers of America, 2009).

**BIOLOGICS AND BIOTECHNOLOGY R&D**

<table>
<thead>
<tr>
<th>Type</th>
<th>DOLLARS (IN MILLIONS)</th>
<th>SHARE %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biologics/Biotechnology R&amp;D</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biotechnology-Derived Therapeutic Proteins</td>
<td>$10,075.7</td>
<td>21%</td>
</tr>
<tr>
<td>Vaccines</td>
<td>$1,159.9</td>
<td>2.4%</td>
</tr>
<tr>
<td>Cell or Gene Therapy</td>
<td>$95.3</td>
<td>0.2%</td>
</tr>
<tr>
<td>All Other Biologics</td>
<td>$796.5</td>
<td>1.7%</td>
</tr>
<tr>
<td>Total Biologics/Biotechnology R&amp;D</td>
<td>$12,127.4</td>
<td>25.3%</td>
</tr>
<tr>
<td>Total Non-biologics/Biotechnology R&amp;D</td>
<td>$32,178.3</td>
<td>67.2%</td>
</tr>
<tr>
<td>Total Uncategorized R&amp;D</td>
<td>$3,597.4</td>
<td>7.5%</td>
</tr>
<tr>
<td>Total R&amp;D</td>
<td>$47,903.1</td>
<td>100%</td>
</tr>
</tbody>
</table>

**DEFINITION OF SPECIALTY DRUGS AND SPECIALTY PHARMACY MANAGEMENT**

To begin the discussion of how to manage specialty pharmacy, one must first understand precisely what type of drugs these are. The first term often heard when talking about specialty pharmacy is “biologic drug.” This is a drug that is made from a living organism. “Biotechnology,” then, refers to the application of biological techniques to research and develop new products such as proteins, hormones, vaccines, monoclonal antibodies, and gene therapy. These drugs have low use but are high cost.

The term “specialty pharmaceuticals” is used interchangeably with “biologics,” but specialty drugs also include non-biologic products with high costs or those that require special handling or intensive patient education to maximize the effectiveness of the drug. In order to simplify the discussion, the term “specialty drug” will be used throughout this document.

Our definition of a specialty drug includes four features: method of administration, nature of the disease being...
treated, cost, and location of administration. We further define specialty pharmacy drugs as having the following characteristics:

- Commonly produced through biotechnology.
- Orphan drugs or used to treat diseases for which there are no available treatments.
- Target underlying disease pathology rather than just treating symptoms.
- Typically administered via injection or infusion, but oral and inhaled agents may also appear on the list.
- Require special handling, administration, or both.
- Have a high need for therapy management by health professionals due to a high incidence of adverse effects and compliance problems requiring monitoring and dosing adjustments.
- High cost as defined by the Centers for Medicare & Medicaid Services CMS as equal to, or greater than, $600 per month.

Based on the above characteristics, the following products are not considered to be specialty drugs:

- Erectile dysfunction drugs.
- Antibiotics.
- Diagnostic agents.

There are some drugs that, clinically speaking, we maintain should be covered under the medical and pharmacy benefit. These are the low molecular weight heparins for clot clots and red and white blood cell stimulators. Clinically, there are scenarios where the drugs can be covered under either benefit and setting limits to one over the other would be inappropriate for patient care.

To help plan sponsors determine what drugs should appear on their specialty drug list (SDL), PSG has developed one that can be found in **ATTACHMENT A.** Further information on where drugs should be dispensed as it relates to the SDL can be found in the Cost Containment section (page 9).

Specialty drugs are considered to be both administratively and clinically intensive, as well as high cost. Many specialty drugs are not biologics. Conversely, many biotech drugs are not considered specialty drugs. For example, insulin is a biologic, but is not considered a specialty drug. Ribavirin is an oral antiviral tablet that is used in the treatment of hepatitis C. Even though it is not made through a biotechnology process, it is considered to be a specialty drug because of the disease it treats and because it is used in conjunction with biologics.

Another important component of specialty drug definition is where the drug is administered:

1. Self-administered agents (SAAs) can be administered either by the patient or caregiver. For example, insulin is a drug that is commonly administered (self-injected) without the assistance of a healthcare professional. Specialty drugs that are self-administered include Enbrel injection for rheumatoid arthritis, Tarceva tablets for lung cancer, and Copaxone injection for multiple sclerosis. It is important to note how the injection is administered (e.g., subcutaneous (under the skin) or intramuscular (in the muscle). The injection itself does not determine if the drug is self-administered. Rather, the FDA labeling stipulates if the drug must be given by a healthcare professional or not. An example of this is Copaxone which is an intramuscular injection and is considered a specialty drug because the patient can administer it themselves. SAAs are considered to be a part of the pharmacy benefit.

2. Office administered agents (OAs) are injected or infused in the physician’s office, infusion center, outpatient clinic, or oncologist’s office. These include vaccines, antibiotic and vitamin injections, Remicade for rheumatoid arthritis, intravenous immunoglobulin (IVIG) for immunodeficiency syndromes, IV chemotherapy and supportive agents, and depot injections of Lupron or Provera. Usually these are either intravenous (IV) or intramuscular (IM) injections and are typically covered under a plan’s medical benefit. Covering these agents under the pharmacy benefit is one way to manage them and will be discussed further.

3. Home-infused agents are those in which a home health nurse is required to administer the drugs to a patient in their home. These include drugs for Gaucher’s disease, pulmonary arterial hypertension, and IVIG. Again, these drugs are typically billed and covered under the medical benefit.

For the purposes of this paper, injections that are administered in a hospital in the in-patient setting are not included as part of the specialty drug discussion.

The term “Specialty Pharmacy Management” is defined as a comprehensive and coordinated system of pharmacological care in which patients with chronic illnesses and complex medical conditions receive expert therapy management services tailored to meet their unique needs. This patient-centric model is organized to dispense/distribute injectable, infusible, and other costly, hard-to-manage therapies within a collaborative framework designed to achieve superior clinical, economic, and overall health outcomes (Armada Health Care, 2009). This definition focuses on the complex nature of the diseases and drugs and includes the dispensing of the drug coupled with the therapy management these patients need.
GOALS OF A SPECIALTY PHARMACY MANAGEMENT PROGRAM FOR PAYERS
The goals for a specialty pharmacy management program for payers are to:

1. Equalize benefits between pharmacy and medical to avoid members choosing the administration site based on their coverage.
2. Optimize cost management by receiving the lowest unit cost from dispensing pharmacies and receive any available rebates from manufacturers.
3. Ensure appropriate use by employing clinical guidelines and criteria, prior authorization, and formulary programs.
4. Improve clinical management by assessing and intervening on adherence and persistency, patient care services, therapy and case management, and demonstrating improved outcomes.
5. Expertly craft the contract to account for changes in the industry, including generic biologics.

Methods To Manage Specialty Pharmacy
The two main questions in relation to benefit design are which benefit should be used for specialty drug coverage (medical or pharmacy) and what member cost sharing should be applied.

EXPLANATION OF PHARMACY VS. MEDICAL BENEFIT COVERAGE
It is not difficult to understand why SAAs should be covered under the pharmacy benefit - the physician writes the prescription, the drug gets filled by a pharmacy, and the member administers (self-injects) the drug.

Medical benefit processing of the drug is more complex. As discussed earlier, this paper focuses on OAAs and home-infused agents. First, an understanding of the billing process for each benefit is necessary. The following table outlines the different requirements of an injectable claim for each benefit. **FIGURE 4**

<table>
<thead>
<tr>
<th>PROVIDER TYPE</th>
<th>PHARMACY BENEFIT (PHARMACY)</th>
<th>MEDICAL BENEFIT (PHYSICIAN, PHARMACY, HOME HEALTH CARE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BILLING TERM</td>
<td>“Bill and Dispense” – purchase, dispense, and then bill based on pharmacy network contract terms.</td>
<td>“Buy and Bill” – purchase, administer, and then bill based on contract terms within the medical network contract.</td>
</tr>
<tr>
<td>DRUG CODING METHOD</td>
<td>National Drug Code (NDC) – 11 digits specific for drug name, manufacturer, form, strength, and container or vial size.</td>
<td>HCPCS J or Q Code – specific to drug or drug class but not specific to manufacturer, strength, or package size.</td>
</tr>
<tr>
<td>PRICING SOURCE</td>
<td>Medi-Span or First DataBank</td>
<td>Vendor agreed upon. For example, could be based on AWP, ASP, or billed charges.</td>
</tr>
<tr>
<td>WHAT IS REIMBURSED</td>
<td>The negotiated cost of the drug and a dispensing fee.</td>
<td>The negotiated cost of the drug and the administration fee.</td>
</tr>
<tr>
<td>PROVIDER IDENTIFICATION</td>
<td>NABP for pharmacy and National Provider ID for provider.</td>
<td>National Provider ID.</td>
</tr>
<tr>
<td>UTILIZATION MANAGEMENT PROGRAMS</td>
<td>Prior authorization, concurrent drug utilization review edits such as drug-drug interactions and high dose checks, copay assigned to drug, and formularies.</td>
<td>Hit or miss prior authorization/precertification/medical review process. Disease management, case management, high-cost case management.</td>
</tr>
<tr>
<td>MEMBER COST-SHARE</td>
<td>Copayment or coinsurance for drug. Office copayment for the administration if not self-administered.</td>
<td>Copayment for office visit. Some plans have coinsurance for drug product, others do not require a cost share for the drug.</td>
</tr>
</tbody>
</table>

**FIGURE 4**
Medical benefit injections are billed by providers under a process called “Buy and Bill.” This process requires the physician to obtain the drug, manage the inventory, administer the product, and submit it to the payer for drug reimbursement and the professional administration fee. Conversely, under the pharmacy benefit, the drug is purchased by the pharmacy, billed to the insurer, and then dispensed to the patient.

For low-cost antibiotics and steroid injections, the “Buy and Bill” scenario did not put much financial burden upon the administering physicians because these drugs have historically been very inexpensive. Now with the advent of very expensive specialty drugs, outlying the dollars to purchase the product without knowing how much they will be reimbursed has moved some physicians to cease stocking these agents. A specialty pharmacy can be used to ship the drug to the patient and bill the patient’s medical benefit for the drug (assuming the SPP is a part of the insurance company’s medical network). The problem then becomes concern over double-billing because the provider’s office might also bill for the drug even though they did not purchase it.

The Healthcare Common Procedure Coding System (HCPCS) was developed by Medicare to provide a standard coding and billing process for healthcare procedures and drugs. It was never intended to cover every procedure or every drug. The “J” and “Q” codes are assigned to drugs administered in the physician office or clinic. Unfortunately, the codes are defined 6-18 months after the drug is launched. In that case, a miscellaneous (undefined) code of J3490 (unclassified drug) or J3590 (unclassified biologics) is used.

J and Q codes are less specific than NDC codes because they correspond to a drug’s chemical name not the manufacturer, strength, or package size. An example of this is insulin. J1820 is defined as injection insulin up to 100 units. This code is not specific to the type of insulin used: Humulin, regular or NPH. Each of these has a different cost. Another example is Remicade, where one unit of the J-code is equal to 10mg. The vial size for Remicade is 100mg, leading to confusion around correct billing.

Using the HCPCS system does not allow payers to track and manage product utilization in the way they can under the pharmacy benefit. Member copayments cannot be tied to specific product selection, formularies cannot be implemented, and DUR edits such as drug-drug interactions or maximum dose edits cannot be done. In addition, because the drug has been administered before the claim is seen, utilization management programs that encourage product selection or prior authorization requirements for appropriate indication or dose cannot be done consistently.

In order to overcome some of these issues, some medical carriers are requiring the NDC of the vial administered to appear on the CMS 1500 form. Advanced carriers have written this requirement into their provider contracts. They are then able to crosswalk the NDC to the PBM system to pull the correct price for the drug. This process is cumbersome and needs to be continually monitored as new drugs and codes become available.

Carriers have also started to require prior authorization/precertification.medical review processes to be conducted for certain specialty drugs. For these, the carrier requires medical-necessity information from physicians before the drug is covered. They compare that information to their approval criteria to determine coverage. Unfortunately, this requires physician offices to remember this requirement for the carrier. If the office fails to do so and the coverage is denied then, depending upon the provider’s contract, the patient might have to pay the full cost of the drug.

For the provider, the issue is complicated because, in some cases, there is a financial incentive to favor a product that requires administration by a healthcare professional rather than one that can be self-injected. The provider markup on injectables can be high. Additionally, the provider receives a drug administration fee that corresponds to whether it was an IV or IM injection, along with the time it takes for infusing (if it is IV). This is especially important in oncology offices where significant revenue is generated by the infusion of chemotherapy and supportive therapy such as red or white blood cell stimulators.

NEW SPECIALTY BENEFIT THAT COMBINES THE PHARMACY AND MEDICAL BENEFIT

Because drugs covered under the medical benefit and pharmacy benefit can have different reimbursement rates, member copays, clinical review, and utilization management rules, it often leads to misaligned financial and utilization incentives for members and physicians. The ultimate goal should be to have the same member contribution and the same price paid for the drug no matter where it is dispensed or administered.
FIGURE 5 demonstrates a proposed benefit in which the member cost share and provider reimbursement is equal:

<table>
<thead>
<tr>
<th>MEDICAL BENEFIT</th>
<th>PHARMACY BENEFIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>CURRENT</td>
<td></td>
</tr>
<tr>
<td>• $20 office visit copay.</td>
<td>• Open retail network.</td>
</tr>
<tr>
<td>• 20% coinsurance for the drug.</td>
<td>• Specialty copay of $80 for 90 days at mail or $40 for 30 days at retail.</td>
</tr>
<tr>
<td>PROPOSED</td>
<td></td>
</tr>
<tr>
<td>• OAA specialty tier: 20% coinsurance: $2500 annual prescription out-of-pocket maximum.</td>
<td>• OAA and SAA specialty tier: 20% coinsurance: $2500 annual prescription out-of-pocket maximum.</td>
</tr>
<tr>
<td>• Selected SAA no longer covered under the medical benefit.</td>
<td>• Coverage only through exclusive specialty pharmacy at deeply discounted rates.</td>
</tr>
<tr>
<td>• All bills from providers required to have NDC on claim form.</td>
<td>• Prior authorization, dosing guidelines, quantity limits implemented.</td>
</tr>
<tr>
<td>• Provider reimbursed same amount as specialty pharmacy contracted rate.</td>
<td>• 30-day supply only.</td>
</tr>
<tr>
<td>• Provider administration fee increased to overcome provider’s loss in revenue from decreased drug price.</td>
<td>• No provider administration fee as patient administers drug.</td>
</tr>
</tbody>
</table>

FIGURE 5

BENEFIT DESIGNS TO CONTROL UTILIZATION FOR SELF ADMINISTERED AGENTS

Increasing the member share of specialty drugs and limiting them to a 30-day supply has been a key cost management strategy. Payers have placed specialty drugs in a fourth tier with copayments or coinsurance with minimum and maximums per prescription. The recent PBMI Prescription Drug Benefit Cost and Plan Design Report 2008-2009 (Pharmacy Benefit Management Institute, LP, 2008-2009), found the average copayment for specialty drugs at retail was $68.50 and $146 at mail. Common coinsurance values were a 30% coinsurance with minimum cost share per prescription of $20 and maximum of $175 at retail. At mail, 30% coinsurance and higher minimums and maximums of $50 and $137, respectively, were reported.

Part D Medicare Advantage Prescription Drug (MAPD) contracting and prescription drug plans (PDP) have taken to employing four-tier benefits for specialty drugs more than commercial payers have. Novartis’s Facts, Figures, & Forecasts, 2008–2009, reports that three-fourths of Part D plans either had or will have a fourth-tier benefit by 2009. In contrast, only 43% of commercial payers could say the same (Managed Care Magazine, 2009).

FIGURE 6 gives an understanding of the member copayments for various benefit designs.

<table>
<thead>
<tr>
<th>DRUG</th>
<th>ESTIMATED 30-DAY DISCOUNTED INGREDIENT COST</th>
<th>FIXED COPAY</th>
<th>20% COINSURANCE</th>
<th>30% COINSURANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple Sclerosis</td>
<td>$2,500</td>
<td>$50</td>
<td>$500</td>
<td>$750</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>$1,400</td>
<td>$50</td>
<td>$280</td>
<td>$420</td>
</tr>
</tbody>
</table>

FIGURE 6

COPAY EFFECT—DOES INCREASING COPAYMENTS CHANGE ADHERENCE?

While the reasons for poor adherence are very complex, it is known that it typically leads to unfavorable outcomes and increased healthcare costs. Researchers have tried to determine if high specialty copayments impact adherence. It was found that tumor necrosis factor (TNF) inhibitor patients with copayments over $250 were 4.6 times more likely to decline to fill the prescription than patients with a copayment of $100 or less (Gleason P G. B., 2008). Another study found that patients with copays over $50 were more likely...
to discontinue their medication than patients with lower copays. (Curkendall S, 2008). For multiple sclerosis patients, a $200 copayment resulted in patients not filling their prescriptions six times more than members with a $100 or less copayment (Gleason P G. B., 2009).

**SUMMARY OF PSG RECOMMENDATIONS**

Payers should review with their medical carriers the member cost share for OAAs and SAAs billed under the medical benefit. These benefits should be aligned between the pharmacy and medical benefit. Payers may discuss implementing a fourth-tier copay depending on their pharmacy benefit philosophy, vendor arrangement, and current plan design. An example of a fourth-tier copay design could be a 20% copayment for specialty drugs, with a $150 maximum per 30-days supply, and an annual out-of-pocket maximum of $2,000 specifically for specialty drugs. These levels should strike the balance between an acceptable cost sharing while maintaining a benefit that is not overly burdensome on the patient.

Optimize Cost Containment

**DISTRIBUTION CHANNELS—RETAIL, SPECIALTY, MAIL, PROVIDER OFFICE**

There are many points of distribution for SAAs. For several years now, payers have been moving to requiring members to receive SAAs from contracted specialty pharmacies. All PBMs either own or contract with a preferred specialty pharmacy at this time. While the discounts payers currently receive are similar between retail and specialty, we anticipate higher discounts from specialty pharmacies in the future. Specialty pharmacies are also owned by health plans, retail pharmacy chains, and wholesalers.

A forceful approach we have observed by the PBMs is to change their contracting to deny filling of specialty drugs unless they are filled through their specialty pharmacy fee schedule. This means that instead of a rate of Average Wholesale Price (AWP) minus 22% at mail for a drug, the payer has to pay AWP minus 15%. This provides increased revenue for the PBM. The other negative impact that we have seen is PBMs creating extensive specialty drug lists that require those drugs to be filled only by their specialty pharmacy. To combat this, PSG’s specialty drug list can be used as a template for PBM negotiations. For example, we feel that cyclosporine and methotrexate are used for many diseases besides their original FDA approval of transplantation and oncology. Requiring these drugs to be filled by a specialty pharmacy is not necessary because of their low cost and widespread use. However, if the patient chooses to receive the drug through the specialty pharmacy for the enhanced education, that should be encouraged but not required. More information on this topic can be found in the Contracting Language section (page 13).

As discussed above, some payers are moving OAAs to the pharmacy benefit by blocking selected J-codes from coverage under the medical benefit. Then they require the drug to be shipped from the specialty pharmacy to the physician’s office for administration. If this approach is followed, it is critical to have an audit process to ensure that there is not double billing for the drug from the physician’s office.

Other payers are allowing physicians to continue to buy and bill for OAAs, but have restricted reimbursement to levels similar to the specialty pharmacy rates. This method allows for the least member inconvenience. Payers may increase the fee that physicians are paid for the actual administration of the drug to compensate for a loss in profit from billing the drug costs and the subsequent margin on those bills.

Employers should question the method their medical carriers are paying physicians for J-codes. If they are using an Average Sale Price (ASP) + 6% methodology or an AWP -15%, then moving OAAs to the pharmacy benefit will not result in as much savings on the drug pricing. Savings might be found in better clinical management and appropriate use. However, medical benefits can require prior authorization before a drug is given to ensure appropriate use.

**LIMITED DISTRIBUTION DRUGS**

Manufacturers may put their specialty drugs in exclusive or limited networks where they only allow dispensing from one or more specialty pharmacies or wholesalers. Limited distribution drugs may have very specific and complex dosing or lab monitoring needed or might be required by the FDA for drug approval. By restricting access to the drug, the manufacturer can ensure that the pharmacies and wholesalers that distribute the drug have training on the necessary monitoring to reduce risks, help the manufacturer track inventory, and provide prescriber information used in marketing.

For drugs with exclusive or limited distribution, usually the contracted specialty pharmacy will forward the prescription to the correct pharmacy for filling. For some vendors, a subcontracted arrangement is in place so the payer does not have to hold a
separate contract with the limited distributor for one drug. Other specialty pharmacies do not offer this service. Because of the few number of drugs involved and the infrequency of prescriptions, these scenarios can typically be handled on a case-by-case basis in the time frame required. Therefore, a payer does have the ability to limit their specialty network and still provide access to these products for their members.

CONTRACTING FOR EXCLUSIVE SPECIALTY PHARMACY SERVICES

To get the best AWP discount, many PBMs have incented their clients to use their specialty pharmacy exclusively. For employer groups, as long as the PBM has processes in place to coordinate the receipt by the patient of limited distribution drugs, the clinical services are sufficient, and the rates have been analyzed and found to be market competitive, then exclusive specialty pharmacy arrangements should be considered.

We have found that health plans receive better discounts if they contract their specialty pharmacy services outside of their PBM arrangement. This may mean using the PBM’s specialty pharmacy as well as another vendor that provides the clinical services or flexibility the plan needs. This also requires the vendors to “earn the business” because if a member or provider is not satisfied with the services of one, they can switch to another. It also provides knowledge in setting rates because there are two vendors to compare against.

At a minimum, the specialty pharmacy vendor chosen should provide the following services:

- Competitive AWP discounts.
- Contracts with local pharmacies to provide emergency supplies or replace lost packages.
- Mailing services through a national mailing company or small courier service that are guaranteed to cover entire service area.
- Tracking services for packages.
- 24-hour access to nurses or pharmacists to answer member questions.
- Support for patient assistance programs.
- Member education concerning the injection technique, the adverse effects from the drug and how to lessen them, the disease process, and how to achieve optimal results from the therapy.
- Refill calls where the actual patient is spoken to and refill necessity is addressed before the next prescription is filled.
- Solid clinical programs that are shown to improve outcomes.
- Prior authorization services with criteria reviewed by practicing providers that follow evidence-based guidelines.
- A comprehensive process for transferring the prescription from the retail pharmacy to the specialty vendor. This includes calling the prescriber and member to inform them of the dispensing process and educating them about the components of the program.
- A provider management department that will make face-to-face calls to providers explaining their services.
- Superior reporting and data collection specific to groups, individuals, and providers.
- Provide performance guarantees relative to their services.

REBATES

Rebates for specialty drugs are becoming more common and should be passed through to the payer by the PBM or contracted by the payer directly in the case of large employers or health plans. Some PBMs provide specialty rebates, others do not. Rebates for OAA drugs billed under the medical benefit are available through either direct contracting or through select vendors (typically not PBMs). While rebates are not available for all specialty drugs, in some well-used classes such as growth hormones, rheumatoid arthritis, or multiple sclerosis, manufacturers are providing rebates similar to those seen on the traditional drug side. Additional information on rebates is discussed in the Contract Language section (page 13).
SUMMARY OF PSG RECOMMENDATIONS

Payers should require SAAs to be covered only through exclusively contracted specialty pharmacy vendors that meet the criteria above. Data for OAAs should be reviewed to determine if the pharmacy benefit should be used for selected agents because the discounts are deeper. Medical carriers should be questioned concerning their reimbursement rates for OAAs to verify that the carrier is current with industry trends. Payers should receive the full value of the rebate either through a higher discount or increased rebate guarantees.

Ensure Appropriate Use Through Utilization Management Programs

PRIOR AUTHORIZATION AND STEP THERAPY

Prior authorization has been used to manage inappropriate utilization of traditional drugs and is very effective at doing the same for specialty drugs. The goals of a prior authorization program are to cover certain drugs for appropriate indications, monitor for responses to—and correct duration of—therapy. A step therapy program requires that a specific drug be used before another, more expensive one will be covered and can be placed within prior authorization criteria sets. This is the case with a high-use class such as growth hormones where a preferred agent is required before a non-preferred agent.

QUANTITY RESTRICTIONS AND DOSE CONSOLIDATION

Specialty drugs are very susceptible to interventions that monitor the dosing and quantity dispensed. Not only does the specialty pharmacy staff ask the member how many vials they need for the next month’s therapy during refill calls, but they are able to limit the quantity prescribed for optimal savings.

CVS Caremark provides an example of a successful dose consolidation case study for the oral chemotherapy drug, Revlimid. A 500,000+ member employer group was spending approximately $1.5 million on Revlimid, they implemented a dose consolidation program, and saved the client 6% or $92,000. This was done by enforcing correct capsule size for prescriptions. For example, a prescription for 25mg of Revlimid written as one 25mg capsule cost $368 versus five 5mg capsules at $1,343. This was a single prescription savings of $975.00 (Andrews, 2008).

PSG strongly believes that every specialty pharmacy prescription should be limited to a 30-day supply. Patients with specialty medications often incur adverse events or clinical, social, or emotional issues that could lead to medication non-compliance, discontinuation, or product switching. Providing more than a 30-day supply of the drug can lead to waste for the payer.

MANAGED FORMULARIES

As the various classes of specialty drugs have an increased number of agents, rebates are becoming available. This leads to formularies for specialty drugs being deployed. All decisions on formulary status should be made by the P&T Committee of the PBM or health plan. The option to switch to the preferred agents should be offered, but not required. FIGURE 7 identifies the classes where payers have implemented formularies for their specialty drugs.

DURATION OF THERAPY

Duration of therapy edits can be embedded in prior authorization criteria for renewal or as a separate program. The goal is to make sure the patient is achieving acceptable treatment...
results with the specialty drug. If not, the therapy should be reevaluated and either the dose should be increased or the drug therapy discontinued. This issue applies especially for hepatitis C therapy. Based on the patient’s genotype, treatment should be for either 24 or 48 weeks. Treatment after that point is not successful. Specialty vendors should have points in their treatment guidelines to stop therapy after these time periods.

**GENETIC TESTING REQUIREMENTS**

As personalized medicine and pharmacogenomics increases, specialty pharmacy vendors should update their criteria to require that specific diagnostic or genetic tests be done to either monitor or start therapies. For example, the oral chemotherapy drug Herceptin is only approved for women that are positive for human epidermal growth factor receptor 2 (HER2). The immunohistochemistry (IHC) or fluorescent in situ hybridization (FISH) tests can be done on breast tissue to see if the tumor is HER2 positive. Requiring this information before the drug is started insures that it is being used for the correct patient.

Another example is for a genetic test that identifies which non-small cell lung cancer (NSCLC) patients are likely to respond to therapy with Tarceva and Iressa. Patients that have epidermal growth factor receptor (EGFR) mutations have been shown to respond better to the drugs than patients that go without them.

To provide comprehensive care for the member, it is important for payers to cover these genetic tests under their medical benefit.

**SUMMARY OF PSG RECOMMENDATIONS**

PSG recommends that all specialty drugs have prior authorization requirements and quantity limits to prevent inappropriate use. Duration of therapy and genetic test requirements should be incorporated into the prior authorization criteria whenever possible. Payers should move into managed formularies for specialty drugs as new drugs become available. The classes that are amendable to formulary include anti-TNF, growth hormone, hepatitis C, infertility, and multiple sclerosis.

**Improve Clinical Management**

**ADHERENCE REPORTS**

Payers should expect their specialty pharmacy vendor to provide payer-specific detail on interventions performed for their members. This includes descriptions and outcomes for physician and member interventions. Patient-level compliance and outcome data is necessary to determine the value of the specialty pharmacy. Items that have appeared on more unique adherence reports include average length of the drug, ongoing compliance, and percentage of patients that stopped in 30 days of therapy.

**EDUCATION PROGRAM GUIDELINES**

Once the patient has met the prior authorization guidelines for coverage of the drug, education needs to begin for all the components of the disease and drug therapy. These guidelines are the maps for the patient care team to know when to address certain issues in the member’s care. It should be expected that these guidelines are approved by some type of medical committee. They should provide specific treatment options for the side effects members might have instead of referring members to the provider for side effect management. For example, oral chemotherapy drugs might cause nausea and vomiting. Members should be told to drink ginger tea or not to drink anything 15 minutes after vomiting to allow their stomach to settle. The specialty pharmacy vendor needs to manage and educate the patient to serve as an assistant to the provider. Telling the member to call their provider for all side effects is not providing the comprehensive care experience that specialty pharmacies offer.

Another example of a sound guideline is focusing on co-morbid conditions that patients on specialty drugs may have. For example, depression commonly occurs in multiple sclerosis patients. A depression screening (using developed question sets) should be placed in the monthly call question schedule. If a patient has a positive indication for depression, the care or disease management vendor should be contacted to follow-up with the patient.

**COORDINATION WITH CARE OR DISEASE MANAGEMENT**

The specialty pharmacy vendor should have in place an electronic data exchange program with the payer’s case or disease management vendor to coordinate the care of the member. If a patient identifies a concern, or if the specialty pharmacy is not able to correct itself, they should work with the other vendors to develop a plan for the member to reach the desired outcome.
PROVEN EFFICACY

For all of the programs mentioned above, the specialty vendor should have data indicating that their programs are effective. They should also provide a utilization management plan for the year so the client can determine which areas they are focusing on and if they met their goals from the previous year. As medical care changes, the specialty pharmacy vendor needs to keep modifying their programs to remain in sync with those changes.

Quality of life questions should also be included in the monthly member questions to assess the effectiveness of therapy or indicate if another issue is hindering compliance.

CONTRACT LANGUAGE

Having the correct contract language with the specialty pharmacy vendor is critical in ensuring the success of the program. Payers must carefully negotiate and review specialty contracts. All contract terms should be negotiated and reviewed at scheduled intervals including specialty drug definitions, discounts, dispensing fees, administrative fees, clinical fees, and rebates.

Payers should also have final authority over what is considered to be a specialty drug and where that drug will be dispensed. Updates to the list should be done quarterly and the contract should have minimum discount language for new drugs, but the quarterly changes should include pricing modifications as well. The contract should indicate that the payer has the right to carve-out a specialty drug to another vendor to receive greater pricing at another pharmacy. While most PBM contracts are 3-5 years in length, it is recommended that specialty pricing be reviewed and negotiated annually.

Rebates are not available for most specialty drugs. Though the market is changing as market share increases among specialty products, PBMs vary on their willingness to share rebates on these products. Many PBMs assert that because specialty drugs require more direct interventions and patient care, they retain rebate dollars to cover the cost of those services. An effective specialty rebate strategy is dependent on the PBM’s contracting rationale concerning your organization.

SUMMARY OF PSG RECOMMENDATIONS

Clinically sound, cost-effective therapy is the goal of all prescription drug programs. Specifically with specialty drugs, payers must focus carefully on all contractual details because these drugs are so expensive. Our recommendations include:

1. Considering an exclusive provider for employers and multiple providers for health plans.
2. Retaining final authority for exclusions and inclusions on the specialty list and channel restrictions.
3. Requiring specialty drug claims to be included in discount guarantees.
4. Contracting for specific AWP discounts for each drug (i.e., do not accept a flat discount for all specialty drugs).
5. Looking for hidden fees (e.g., postage, administration, prior authorization administration).
6. Requesting rebates.
7. Reviewing and negotiating specialty contract terms annually.
8. Enacting performance guarantees related to reporting and operational measures.

Generic Biologics

WHY THE APPROVAL PROCESS IS DIFFERENT

Whether the nomenclature is “follow-on biologics” (FOB), “follow-on protein products”, biosimilars, or biogenerics, it is understood that non-innovator biologic agents will save consumers and payers billions of dollars. Biologics are large, complex, heterogeneous molecules, for which the manufacturing process can be a determinant of the end product. The FDA’s current generic approval process was designed to address chemical entities, but not biological entities. Therefore, the FDA did not believe that they had regulatory authority to approve the use of generic biologics (biogenerics). Federal legislation was recently enacted that gave the FDA the requisite authority along with control over the required documentation for approval.

The FDA acknowledges that science has reached a point where the agency has the ability to determine whether biopharmaceuticals—brand or generic—are the same or slightly different. The FDA has the scientific expertise to determine on a case-by-case basis whether a brand or generic biopharmaceutical is safe and effective. In fact, the FDA establishes interchangeability each time an innovator company makes post-approval changes such as changing a manufacturing process or cell line. The FDA uses sound scientific principles to determine whether the level of “sameness” is acceptable or not. The same science that the FDA applies to brands applies equally to biogenerics. Further, the FDA has established interchangeability for some simple proteins.

Biogeneric companies need an abbreviated approval pathway to avoid undertaking the same large-scale clinical development process as the originator companies, thereby allowing them to market their product at a discount over the brand while maintaining a healthy profit margin. The high barriers to market entry will necessitate a smaller price differential between brand and generic products than that seen in regular generics and initial physician and patient reluctance to take up biogenerics may limit the impact of competition on originator companies.

**CURRENT STATE OF LEGISLATION**

On March 30, 2010, President Obama signed into law the congressional health care reconciliation bill. Within this bill is the “Biologics Price Competition and Innovation Act.” This act allows for approval of two different product types: biosimilar products and interchangeable products, to be implemented by the Secretary of Health and Human Services. Biosimilars are unique products that are not seen as identical to, or the same as, the innovator’s products. Interchangeable products, however, are analogous to A-rated products under the Hatch-Waxman Amendments. Interchangeable drugs could be substituted by a pharmacist for the original innovator drug without first seeking the permission of the prescribing physician.

For biosimilar products, the FDA may approve these products based on the following: analytic studies which show that the product is “highly similar to the [pioneer] product notwithstanding minor differences in clinically inactive compounds,” animal toxicology studies, and one or more human studies that assess immunogenicity, pharmacokinetics, or pharmacodynamics. The FDA is at liberty to waive one of these elements as unnecessary during its review.

For interchangeable products, the FDA approves the biosimilar product as “interchangeable” with the innovator products. Criteria the FDA must abide by include the following: FDA must find that the product satisfies the requirement for biosimilarity, determine that the biosimilar product will likely produce the same clinical result as the innovator product, FDA must determine that switching between the innovator product and biosimilar does not result in diminished safety or efficacy.

The Secretary of Health and Human Services is required to implement the FOB review process. On October 1, 2010, the Secretary must present to Congress a five-year plan for its proposed process. The Secretary may release guidance for the review of FOBs (either particular products or for a given therapy class of products) that may include the necessary tests or criteria that would need to be met by FOBs to show biosimilarity or interchangeability.

The company making the innovator drug will be given 12 years of data exclusivity (with a potential further six months for pediatric studies) during which time a generic biologic cannot be released. Additionally, during the first four years of exclusivity, the FOB applicant cannot submit a FOB application. An additional one year of exclusivity will be granted to the first interchangeable biologic product. Biosimilars which are not interchangeable are not eligible for this exclusivity.

The new legislation also addresses several issues regarding patent infringement to protect the biologic “innovator” company. Previously, under Hatch-Waxman, the pioneering company provides public notice of the protected patents. However, under this new legislation for FOBs, the notice of such patents will be private. One very unique part of this legislation to note is that the FOB applicant must provide a copy of its application and a description of its manufacturing processes to the pioneer within 20 days of acceptance of the application for review. If the FOB fails to do this, the pioneer can bring an action against the FOB for declaration of infringement, validity, or enforceability. Parties (for the pioneer) given access to this information cannot become involved in patent prosecution nor disclose the information they receive with other parties without written consent from the FOB applicant. The pioneer must provide a list of all relevant patents within 60 days of the FOB application and manufacturing process. The pioneer should list which patents it could assert, the patents to which it has an exclusive license, and the patents it is willing to license. Subsequently, the FOB then has 60 days from the time it receives the list of patents from the pioneer to provide its contentions. Finally, the pioneer then has 60 days, after receiving the FOB contentions, to respond.

**POTENTIAL SAVINGS**

In June of 2008, the Congressional Budget Office’s (CBO) research supported that enacting the Biologics Price Competition and Innovation Act of 2007 would reduce total expenditures on biologics in the United States by $0.2 billion over the 2009-2013 period and by about $25 billion over the 2009-2018 period (over that 10-year period, such savings would be roughly equal to 0.5% of national spending on prescription drugs, valued at wholesale prices). The CBO also said there would be a $52 million reduction of budget deficits for the 2009-2013 period and $6.6 billion for 2009-2018 period. Further, there would be $1 billion in Medicare
Part B savings in 2018 and a 20% to 25% sales-weighted market average discount on biosimilars relative to innovator drugs during the first year of competition. The CBO’s report estimates were based on the assumption that biosimilars would hit the U.S. marketplace in 2012, which appears to be the case.

SUMMARY OF PSG RECOMMENDATIONS

A health reform fact sheet (available at www.healthreform.gov) supports lower prescription drug costs and “accelerating access to make affordable biologic drugs available through establishment of a regulatory, scientific and legal pathway for FDA approval of biologic drugs.”

PROGRAM EVALUATION

After implementation of the specialty program, evaluation of the effectiveness must be done. A few areas that can be reviewed include the following:

• Number of patients using the specialty pharmacy versus the retail or mail channel.
• Member and provider disruption and satisfaction scores.
• Savings seen by payer.
• Favorable clinical outcomes.
• Customer service and account management experience.

FINAL CONSIDERATIONS

A tsunami of specialty drugs is moving through the drug pipeline. As discussed, these drugs are expensive to acquire, are expensive to handle, and require careful management by health care professionals to avoid adverse impact on patients as well as to minimize waste. The expanding number of specialty drugs will offer new treatment opportunities to millions of people and introduce new challenges to payers looking for ways to mitigate the burgeoning expense.

The FDA approval process for biosimilars is necessarily more costly than the approval process for common generics. This will significantly reduce the savings between biosimilar and brand specialty drugs compared to the savings observed in the oral solids market. Any reduction in ingredient cost for specialty medications will be welcome but biosimilars will do comparatively little to reduce the rate of increase in expenditures.

To meet the growing challenge, payers must review their programs to assure comprehensive cost containment measures are in place, clinical programs are measured for effectiveness, and reporting tools are available and are being used. Failure to do so will result in the cost of specialty drugs siphoning off a disproportionate share of the healthcare dollar.

References


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<td>Leukine 500 mg/mL Vial</td>
<td>U</td>
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<tr>
<td>Leukocyte (WBC) Stimulants</td>
<td>Neulasta 6 mg/0.6 mL syringe</td>
<td>SQ</td>
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<td>Leukocyte (WBC) Stimulants</td>
<td>Neupogen 300 mcg/0.5 mL Syr</td>
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<td>Leukocyte (WBC) Stimulants</td>
<td>Neupogen 300 mg/mL Vial</td>
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<td>Leukocyte (WBC) Stimulants</td>
<td>Neupogen 400 mg/mL Vial</td>
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<tr>
<td>Leukocyte Adhesion Inhibit A, alpha(4)-mediated IgG4k MC AB</td>
<td>Tysabri 300 mg/15 mL Vial</td>
<td>IV</td>
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<tr>
<td>LHRR(GNRH) Agonist Analag Pituitary Supressants</td>
<td>Lupron Depo 11.25 mg 3MO Kit</td>
<td>IM</td>
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<tr>
<td>LHRR(GNRH) Agonist Analag Pituitary Supressants</td>
<td>Lupron Depo 3.75 mg Kit</td>
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<td>LHRR(GNRH) Agonist Analag Pituitary Supressants</td>
<td>Suprefilin LA 50 mg Kit</td>
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<tr>
<td>LHRR(GNRH) Agonist Analag Pituitary Supressants</td>
<td>Synarel 2 mg/mL Nasal Spray</td>
<td>NS</td>
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<tr>
<td>LHRR(GNRH) Agonist Analag Pituitary Supressants</td>
<td>Vantas 50 mg Kit</td>
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<td>LHRR(GNRH) Agonist Analag Pituitary Supressants</td>
<td>Getrotide 2.25 mg Kit</td>
<td>SQ</td>
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<tr>
<td>LHRR(GNRH) Agonist, Pituitary Supressants Agents</td>
<td>Getrotide 3 mg Kit</td>
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<tr>
<td>LHRR(GNRH) Agonist, Pituitary Supressants Agents</td>
<td>Ganirelix AC 250 mg/0.5 mL</td>
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<tr>
<td>LHRR(GNRH) Agonist, Pituitary Supressants Agents</td>
<td>Lupron Depot-Ped 11.25 mg kit</td>
<td>IM</td>
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<tr>
<td>LHRR(GNRH) Agonist, Pituitary Supressants Agents</td>
<td>Lupron Depot-Ped 15 mg kit</td>
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<td>LHRR(GNRH) Agonist, Pituitary Supressants Agents</td>
<td>Lupron Depot-Ped 7.5 mg Kit</td>
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<tr>
<td>Luteinizing Hormones</td>
<td>Lueris 75 units Vial</td>
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<tr>
<td>Metabolic Deficiency Agents</td>
<td>Cystadane Powder</td>
<td>PV</td>
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<tr>
<td>Metabolic Disease Enzyme Replacement, Fabry's DX</td>
<td>Fabrazyme 35 mg Vial</td>
<td>IV</td>
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<td>Metabolic Disease Enzyme Replacement, Fabry's DX</td>
<td>Fabrazyme 5 mg Vial</td>
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<td>Metabolic Disease Enzyme Replacement, Gaucher's DX</td>
<td>Ceredase 80 units/mL Vial</td>
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<td>Metabolic Disease Enzyme Replacement, Gaucher's DX</td>
<td>Ceredase 200 units/mL Vial</td>
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<td>Metabolic Disease Enzyme Replacement, Gaucher's DX</td>
<td>Cerezyme 200 units Vial</td>
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<tr>
<td>Metabolic Disease Enzyme Replacement, Gaucher's DX</td>
<td>Cerezyme 400 units Vial</td>
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<tr>
<td>Metabolic Disease Enzyme Replacement, Pompe Disease</td>
<td>Myozyme 50 mg/mL Vial</td>
<td>IV</td>
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<tr>
<td>Metabolic Disease Enzyme Replacement, Mucopolysaccharidoses</td>
<td>Aldurazyme 2.9 mg/5 mL Vial</td>
<td>IV</td>
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<tr>
<td>Metabolic Disease Enzyme Replacement, Mucopolysaccharidoses</td>
<td>Elaprase 6 mg/3 mL Vial</td>
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<td>Metabolic Disease Enzyme Replacement, Mucopolysaccharidoses</td>
<td>Niglazyme 5 mg/mL Vial</td>
<td>IV</td>
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<tr>
<td>Metabolic Disease Enzyme Replacement, Mucopolysaccharidoses</td>
<td>Adagen 250 units/mL Vial</td>
<td>IV</td>
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<tr>
<td>Metallic Poison, Agents to Treat</td>
<td>Exjade 125 mg Tablet</td>
<td>PO</td>
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<tr>
<td>Metallic Poison, Agents to Treat</td>
<td>Exjade 250 mg Tablet</td>
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<tr>
<td>Metallic Poison, Agents to Treat</td>
<td>Exjade 500 mg Tablet</td>
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<tr>
<td>Monoclonal Antibodies to Immunoglobulin E(IGE)</td>
<td>Xolair 150 mg Vial</td>
<td>SQ</td>
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<tr>
<td>Monoclonal Antibody-Human Interleukin 12/23 Inhibitor</td>
<td>Stelara 45 mg/0.5 mL Vial</td>
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<td>Movement Disorders (Drug Therapy)</td>
<td>Xenazine 12.5 mg Tablet</td>
<td>PO</td>
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<tr>
<td>Movement Disorders (Drug Therapy)</td>
<td>Xenazine 25 mg Tablet</td>
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<tr>
<td>Mucolytics</td>
<td>Pulmozyme 1 mg/mL Ampul</td>
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<tr>
<td>Ocular Photoactivated Vessel-occluding Agents</td>
<td>Visudyne 15 mg Vial</td>
<td>IV</td>
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<tr>
<td>Ophthalmic Endothelial Growth Factor Antagonists</td>
<td>Macugen 0.3 mg/microlitters</td>
<td>IO</td>
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<tr>
<td>Ophthalmic VEGF-A Receptor Antag. RCMB MC Antibody</td>
<td>Lucentis 0.5 mg Vial</td>
<td>IO</td>
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<tr>
<td>Photoactivated; Antineoplastic Agents (Systemic)</td>
<td>Photofrin 75 mg Vial</td>
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<tr>
<td>Photoactivated; Antineoplastic Agents (Systemic)</td>
<td>Uvadex 20 mg/mL Vial</td>
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<tr>
<td>PKU TX Agent: cofactor of Phenylalanine Hydroxylase</td>
<td>Kuvan 100 mg Tablet</td>
<td>PO</td>
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<tr>
<td>Platelet Proliferation Stimulants</td>
<td>Neumega 5 mg Vial</td>
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<tr>
<td>Protein C Preparations</td>
<td>Ceprotin 800-1,200 units Vial</td>
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<td>Protein C Preparations</td>
<td>Ceprotin 200 units Vial</td>
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<tr>
<td>Pulmonary Antihypertensives, Prostacyclin-type</td>
<td>Epoprostenol Sodium 0.5 mg/mL</td>
<td>IV</td>
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<tr>
<td>Pulmonary Antihypertensives, Prostacyclin-type</td>
<td>Epoprostenol Sodium 1.5 mg/mL</td>
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<tr>
<td>Pulmonary Antihypertensives, Prostacyclin-type</td>
<td>Flosan 0.5 mg Vial</td>
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<td>Pulmonary Antihypertensives, Prostacyclin-type</td>
<td>Flosan 1.5 mg Vial</td>
<td>IV</td>
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<tr>
<td>Pulmonary Antihypertensives, Prostacyclin-type</td>
<td>Remodulin 1 mg/mL Vial</td>
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<td>Pulmonary Antihypertensives, Prostacyclin-type</td>
<td>Remodulin 10 mg/mL Vial</td>
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<td>Pulmonary Antihypertensives, Prostacyclin-type</td>
<td>Remodulin 2.5 mg/mL Vial</td>
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<tr>
<td>Pulmonary Antihypertensives, Prostacyclin-type</td>
<td>Remodulin 5 mg/mL Vial</td>
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<td>Pulmonary Antihypertensives, Prostacyclin-type</td>
<td>Tyasol 1.74 mg/2.9 mL Solution</td>
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<tr>
<td>CLASS</td>
<td>LABEL NAME</td>
<td>ROUTE OF ADMIN</td>
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<tr>
<td>PULMONARY ANTIHYPERTENSIVES, PROSTACYCLIN-TYPE</td>
<td>TYVASO INHALATION REFILL KIT</td>
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<td>TYVASO INHALATION STARTER KIT</td>
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<tr>
<td>PULMONARY ANTIHYPERTENSIVES, PROSTACYCLIN-TYPE</td>
<td>VENTAVIS 10 MCG/1 ML SOLUTION</td>
<td>IH</td>
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<tr>
<td>PULMONARY ANTIHYPERTENSIVES, PROSTACYCLIN-TYPE</td>
<td>VENTAVIS 20 MCG/2 ML SOLUTION</td>
<td>IH</td>
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<tr>
<td>SOMATOSTATIC AGENTS</td>
<td>OCTREOTIDE ACET 1,000 MCG/ML VIAL</td>
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<tr>
<td>SOMATOSTATIC AGENTS</td>
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<td>OCTREOTIDE ACET 100 MCG/ML VL</td>
<td>UJ</td>
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<td>SOMATOSTATIC AGENTS</td>
<td>OCTREOTIDE ACET 200 MCG/ML VL</td>
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<td>OCTREOTIDE ACET 50 MCG/ML VIAL</td>
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<td>SOMATOSTATIC AGENTS</td>
<td>OCTREOTIDE ACET 500 MCG/ML AMP</td>
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<td>OCTREOTIDE ACET 500 MCG/ML VL</td>
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<td>SANDOSTATIN 0.05 MG/ML AMPUL</td>
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<td>SANDOSTATIN 0.1 MG/ML AMPUL</td>
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<td>SOMATOSTATIC AGENTS</td>
<td>SANDOSTATIN 0.2 MG/ML VIAL</td>
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<td>SOMATOSTATIC AGENTS</td>
<td>SANDOSTATIN 1 MG/ML VIAL</td>
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<td>SANDOSTATIN LAR 10 MG KIT</td>
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<td>SANDOSTATIN LAR 20 MG KIT</td>
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<td>SOMATULINE 120 MG/0.5 ML SYRGE</td>
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<td>EMCYT 140 MG CAPSULE</td>
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<td>TESLAC 50 MG TABLET</td>
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<td>SYSTEMIC ENZYME INHIBITORS</td>
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<td>ZEMAIRA 1,000 MG VIAL</td>
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<td>THROMBIN INHIBITORS,SEL.,DIRECT,REV.,HIRUDIN TYPE</td>
<td>REFLUDAN 50 MG VIAL</td>
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<td>THROMBOPOIETIN RECEPTOR AGONISTS</td>
<td>NPLATE 250 MCG VIAL</td>
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<td>PROMACTA 25 MG TABLET</td>
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<td>THYROID FUNCTION DIAGNOSTIC AGENTS</td>
<td>THYROGEN 1.1 MG VIAL</td>
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