



Strategic Issues in Managing the Specialty Pharmacy Benefit



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- Specialty pharmacy goals:
 - Provide a reliable source for hard-to-find injectables
 - Provide access to professionally trained staff on a 24-hour basis
 - Integrate specialty medications with other medications for a robust drug utilization review and patient safety profiling system
 - Design and deploy a comprehensive patient education strategy on how to best manage the disease, achieve desired outcomes, minimize negative consequences, etc.

- Specialty pharmacy goals, continued:
 - Achieve competitive pricing
 - Create a streamlined and more accurate claims processing system
 - Eliminate inappropriate utilization
 - Enhance predictive modeling
 - Improve outcomes reporting, including pharmacoeconomic impact assessments

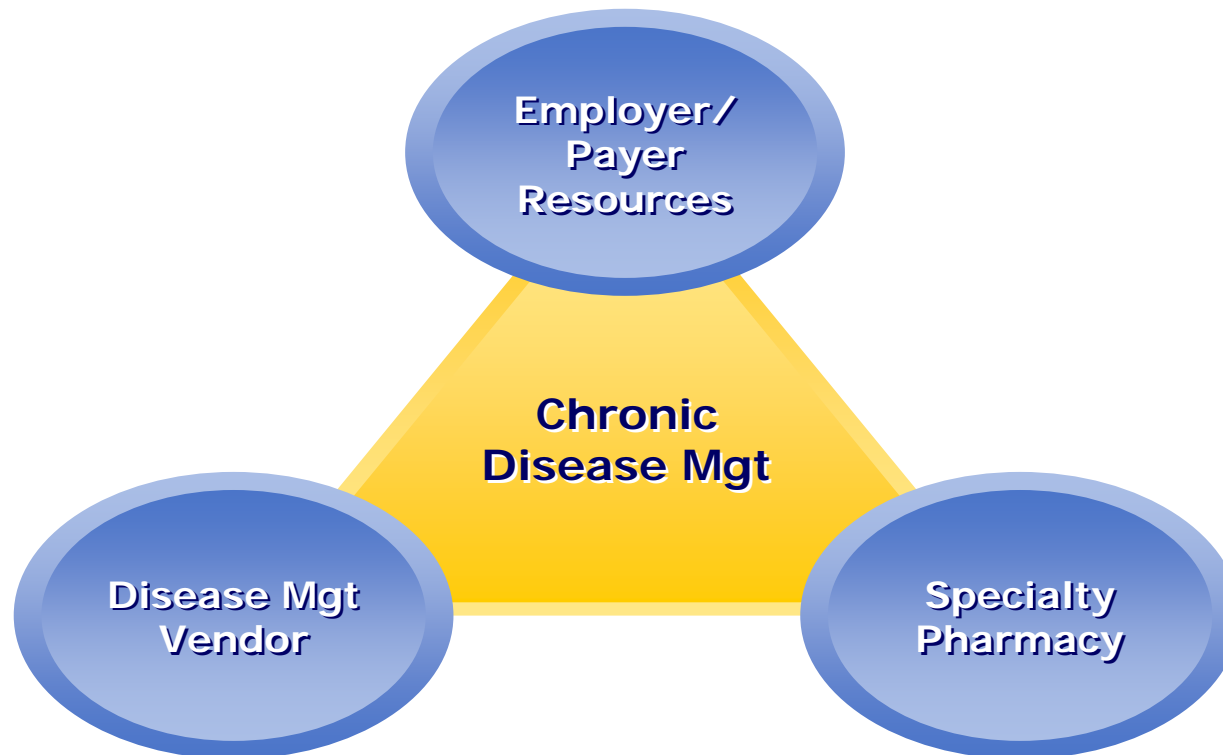
- Data analysis
 - Understand where your specialty pharmacy costs and utilization are today
 - Pharmacy claims
 - Run reports from your current PBM / health plan
 - Identifies those specialty pharmacy claims being filled in retail pharmacy or mail order channel
 - Medical utilization
 - Mine medical claims data for J-Code billing information
 - “Crosswalk J-Code to drug level codes “NDCs”
 - If actual data is unavailable or not cost effective to obtain, predictive modeling can be done based on your group size, demographics, etc.

- Data analysis
 - Top therapeutic areas
 - Concentration of providers
 - Medical and pharmacy
 - Concentration of patients

- Will program participation be voluntary or mandatory?
 - This decision will impact every other implementation step
 - Many employers implement a voluntary period, followed by a mandatory conversion
 - Some segment disease areas as either voluntary or mandatory

- The program will be phased in over what period of time?
 - Most recommend at least one year for successful implementation
 - Many have transitioned over more than one year to ensure that appropriate communication plans, operational processes, financial underwriting changes, etc. are in place
 - Overall implementation could include a voluntary implementation window, followed by a gradual implementation to a mandatory system

Who's in charge of UM / DM?
Will it vary by disease state?
(e.g. Asthma vs. Gaucher's disease)



- Will all providers be required to use the service?
 - Oncology is an issue for many plans
 - Reimbursement adjustments are common, though not at 100% offset
 - At some point, it becomes an issue of parity
 - Rx Director, 400k+ health plan in NY:

“Count on losing some physicians from your network after you implement a mandatory specialty distribution contract. Physicians who rely on their own markup of specialty products may discontinue their relationships with MCOs”

- What will the communication plan entail?
 - Provider panel
 - Program goals
 - Implementation timelines
 - Operational issues
 - Help line
 - Members
 - Program goals
 - Implementation timelines
 - Where benefits are impacted
(change in copay/co-insurance)
 - Help line



Stakeholder	Pros	Cons
Patient	<ul style="list-style-type: none">▪ Reimbursement support▪ Access to additional clinical resources▪ Availability of home delivery	<ul style="list-style-type: none">▪ Minimizes importance of retail pharmacy▪ Could cost more out of pocket, depending on plan design▪ Operational processes could confuse patient and/or delay care

Strategic Issues in Specialty Pharmacy Management

Stakeholder	Pros	Cons
Provider	<ul style="list-style-type: none"><li data-bbox="586 506 1024 671">▪ No need to hold expensive inventory<li data-bbox="586 706 1024 821">▪ Reimbursement support<li data-bbox="586 856 1024 956">▪ Convenience of one supplier	<ul style="list-style-type: none"><li data-bbox="1062 506 1627 671">▪ Reduced ability to generate incremental revenue<li data-bbox="1062 706 1646 821">▪ Operational process could be cumbersome

Strategic Issues in Specialty Pharmacy Management

Stakeholder	Pros	Cons
Employer	<ul style="list-style-type: none"><li data-bbox="554 511 963 668">▪ Better coordination of care<li data-bbox="554 711 944 868">▪ Better understanding of data<li data-bbox="554 911 934 1011">▪ Potential for reduced costs	<ul style="list-style-type: none"><li data-bbox="1043 511 1605 611">▪ Potential for provider disruption<li data-bbox="1043 654 1605 753">▪ Potential for member complaints<li data-bbox="1043 796 1757 953">▪ Services may shift to alternative channels (e.g. hospital, home health, etc.)

Strategic Issues in Specialty Pharmacy Management

Stakeholder	Pros	Cons
Manufacturer	<ul style="list-style-type: none">▪ Reduction in number of contracts/orders to manage▪ Potential for increasing product use (reimbursement support)	<ul style="list-style-type: none">▪ Limitations on product use via managed care strategies▪ Potential for price erosion via price reductions demanded via contracting process

Strategic Issues in Specialty Pharmacy Management

Stakeholder	Pros	Cons
PBM	<ul style="list-style-type: none">▪ Sell a high margin business to a captive client base▪ Gain efficiencies in reporting/claims processing▪ Diversify revenue/profit sources	<ul style="list-style-type: none">▪ Change in philosophy (mail order vs. localized delivery)▪ Potential for pricing erosion over time

Choosing a Specialty Pharmacy Provider



- Independent specialty pharmacy providers
 - National: McKesson
 - Large regional: IVPcare, Medmark, Apothecary Shops
 - Local: Highly fragmented in local markets
- PBM-owned specialty pharmacies
 - The “big-three” each have completed major acquisitions in the last 2 years
 - Many regional firms rapidly developing strategy

- Key questions:
 - Distribution strategy
 - Mail order vs. regional
 - Clinical services
 - Disease-specific expertise
 - Reasonable access to clinicians
 - Interventions
 - Outcomes measurement
 - Breadth of product line
 - Core products
 - Strategy to gain access to limited distribution drugs

- Key questions:
 - Implementation
 - Success in your markets
 - Skill in communicating with patients/physicians
 - Ability to assist in marketing/program enrollment

- Key questions:
 - Reporting
 - Operational
 - Progress towards performance standards
 - Clinical
 - Patients meeting clinical guidelines
 - Financial
 - Cost and utilization summaries, predictive modeling for future budgetary decisions

■ Key questions:

● Pricing

- Beware blended rates... product-specific discounts are the way to go
- Negotiate the ability to share in rebates derived from specialty pharmaceuticals
 - Limited now, importance may grow in the future as more competition enters key therapeutic areas
- Establish ground rules for new product introductions

- Evaluation methodology
 - Qualitative
 - Financial
 - Site visits
 - References

Future Issues in Specialty Pharmacy Management



- More competition
 - From specialty pharmacy providers
 - From biotech firms
- Better data analytics to support:
 - Outcomes research (clinical and economic)
 - Evidence-based coverage criteria
- Customized care
 - Focused on individual patients

- Better diagnostics
 - Predict which patients are more likely to benefit from therapy
- Introduction of generic biologics
 - Requires a change in current pharmaceutical regulations by the FDA
 - Major investments by generic biopharmaceutical firms

- Localization or regionalization of the distribution model
 - Many new products will require customization for individualized patients
 - Dosage forms may require infusions at skilled facilities, rather than simple self injections



A View Towards the Future





Last Hope for Lymphoma, \$28,000 a Dose

By LUCETTE LAGNADO

GOOD TO the last drop," says Marie, a patient with advanced lymphoma, as a Lucite-coated hypodermic syringe pumps a \$28,000 dose of Zevalin into her system.

Less than 10 minutes later, the 79-year-old Medicare beneficiary is done, the ninth patient at Massey Cancer Center in Richmond, Va., to get the drug, which is considered so safe she doesn't have to linger for observation.

Zevalin, made by Idec Pharmaceuticals Corp., is one of a new class of biotech cancer treatments that use monoclonal antibodies, armed with radioactive isotopes, to deliver potentially lethal doses of radiation to tumor cells. Generally taken after other treatments fail, it comes in a single dose, which is a great relief to patients who have already endured many months of chemotherapy. It significantly reduces some of the unpleasant side-effects associated with traditional chemotherapy, such as nausea and hair loss. And it also keeps patients out of the hospital, says Harold Chung, a Massey oncologist who also is Marie's doctor.

But despite its \$28,000 price tag, Zevalin doesn't necessarily work. And that is raising difficult questions about whether it and other very expensive therapies are worth the price. The costs are especially tough on cancer centers caring for the underinsured, where doctors worry about how to give top-of-the-line drugs to rich and poor patients alike without going bankrupt.

Thomas Scully, who presides over the nation's Medicare system, says he was as-



Melvin Fratkin of Virginia Commonwealth University holds a syringe that is used to deliver Zevalin.

Charles Leibold/StatlerPhotography.com

tounded when he first heard how much Zevalin cost. "You have got to be kidding," he says he told aides. The Centers for Medicare and Medicaid Services, which runs the Medicare program and administers the funds for Medicaid, debated whether to reimburse Zevalin and other

high-priced cancer treatments but eventually gave the go-ahead.

Chief medical officer Sean Tunis says it's common practice for Medicare to offer reimbursement for most drugs approved by the Food and Drug Administration. But continuing that approach means Medicare costs could skyrocket in coming years. Dr. Tunis adds that the FDA is now approving some treatments, Zevalin included, under its "accelerated" approval process, which means more studies are needed to make sure the drugs are safe and effective. In short, prices are going up, even though it's not clear how much benefit the drugs provide.

"It's not that I'm a cheapskate, but what Please Turn to Page B2, Column 6

Costly Care

Cancer treatments are creating burdens for patients and the healthcare system. A sampling:

DRUG	TREATMENT	COST
Zevalin	Lymphoma	\$28,000 per injection
Fludara (Fludarabine)	Leukemia	\$400-\$750 per day per infusion
Rituxan	Lymphoma	Typical infusion costs \$3,530
Taxol	Breast cancer	\$1,757 per infusion

Sources: Dalton Oncology Clinic Pharmacy; Massey Cancer Center, Richmond, Va.; IDEC Pharmaceuticals



Steep Price of Roche AIDS Drug May Put It Out of Patients' Reach

By VANESSA FUHRMANS

A new AIDS drug that promises to help patients who have failed to respond to other medications is likely to carry a price tag more than double the most expensive treatments on the market, setting the stage for a wrenching debate over who will get it and who will pay for it.

Roche Holding AG said it will price the drug, called Fuzeon, in Europe at €18,980 (\$20,424) for a year's supply. Though Fuzeon isn't expected to receive marketing approval in the U.S. and Europe for several weeks, the Swiss drug maker took the unusual step of disclosing the European price now to provide advance notice to health-care officials in Europe and AIDS-treatment programs

Montgomery, chief of the California Department of Health Services' Office of AIDS. He estimates some 30% of the program's 25,000 patients show signs of resistance to at least one or two existing AIDS drugs and might benefit from Fuzeon. "But we just don't know if we'll have the money to pay for it."

Doctors and patient groups consider Fuzeon the biggest advance in AIDS treatment since the advent of so-called protease inhibitors in the mid-1990s because of its ability to beat down the hardest forms of the virus. Unlike existing AIDS drugs, which block replication of the virus after it infects a cell, Fuzeon stops it from entering a cell in the first place.

In each of two large-scale clinical trials, results of which were published last year, one group of patients was given a

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