

Therapy Optimization for Targeted Therapies

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Summary

Therapy optimization programs for uncommon diseases such as multiple sclerosis conducted by specialty pharmacy companies are an alternative to current disease management programs. Because of the delivery system already in place, specialty pharmacies offer advantages for achieving improved patient outcomes. Payers should consider developing therapy optimization programs through a specialty pharmacy.

Key Points

- Outcome-driven programs will become the norm.
- Targeted therapies are typically injectable, expensive biologic agents.
- Specialty pharmacies are an efficient site for therapy optimization programs for uncommon diseases such as multiple sclerosis.
- Therapy optimization encompasses more than medication compliance, adherence, and persistence.
- Therapy optimization includes managing concomitant diseases or conditions that contribute to poor outcomes from the target disease.

HEALTH PLANS ARE CURRENTLY PAYING disease-management companies significant sums for what amounts to difficult-to-calculate results. Without stellar results, this is not a sustainable model, and traditional disease management programs may not be sustainable for the average payer. A need exists for outcome-driven disease management programs.

Specialty pharmacies, which have an established process of care already in place, represent a new model for delivering disease management services, and are poised to become the norm. Managed care payers will be able to supplement their existing disease management programs for common diseases with programs for uncommon diseases through specialty pharmacies.

The specialty pharmacies model is funded by the acquisition cost of the product and offers long-term sustainability. Additionally, the process of delivering expensive injectable and biologic agents directly to the door of patients on the right day at the right temperature is already established. By incorporating an outcomes-oriented disease management program into this established delivery process, a payer can easily begin to achieve measurable outcomes for patients serviced by these pharmacies. The process is sustainable because patients will need to continue to receive their medication through this delivery channel.

Use of Specialty Pharmacies to Deliver Outcomes

About 80 percent of health plans now have contracts with specialty pharmacies for preferred distribution of expensive injectable biologic agents. These biologic agents are considered target therapies—they target in a somewhat imprecise manner the biologic root of a disease. The majority of the specialty pharmacy companies in the U.S. have the capability of putting an outcomes driven disease management program in place. Some already have operational programs.

Specialty pharmacy companies got their start by primarily providing injectable products that few retail pharmacies were willing to stock because of storage requirements or cost. They originally provided a product for payers at a discount (Exhibit 1). They then began programs in persistency, adherence, and compliance, and expanded to provide data to payers.

The next logical step for specialty pharmacy companies is to develop therapy optimization programs. This role extends beyond enhancing compliance, adherence, and persistency or simply having nurses or pharmacists answer patient and provider questions. A number of companies have already developed true therapy optimization programs for multiple sclerosis including MedMark, ivpcare, and Pharmacare.

Exhibit 1: Stages of Specialty Pharmacy Company Development

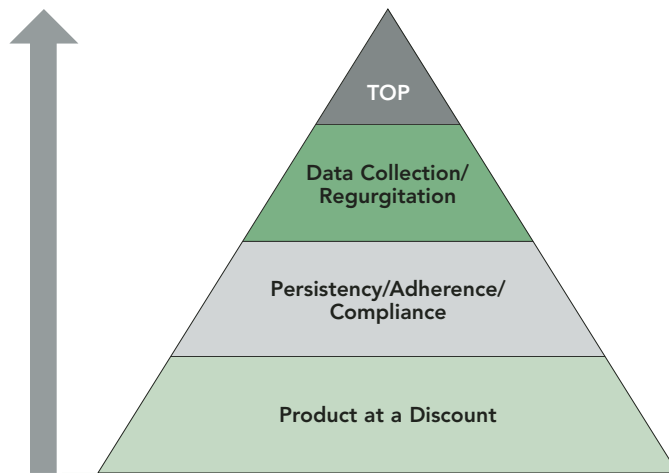
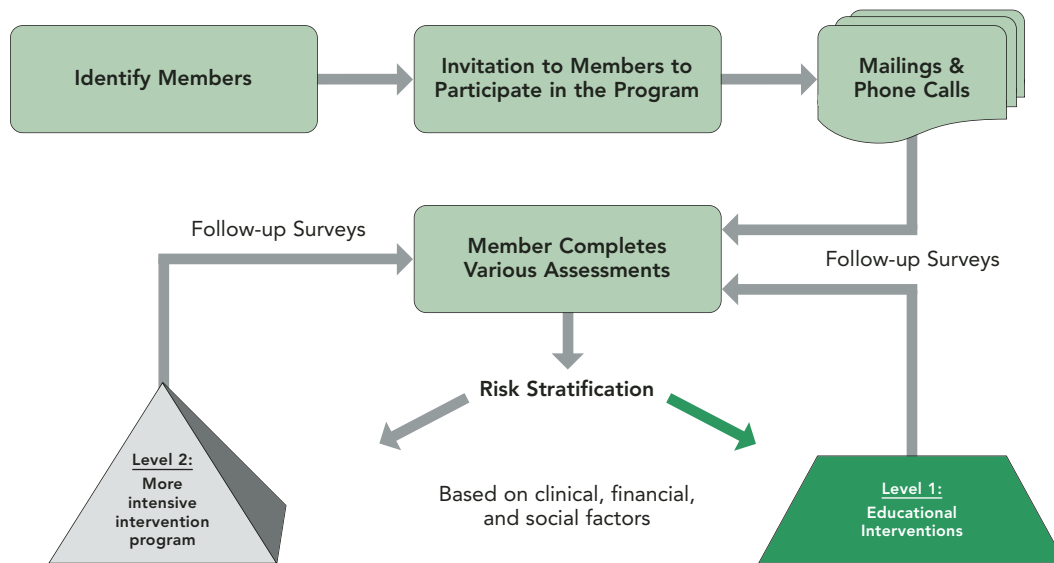


Exhibit 2: Therapy Optimization Process



Critical components of a therapy optimization program include:

- population identification
- evidence-based practice guidelines
- physician and patient decision support
- measurements of processes and outcomes
- interventions to improve processes and outcomes
- communication.

The structure of a therapy optimization program can vary but one example is given in Exhibit 2. After identifying potential participants and inviting them to join the program, participants are stratified based on a needs assessments. It is not practical for payers and specialty pharmacy providers to build a program for a single

disease. Therefore, once a single disease program is established, other diseases need to be incorporated into the program. The major disease targets include hemophilia, rheumatoid arthritis, pulmonary arterial hypertension, hereditary emphysema, psoriasis, and multiple sclerosis.

The procedures for a therapy optimization program are simple to design and computerize, but the difficulty with current disease management programs has been putting the process into operation across an entire population. All of the specialty pharmacy companies in the U.S. have computer systems that are capable of handling such a program. Many of their systems are more sophisticated than the traditional disease management vendors.

Exhibit 3: Demographics of MS

- Age of onset, 20 to 45 years¹
- Gender 70% women¹
- Geography incidence increases with distance from equator¹
- Incidence 8,500 to 10,000 new cases per year¹
- Prevalence, 350,000 in U.S.²
- Nature & Nurture: Complex interaction of genetics and environmental factors

Exhibit 4: MS Symptoms

Predictable Deficits Along an Unpredictable Time Course

- Fatigue
> 75% to 90%
- Depression
> 50% to 70%, 7.5% higher suicide rate
- Sensory
> 20% to 55% initial presentation
- Spasticity
> 40% initial, 60% in disease progression
- Pain
> 80%
- Bladder
> 75%
- Sexual Dysfunction
> 40% (men); 50% (women)
- Bowel
> 50%
- Optic Neuritis
> 14% to 23% initial presentation
- Cerebellar System
> ataxia, intention tremor, dysarthria

Exhibit 5: Components of MS Therapy Optimization

- Monitoring/Documenting:
 - > Safety/Tolerability
 - > Adherence/Compliance/Persistency
 - > Relapses
 - > Disability Scale: Telephone/Mail Out Form
 - > Symptoms of Disease Progression
 - > Depression Assessment/Intervention
- Interventions
 - > Co-morbid condition(s)
 - > Symptom management assistance
- Data Analysis and Outcome Improvement
- Patient Education

Multiple Sclerosis as an Example

Multiple sclerosis (MS) is an example of a relatively uncommon disease treated with specialty injectable biologic agents. MS is a good candidate disease for a therapy optimization program for numerous reasons. It is an immune system disease that occurs most often in women and begins at a young age (Exhibit 3).^{1,2} It is the leading cause of disability among younger women with approximately 350,000 cases in the U.S. This disease results in significant symptoms and functional deficits over an unpredictable time course (Exhibit 4).¹ Depression, falls, and fractures as a result of spasticity, steroid-induced osteoporosis, and bladder dysfunction are common complicating problems.

The components of a therapy optimization program for MS are detailed in Exhibit 5. Three major issues in MS that are important focuses of a therapy optimization program are 1) preventing relapse, 2) ensuring compliance with medications, and 3) managing concomitant diseases and conditions.

The primary endpoint of MS therapy is to prevent relapse. Preventing relapses is important because each symptomatic exacerbation likely results in irreversible damage to the nervous system, much like a heart attack irreversibly damages the heart. Preventing relapses should delay the almost universal disability that occurs with MS.

According to the National Multiple Sclerosis Society, medication should be started early in the disease to prevent relapses and exacerbations and continued unless the patient is not getting a clinical effect or the medication becomes contraindicated.³ If either condition exists, the patient should be switched to another medication. An evaluation of medication efficacy must be built into the therapy optimization process.

Targeted therapies cannot be effective if the patient does not take them. Unrealistic patient expectations, suboptimal treatment response, complicated administration, intolerable side effects, and depression are all reasons patients stop therapy. The drugs for MS cause significant side effects such as flu-like symptoms, malaise, fatigue, and depression.⁴

Another contributor to noncompliance is the cost of these agents. A major trend in targeted therapies is to shift a significant portion of the cost of therapy to the patient through higher co-pays, co-insurance, maximum out-of-pocket expenditures, and deductibles. This has the potential to decrease patient compliance because of the financial burden and negate any benefits of the medication.

To prevent noncompliance and promote persistence with therapy, a therapy optimization program would identify and resolve any problems the patient was having with the medication. This may be difficulty with the injection, difficulty affording the medication, an injection site reaction, or a different adverse effect.

The third major focus of an MS therapy optimization program is managing concomitant diseases and conditions. Therapy is not just medication, and therapy optimization is not just ensuring product delivery and compliance. Other problems that are contributing to poor outcomes need to be addressed, such as the presence of other diseases, depression, frequent falls, fractures, urosepsis, or osteoporosis. A therapy optimization program must treat the patient as a whole, rather than simply focusing on one disease or one medication. When these contributing issues and biologic therapy are effectively managed, patients will remain productive and functional for a longer period of time. Patient education is an important component of any therapy optimization program. A well-educated patient can be an active participant in managing her disease.

Specialty pharmacies are an efficient site for MS therapy optimization programs because they already dispense much of the medication used to prevent

relapses, are already knowledgeable about the disease process and therapy, and currently make monthly calls to patients. They also have the ability to bill for both medical and pharmacy benefits and collect or track data over time, which differentiates them from the routine retail pharmacy.

Benefits of Therapy Optimization Programs

Therapy optimization programs present multiple economic benefits (Exhibit 6). For providers, those benefits include the ability to track patient progress, glean valuable information to improve clinical decisions. Many physician practices cannot currently provide such data tracking. The benefits to a managed care organization are the development of an evidence-based formulary, improved patient outcomes such as reduced hospitalizations for relapses, and improvements in the consistency of care provided to MS patients.

Conclusion

Therapy optimization programs for diseases such as MS, which requires costly injectable biologic agents, are one small component of an improved healthcare system that can be implemented quickly by most health plans and by most large medical groups by contracting with a specialty pharmacy. **JMCM**

References

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Exhibit 6: Economic Benefit of Therapy Optimization Program for MS

- Prevention of Relapses
- Direct medical cost avoidance from disability progression
 - > Medical costs elevate as disability progresses
- Depression Screening
 - > Rapid treatment of depression
- Prevention of Events of Disease Progression
 - > Urosepsis
 - > Falls and fractures
- Delay of Disability
 - > Results in fewer lost productive years

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