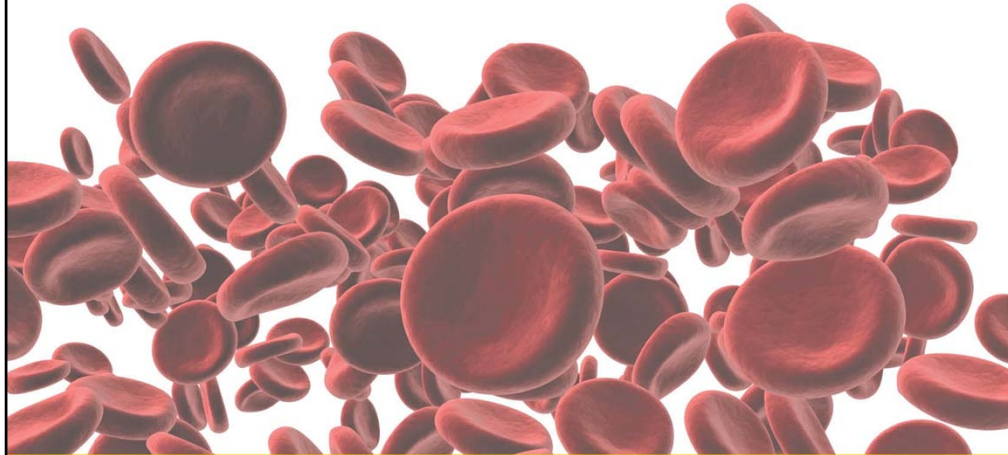


Challenges and Opportunities for Managing Hemophilia



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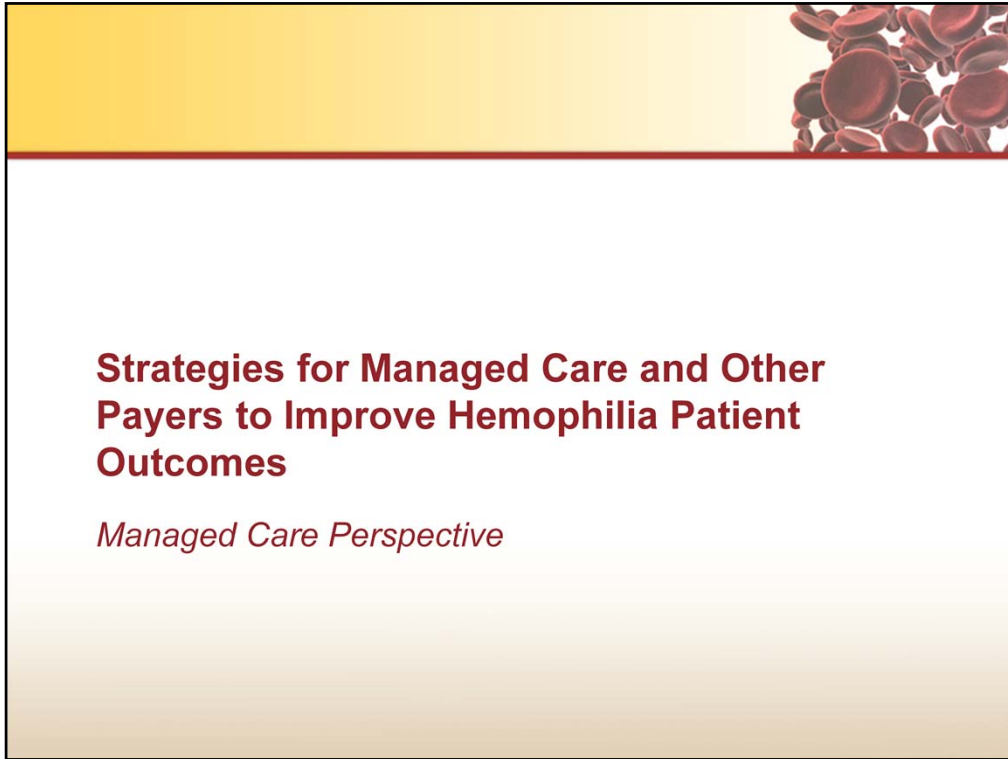


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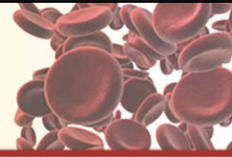
Welcome to the continuing education activity entitled “Challenges and Opportunities for Managing Hemophilia”. We are pleased to provide you with what we hope will be an informative and meaningful program.

We would like to acknowledge that this activity is supported by an educational grant from Novo Nordisk and we would like to thank them for their support.



This presentation, entitled “Strategies for Managed Care and Other Payers to Improve Hemophilia Patient Outcomes,” will provide information from the Managed Care perspective.

Objectives

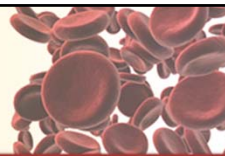


- Evaluate managed care's current approach to hemophilia
 - *Hemophilia is an example of a chronic and costly condition with low incidence*
 - *A need exists for payers to better understand the intricacies and complexity of hemophilia treatment*
- Improve integration of available resources to drive high quality and cost effective care
 - *Examples of potential resources that add value for payers:*
 - *Hemophilia Treatment Centers (HTCs)*
 - *Liaison with national recognized clinical experts*
 - *Specialty pharmacy providers – may be internal to the health plan*
- Identify key hemophilia-related issues for P&T committee discussions
- Explore the evolution of hemophilia management and managed care's approach over next 3 to 5 years

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The objectives of this presentation are to evaluate managed care's current approach to hemophilia as an example of a chronic and costly condition with low incidence; to improve the integration of available resources to drive high quality and cost effective care; and to identify the key hemophilia-related issues that Pharmacy and Therapeutics, or P&T, committees and technology assessment committees need to look at when they review products and treatment approaches, and to explore the evolution of hemophilia management and managed care's likely approach over the next three to five years.

Managed Care's Current Approach to the Management of Hemophilia



- Current medical and pharmacy policies may include prior authorization or pre-certification for therapies
 - Objectives:
 - *Verify diagnosis*
 - *Ensure products and technologies are being used within labeling and best clinical practices*
 - Goal:
 - *Encourage appropriate care*
- Case management services are often made available to
 - *Minimize barriers to access*
 - *Improve quality of care*
- Coordinate care with HTC and specialty pharmacy providers

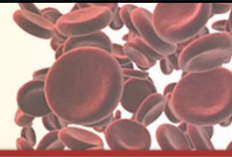
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Currently, medical and pharmacy policies are often enshrined and applied via the use of prior authorization or precertification for therapy. The goals of these processes are to verify the patient's diagnosis and ensure that these are the products, technologies, and services that will best serve that particular patient; and that these products and technologies are being used within the labeling and, importantly, that best clinical practices or professionally accepted and created guidelines are utilized to guide treatment. The goal is to encourage appropriate care, which will then lead to better outcomes.

In addition to utilization management, managed care companies also provide case management services, and the goal here is to coordinate care with the patient's benefits, thereby minimizing the barriers to access and hopefully improving the quality of care. Very importantly, the health plan can coordinate with both the Hemophilia Treatment Center, or HTC, and the specialty pharmacy provider.

Hemophilia Compared to More Prevalent Chronic Conditions

(e.g., diabetes or hypertension)



- Hemophilia
 - A chronic condition involving ongoing, costly care
 - A complex disease requiring clinical experience and expert judgment to manage appropriately
 - Requires compliance with best clinical practices to
 - Use medications appropriately
 - Reduce emergency department visits
 - Minimize hospital admissions
- Hemophilia incurs higher aggregate costs of care despite a relatively low incidence
- HTC are specialized patient care and support resources that play an important role to improve outcomes
 - Comparable organizations are not available for many other conditions

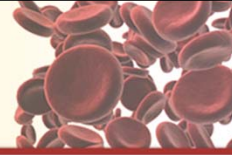
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One of the salient points about hemophilia is that it is a chronic condition that involves ongoing costly care, and so in this respect it looks a lot like care for patients who receive a transplant and need extensive follow-up and medication afterward. Hemophilia is a complex disease and managed care companies are not expert at managing the disease. They are expert at managing the benefits that patients have and coordinating care, but there is a real need for true experts in this field, and those experts are often found at university centers and HTCs. What we want to do here is to be sure that patients are cared for in the best way according to guidelines and that medications are used appropriately.

With appropriate use of medications and availability of medications in the patient's home, we would hope that this would reduce exposure to emergency department and the need for emergency visits and minimize hospital admissions, which in many ways represent a sort of failure of outpatient care, although hospitalization is sometimes important to restructure a patient's treatment and get his care back on track, or there may be unforeseen trauma or other problem. Generally speaking, however, we want to minimize the number of hospital admissions because of complications of hospital admission and because patients are best treated in their own home.

Hemophilia is of course very special in that there are very high costs and low incidence, which means that most managed care companies do not see many hemophilia patients, and thus they need to rely on experts from the different disciplines in order to help them. Many of those disciplines come together in the HTC and they provide specialized patient care and sometimes care that is not available in the community, such as care from an orthopedist, from a dentist, and from others who are familiar with the treatment of patients with hemophilia.

Health Plans' Case Management Services



- **Case manager is a clinician**
 - *Nurse or a clinical pharmacist*
- **Objectives**
 - *Minimize barriers to access to care*
 - *Help improve outcomes*
- **Case management may provide one or more of the following services**
 - *Coordination of care between providers (e.g., HTC)*
 - *Assistance with access and financing of drug therapy*
 - *Address the needs of the caregiver for pediatric patients*
 - *Education*
 - *Training*
 - *Emotional support services in some plans*
- **How can payers better coordinate their case management services with those provided by the HTCs?**
 - *Opportunity to enhance quality outcomes*

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Case management services are usually provided by a clinician such as a nurse or a clinical pharmacist. Managed care plans may offer other services that do not involve a clinician, such as review of benefits or billing. Most hemophilia patients are eligible for case management and many managed care systems have a staff nurse. If case management is conducted through a specialty pharmacy it may be a pharmacist. The goals here are to minimize access barriers and improve outcomes.

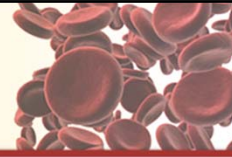
The case manager will help coordinate care. For example, if the patient has been seen at a HTC but needs to receive care at home, the managed care case manager can help find someone who is available and in that patient's network to provide home care. The family may require financing or special financial arrangements to pay for the drug therapy coinsurance and copays, and specialty pharmacy or some other division of the managed care plan may be able to address that.

There are other needs that the caregivers have, especially for pediatric patients. These may include education, training, and emotional support for parents and other family members, and many managed care plans can help move them in the right direction. The managed care plan may have employee assistance programs that may also be part of their health plan, and coordination of care with behaviorists and other specialists can be extremely helpful in supporting both the patient and their family.

There is always an opportunity to get better at what we do. Closer coordination with HTCs is welcome and can often help with patient care. Many times this is a matter of the case

manager and someone at the HTC spending time together to understand each other's roles and how they can contact one another to better coordinate care for that particular patient, and help that patient to follow the treatment plan that has been established by the HTC.

Patient Management and Support Opportunities



HTCs

- **Deliver care**
 - *Team of providers and support staff*
- **Support services**
 - *Emotional support*
 - *Educational – Examples:*
 - Training regarding IV therapy administration*
 - Importance of therapy adherence*
 - *Physical therapy*
 - *Financial*
- **Coordinate care with...**
 - *Health plans*
 - *Specialty pharmacy providers (SPPs)*
 - *Other resources outside of the HTC*

There exist opportunities for health plans to enhance coordination between HTCs and SPPS

Specialty Pharmacies

- **Pharmacist assessment assay management**
 - *Can affect quality and cost of care*
- **Coordination with HTCs about possible issues with:**
 - *Therapy adherence*
 - *Therapy administration*
- **Coordination with the health plan**
 - *Prior authorization processing*
 - *Payment for care*
- **Education**
 - *Reinforcement of HTC-provided training regarding IV therapy administration*
 - *Financial counseling*
- **Identifies need for emotional support and refers to appropriate medical provider**
- **Provision of emergency supplies as needed**

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HTCs provide a number of services including supporting the patient, diagnosing, creating treatment plans, etc., and specialty pharmacies may provide complementary or even slightly overlapping services here. Many times the managed health plan can help to coordinate this.

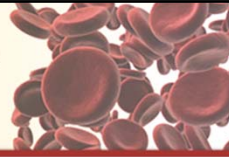
Specialty pharmacy is generally either part of the health plan such as a holding or subsidiary, or under contract to the health plan so they are an agent of the health plan. Being able to coordinate these two can be extremely important. For instance, the managed care plan can help ensure that the specialty pharmacies receive the right prescriptions and treatment plans from the HTC so that they can have that material ready for the patient and ask questions if the patient requests something different. If there is a disconnect, we ask, “What can we do about that?”

There may also be a need for coordination of the prior authorization and payment such that the specialty pharmacy can work with the health plan to be sure that the health plan has approved the treatment plan and the prescriptions and that the prior authorizations are in place.

Since the specialty pharmacy is being paid for the medication, it is in their best interest to become part of the health plan if they are not already.

Also, both the HTC and the specialty pharmacy have a role in the education of the family. HTCs educate the family in a broad range of topics, and specialty pharmacies will focus specifically on drug storage and administration and ensuring families have what they need for that. Specialty pharmacies may also provide visits by home health or other nursing staff in order to make sure that the family is equipped to deliver care both routinely and on an emergent basis.

External Medical Experts Can Help Address the Complexities of Managing Hemophilia



- HTC directors are medical experts who work with insurers
 - *Clinical expertise derived from working with hemophilia patients on a daily basis*
- Health plans can work with the National Hemophilia Foundation and its Medical and Scientific Advisory Council to identify appropriate experts
- Relationship objective: Improve quality of care and maximize the value of our investment in hemophilia management
- Role of external medical expert...
 - *Support the P&T review process when new products are reviewed*
 - *Provide insights from clinical practice that may not be found in the literature*
 - *Support the retrospective review of claims to ensure appropriate coverage*
 - *Help payers with application of best clinical practices*

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Most health plans appropriately see HTCs as the medical experts with clinical expertise residing in the multidisciplinary staff that works every day with hemophilia patients. Health plans have rules by which case management staff and others must abide. It is helpful if the HTC works with the health plan to ensure that clinical events are documented and copies of records are received so the health plan can see that benefits are applied correctly and claims get paid for on a regular basis, including claims that are billed from the HTC.

Health plans also can work with the National Hemophilia Foundation and others to develop clinical policies and receive expert advice from the physicians, nurses and other HTC staff, in order to establish the appropriate formulary placing and clinical policies for the regulation of clotting factor concentrate and other services that patients requires.

The objective here is to improve the quality of care and maximize the value of the investment in hemophilia management, meaning that we are putting a lot of time and attention into the care of these patients and we really have their best interests in mind.

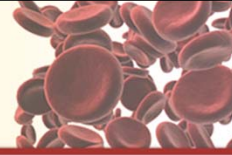
For instance, if the patient needs prophylaxis, the health plan wants to make sure that the need for prophylaxis is properly documented so that the health plan can refer to that, plan for the expense of prophylaxis, and make sure that payment is processed. Good and proper documentation is necessary to be sure that prophylaxis is the right thing for this particular patient and that the treatment duration is appropriate.

That usually starts with a good P&T process. The clotting factor concentrates are almost all covered by every health plan, so what the P&T process does is to help inform the utilization management programs and clinical policy criteria that will be applied by the payer.

Payers will also use retrospective review of claims to look for appropriate coverage. They will identify patients whose expenses are high or for whom some other detail triggered a review. This is where proper record-keeping, consistent use of the same dosing, and documentation when dosing has changed are helpful to ensure that payment continues to the appropriate providers.

Payers want to be able to provide best clinical practice, or to enable those practices for the patients, and documentation and data are fundamental to accomplishing that.

Hemophilia-Related Issues for Health Plans to Consider



- Need for hemophilia education within the health plan
 - Example: Examination of available therapies and those in the pipeline
- Capitalizing on the capabilities of, and enhancing relationships with HTC's and The National Hemophilia Foundation
 - Objective: Achieve higher quality and more cost-effective care
- Encouraging care that is consistent with best clinical practices
 - Relying on clinical trials and evidence-based guidelines, as available
- Examine the potential of investment in care today to achieve enhance long-term clinical outcomes and cost savings in the future
- Cost sharing is growing in response to overall healthcare premium pressures and can have an adverse effect on patients' compliance and persistence
 - Coinsurance has little effect on total plan sponsor costs unless there is no cap on patient out-of-pocket costs¹

1. Willey V.J. *Health Aff.* 2008;27:824-834.

In order for much of this to happen, health plans need additional information about hemophilia. If there is a certain nurse or group of nurses who are dedicated to hemophilia care, learning more about current therapies and how they are used can be extremely helpful. This is especially helpful in specialty pharmacy settings where pharmacists need to learn about new uses, for example how prophylaxis works. Adding this information to the training regimens of managed care staff can be very helpful in creating good communications and conveying the issues and special considerations for this population.

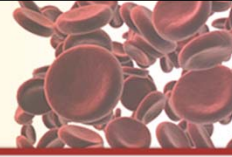
Tapping into the HTC's and the National Hemophilia Foundation to work on higher quality care and to discuss the most cost effective means to achieve that quality of care can be very helpful. Health plans want to encourage care that is consistent with best practices, and many times they will write their clinical policy bulletins in order to point the physicians and others in the right direction. Many times, however, the physicians and others who are caring for patients are doing things the right way, and there is a disconnect with the health plan due to lack of education or poor documentation.

Many payers, especially employers, should look at the potential for financial investment and quality care today to achieve a better outcome in the longer term. For instance, in hemophilia, quality care today would entail treating children with severe hemophilia with prophylaxis so that in the future, they will not carry a disability because they successfully prevented joint bleeds, were able to participate in physical activity and sports, and did not

develop the sequelae that come later in life in patients suffering joint disease. Higher cost treatment can pay off not only to that individual, but also to communities, employers, and families.

We must recognize that cost sharing is a serious issue. It has increased significantly over the past few years as healthcare costs continue to go up. Cost sharing, coinsurance, and other out of pocket expenses are ways for overall premiums to be held down. Patients may need help to meet their cost sharing obligations. Many times the specialty pharmacy or some other branch of the health plan will be able to move the patient in the right direction towards those entities and organizations that can help with cost sharing. We must recognize that cost sharing is a fact of life, but that there are ways to deal with it. Industry has been helpful in dealing with that as well.

Hemophilia-Related Issues for Health Plans to Consider (cont'd)



- Potential role of specialty pharmacy providers and coordination with HTC's
- Managed care's support for telemedicine
 - *Encourage better communication between HTC's, hematologists and patients*
 - *Encourage care that is consistent with best clinical practices that might yield cost savings*
- Improved understanding of needs and coordination of care between HTC's, community hematologists, specialty pharmacy providers, and payers

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There is more of a role for specialty pharmacy providers and health plans to coordinate with the HTC's and work with patients. One way to do this is to use telemedicine support; many health plans now have linkages or contracts with telemedicine providers. They may also pay for email consultation and other sorts of connectivity for caring for patients who are not immediately in the office in front of the practitioner. Finally, there are always possibilities to increase understanding of patients' needs and coordination of care between HTC's, community hematologists, specialty pharmacy providers, and payers.