

Challenges in Patient Management

- Significant patient variation in Factor utilization
 - Age
 - Activity
 - Body Weight
 - Annual Bleed Rate
 - Severity of Disease
- Lack of awareness of treatment guidelines

MASAC Guidance

The risk of inhibitors vs pathogenic safety should be discussed with all patients.

- For PTPs: patients already receiving rFVIII may stay on treatment

“There is a lack of awareness among health plans of national guidelines, despite endorsement by clinical organizations such as American Society of Hematology.”

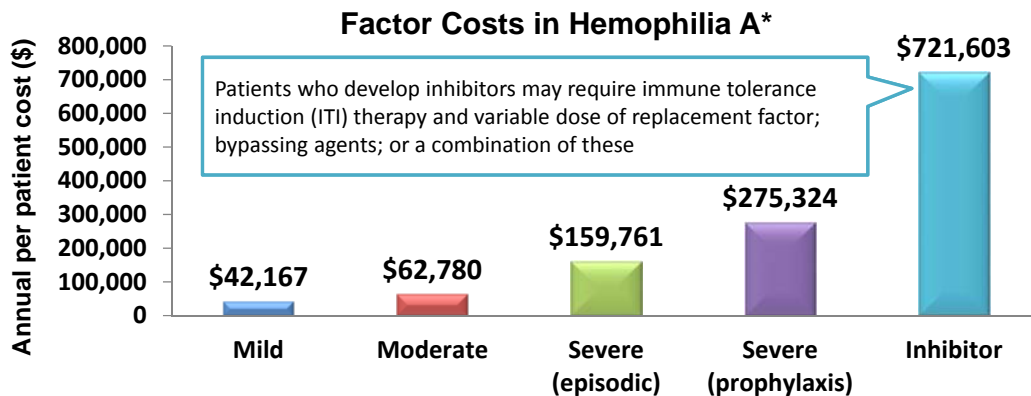
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Factor and Inhibitors Contribute Significantly to Annualized Factor Costs Across Hemophilia Members

Recognizing the differences in usage among populations can serve as an opportunity to optimize individual patient care and manage overall costs



“Unit price...and use alone are not the sole attributes in considering cost of patient care.”

*Factor costs in hemophilia B are similar
Reference prices: Medicare Average Sales Price.

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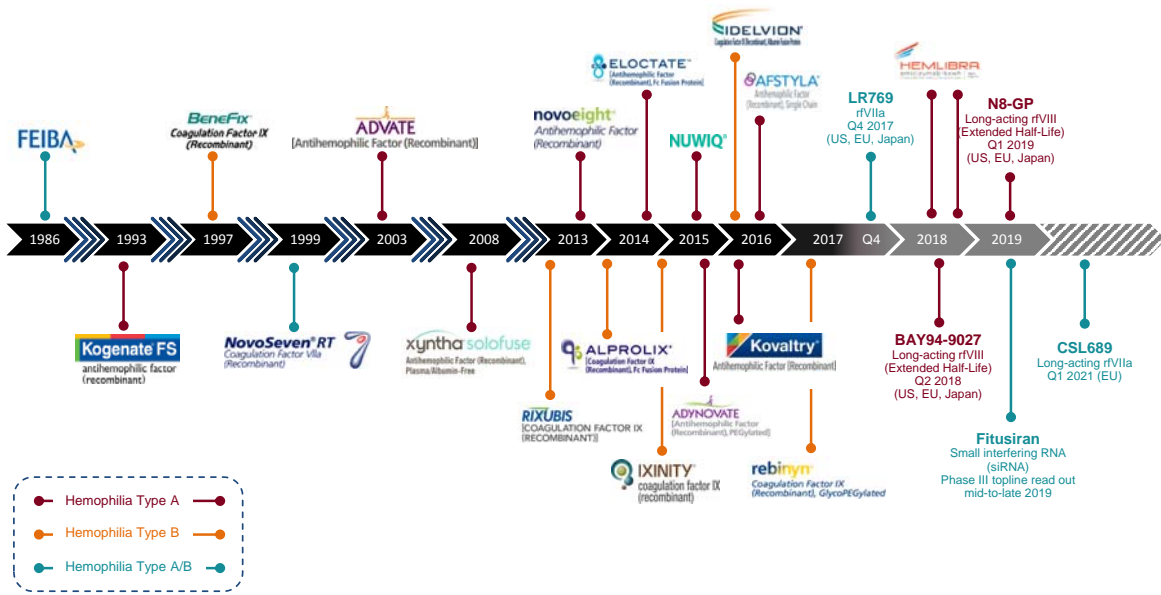
Source: Valentino LA et al. *Haemophilia*. 2015;21:559-567; Sherman A, et al. *Front Immunol*. 2017;8:1-12. Hemophilia Utilization Group Study (HUGS). 2011; Zhou Z-Y, et al. *J Med Econ*. 2015;18:457-465;

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Hemophilia Market

New products, methods of administration and innovations



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19

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New and Emergent Agents Are Generating Excitement But More Reliance on Efficient Partnerships

Despite product advances and options, effective management of hemophilia relies on preventing bleeds and encouraging local touchpoints for members



New products may provide stability and predictability

- Members rarely switch and stay with plan longer than the average of 2 years
- Payers are cautious of uptake of new treatments before changing policy
- Cost-effectiveness opinions, such as ICER decisions, largely go unnoticed
- Excitement continues for gene therapy with 10-year management reprieve, but concerns of price looms for disease-modifying intervention



Distribution channel gaps point to unnecessary costs

- Plans may incur extra reimbursement for factor, as well as facility and physician charges from some HTC/ providers
- ER-related brown-bagging by patients are an option at some institutions, but home care/ SPPs can mitigate the need
- Education to consumers and data sharing with payers are encouraged



SPPs and HTCs have competing goals but favor stronger engagement with payers

- SPPs are equipped to provide similar care coordination and services as HTCs while offering reduced cost burden and increased patient savings, thus competing with 340B model
- HTCs maintain that a better treatment plan can result in reduced reliance on out-of-state hospitalization and address cause of bleed and psychosocial issues

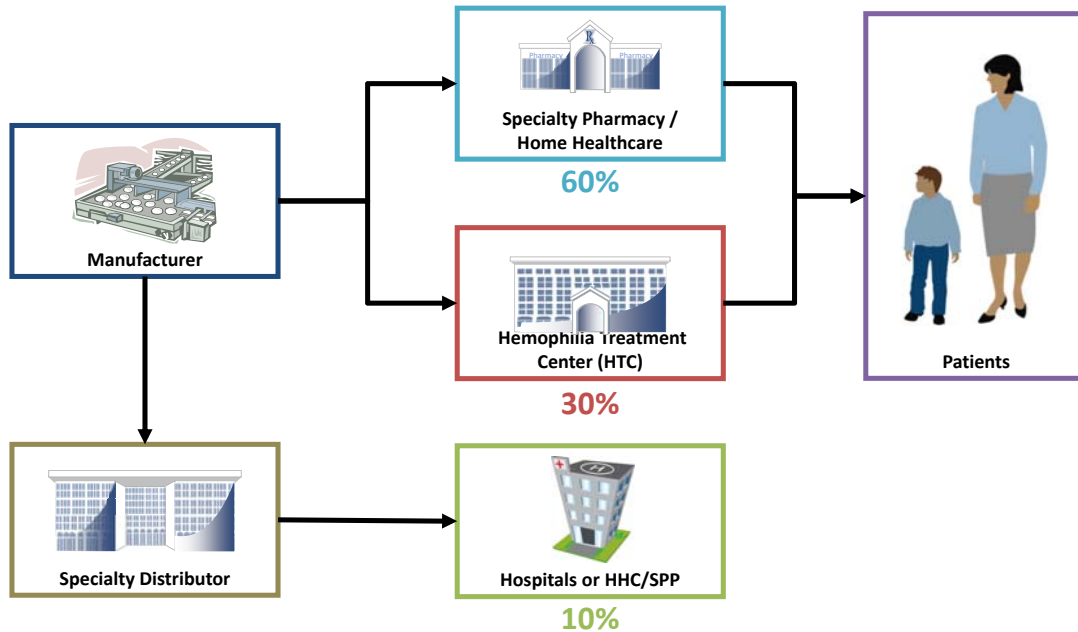
“The development of inhibitors is one of the most serious complications of hemophilia and carries with it significant cost for treatment. Health plans may be aware of members who have inhibitors, but rarely have a plan in place to manage them.”

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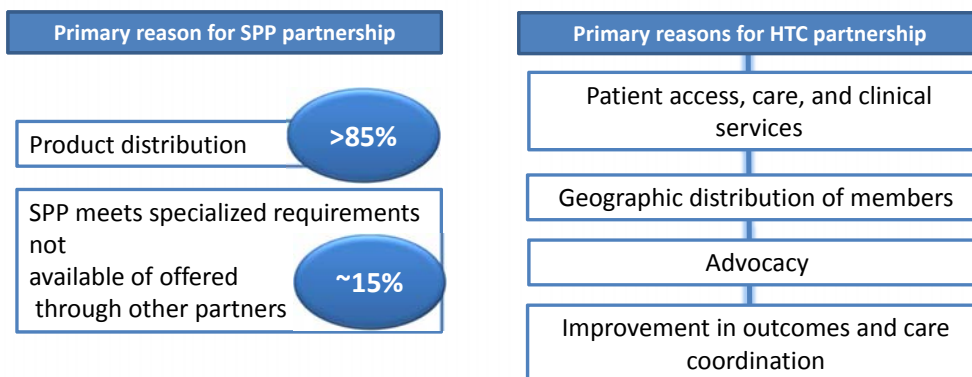
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Hemophilia Products Can Be Distributed Through Three Main Channels

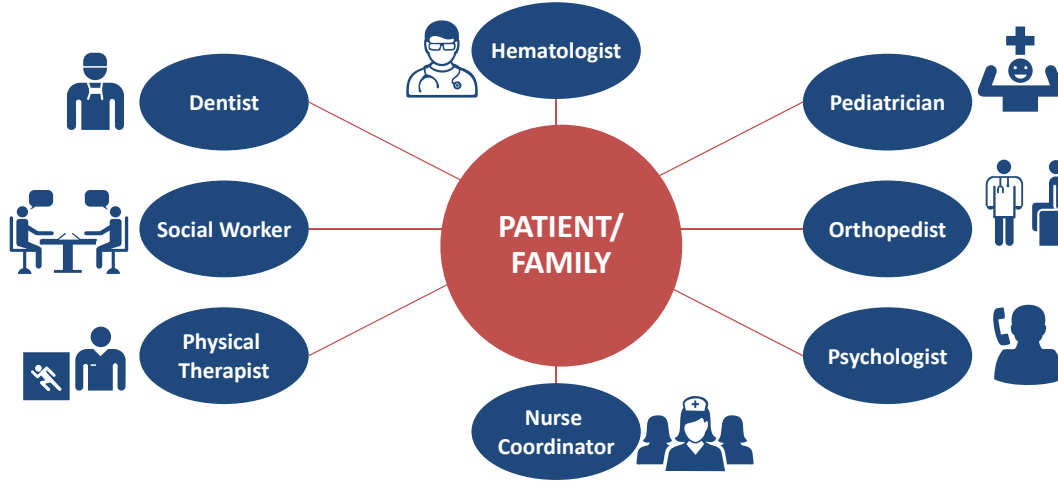


Stakeholder Relationship and Services Models

The majority of health plans partner with multiple specialty pharmacies and HTCs; some have over 10 contracts



The HTC Comprehensive Care Model



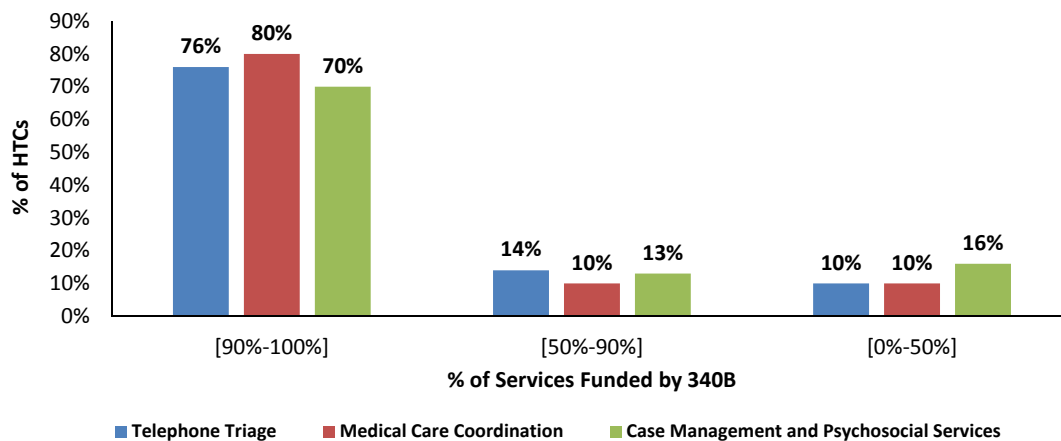
Most aspects of patient care are addressed:
physical, emotional, psychological, educational, financial, and vocational needs

Source: Smith PS, Levine PH. The benefits of comprehensive care of hemophilia: a five-year study of outcomes. *Am J Public Health.* 1984;74:616-617.

340B Program Discounts Supports Integrated Care Coordination and Unbilled Ancillary Services



Most HTCs fund unbilled telephone triage, medical care coordination, and case management/psychosocial services almost entirely through 340B



N=31 HTCs with established 340B programs.
Trujillo M, Forsberg AD, Drake J, Cheng D, McLaughlin K, McKernan L. National Survey of the 340B Drug Pricing Program: Quantitative Evaluation of the Services Provided by the U.S. Hemophilia Treatment Centers. Presented at: WFH 2016 World Congress; July 24-28, 2016; Orlando, FL.

Specialty Pharmacy Patient Care Management



Primary role:

Dispensing factor products and monitor patient between visits to provider



CLINICAL

- Completing assessments by hemophilia experienced clinicians
Historical frequency and location of bleeds; Type of IV access; Presence of inhibitors; Weight
- Prescribed medication
Diagnosis; Units/kg; Comparison of dose to MASAC and/or prescribing information
- Re-assessments
Number of bleeds since last contact; Doses on hand; Reconciliation of remaining doses; Reported ER/Hospitalization; Upcoming procedures



FINANCIAL

- Assay management
Percent variance from the prescribed dose; Broad inventory required for assay selection; Prescribed dose must be appropriate; Variance should be less than 2% from prescribed dose
- Economic assessment
Reconciling inventory in home; Quarterly utilization and claim trends; Identification of outliers and expected utilization changes; Pipeline updates; Collaboration with the third party health plan



OUTREACH

- Communications
Monitoring of reported bleeds; Adherence to plan; monitoring usage and stockpiling; Identification of barriers to optimal outcomes; demographic needs assessment; tools audit; collaboration with HTC or prescribing HCP
- Utilization assessment
Evaluation of consistency with expectations for factor dispensed

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Yet, Challenges and Gaps in Efficiencies Remain



- **Clinical data sharing between HTCs and health plans is needed** to better measure outcomes due to variances in EHRs and systems;
- 340B pricing (11-40% of AMP) allows eligible HTC entities to continue care coordination and support services, HTCs risk closures if 340B funding is decreased or reduction in provider reimbursement for services
- **Lack of measurable cost savings passed to health plans creates a potential challenge**
- **A greater proportion of specialty benefit has now moved to pharmacy:** SPP now compete with HTCs and have greater ability to review claims and monitor home utilization, bleeds, and joint health; can recommend changes to assay and use of factor

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26






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Stakeholders Seek Efficient Partnership in Care Coordination and Services

Participants were asked to break out into channel groups and asked to identify opportunities

HEALTH PLAN	<ul style="list-style-type: none"> <input type="checkbox"/> Risk sharing contracts with HTCs <input type="checkbox"/> Centers of excellence <input type="checkbox"/> New products with longer duration of action with fewer bleeds <input type="checkbox"/> Standards of patient services and touchpoints for SPPs <input type="checkbox"/> Revision, awareness and implementation of MASAC guidelines
SPP	<ul style="list-style-type: none"> <input type="checkbox"/> Open dialogue with plan and HTC care managers <input type="checkbox"/> Collaboration with plans about utilization goals and management <input type="checkbox"/> Geomapping access to help identify patients for nurses and services
HTC	<ul style="list-style-type: none"> <input type="checkbox"/> Contract with SPP pharmacists for shared savings with pharmacy services <input type="checkbox"/> Reimbursement model for SPP services as well as health care services <input type="checkbox"/> Closer and more frequent engagement with health plans <input type="checkbox"/> Better integration and fewer duplication of services

Opportunities for Improving Care Coordination

	<p>Encourage home use and monitoring of costly members</p> <ul style="list-style-type: none"> • Medical claims reveal costs and expenditures with hospitalization, reduced mobility with administration, and increased bleeding • Per unit cost dramatically increases in ER; inhibitor patients add to existing cost
	<p>Implement adherence programs for prophylaxis and to monitor utilization of factor</p> <ul style="list-style-type: none"> • Case manager and ancillary services can help mitigate such costs • 100% self infusion is the goal when the patient is able to self-administer
	<p>Provider/Hospital education on assay management</p> <ul style="list-style-type: none"> • At hospital, lack of factor availability triggers variable dosing and divergence from SPP order, driving potential change of product and higher costs • Expense recommended at +/- 10% on average, although some systems require a lower threshold (3%) • Inventory is a challenge while there is a perception of patients stockpiling at their house due to excess product from SPP

Recommendations for Implementing Change

Streamlined standards of practice, guidelines, and data sharing

1

Risk-sharing for preferred products across stakeholders that provide value with durable outcomes and guidance on assay management

2

Patient home care and self infusion encouraged through provider education and nurse services

3

Removal of “any willing provider” for efficient distribution and optimal care coordination through trained HTC and SPP

4

Minimize costs for duplication of care coordination performed through unbilled SPP and HTC services

“Participants advocate that stakeholders should meet periodically to review charts of individual patients and understand the specific costs associated with their care.”

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Questions for health plan considerations

When evaluating processes and procedures to optimize hemophilia treatment and costs, health plans may want to consider the following:

- How might the roles and services provided by SPPs and HTC alter your partnerships in hemophilia management?
- What opportunities do you envision for contracting with manufacturers?
- How might you alter auditing of distribution and dispensing to ensure appropriate factor and assay utilization?
- How might you implement policies to effectively identify appropriate members who can benefit from prophylaxis treatment to prevent bleeds or switching product?
- How do you envision members with inhibitors impacting your management? What plans do you have in place to manage members who develop inhibitors?
- What mechanisms are needed to share best practices in this space?

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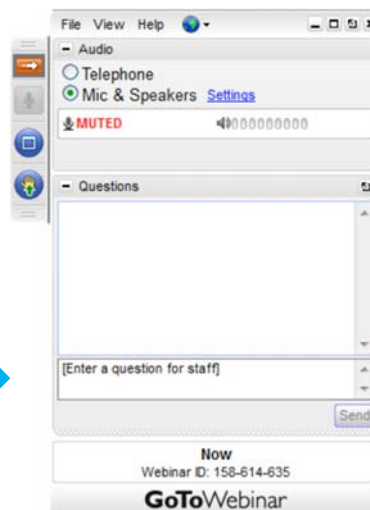
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QUESTIONS?

31

How to Ask Questions



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