Hemophilia Market Insights -Understanding Hemophilia Patient Management and Reimbursement -Proceedings from the 2018 AMCP Market Insights Program

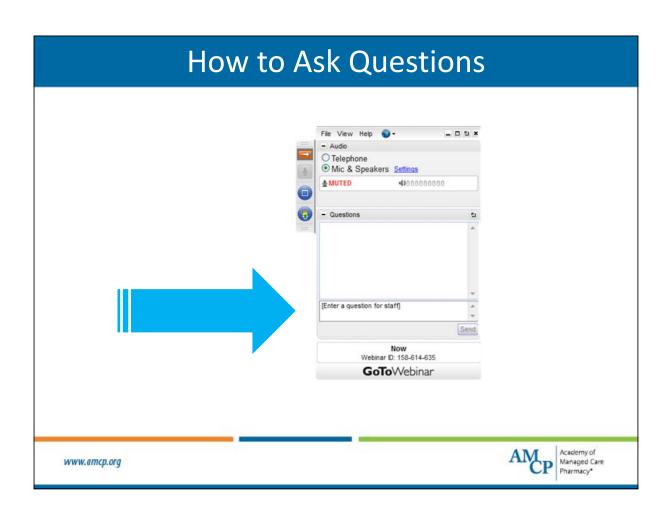
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AM Academy of Managed Care Pharmacy*

AMCP Market Insights Program

- Unique double-blinded program addressing needs of AMCP members- both corporate and payers
- Multidisciplinary program allowing interaction between key opinion leaders, practicing clinicians and payers to address the needs of AMCP members, such as disease utilization management
- Topics are based upon disease condition and payer challenges and approaches, with a goal to find mutual solutions

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Objectives of Market Insights Programs

- 1 Provide AMCP members relevant information regarding current and future management of hemophilia
- 2 Understand and evaluate current business models supporting hemophilia care
- Determine the evolution and changes to services and stakeholders relating to coverage and reimbursement decision making for hemophilia

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Market Insights: Hemophilia Summit I

In April 2018, an AMCP Market Insights Summit was held in Boston, MA



Participants across US, with 111,000 to 25 million covered lives (N=11)

Health plans/Medical directors
Pharmacy directors/Specialty Pharmacies and
PBMs
Hemophilia Treatment Centers/Patient Advocacy



A roundtable format, with presentations and group discussion on current and future management of hemophilia, including recommendations for industry

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Multi-Sponsored Market Insights





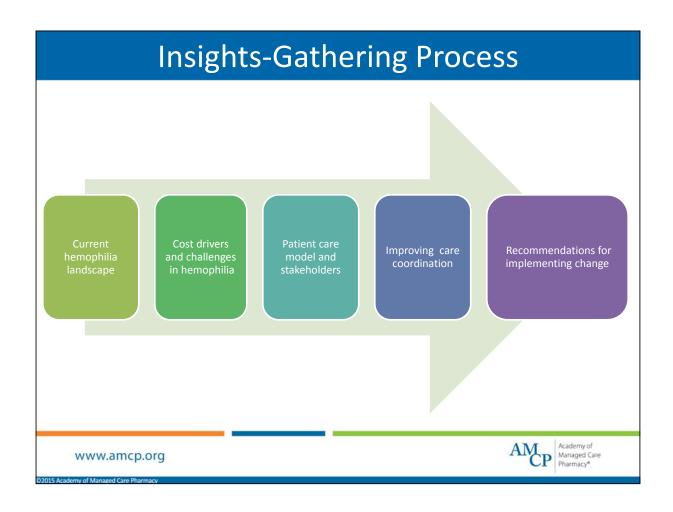


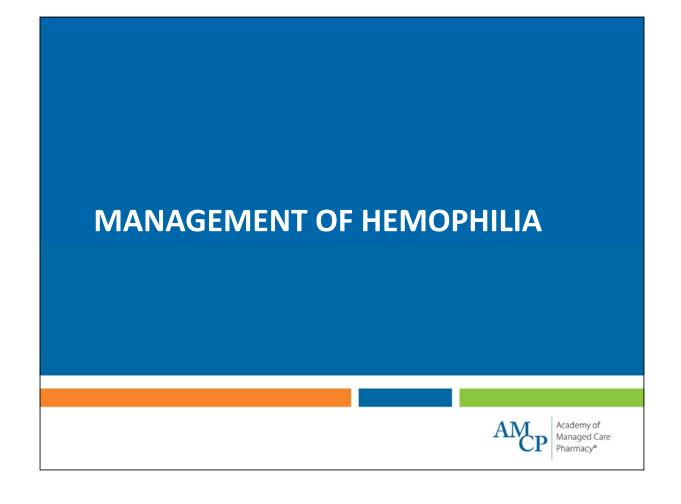


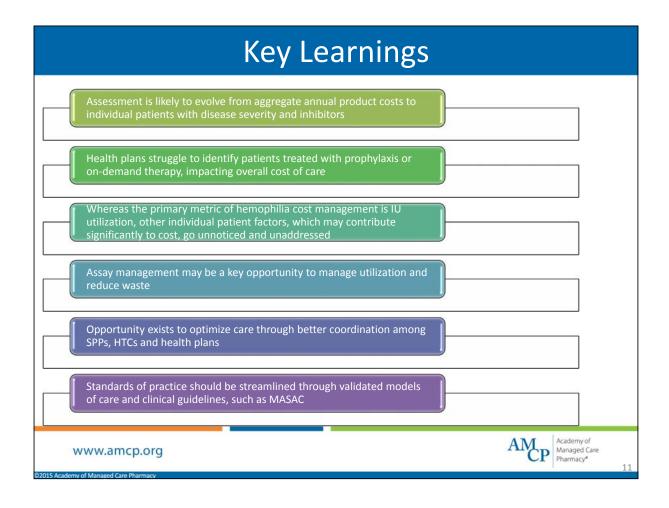


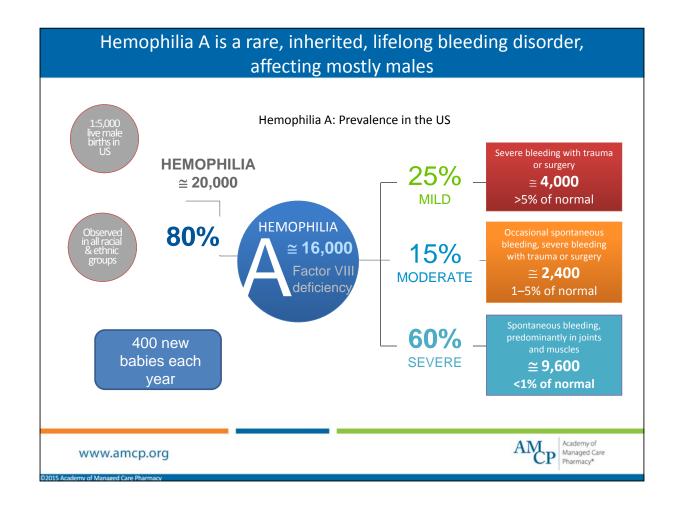
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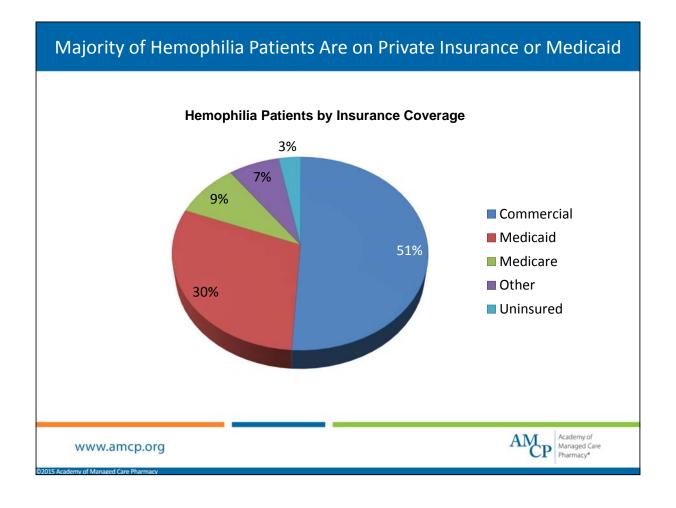


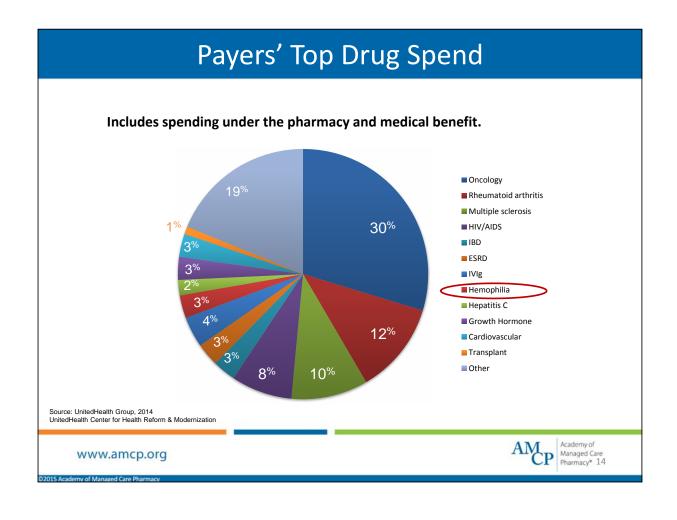












Growing Awareness and Perception of Hemophilia Products Signal Increased Management



Price increases with innovative hemophilia agents

- New products with extended half-life
- Novel hemophilia pipeline



Dose, waste and inventory management

- Assay management
- Appropriate dose and frequency
- Reconciling inventory with Rx



Increased use of hemophilia products

- Expanded use of prophylaxis
- Inhibitor treatments



Complexity of disease

- Evnanded use of prophylav
- Inhibitor treatments
- New products with different dosing schedules



Aging Population

- Co-morbidity
- Complications
- Hospitalizations/ Joint replacements

Level of management over the next year



"Cost drivers include ER visits, poor care coordination, patient adherence, and a population with growing longevity."

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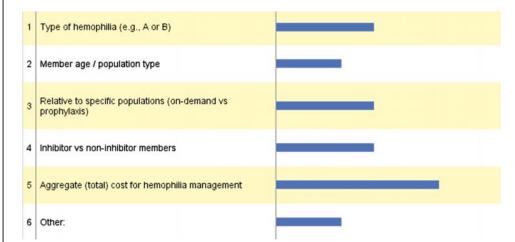
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15



Representative Profiles and Decision-Making Attributes

Participants cite a range of factors in managing hemophilia



"Health plans currently view costs in aggregates of factor units, and not by individual attributes such as age, on-demand versus prophylaxis use, inhibitor treatment, type of patient, or adherence."

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Challenges in Patient Management

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

MASAC Guidance

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

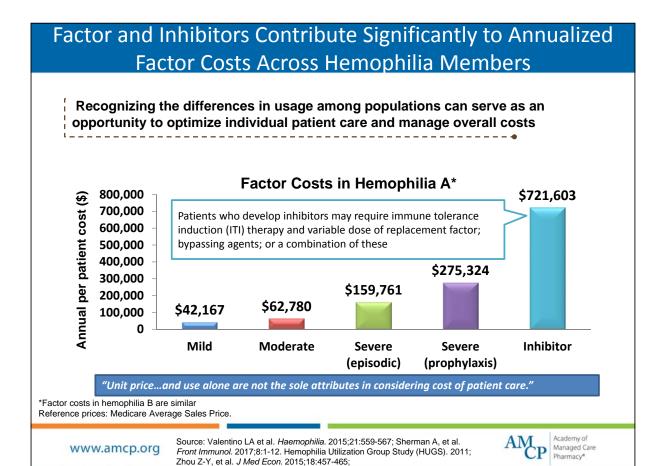
- For PTPs: patients already receiving rFVIII may stay on treatment
- Lack of awareness of treatment guidelines

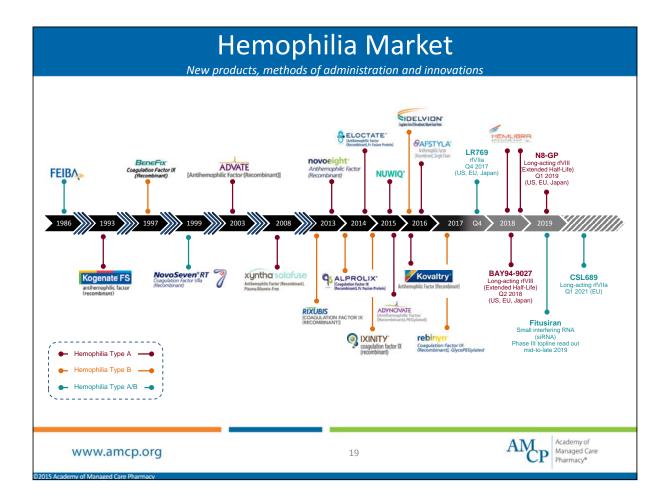
"There is a lack of awareness among health plans of national guidelines, despites endorsement by clinical organizations such as American Society of Hematology."

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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 HTCs/ 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



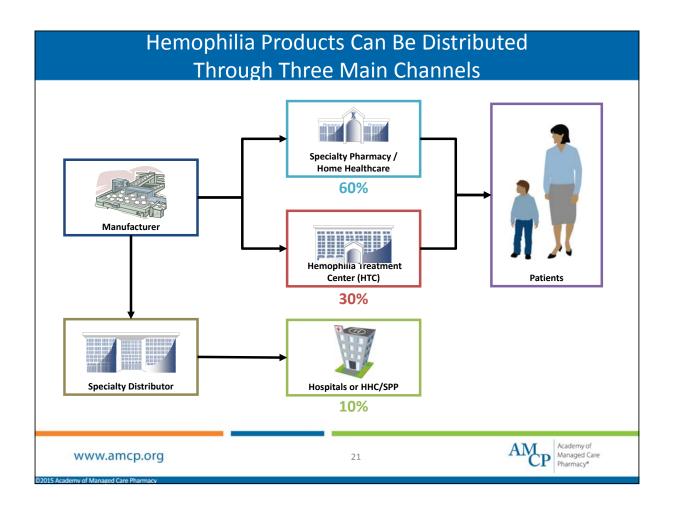
SPPs and HTCs have competing goals but favor stronger engagement with payers

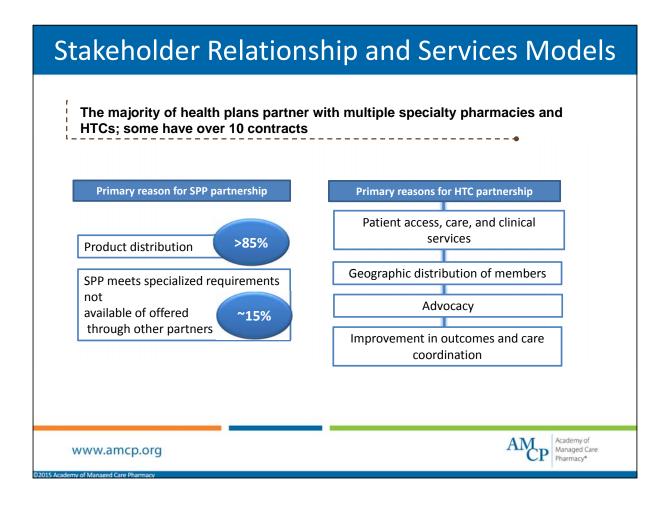
- SPPs are equipped to provide similar care coordination and services as HTCs while offering reduced cost burden and increased patient savings, thus competing with 340B model
- HTCs maintain that a better treatment plan can result in reduced reliance on out-of-state hospitalization and address cause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

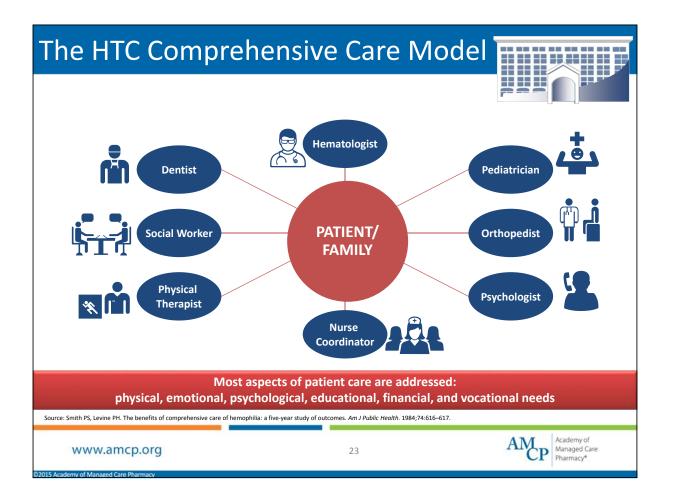
"The development of inhibitors is one of the most serious complications of hemophilia and carries with it significant cost for treatment. Health plans may be aware of members who have inhibitors, but rarely have a plan in place to manage them."

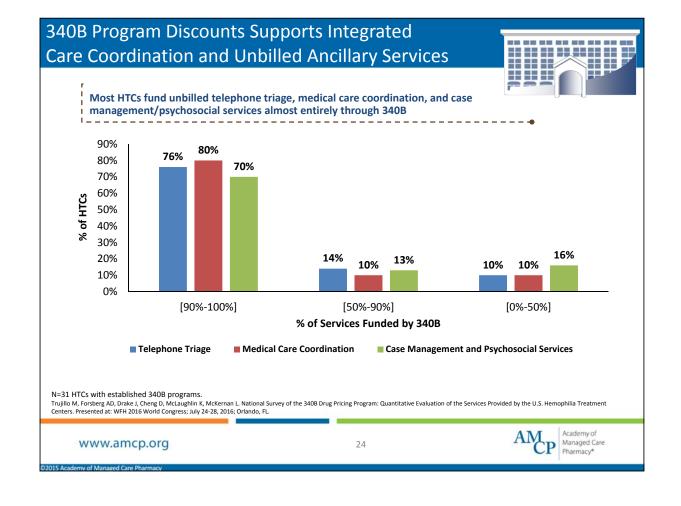
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Specialty Pharmacy Patient Care Management



Primary role:

Dispensing factor products and monitor patient between visits to provider



- 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



Assay management
Percent variance from the
prescribed dose; Broad inventory
required for assay selection;

required for assay selection;
Prescribed dose must be
appropriate; Variance should be
less than 2% from prescribed dose

Reconomic 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



- Communications
 Monitoring of reported bleeds; Adherence to plan;
 monitoring usage and stockpiling; Identification of barriers to optimal outcomes;
 - 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





SPP
Dispensation of factor,
and assay management, nursing
services, monitoring of adherence



- 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



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	 □ Risk sharing contracts with HTCs □ Centers of excellence □ New products with longer duration of action with fewer bleeds □ Standards of patient services and touchpoints for SPPs □ Revision, awareness and implementation of MASAC guidelines
SPP	 □ Open dialogue with plan and HTC care managers □ Collaboration with plans about utilization goals and management □ Geomapping access to help identify patients for nurses and services
нтс	 □ Contract with SPP pharmacists for shared savings with pharmacy services □ Reimbursement model for SPP services as well as health care services □ Closer and more frequent engagement with health plans □ Better integration and fewer duplication of services
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Opportunities for Improving Care Coordination



Encourage home use and monitoring of costly members

- 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



Implement adherence programs for prophylaxis and to monitor utilization of factor

- Case manager and ancillary services can help mitigate such costs
- 100% self infusion is the goal when the patient is able to self- administer



Provider/Hospital education on assay management

- 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

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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 HTCs and SPP



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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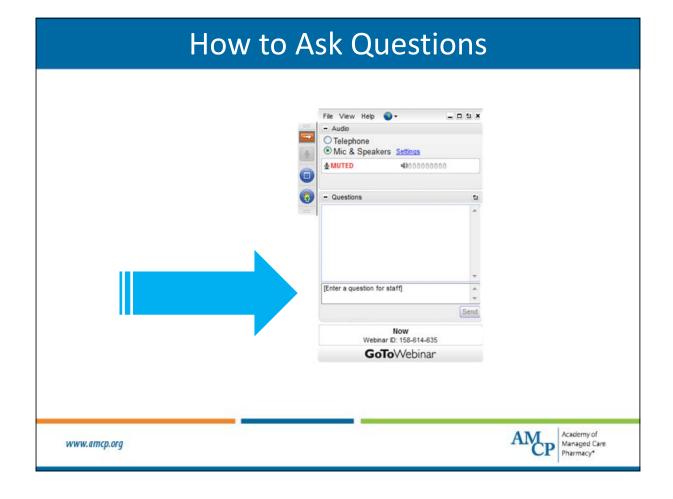
Questions for health plan considerations

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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