HEMOSTASIS 2.0

# Rethinking Hemophilia Management and Monitoring with Anti-TFPIs and FVIII Mimetics

CME OUTFITTERS

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Sheraton Grand Chicago (Room Chicago 9/10) • Chicago, Illinois

HEMOSTASIS 2.0

# Rethinking Hemophilia Management and Monitoring with Anti-TFPIs and FVIII Mimetics

The treatment landscape for hemophilia A and B is expanding with strategies and therapies to optimize efficacy, provide durable hemostasis restoration, and improve safety. These contemporary approaches to care have also led to new pathways and assays for clinical and laboratory monitoring.

In this live activity, an interdisciplinary faculty, including a renowned patient advocate who has lived with hemophilia for many years, discuss the impact of key advances in treatment and monitoring on quality of care and outcomes. A focused segment on shared decision making (SDM) keeps the conversation grounded in counseling and collaboration, and includes both clinician and patient perspectives.

## Learning Objectives

**At the conclusion of this activity, learners will be able to better:**

- Assess the clinical efficacy, durability in restoring hemostasis, and safety of anti-TFPIs and FVIII mimetics for the management of hemophilia
- Develop a clinical and laboratory monitoring plan of the hemostatic status in patients receiving anti-TFPIs and FVIII mimetics
- Implement SDM strategies to engage patients with hemophilia and their caregivers in the treatment plan

## Target Audience

Hematologists, hematologist/oncologists, nurse practitioners (NPs), physician associates (PAs), and other clinicians involved in the care of patients with hemophilia.

## Financial Support

Supported by an educational grant from Novo Nordisk, Inc.

## Faculty

**Amy Shapiro, MD (Moderator)**
*Medical Director*
*Indiana Hemophilia and Thrombosis Center*
*Indianapolis, Indiana*

**Maya Bloomberg, MSN, APRN**
*Hematology Nurse Practitioner*
*University of Miami Hemophilia Treatment Center*
*Miami, Florida*

**Mark W. Skinner, JD**
*President and CEO, Institute for Policy Advancement Ltd*
*Washington, DC*
*Assistant Professor*
*Department of Health Research Methods, Evidence and Impact*
*McMaster University*
*Hamilton, Ontario*
*Canada*

**Allison P. Wheeler, MD, MSCI**
*Associate Professor*
*Department of Pathology, Transfusion Medicine and Coagulation*
*Department of Pediatrics, Division of Pediatric Hematology*
*Director, Vanderbilt Benign Hematology Research Program*
*Vanderbilt University School of Medicine*
*Nashville, Tennessee*

 

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## Credit Information

### JOINTLY ACCREDITED PROVIDER

In support of improving patient care, CME Outfitters, LLC, is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

### IPCE CREDIT

This activity was planned by and for the healthcare team, and learners will receive 1.0 Interprofessional Continuing Education Credit for learning and change.

### PHYSICIANS (ACCME)

CME Outfitters, LLC, designates this live activity for a maximum of 1.0 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

### NURSES (ANCC)

This activity is designated for 1.0 contact hours. California Residents: This continuing nursing education activity was approved by the California Board of Registered Nursing. CME Outfitters LLC's provider number is CEP15510.

### PAS (AAPA)

CME Outfitters, LLC, has been authorized by the American Academy of PAs (AAPA) to award AAPA Category 1 CME credit for activities planned in accordance with AAPA CME Criteria. This activity is designated for 1.0 AAPA Category 1 CME credits. Approval is valid until 06/05/2024. PAs should only claim credit commensurate with the extent of their participation.

### ABIM MOC

Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 1.0 medical knowledge MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

### MIPS IMPROVEMENT ACTIVITY

Completion of this accredited CME activity meets the expectations of an Accredited Safety or Quality Improvement Program (IA_PSPA_28) for the Merit-based Incentive Payment Program (MIPS). Clinicians should submit their improvement activities by attestation via the CMS Quality Payment Program website.

### ROYAL COLLEGE MOC

Through an agreement between the Accreditation Council for Continuing Medical Education and the Royal College of Physicians and Surgeons of Canada, medical practitioners participating in the Royal College MOC Program may record completion of accredited activities registered under the ACCME's "CME in Support of MOC" program in Section 3 of the Royal College's MOC Program.

 

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## Faculty

### Amy Shapiro, MD (Moderator)

Amy Shapiro, MD, is the medical director and CEO of the Indiana Hemophilia and Thrombosis Center in Indianapolis and adjunct senior investigator, clinical track, at the Blood Research Institute in Milwaukee, Wisconsin. After receiving her medical training at New York University School of Medicine in New York City, Dr. Shapiro completed her internship, residency, and fellowship in pediatric hematology/oncology at the University of Colorado Health Sciences Center in Denver.

Author or co-author of more than 320 journal articles, abstracts, and textbook chapters, Dr. Shapiro is clinically focused on improving treatment for people with rare bleeding disorders. She has served on the National Hemophilia Foundation's Medical and Scientific Advisory Council, as well as several boards for the National Institutes of Health in data safety monitoring and clinical trial review. As one of the founders of the American Thrombosis and Hemostasis Network (ATHN), she has served as co-chair of the board of directors and remains active on various ATHN committees.

Dr. Shapiro has been honored as the National Bleeding Disorder Foundation Physician of the Year and, most recently, received their Leadership in Research Award. Among other accomplishments, she has received the Distinguished Hoosier Award in Indiana.

### Maya Bloomberg, MSN, APRN

Maya Bloomberg, MSN, APRN, is a board-certified family nurse practitioner specializing in nonmalignant hematology at Sylvester Comprehensive Cancer Center and Jackson Memorial Hospital in Miami, Florida, and is the adult nurse coordinator at the University of Miami Hemophilia Treatment Center. She earned both a bachelor of science and a master of science in nursing from the University of Miami. She has worked as a hematology nurse practitioner for more than 10 years, specializing in congenital bleeding disorders and sickle cell disease. She is actively involved in research and has had two manuscripts published on the topics of home infusion of factor replacement and prescribing practices among hemophilia treatment center (HTC) providers. Her social media presence (@theHemeNP) is devoted to providing reliable, easy to understand information to empower patients and bridge health disparities.

 

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## Faculty

### Mark W. Skinner, JD

Mark W. Skinner, JD, is the president/CEO of the Institute for Policy Advancement Ltd, specializing in patient-centered outcomes research. He is an assistant professor in the Department of Health Research Methods, Evidence and Impact at McMaster University. Mr. Skinner has previously led both national and international patient organizations, including the World Federation of Hemophilia and the National Hemophilia Foundation. He is the principal investigator for the Patient Reported Outcomes Burdens and Experiences (PROBE) study, a global research project to enhance the direct patient voice in healthcare decision making. He holds numerous roles as an advisor on critical blood safety and supply matters, including having served on the U.S. Health and Human Services Advisory Committee on Blood and Tissue Safety and Availability. Mr. Skinner also serves on the boards of the Institute for Clinical and Economic Review (ICER) and the National Organization for Rare Disorders (NORD), and formerly served on the board of the Patient-Centered Outcomes Research Institute (PCORI) Advisory Panel on Rare Disease, where he was an inaugural member. Previously, he was vice president of state programs at the American Insurance Association and administrative assistant/chief of staff to the Speaker of the Kansas House of Representatives. He holds degrees in public and business administration from Kansas State University and a juris doctorate from Washburn University School of Law.

### Allison P. Wheeler, MD, MSCI

Allison P. Wheeler, MD, MSCI, received her medical training at the University of Massachusetts in Boston. She subsequently completed her pediatric hematology/oncology and blood banking/transfusion medicine fellow training at Vanderbilt University Medical Center in Nashville, Tennessee. Since completion of her training in 2014, she has worked at Vanderbilt as faculty in pediatrics and pathology. Dr. Wheeler divides her clinical time between pediatric patients with hemostatic and thrombotic disorders and responsibilities as the co-medical director of the coagulation laboratory. Additionally, she is the director of research for benign hematology with a robust collaborative research portfolio and a personal research interest in women with heavy menstrual bleeding. Her academic work has expanded to include investigation into the use of COVID Convalescent Plasma (CCP) as a treatment option for COVID-19; vaccine safety; and investigation of diversity, equity, and inclusion in medicine. Dr. Wheeler spends as much time outside as she can when not working.

 

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## Disclosure Declarations

It is the policy of CME Outfitters, LLC, to ensure independence, balance, objectivity, and scientific rigor and integrity in all of their CE activities. Faculty must disclose to the participants any relationships with commercial companies whose products or devices may be mentioned in faculty presentations, or with the commercial supporter of this CE activity. CME Outfitters, LLC, has evaluated, identified, and mitigated any potential conflicts of interest through a rigorous content validation procedure, use of evidence-based data/research, and a multidisciplinary peer review process.

**Dr. Shapiro** reports the following financial relationships:

- Advisory Board: Be Biopharma; CSL Behring; Genentech, Inc./Roche; Novo Nordisk; Pfizer Inc.; Sanofi-Genzyme/Bioverativ Inc.; and Takeda Pharmaceuticals U.S.A., Inc.
- Consultant: Kedrion Biopharma Inc. and Novo Nordisk
- Research Support: Genentech, Inc./Roche; Kedrion Biopharma Inc.; Novo Nordisk; Pfizer Inc.; Sanofi-Genzyme and Kedrion Biopharma Inc.
- Speakers Bureau: Genentech, Inc./Roche; Kedrion Biopharma Inc.; and Sanofi-Genzyme

**Ms. Bloomberg** reports the following financial relationships:

- Advisory Board: Genentech, Inc.; Novo Nordisk; Pfizer Inc.; Sanofi; and Takeda Pharmaceuticals U.S.A., Inc.
- Speakers Bureau: Bayer; Genentech, Inc.; Novo Nordisk; and Sanofi

**Mr. Skinner** reports the following financial relationships:

- Advisory Board/Governance Boards: Blue Cross Blue Shield MAP; Institute for Clinical and Economic Review (ICER); National Organization for Rare Disorders, Inc. (NORD); Pfizer inc. (DSMB); Spark Therapeutics, Inc. (DSMB); and World Federation of Hemophilia USA (WFH USA)
- Consultant: National Bleeding Disorders Foundation (NBDF)
- Research Support: Mr. Skinner's institution received research support for the PROBE Study and core outcomes studies as part of independent investigator-initiated research projects: Band Therapeutics, LLC; Bayer; BioMarin; CSL; Novo Nordisk; Roche/Genentech, Inc.; Sanofi; Takeda Pharmaceutical Company Limited; and Vega Therapeutics Inc.

**Dr. Wheeler** reports the following financial relationships:

- Advisory Board: Bayer; CSL Behring; Genentech, Inc.; Novo Nordisk; Pfizer Inc.; Sanofi; Takeda Pharmaceuticals U.S.A., Inc.; and Vega Therapeutics Inc.
- Research Support: Octapharma Plasma

The following individuals have no financial relationships to disclose:

- Rebecca Vargas-Jackson, MD (Peer Reviewer)
- Elizabeth Naber, MSN, RN, CCRN-K, CNRN, TCRN (Peer Reviewer)
- Nichole Lainhart (Planning Committee)
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- Sandra Caballero, PharmD (Planning Committee)
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Faculty of this CE activity may include discussions of products or devices that are not currently labeled for use by the U.S. Food and Drug Administration (FDA). The faculty have been informed of their responsibility to disclose to the audience if they will be discussing off-label or investigational uses (any uses not approved by the FDA) of products or devices.

 

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## Instructions for Interactive Technology

Use one of the iPads provided at your table to answer polling questions, view onsite presentations, and submit questions to the faculty.

### ASK FACULTY A QUESTION

Select the Ask Question tab below the slide viewer to submit a question. If your question is for a specific faculty member, please include their name. Your question will be shared with the faculty for the question-and-answer portion of the session.

### VIEW AND TAKE NOTES ON PRESENTATION SLIDES

Select the Take Notes tab to take notes during the meeting. All of the notes you take during the meeting will be emailed to the address provided within 5 business days.

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