fibryga®
Fibrinogen (Human)

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Formulary Integration

A guide for adding fibryga to your hospital's formulary.

Please see Indications and Select Important Safety Information on page 4 and Important Safety Information throughout.

Version **2.0**

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Adding Fibryga to Your Hospital's Formulary

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SECTION A

Adding Fibryga to Your Hospital's Formulary

The First Step Toward Changing Your Hospital's Major Bleeding Management Protocols

Thank you for recognizing the need and advocating to improve major bleeding protocols within your hospital system through the use of fibrinogen concentrates like fibryga.

This guide is designed to help you navigate the process of proposing the addition of fibryga to your institution's formulary.

By following these steps, you will be equipped to make a compelling case to the Pharmacy & Therapeutics (P&T) Committee about the benefits and risks of fibryga and how it can help evolve the standard of care at your institution.

Note that all institutions have their own timelines and processes for adding products to formulary. Make sure to modify your approach to the specific needs within your organization.

INDICATIONS AND SELECT IMPORTANT SAFETY INFORMATION

Indications and Usage

Fibryga is a human fibrinogen concentrate indicated for fibrinogen supplementation in bleeding patients with acquired fibrinogen deficiency and in treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.

Fibryga is not indicated for dysfibrinogenemia.

Contraindications

Fibryga is contraindicated in individuals who have manifested severe immediate hypersensitivity reactions, including anaphylaxis, to fibryga or its components (Sodium Citrate Dihydrate; Glycine; L-Arginine Hydrochloride).

Please see Important Safety Information throughout. Please see fibryga full Prescribing Information.

To report suspected adverse reactions, contact Octapharma USA, Inc. at 1-866-766-4860 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Why Fibryga

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Please see Indications and Select Important Safety Information on page 4 and Important Safety Information throughout.

SECTION B

Why Fibryga

Indication[1]:

Fibryga is a human fibrinogen concentrate (FC) indicated for:

- fibrinogen supplementation in bleeding patients with acquired fibrinogen deficiency
- treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia

Limitation of Use[1]:

- Fibryga is not indicated for dysfibrinogenemia.

Details About Fibryga:

Precise amount of fibrinogen per vial (1 g/vial)

Virally inactivated and nanofiltered

Shelf stable at room temperature for up to 48 months

Supplied with a transfer device that includes a particle filter (Nextaro®)

Rapidly reconstituted within 5 to 10 minutes

Nextaro® is a registered trademark of sfm medical devices GmbH.

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Monitor patients for early signs of hypersensitivity or allergic reactions. If necessary, discontinue administration and institute appropriate treatment.

Thrombotic events have been reported in patients receiving fibryga. Treatment with human fibrinogen concentrate has been associated with thrombosis at target plasma fibrinogen levels that were below 150 mg/dL. The thrombotic risks may be greater when the target fibrinogen plasma level is 150 mg/dL. Weigh the benefits of administration versus the risks of thrombosis.

Fibryga is made from pooled human plasma. Products made from human plasma may contain infectious agents, e.g., viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

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Securing a P&T Committee Review

SECTION C

Securing a P&T Committee Review

The P&T Committee is a multidisciplinary team responsible for managing the formulary system in a hospital setting. This committee evaluates new drugs, reviews therapeutic guidelines, and develops policies related to drug use.

The following process has been implemented successfully in many top-tier institutions across the United States.[2]

Proposal Team

Recruit members for your team who will help you craft your narrative and help provide support during the committee review.

Key proposal team members include the following specialties: **anesthesiology, surgery, and pharmacy.**

P&T Agenda

Identify your P&T Committee members, and follow the process required to secure a spot on an upcoming meeting agenda.

P&T Presentation

Engage your proposal team to help build your presentation, and to possibly attend and participate in your P&T meeting.

Preparing for P&T Committee Review

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SECTION D

Preparing for P&T Committee Review

Fibryga Essentials

These resources will help you gain an understanding of fibryga, including the prescribing information, clinical profile, and clinical data.

Please click the below buttons to find the relevant information you may need.

Product Website	AFD Clinical Study Publication 1
AFD Clinical Study Publication 2	Additional Resources
Prescribing Information	CFD Clinical Study Publication 1
CFD Clinical Study Publication 2	CFD Clinical Study Publication 3

Please click this link to reach out to US Medical Affairs if you would like additional information about fibryga, including clinical studies.

Proposal Development

SECTION E

Proposal Development

Ensure you are covering the following key topics when developing your proposal:

- ☐ Highlight the unmet needs around fibrinogen replacement within your hospital setting for managing major bleed scenarios, especially where the current standard of care falls short.
- ☐ Clearly identify the specific patient populations who are underserved by current protocols that utilize cryoprecipitate (cryo) to replace fibrinogen in major bleeding scenarios.
- ☐ Demonstrate how fibrinogen concentrates (FC) like fibryga may improve patient outcomes when utilized in the management of major bleeding.[2]
- ☐ Showcase the rapid administration and clinical benefits and risks of fibryga and how it may improve patient outcomes.[2]
- ☐ Share case studies from your experience or from other institutions that are similar in location, size, level and experience that have successfully adopted fibryga.

SELECT IMPORTANT SAFETY INFORMATION

Adverse Reactions

The most serious adverse reactions observed with fibryga are thromboembolic episodes and anaphylactic-type reactions.

The most common adverse reactions observed in clinical studies with fibryga in acquired fibrinogen deficiency (>5% of patients) were abnormal hepatic function, acute kidney injury, anemia, atrial fibrillation, delirium and renal failure.

The most common adverse reactions observed in clinical studies with fibryga in congenital fibrinogen deficiency (>5% of patients) were nausea, vomiting, pyrexia (fever) and thrombocytosis.

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Resources

Below are evidence-based content examples, based on specialty, to consider for your P&T Committee presentation.

They may help build your case around fibrinogen replacement in the context of major bleeding management and how fibrinogen concentrate (FC) can help address those needs by providing a different treatment approach.

To view specific content, simply click the appropriate link.

Cardiac | **Obstetrics** | **Trauma**

SECTION F

Cardiac Resources

Burden of major bleeding and low fibrinogen levels:

- Low plasma fibrinogen is an independent risk factor in perioperative bleeding.[3,4]
- Hypofibrinogenemia is observed in ~1/3 of cardiac surgery patients.[5]
- Up to 10% of cardiac surgeries are associated with severe or massive perioperative bleeding.[6]

Limitations of cryoprecipitate, the current standard of care:

- Cryoprecipitate (cryo) was initially developed to treat hemophilia A and von Willebrand disease. Its application has since expanded to fibrinogen replenishment in major bleeding scenarios.[7,8]
- Despite rapid diagnosis via point-of-care testing, cryo availability is typically delayed by 25 to 45 minutes due to the need for ordering, thawing, and pooling from the blood bank.[9-11]
- Because cryo must be used within 4 to 6 hours of thawing, it leads to wastage rates of 7% to 33% and delays in treatment with thaw times of 15 to 30 minutes.[9,12,13]

Clinical profile of fibrinogen concentrate:

- EU guidelines recommend fibrinogen supplementation treatment with FC or cryo if major bleeding is accompanied by hypofibrinogenemia.[10,13-15]
- In cardiac procedures, FC use has been shown to decrease perioperative blood loss and transfusion requirements.[16,17]
- The use of FC allows precise, consistent dosing, storage at room temperature, quick preparation without blood-type matching, and lower risk of infectious transmission through viral inactivation.[3,18,19]
- The American Society of Anesthesiologists (ASA) and the American College of Surgeons (ACS) recognize FC as a suitable alternative to cryo in patients with excessive bleeding and hypofibrinogenemia–scenarios where rapid and precise hemostasis is essential.[20,21]

SELECT IMPORTANT SAFETY INFORMATION

Contraindications

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SECTION F

Obstetrics Resources

Burden of major bleeding and low fibrinogen levels:

- PPH accounts for about 14% of maternal deaths in the US.[22]
- Low fibrinogen levels are directly correlated with bleed severity during PPH.[23,24]
- In pregnancy, fibrinogen levels below 200 mg/dL have a 100% positive predictive value for progressing to severe PPH.[23,25]
- With each decrease of 100 mg/dL below 400 mg/dL the likelihood of severe bleeding is more than doubled.[23]

Limitations of cryoprecipitate, the current standard of care:

- Cryoprecipitate (cryo) was initially developed to treat hemophilia A and von Willebrand disease. Its application has since expanded to fibrinogen replenishment in major bleeding scenarios.[7,8]
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Clinical profile of fibrinogen concentrate:

- Clinical studies have shown that use of fibrinogen concentrate can restore fibrinogen levels, enhance maternal outcomes, and decrease blood product utilization compared to cryo.[26-28]
- Real-world experience has demonstrated that FC is effective in achieving bleeding control for patients with PPH.[29]

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

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SECTION F

Trauma Resources

Burden of major bleeding and low fibrinogen levels:

- Fibrinogen is the first coagulation factor to drop to critically low levels during bleeding, with levels of 150 to 200 mg/dL significantly increasing the risk of severe bleeding.[8,29-32]
- Following acute trauma, fibrinogen levels below 150 mg/dL are linked to a significantly higher 28-day mortality rate (odds ratio [OR] 4.9).[33]
- There is an ~4 times higher mortality rate in trauma patients with coagulopathy versus those without.[34]

Limitations of cryoprecipitate, the current standard of care:

- Cryoprecipitate (cryo) was initially developed to treat hemophilia A and von Willebrand disease. Its application has since expanded to fibrinogen replenishment in major bleeding scenarios.[7,8]
- Despite rapid diagnosis via point-of-care testing, cryo availability is typically delayed by 25 to 45 minutes due to the need for ordering, thawing, and pooling from the blood bank.[9-11]
- Because cryo must be used within 4 to 6 hours of thawing, it leads to wastage rates of 7% to 33% and delays in treatment with thaw times of 15 to 30 minutes.[9,12,13]

Clinical profile of fibrinogen concentrate:

- Fibrinogen concentrate (FC) use during trauma has demonstrated a reduction in blood loss and transfusion vs both cryo and control (did not receive FC within one hour after emergency admission).[36-38]

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont.)

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