TABLE I. Products Licensed in the U.S. to Treat HEMOPHILIA

A. Recombinant FACTOR VIII Concentrates

The table includes bioengineered recombinant factor concentrates with altered properties with clinical implications such as extended half-life. Please refer to the individual prescribing information and review scientific publications that summarize properties for each product.

Product Name	**Manufacturer /distributor**	**Bioengi - neering**	**Cell Type Used in Culture**	**Genera-tion/ Human or Animal Protein in Culture**	**Method of Viral Inactivation or Depletion**	**Stabilizer in Final Vial**	**Doses for Routine Prophylaxis Per Manufacturer's Prescribing Information**
Advate	SHIRE (Baxalta, Baxter)	None	Chinese Hamster Ovary (CHO)	Third/ None	1. Immunoaffinity chromatography 2. Solvent/detergent	1. Mannitol, 3.2-8%w/v 2. Trehalose, 0.8-2% w/v	1) 25-40IU/kg 3-4 times/wk or every three days to maintain trough level >1% 2) Adjust dose based on clinical response
ADYNOVATE Approved 2015	SHIRE (Baxalta, Baxter)	PEGylation	Chinese Hamster Ovary (CHO)	Third/ None	1. Immunoaffinity chromatography 2. Solvent/detergent (Tris/polysorbate 80)	1. Mannitol 2. Trehalose	1) Adults, adolescents ≥12 yo 40-50 IU/kg 2 times a week. 2) Children <12 yo 55-70 IU/kg 2 times a week 3) Adjust dose based on clinical response.
AFSTYLA Approved 2016	CSL Behring	Single chain rFVIII	Chinese Hamster Ovary (CHO)	Third/ None	1. Solvent/detergent 2. Nanofiltration, 20nm	Sucrose, 6mg/mL	1) Adults, adoles >12yo: 20-50 IU/kg 2-3 times/wk. 2) Children <12yo: 30-50 IU/kg 2-3 times/wk. 3) More frequent or higher doses may be required to account for the higher clearance in young children.

Product Name	**Manufacturer /distributor**	**Bioengi - neering**	**Cell Type Used in Culture**	**Genera- tion/ Human or Animal Protein in Culture**	**Method of Viral Inactivation or Depletion**	**Stabilizer in Final Vial**	**Doses for Routine Prophylaxis Per Manufacturer's Prescribing Information**
ELOCTATE Approved 2014, revised 2016	BIOVERATIV (Biogen Idec)	B-Domain Deleted, IgG-1 Fc-domain Fusion Protein	Human Embryonic Kidney (HEK)	Third/ None	1. Detergent (Polysorbate 20) 2. Nanofiltration, 15 nm	Sucrose	1) 50 IU/kg every 4 days. Adjust to 25-65 IU/kg every 3-5 days based on clinical response. 2) Children<6 yo: 50 IU/kg 2X/wk. Adjust dose to 25-65 IU/kg every 3-5 days. 3) Children may require up to 80 IU/kg given more frequently.
Kogenate FS Helixate FS	Bayer (Helixate FS** distributed by CSL Behring)	None	Baby Hamster Kidney (BHK)	Second/ Human Plasma Protein Solution	1. Immunoaffinity chromatography 2. Solvent/detergent	Sucrose, 0.9-1.3%/vial	1) Adults: 25 IU/kg 3X per week. 2) Children: 25 IU/kg every other day.
Kovaltry Approved 2016	Bayer	None	Baby Hamster Kidney (BHK)	Third/ None	1. Detergent 2. Nanofiltration, 20nm	Sucrose, 1%	1) Adults, adolescents: 20-40 IU/kg 2-3 X/wk 2) Children <u><12 Years: 25-50 IU/kg 2-3 X/wk or QOD</u> 3) <u>Adjust dose based on clinical response</u>
NovoEight	Novo Nordisk (Bagsvaerd, Denmark)	B-domain truncated	Chinese Hamster Ovary (CHO)	Third/None	1. Immunoaffinity chromatography 2. Solvent/detergent 3. Nanofilter, 20nm	Sucrose, 3 mg/mL	1) Adults, adolescents: 20-50 IU/kg 3X/wk or 20-40 IU/kg QOD 2) Children <12 yrs: 25-60 IU/kg 3X/wk or 25-50 IU/kg QOD

Product Name	**Manufacturer /distributor**	**Bioengi - neering**	**Cell Type Used in Culture**	**Genera- tion/ Human or Animal Protein in Culture**	**Method of Viral Inactivation or Depletion**	**Stabilizer in Final Vial**	**Doses for Routine Prophylaxis Per Manufacturer's Prescribing Information**
Nuwiq	Octapharma	B-domain deleted	Human Embryonic Kidney (HEK)	Third/ None	1. Solvent/detergent 2. Nanofilter, 20 nm	Sucrose, 5.4 mg/mL	1) Adults, adolescents 12+ yrs: 30-40 IU/kg every other day 2) Children 2-11 yrs: 30-50 IU/kg 3 X/wk or every other day
Recombinate	SHIRE (Baxalta, Bayer)	None	Chinese Hamster Ovary (CHO)	First/ Bovine Serum Albumin	1. Immunoaffinity chromatography 2. Solvent/detergent	Human albumin, 25mg/mL	Not provided
Xyntha	Pfizer	B-domain deleted	Chinese Hamster Ovary (CHO)	Third/ None	1. Affinity chromatography 2. Solvent/detergent 3. Nanofiltration, 35 nm	Sucrose	Not provided

- **As of 12/31/2017, Bayer is no longer producing Helixate FS. Given a 2-year expiration date for all product already produced, there should be no Helixate FS available after 12/31/2019.

TABLE I. **Products Licensed in the U.S. to Treat HEMOPHILIA A (Continued)**

B. Human Plasma-derived Immunoaffinity-purified FACTOR VIII Concentrates

Product Name	Manufacturer	Method of Viral Inactivation or Depletion	Heparin in Final Vial	Specific Activity of Final Product (IU factor VIII/mg total protein after addition of stabilizer)
Hemofil M	SHIRE (Baxalta, Baxter)	1. Immunoaffinity chromatography 2. Solvent/detergent (TNBP/Octoxynol 9) 3. Nanofiltration, 20 nm	None	2-20
Monoclate-P**	CSL Behring	1. Immunoaffinity chromatography 2. Pasteurization (60°C, 10h)	None	5-10

- **CSL-Behring has announced that they are no longer producing MonoclateP as of March 2018. They anticipate that supplies of this product will be depleted by December 31, 2018.

TABLE I. Products Licensed in the U.S. to Treat HEMOPHILIA A (Continued)

C. Human Plasma-derived Concentrates that Contain FACTOR VIII and VON WILLEBRAND FACTOR

Product Name	**Manufacturer/ Distributor**	**Method of Viral Inactivation or Depletion**	**Heparin in Final Vial (units/ml)**	**Specific Activity of Final Product** **(IU FVIII /mg total protein after addition of stabilizer)**
Alphanate	Grifols	1. Affinity chromatography 2. Solvent/detergent (TNBP/polysorbate 80) 3. Dry heat (80ºC, 72h)	<1.0	7.5-21
Humate-P	CSL Behring GmbH (Marberg, Germany)	1. Pasteurization(wet heat) (60ºC, 10 hrs)	None	1-2
Koate-DVI	Grifols, distributed by Kedrion Biopharma	1. Solvent/detergent (TNBP/polysorbate 80) 2. Dry heat (80ºC, 72h)	None	9-22

TABLE I. Products Licensed in the U.S. to Treat HEMOPHILIA A (continued)

D. Desmopressin Formulations to Treat MILD HEMOPHILIA A

Product Name	Manufacturer	U.S. Distributor	Formulation	Recommended Dosage and Administration
DDAVP Injection	Ferring AB (Malmo, Sweden)	Aventis Pharma	For parenteral use (IV or SQ), 4 mcg/ml in a 10-ml vial	1) 0.3 mcg/kg, mixed in 30 ml normal saline solution, infused I.V. slowly over 30 minutes. Maximum dose 24 mcg. May be repeated after 24 hours. 2) 0.3 mcg/kg by subcutaneous injection. Maximum dose 24 mcg. May be repeated after 24 hours. 3) DO NOT USE IN CHILDREN UNDER THE AGE OF 2 YEARS. 4) USE WITH CAUTION IN PREGNANT WOMEN DURING LABOR AND DELIVERY (15)
Stimate Nasal Spray for Bleeding	Ferring AB (Malmo, Sweden)	CSL Behring	Nasal spray, l.5 mg/ml. The metered dose pump delivers 0.1 ml (150 mcg) per actuation. The bottle contains 2.5 ml with spray pump capable of delivering 25 150-mcg doses or 12 300-mcg doses.	1) In patients weighing <50 kg, give one spray in one nostril (dose = 150 mcg). May be repeated after 24 hours. 2) In patients weighing >50 kg, give one spray in each nostril (dose = 300 mcg). May be repeated after 24 hours. 3) DO NOT USE IN CHILDREN UNDER THE AGE OF 2 YEARS. 4) USE WITH CAUTION IN PREGNANT WOMEN DURING LABOR AND DELIVERY. (15)

TABLE II. Products Licensed in the U.S. to Treat HEMOPHILIA B

A. Recombinant FACTOR IX Concentrates

The table includes bioengineered recombinant factor concentrates with altered properties such as extended half-life with clinical implications. Please refer to the individual prescribing information and review scientific publications that summarize properties for each product.

Product Name	**Manufacturer**	**Bioengineering**	**Cell type used in Culture**	**Generation/ Human or Animal Protein Used in Culture Medium**	**Method of Viral Inactivation or Depletion**	**Stabilizer in Final Vial**	**Doses for Routine Prophylaxis Per Manufacturer's Prescribing Information**
ALPROLIX Approved 2014	BIOVERATIV (Biogen Idec)	IgG-1 Fc Domain Fusion Protein	Human Embryonic Kidney (HEK)	Third/ None	1. Affinity chromatography 2. Nanofiltration, 35nm	1. Sucrose 2. Mannitol	1) 50 IU/kg every 7 days OR 100 IU/kg every 10 days. 2) Adjust dosing based on individual response.
BeneFix	Pfizer	None	Chinese Hamster Ovary (CHO)	Third/ None	1. Affinity chromatography 2. Nanofiltration, 35 nm	Sucrose	Not provided

Product Name	**Manufacturer**	**Bioengineering**	**Cell type used in Culture**	**Generation/ Human or Animal Protein Used in Culture Medium**	**Method of Viral Inactivation or Depletion**	**Stabilizer in Final Vial**	**Doses for Routine Prophylaxis Per Manufacturer's Prescribing Information**
IDELVION Approved 2016	CSL Behring	Albumin-Fusion Protein	Chinese Hamster Ovary (CHO)	Third/ None	1. Solvent/detergent (polysorbate 80) 2. Nanofiltration	1. Sucrose 2. Mannitol	1) For patients > 12 yrs, 25-40 IU/kg every 7 days. 2) Patients well controlled on above may be switched to 50-75 IU/kg every 14d. 3) For patients <12 yrs, 40-55 IU/kg every 7 days. 4) Adjust dosing based on individual response.
Ixinity Approved 2015	APTEVO Therapeutics	None	Chinese Hamster Ovary (CHO)	Third/ None	1. Solvent detergent 2. Ion exchange chromatography 3. Nanofiltration, 20 nm	1. Mannitol 2. Trehalose	Not provided
Rebinyn Approved 2017	NOVO NORDISK	PEGylation	Chinese Hamster Ovary (CHO)	Third/ None	1. Solvent detergent 2. Nanofiltration, 20 nm	1. Sucrose, 10 mg 2. Mannitol, 25 mg	Not approved for prophylaxis
Rixubis Approved 2013	SHIRE Baxter/ Baxalta	None	Chinese Hamster Ovary (CHO)	Third / None	1. Solvent-detergent 2. Nanofiltration, 15 nm	1. Mannitol 2. Sucrose	1) PUPS, 40-60 IU/kg 2X/wk. 2) Titrate dose depending on clinical response.

TABLE II. Products Licensed in the U.S. to Treat HEMOPHILIA B (Continued)

B. Human Plasma-derived Coagulation FACTOR IX Concentrates

Product Name	Manufacturer	Method of Viral Inactivation or Depletion	Heparin in Final Vial (Units/IU Factor IX)	Specific Activity (IU factor IX/mg total protein after addition of stabilizer)
AlphaNine SD	Grifols	1. Dual affinity chromatography 2. Solvent/detergent (TNBP/polysorbate 80) 3. Nanofiltration	0.04	>150
Mononine	CSL Behring	1. Immunoaffinity chromatography 2. Sodium thiocyanate 3. Nanofiltration	None	>190

TABLE III. Products Licensed in the U.S. to Treat VON WILLEBRAND DISEASE

A. Desmopressin Formulations to Treat TYPE 1 and Some TYPE 2 VWD

Product Name	Manufacturer	U.S. Distributor	Formulation	Recommended Dosage and Administration
DDAVP Injection	Ferring AB (Malmo, Sweden)	Aventis Pharma	For parenteral use (IV or SQ), 4 mcg/ml in a 10-ml vial	1) 0.3 mcg/kg, mixed in 30 ml normal saline solution, infused I.V. slowly over 30 minutes. Maximum dose is 24 mcg. May be repeated after 24 hours. 2) 0.3 mcg/kg by subcutaneous injection. Maximum dose is 24 mcg. May be repeated after 24 hours. DO NOT USE IN CHILDREN UNDER THE AGE OF 2 YEARS. USE WITH CAUTION IN PREGNANT WOMEN DURING LABOR AND DELIVERY. (15)
Stimate Nasal Spray for Bleeding	Ferring AB (Malmo, Sweden)	CSL Behring	Nasal spray, l.5 mg/ml. The metered dose pump delivers 0.1 ml (150 mcg) per actuation. The bottle contains 2.5 ml with spray pump capable of delivering 25 150-mcg doses or 12 300-mcg doses.	1) In patients weighing <50 kg, give one spray in one nostril (dose = 150 mcg). May be repeated after 24 hours. 2) In patients weighing >50 kg, give one spray in each nostril (dose = 300 mcg). May be repeated after 24 hours. DO NOT USE IN CHILDREN UNDER THE AGE OF 2 YEARS. USE WITH CAUTION IN PREGNANT WOMEN DURING LABOR AND DELIVERY. (15)

TABLE III. Products Licensed in the U.S. to Treat VON WILLEBRAND DISEASE (Continued)

B. Recombinant VON WILLEBRAND FACTOR Concentrate

Product Name	Manufac-turer	Cell Type used in Culture	Gener-ation/ Human or Animal Protein Used in Culture Medium	Method of Viral Inactivation or Depletion	Stabilizer In Final Vial	Specific Activity (VWF units/ mg protein)
VONVENDI	SHIRE (Baxter, Baxalta)	Chinese Hamster Ovary (CHO)	Third/ None	1. Affinity chromatography 2. Solvent/ detergent (Tris/Polysorbate 80)	1. Mannitol, 20mg/mL 2. Trehalose, 10mg/mL	99-147

TABLE III. Products Licensed in the U.S. to Treat VON WILLEBRAND DISEASE (Continued)

C. Human Plasma-derived Concentrates that Contain FACTOR VIII and VON WILLEBRAND FACTOR

Product Name	Manufacturer	Method of Viral Inactivation or Depletion	Heparin in Final Vial (units/ml)	Specific Activity**** (IU VWF/mg total protein after addition of stabilizer)	Ratio of VWF: FVIII	FDA Approved for von Willebrand Disease?
Alphanate	Grifols	1. Affinity chromatography 2. Solvent/detergent (TNBP/polysorbate 80) 3. Dry heat (80ºC, 72h)	<1.0	9-28	1.3:1	Yes
Humate-P	CSL Behring GmbH (Marberg, Germany)	1. Pasteurization (60ºC, 10 hrs)	None	3.6-11.2	1.8-2.4:1	Yes
Wilate	Octapharma (Vienna, Austria)	1. Solvent/detergent (TNBP/Octoxynol-9) 2. Dry heat (100º C, 2 hr)	None	>60	1:1	Yes

**** The higher the specific activity, the greater the purity is considered to be.**

TABLE IV. BYPASSING AGENTS (BPA) Licensed in the U.S. to Treat PATIENTS WITH INHERITED HEMOPHILIA A or B and INHIBITORS

A. Human Plasma-derived Activated Prothrombin Complex Concentrate for Use in Patients with INHERITED Hemophilia A or B and INHIBITORS to FACTOR VIII or IX

Product Name	**Manufacturer**	**Method of Viral Inactivation or Depletion**	**Heparin in Final Vial (units/ml)**	**Specific Activity** **(IU factor/mg total protein after addition of stabilizer)**
FEIBA	SHIRE (Baxter/Baxalta) (Vienna, Austria)	1. Vapor heat (10h, 60ºC, 190 mbar plus 1h, 80ºC, 375 mbar) 2. Nanofiltration, 35nm	None	0.8

TABLE IV. BYPASSING AGENTS (BPA) Licensed in the U.S. to Treat PATIENTS WITH INHERITED HEMOPHILIA A or B and INHIBITORS (Continued)

B. Recombinant FACTOR VIIa Concentrate For Use in Patients with INHERITED Hemophilia A or B and INHIBITORS to FACTOR VIII or IX

Product Name	Manufacturer		Cell type used in Culture	Generation/ Human or Animal Protein Used in Culture Medium	Method of Viral Inactivation or Depletion	Stabilizer In Final Vial
NovoSeven RT	Novo Nordisk (Bagsvaerd, Denmark)		Baby Hamster Kidney (BHK)	Second/Newborn Calf Serum	1. Affinity chromatography 2. Solvent/detergent (TNPB/polysorbate 80)	1. Mannitol, 25 mg/ml 2. Sucrose, 10 mg/ml

TABLE IV. PRODUCTS licensed in the U.S. to Treat PATIENTS WITH INHERITED HEMOPHILIA A and INHIBITORS (Continued)

C. Recombinant HUMANIZED BISPECIFIC FIXa- and FX- directed monoclonal antibody for Use in Patients with INHERITED Hemophilia A and INHIBITORS to FACTOR VIII

Product Name	Manufacturer/ distributor	Bioengineering	Cell type used in Culture	Generation/ Human or Animal Protein Used in Culture Medium	Method of Viral Inactivation or Depletion	Stabilizer in Final Vial	Doses for Routine Prophylaxis Per FDA-approved Manufacturer's Prescribing Information
HEMLIBRA (emicuzimab-KXWH) Approved 2017	Genentech/Roche	Recombinant humanized monoclonal antibody	Chinese Hamster Ovary (CHO)			L-arginine L-histidine Poloxamer 188 L-aspartic acid	1) 3mcg/kg SQ weekly for 4 weeks 2) Then 1.5 mg/kg SQ once every week 3) Discontinue BPA prophylaxis while on HEMLIBRA

TABLE V. Products Licensed in the U.S. to Treat Non-congenital Hemophilia Patients with ACQUIRED HEMOPHILIA A

A. Recombinant Factor Concentrates for Use in Patients with ACQUIRED INHIBITORS to FACTOR VIII

Product Name	Manufacturer	Cell type Used in Culture	Generation/ Human or Animal Protein Used in Culture Medium	Method of Viral Inactivation or Depletion	Stabilizer In Final Vial	Heparin in Final Vial (units/ml)
NovoSeven RT (rhFVIIa)	Novo Nordisk (Bagsvaerd, Denmark)	Baby Hamster Kidney (BHK)	Second/ Newborn Calf Serum	1. Affinity chromatography 2. Solvent/detergent (TNPB/polysorbate 80)	1. Mannitol, 25 mg/ml 2. Sucrose, 10 mg/ml	None
OBIZUR (porcine rpFVIII)	SHIRE (Baxter, Baxalta)	Baby Hamster Kidney (BHK)	Second/ Fetal Bovine Serum	1. Solvent/detergent (polysorbate 80) 2. Nanofiltration, 15 nm	1. Sucrose, 1.9 mg/ml	None

TABLE VI. Products Licensed in the U.S. to Treat RARE BLEEDING DISORDERS

A. Human Plasma-derived Concentrate to Treat AFIBRINOGENEMIA and HYPOFIBRINOGENEMIA (FACTOR I deficiency)

Product Name	**Manufacturer**	**Method of Viral Inactivation or Depletion**	**Stabilizer in final vial**	**Heparin in Final Vial (units/unit factor I)**	**Specific Activity** **(mg factor I/mg total protein after addition of stabilizer)**
RiaSTAP	CSL Behring	1. Pasteurization (60°, 20 hours)	Human albumin	None	20

TABLE VI. Products Licensed in the U.S. to Treat RARE BLEEDING DISORDERS (Continued)

B. Recombinant Factor VIIa Concentrate for Treatment of FACTOR VII DEFICIENCY

Product Name	Manufacturer	Cell type used in Culture	Generation/ Human or Animal Protein Used in Culture Medium	Method of Viral Inactivation or Depletion	Stabilizers In Final Vial
NovoSeven RT	Novo Nordisk (Bagsvaerd, Denmark)	Baby Hamster Kidney (BHK)	Second/ Newborn Calf Serum	1. Affinity chromatography 2. Solvent/detergent (TNPB/polysorbate 80)	1. Mannitol, 25mg/ml 2. Sucrose, 10 mg/ml

TABLE VI. Products Licensed in the U.S. to Treat RARE BLEEDING DISORDERS (continued)

C. Human Plasma-derived Concentrate to Treat FACTOR X DEFICIENCY

Product Name	Manufacturer	Method of Viral Inactivation or Depletion	Stabilizer in final vial	Heparin in Final Vial (units/unit factor X)	Specific Activity (units factor X/mg total protein after addition of stabilizer)
Coagadex	BioProducts Laboratory (BPL)	1. Solvent/detergent 2. Nanofiltration, 15nm 3. Dry heat, 80°C, 72hr	1. Sucrose	None	80-137

TABLE VI. Products Licensed in the U.S. to Treat RARE BLEEDING DISORDERS (continued)

D. Human Plasma-derived Concentrate to Treat FACTOR XIII DEFICIENCY

Product Name	Manufacturer	Method of Viral Inactivation or Depletion	Stabilizer in final vial	Heparin in Final Vial (units/unit factor XIII)	Specific Activity (units factor XIII/mg total protein after addition of stabilizer)
Corifact	CSL Behring	1. Pasteurization (60°, 10 hours) 2. Ion exchange chromatography	1. Human albumin 2. Glucose	None	3.1-13.3

TABLE VI. Products Licensed in the U.S. to Treat RARE BLEEDING DISORDERS (continued)

E. Recombinant Factor XIII Concentrate for Treatment of FACTOR XIII-A SUBUNIT DEFICIENCY

Product Name	Manufac-turer	Method of Viral Inactivation or Depletion	Cell type used in Culture	Generation/ Human or Animal Protein Used in Culture Medium	Stabilizer In Final Vial	Specific Activity (IU factor XIII/mg total protein)
TRETTEN	NovoNordisk (Bagsvaerd, Denmark)	1. Affinity chromatography 2. Nanofiltration, 35 nm	Yeast (Saccharomyces cerevisiae)	Third/ None	Sucrose	200-360

TABLE VI. Products Licensed in the U.S to Treat RARE BLEEDING DISORDERS (Continued)

F. Human Plasma-derived Prothrombin Complex Concentrates for Use in Patients with FACTOR II or FACTOR X DEFICIENCY.

(NOTE THAT CONTENT OF THESE FACTORS VARIES FROM LOT TO LOT AND PRODUCT TO PRODUCT)

Product Name	**Manufacturer**	**Method of Viral Inactivation or Depletion**	**Heparin in Final Vial (units/unit factor IX)**	**Specific Activity (IU factor IX/mg total protein after addition of stabilizer)**	**Relative Content of Factors (FIX = 100)**
Bebulin	SHIRE (Baxter/Baxalta) (Vienna, Austria)	1. Vapor heat (10h, 60ºC, 190 mbar pressure plus 1h, 80ºC, 375 mbar) 2. Nanofiltration, 35 nm	<0.15	2.0	X> II> IX>VII
Profilnine	Grifols	1. Solvent/detergent (TNBP/ polysorbate 80)	None	4.5	II> IX= X>VII

TABLE VII. Factor Products Licensed in the U.S. for Use in INDIVIUALS WITH THROMBOSIS RISK

A. Products to Treat ANTITHROMBIN DEFICIENCY

Product Name	Generic name	Manufac-turer	Human or Animal Protein Used in Culture Medium	Method of Viral Inactivation or Depletion	Stabilizer In Final Vial	Heparin in Final Vial, IU/IU AT	Specific Activity (IU AT/mg total protein after addition of stabilizer)
ATryn	Antithrombin, recombinant human	Revo Biologics (formerly GTCBiothera-peutics)	Goat milk	1. Dry heat 2. Nanofiltration 3. Ion exchange chromatography	Glycine	None	7 IU AT activity/mg For use only to prevent peri-operative and peri-natal thrombi, Not approved to treat PE.
Thrombate	Antithrombin, plasma-derived	Grifols	Human plasma	1. Pasteurization (60°, 10hrs) 2. Nanofiltration	Alanine (0.075 to 0.125 M)	<0.1 IU	Minimum 6.4 IU AT activ-ity/mg

TABLE VII. Factor Products Licensed in the U.S. for Use in INDIVIUALS WITH THROMBOSIS RISK (continued)

B. Human Plasma-derived Protein C Concentrate to Treat PROTEIN C DEFICIENCY

Product Name	Generic Name	Manufac-turer	Method of Viral Inactivation or Depletion	Stabilizer In Final Vial	Heparin in Final Vial	Specific Activity (IU PC/mg total protein after addition of stabilizer)
Ceprotin	Protein C, plasma-derived	SHIRE (Baxter/ Baxalta)	1. Detergent (Polysorbate 80) 2. Immuno-affinity chromatography 3. Vapor heating 10hr,60°,190±25mbar 1hr,80°,340-410mbar	Albumin (8mg/mL)	Trace amount	8-17

TABLE VIII. Blood Bank Components Licensed in the U.S. to Treat RARE BLEEDING DISORDERS

A. Fresh Frozen Plasma Products to Treat Patients with FACTOR V or FACTOR XI DEFICIENCY

Product Name	Manufacturer	Distributor	Method of Viral Inactivation or Depletion	Pool Size, Number of Donors per Unit	Volume per unit, ml
Donor Retested Fresh Frozen Plasma	Some community blood centers	Some community blood centers	1. Donors must test negative on second donation in order for first donation to be released.	1	250-500 ml
OCTAPLAS, frozen pooled plasma, blood group specific	Octapharma	Octapharma	1. TNBP/Octoxynol-9 2. Immune neutralization 3. Affinity ligand chromatography removal (prions only)	630-1520	200 ml

TABLE VIII. Blood Bank Components Licensed in the U.S. to Treat RARE BLEEDING DISORDERS (Continued)

B. Cryoprecipitate to Treat Patients with DYSFIBRINOGENEMIA

Product Name	Manufacturer	Distributor	Method of Viral Inactivation or Depletion	Pool Size, Number of Donors per Dispensed Unit	Volume per unit, ml
Cryoprecipitate	Some community blood centers	Some community blood centers	None	1	15-25
Cryoprecipitate, pooled	Some community blood centers	Some community blood centers	None	5 6	60-100 90-150

TABLE IX. ANTIFIBRINOLYTIC AGENTS

A. Aminocaproic Acid

Product Generic Name	Brand Name	Manufacturer	Form	Dosing	Comments
Aminocaproic Acid	Amicar	Xanodyne Clover (generic) Mikart (generic)	Oral suspension, 250 mg/ml	50-100 mg/kg po q 6 hr	Do not use in presence of hematuria
Aminocaproic Acid	Amicar	Xanodyne Clover (generic) Mikart (generic)	Tablet, 500 mg 1 gm	50-100 mg/kg po q 6 hr	Do not use in presence of hematuria
Aminocaproic Acid	Amicar	American Regent Hospira	IV, 250 mg/ml	1 gm/hr IV as continuous infusion	Do not use in presence of hematuria

B. Tranexamic Acid

Product Brand Name	Manufacturer	Form	Dosing	Comments
Cyklokapron	Pfizer	IV, 100 mg/ml	10 mg/kg IV q 6-8 hr	Do not use in presence of hematuria
Lysteda	Xanodyne	PO, 650 mg tablets	Adult dose: 1300 mg q 8 hr X 5 days during menses Pediatric dose: 15-20 mg/kg q 8 hr X 5 days	Patients should not take Prothrombin Concentrate Concentrates (PCCs) while on Lysteda