Pharmacy Management Drug Policy

SUBJECT: Antihemophilic Agents
POLICY NUMBER: PHARMACY-71
EFFECTIVE DATE: 5/1/19
LAST REVIEW DATE: 03/29/2019

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. Medical or drug policies apply to commercial and Health Care Reform products only when a contract benefit for the specific service exists.

DESCRIPTION:

Coagulation disorders result from defects in the hemostasis system that is responsible for vascular constriction, primary platelet plug formation, and clot formation through fibrin. Coagulation disorders that result in bleeding may be caused by defects in coagulation factors, enhanced fibrinolytic activity, or a defect in the quantity or quality of platelets. Specific coagulation disorders include hemophilia, congenital factor deficiencies, Glanzmann's Thrombasthenia, and von Willebrand disease (VWD).

Hemophilia is a bleeding disorder caused by a congenital deficiency in a plasma coagulation protein. Hemophilia A is caused by a factor VIII deficiency, while hemophilia B is caused by a factor IX deficiency. Hemophilia A and B are X-linked recessive diseases that primarily affect males. Signs and symptoms include ecchymosis, hemarthrosis, anemia, hematuria, excessive bleeding with trauma or surgery, and joint pain, swelling, and erythema. Laboratory tests that may help confirm a diagnosis of hemophilia include prolonged activated partial thromboplastin time (aPTT) and decreased factor VIII or IX levels accompanied by normal prothrombin time (PT), normal platelet count, normal von Willebrand factor antigen and activity, and normal bleeding time.

Coagulation factors are responsible for clot formation and stabilization. Most coagulation factor deficiencies of factors II, V, VII, X, and XIII exhibit an autosomal recessive pattern. These deficiencies affect males and females equally, but females tend to be at an increased risk for bleeding due to changes associated with menstruation and childbirth. Signs and symptoms of congenital factor deficiencies include excessive bleeding with trauma or invasive procedures, muscle and joint bleeding, menorrhagia and postpartum bleeding, and mucosal tract bleeding. Laboratory tests that may help confirm a diagnosis of a congenital factor deficiency include deficiency of a particular factor as well as PT and aPTT values.

Glanzmann's Thrombasthenia is an autosomal recessive bleeding disorder caused by a defect in the platelet integrin $alpha_{IIb}beta_3$. Signs and symptoms are limited to bleeding that occurs primarily in mucocutaneous areas. Laboratory tests that may help confirm a diagnosis of Glanzmann's Thrombasthenia include a normal platelet count as well as examination of a non-anticoagulated peripheral blood smear showing isolated platelets that are not clumped.

Von Willebrand Disease (VWD) is the most common congenital bleeding disorder and is caused by a defect in the quantity or quality of von Willebrand factor (VWF), which is a glycoprotein that is responsible for platelet aggregation and coagulation. VWF binds factor VIII and prevents its degradation by plasma proteases, increasing its half-life. VWD is inherited through autosomal means and displays an equal prevalence among males and females. Signs and symptoms include easy bruising, postoperative bleeding, epistaxis, gingival bleeding upon minor insult, and menorrhagia. Laboratory tests that may help confirm a diagnosis of VWD include VWF deficiency, decreased VWF affinity for platelet GP 1b, decreased platelets, and decreased VWF binding affinity for factor VIII.

Product Information:
Factor VIIa (NovoSeven®RT)
Recombinant factor VIIa is a vitamin K-dependent glycoprotein that promotes hemostasis by activating the extrinsic pathway of the coagulation cascade. It replaces deficient activated coagulation FVII, which complexes with tissue factor and may activate coagulation factor X to Xa and factor IX to IXa. When complexed with other factors, coagulation factor Xa converts prothrombin to thrombin, a key step in the formation of a fibrin-platelet hemostatic plug.

Factor XIII (Corifact®)
Factor XIII is an endogenous plasma glycoprotein found in platelets, monocytes and macrophages that is converted to activated factor XIII in the presence of calcium ions. Once activated, factor XIII cross-links fibrin and plasmin inhibitor to protect and strengthen the hemostatic platelet plug.

Factor XIII (Tretten®)
Factor XIII is the terminal enzyme in the blood coagulation cascade. When activated by thrombin at the site of vessel wall injury, factor XIII plays an important role in the maintenance of hemostasis through crosslinking of fibrin and other proteins in the fibrin clot. The A-subunit is involved, along with thrombin, in the activation of factor XIII.

Factor VIII and von Willebrand factor (Alphanate®, Humate-P®, Wilate®, Vonvendi®)
Factor VIII (FVIII) and von Willebrand factor (VWF), obtained from pooled human plasma, are used to replace endogenous FVIII and VWF in patients with hemophilia or VWD. FVIII in conjunction with activated factor IX, activates factor X which converts prothrombin to thrombin and fibrinogen to fibrin. VWF promotes platelet aggregation and adhesion to damaged vascular endothelium and acts as a stabilizing carrier protein for FVIII. Circulating levels of functional VWF are measured as ristocetin cofactor activity (VWF:RCo).

Factors IX, II, X, and VII (Bebulin® and Profilnine®)
Bebulin and Profilnine contain coagulation factors IX, II, X and low levels of factor VII. Factor IX is a vitamin K-dependent coagulation factor which is synthesized in the liver. Factor IX is activated by factor XIa in the intrinsic coagulation pathway. Activated factor IX (IXa), in combination with factor VII, activates factor X to Xa, resulting ultimately in the conversion of prothrombin to thrombin and the formation of a fibrin clot. The infusion of exogenous factor IX to replace the deficiency present in hemophilia B temporarily restores hemostasis. Hemophilia B is an X-linked recessively inherited disorder of blood coagulation characterized by insufficient or abnormal synthesis of the clotting protein factor IX.

Factor IX (AlphaNine SD®, Alprolix®, BeneFIX®, Ixinity®, Mononine®, Rixubis®, Idelvion®, Rebinyn®):
Policy products replace deficient clotting factor IX. Factor IX is a vitamin K-dependent coagulation factor which is synthesized in the liver. Factor IX is activated by factor XIa in the intrinsic coagulation pathway. Activated factor IX (IXa) in combination with factor VII activates factor X to Xa, resulting in the conversion of prothrombin to thrombin and the formation of a fibrin clot. Hemophilia B is an X-linked inherited disorder of blood coagulation characterized by insufficient or abnormal synthesis of the clotting protein factor IX. The infusion of exogenous factor IX to replace the deficiency present in hemophilia B temporarily restores hemostasis.

Factor VIII (Human – Hemofil M®, Koate®, Koate-DVI®, Monoclate-P®; Recombinant - Advate®, Adynovate®, Afstyla®, Eloctate®, Helixate FS®, Kogenate FS®, Kogenate FS with Vial Adapter®, Kogenate FS with Bio-Set®, Kovaltry®, NovoEight®, Nuwiq®, Obizur®, Recombinate®, Xyntha®, Xyntha® Solofuse™, Jivi):
Factor VIII replacement, necessary for clot formation and maintenance of hemostasis, activates factor X in conjunction with activated factor IX. Activated factor X converts prothrombin to thrombin, which converts fibrinogen to fibrin, and with factor XIII forms a stable clot.

- Congenital hemophilia A: Inherited factor VIII deficiency.
- Acquired hemophilia A: Normal factor VIII genes with development of autoantibodies (inhibitors) against factor VIII. The autoantibodies neutralize circulating factor VIII and create a functional deficiency.

Factor VIII anti-inhibitor (Feiba®)
Feiba (anti-inhibitor coagulant complex) is a freeze-dried sterile human plasma fraction with factor VIII inhibitor bypassing activity. One unit of activity is defined as that amount of Feiba that shortens the activated partial thromboplastin time (aPTT) of high titer factor VIII inhibitor reference plasma to 50% of the blank value. Multiple interactions of the components in Feiba restore the impaired thrombin generation of hemophilia patients with inhibitors.

emicizumab-kxwh injection (Hemlibra)
Hemlibra is a bispecific factor IXa- and factor X-directed antibody indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients ages newborn and older with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors

POLICY:
Based upon our criteria and review of the peer-reviewed literature, treatment with the following products has been medically proven to be effective and therefore, appropriate if the following criteria are met:

NovoSeven®RT

A. Congenital Hemophilia A and B
1. Prescribed by or in consultation with a hematologist;
2. Diagnosis of congenital hemophilia A (factor VIII deficiency) or B (factor IX deficiency) with inhibitors (factor VIII or IX antibodies);
3. Request is for one of the following:
   a. Control and prevention of bleeding episodes;
   b. Perioperative management.

B. Congenital Factor VII Deficiency
1. Prescribed by or in consultation with a hematologist;
2. Diagnosis of congenital factor VII deficiency;
3. Request is for one of the following:
   a. Control and prevention of bleeding episodes;
   b. Perioperative management.

C. Glanzmann's Thrombasthenia
1. Prescribed by or in consultation with a hematologist;
2. Diagnosis of Glanzmann's thromboasthenia;
3. Condition is refractory to platelet transfusions;
4. Request is for one of the following:
   a. Control and prevention of bleeding episodes;
   b. Perioperative management.

D. Acquired Hemophilia
1. Prescribed by or in consultation with a hematologist;
2. Diagnosis of acquired hemophilia as evidenced by the presence of coagulation factor VIII inhibitors (autoantibodies);
3. Request is for one of the following:
   a. Control and prevention of bleeding episodes;
   b. Perioperative management.

Corifact®

E. Congenital Factor XIII Deficiency
1. Prescribed by or in consultation with a hematologist;
2. Diagnosis of congenital factor XIII deficiency;
3. Request is for one of the following uses:
   a. Control and prevention of bleeding;
   b. Perioperative management;
   c. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

Tretten®

F. Congenital Factor XIII A-Subunit Deficiency
1. Prescribed by or in consultation with a hematologist;
2. Diagnosis of congenital factor XIII A-subunit deficiency;
3. Request is for routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

Alphanate®, Humate-P®

G. Congenital Hemophilia A
1. Prescribed by or in consultation with a hematologist;
2. Diagnosis of congenital hemophilia A (factor VIII deficiency);
3. Request is for control and prevention of bleeding episodes;
4.
5. If Humate-P is prescribed, age ≥ 18 years.

Alphanate®, Humate-P®, Wilate®, Vonvendi

H. Von Willebrand Disease
1. Prescribed by or in consultation with a hematologist;
2. Humate P or Wilate (a and b):
   a. Diagnosis of Von Willebrand disease (VWD) Type 1 or 2 or 3
   b. Request is for (i or ii):
      i. Control and prevention of bleeding episodes;
      ii. Perioperative management;
3. Alphanate (a and b):
   a. Diagnosis of Von Willebrand disease (VWD) Type 1 or 2 or 3
   b. Request is for perioperative management.

Bebulin®, Profilnine®

I. Congenital Hemophilia B
1. Prescribed by or in consultation with a hematologist;
2. Diagnosis of congenital hemophilia B (factor IX deficiency);
3. Request is for control and prevention of bleeding episodes;
4. If Bebulin is prescribed, age ≥ 18 years;
5. If Profilnine is prescribed, age ≥ 16 years.

AlphaNine SD®, Alprolix®, BeneFIX®, Ixinity®, Mononine®, Rixubis®

J. Congenital Hemophilia B
1. Prescribed by or in consultation with a hematologist;
2. Diagnosis of congenital hemophilia B (factor IX deficiency);
3. Request is for any of the following:
   a. Control and prevention of bleeding episodes;
   b. Perioperative management;
   c. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes;
4. If Ixinity is prescribed, age ≥ 12 years.

Human – Hemofil M®, Koate®, Koate-DVI®, Monoclate-P®; Recombinant - Advate®, Adynovate®, Afstyla®, Eloctate®, Helixate FS®, Kogenate FS®, Kogenate FS with Vial Adapter®, Kogenate FS with Bio-Set®, Kovaltry®, NovoEight®, Nuwiq®, Recombinate®, Xyntha®, Xyntha® Solofuse™,Jivi

K. Congenital Hemophilia A
1. Prescribed by or in consultation with a hematologist;
2. Diagnosis of congenital hemophilia A (factor VIII deficiency);
3. Request is for one of the following uses:
   a. Control and prevention of bleeding episodes
   b. Perioperative management
   c. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes:
4. Member does not have von Willebrand disease (VWD)

L. Acquired Hemophilia A
1. Prescribed by or in consultation with a hematologist;
2. Diagnosis of acquired hemophilia A
3. Request is for one of the following uses:
   a. Control and prevention of bleeding episodes
   b. Perioperative management
   c. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes:
4. Member does not have von Willebrand disease (VWD).

Feiba®

M. Congenital Hemophilia A and B
1. Prescribed by or in consultation with a hematologist;
2. Diagnosis of congenital hemophilia A (factor VIII deficiency) or B (factor IX deficiency) with inhibitors (antibodies to factor VIII or IX);
3. Request is for any of the following:
   a. Control and prevention of bleeding episodes
   b. Perioperative management
   c. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes:

N. Other diagnoses/indications: Refer to Pharmacy-32 Off-Label Use of FDA Approved Drugs

Hemlibra®

O. Hemophilia A

1. Prescribed by or in consultation with a hematologist
2. Diagnosis of hemophilia A with or without factor VIII inhibitors
3. Request is for:
    a. Control and prevention of bleeding episodes
    b. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes

POLICY GUIDELINES:

1. This policy is applicable to Managed Medicaid members (MMC, HARP).
2. This policy is applicable to clotting factor products in all non-inpatient settings, including the home. All FDA-approved human plasma-derived clotting factors and recombinant clotting factors are covered, for all FDA approved indications of these drugs.
3. Individuals can keep their current provider and current factor products and no use management will be implemented based on the timeframes below
    a. Clotting factor provider:
        i. Current members receiving clotting factor for the treatment of clotting factor disorders are permitted to keep their current provider of blood factor for two (2) years after the July 1, 2017, transition date.
        ii. Individuals who are newly enrolled to the plan after the July 1, 2017, transition date, are permitted to keep their current provider of clotting factor for two (2) years from their effective date of enrollment.
    b. Clotting factor product
        i. Current members receiving non–inpatient clotting factor, will be granted immediate authorization for medically necessary clotting factor products and services in accordance with their individualized service plan. A change to the individualized service plan for these services and products will not be initiated for at least ninety (90) days from the July 1, 2017, transition date.
        ii. Individuals who are newly enrolled to the plan receiving non–inpatient clotting factor, will be granted immediate authorization for medically necessary clotting factor products and services in accordance with their individualized service plan. A change to the individualized service plan for these services and products will not be initiated for ninety (90) days from the effective date of enrollment, or until the Health Plan´s person centered services plan is in place, whichever is later.
4. The plan may, through care management or case management, suggest other providers or factor products after the pertinent time frame above.
5. All determinations for clotting factor products will be handled as quickly as the enrollee's condition requires and within expedited service authorization review timeframes. Provider's clinical recommendations, the enrollee's person-centered services plan, and the provider's individual service plan will be considered in determining the appropriateness of requested clotting factor products, treatment strategies, and associated services. It is especially important to note/assure that all service authorization determinations must be made pursuant to the enrollee's person-centered services plan and in coordination with the enrollee's providers.
6. Emergency dispensing of factor products will be granted when there is an urgent need and authorization is still pending.
7. Step therapy will not be required in the authorization of clotting factor products.

8. Coverage will be provided for medically necessary ancillary supplies and services required for the administration of the prescribed clotting factor product.
9. All denials and appeals will be reviewed by physicians whom have clinical expertise in treating bleeding disorders.
10. The Health Plan will make reasonable attempts to engage in a peer-to-peer discussion with the prescribing health care professional before issuing a denial regarding a clotting factor product or service.
11. The Health Plan will consult with a licensed Hematologist as part of any appeal review of an adverse determination regarding clotting factor products and services for the treatment of blood clotting disorders.
12. Managed Medicaid: Initial approval will be for 6 months. Subsequent recertification requests will be for 12 months at a time and will be reviewed utilizing the same criteria above.

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.
Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

HCPCS Codes	Description
J7175	Injection, factor x, (human), 1 i.u.
J7179	Injection, von willebrand factor (recombinant), (vonvendi), 1 i.u. vwf:rco
J7180	Injection, factor XIII (antihemophilic factor, human), 1 IU
J7181	Injection, factor XIII A-subunit, (recombinant), per IU
J7182	Injection, factor VIII, (antihemophilic factor, recombinant), (NovoEight), per IU
J7183	Injection, von Willebrand factor complex (human), Wilate, 1 IU vWF:RCo
J7185	Injection, factor VIII (antihemophilic factor, recombinant) (Xyntha), per IU
J7186	Injection, antihemophilic factor VIII/von Willebrand factor complex (human), per factor VIII i.u.
J7188	Injection, factor VIII (antihemophilic factor, recombinant), per IU
J7187	Injection, von Willebrand factor complex (Humate-P), per IU VWF:RCO
J7189	Factor VIIa (antihemophilic factor, recombinant), per 1 mcg
J7190	Factor VIII (antihemophilic factor, human) per IU
J7192	Factor VIII (antihemophilic factor, recombinant) per IU, not otherwise specified
J7193	Factor IX (antihemophilic factor, purified, non-recombinant) per IU
J7194	Factor IX complex, per IU
J7195	Injection, factor IX (antihemophilic factor, recombinant) per IU, not otherwise specified
J7198	Antiinhibitor, per IU
J7199	Hemophilia Clot Factor Noc
J7200	Injection, factor IX, (antihemophilic factor, recombinant), Rixubis, per IU
J7201	Injection, factor IX, FC fusion protein (recombinant), per IU
J7202	Injection, factor ix, albumin fusion protein, (recombinant), idelvion, 1 i.u.
J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu
J7205	Injection, factor viii fc fusion (recombinant), per iu
J7207	Injection, factor viii, (antihemophilic factor, recombinant), pegylated, 1 i.u.

HCPCS Codes	Description
J7209	Injection, factor viii, (antihemophilic factor, recombinant), (nuwiq), 1 i.u.
J7210	Injection, factor VIII, (antihemophilic factor, recombinant), (Afstyla)
J7211	Injection, factor VIII, (antihemophilic factor, recombinant), (Kovaltry), 1 IU
J7170	inj. emicizumab-kxwh, 0.5 mg
C9141	Jivi

UPDATES:

Date	Revision
5/19	P&T Committee Approval
2/19	Revised
11/17	P&T Approval
10/17	Created

REFERENCES:

1. Trinkman H, Beam D, Hagemann T. Coagulation Disorders. In: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. Pharmacotherapy: A Pathophysiologic Approach, 10e New York, NY: McGraw-Hill. Accessed November 8, 2017.
2. Mannucci PM, Leung LK, Tirnauer JS. Rare Inherited Coagulation Disorders. UpToDate. 2017. Available at uptodate.com. Accessed November 8, 2017.
3. NovoSeven RT Prescribing Information. Plainsboro, NJ: Novo Nordisk, Inc.; October 2015. Available at http://www.novo-pi.com/novosevenrt.pdf. Accessed April 26, 2017.
4. Factor VIIa (activated), recombinant human: Drug Information (Lexicomp). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at uptodate.com. Accessed April 26, 2017.
5. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia. Jan 2013; 19(1): e1-47.
6. Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF): Database of treatment guidelines. Available at https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations. Accessed April 28, 2017.
7. Corifact Prescribing Information. Kankalee, IL: CSL Behring LLC; March 2015. Available at http://labeling.cslbehring.com/PI/US/Corifact/EN/Corifact-Prescribing-Information.pdf. Accessed April 26, 2017.
8. Factor XIII, concentrate from human plasma: Drug Information (Lexicomp). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at uptodate.com. Accessed April 26, 2017.
9. Tretten Prescribing Information. Plainsboro, NJ: Novo Nordisk; November 2016. Available at http://www.novo-pi.com/tretten.pdf. Accessed April 26, 2017.
10. Factor XIII A-subunit, recombinant human: Drug Information (Lexicomp). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at uptodate.com. Accessed April 26, 2017.
11. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. *Haemophilia.* Jan 2013; 19(1): e1-47.
12. Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF): Database of treatment guidelines. Available at https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations. Accessed April 28, 2017.

13. Factor XIII A-subunit, recombinant human: Drug Information (Lexicomp). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at uptodate.com. Accessed April 26, 2017.
14. Alphanate Prescribing Information. Los Angeles, CA: Grifols Biologicals Inc.; March 2015. Available at http://www.alphanate.com/documents/24721175/24744788/Alphanate+PI_Nav_Footer/ddecc393-94e6-43bc-aa92-9133b96dc960. Accessed April 26, 2017.
15. Humate-P Prescribing Information. Kankakee, IL: CSL Behring, LLC; June 2014. Available at http://labeling.cslbehring.com/PI/US/Humate-P/EN/Humate-P-Prescribing-Information.pdf. Accessed April 26, 2017.
16. Wilate Prescribing Information. Hoboken, NJ: Octapharma USA Inc.; August 2015. Available at http://www.wilateusa.com/images/PDF_Files/WILATE_FPI_US_additional_Perioperative_Indication_8_2015.pdf. Accessed April 26, 2017.
17. Human-plasma derived von Willebrand factor (contains factor VIII): Drug Information (Lexicomp). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at uptodate.com. Accessed April 26, 2017.
18. Bebulin Prescribing Information. Westlake Village, CA: Baxter Healthcare Corporation; September 2015. Available at http://www.shirecontent.com/PI/PDFs/BEBULIN_USA_ENG.pdf. Accessed April 26, 2017.
19. Profilnine Prescribing Information. Los Angeles, CA: Grifols Biologicals, Inc.; May 2014. Available at http://www.grifolsusa.com/documents/10192/89476/ft-profilnine-us-en/03a3eed9-2e02-4e7f-ae7b-9bff623d8535. Accessed April 26, 2017.
20. Prothrombin complex concentrate, 3-factor, unactivated, from human plasma: Drug Information (Lexicomp). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at uptodate.com. Accessed April 26, 2017.
21. Alprolix Prescribing Information. Cambridge, MA: Biogen Idec, Inc.; April 2017. Available at https://www.alprolix.com/pdfs/PrescribingInformation.pdf. Accessed April 26, 2017.
22. BeneFix Prescribing Information. Philadelphia, PA: Wyeth Pharmaceuticals, Inc.; August 2015. Available at http://labeling.pfizer.com/showlabeling.aspx?id=492. Accessed April 26, 2017.
23. Ixinity Prescribing Information. Berwyn, PA: Aptevo BioTherapeutics LLC, a subsidiary of Emergent BioSolutions, Inc.; August 2016. Available at http://ixinity.com/sites/all/themes/visia/images/pdfs/IXINITY_PI_Aptevo.pdf. Accessed April 26, 2017.
24. Mononine Prescribing Information. Kankakee, IL: CSL Behring LLC; April 2016. Available at http://labeling.cslbehring.com/PI/US/Mononine/EN/Mononine-Prescribing-Information.pdf. Accessed April 26, 2017.
25. Rixubis Prescribing Information. Westlake Village, CA: Baxter US, Inc.; March 2016. Available at http://www.shirecontent.com/PI/PDFs/RIXUBIS_USA_ENG.pdf. Accessed April 26, 2017.
26. Factor IX, recombinant human with Fc fusion: Drug Information (Lexicomp). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at uptodate.com. Accessed April 26, 2017.
27. Factor IX, recombinant human: Drug Information (Lexicomp). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at uptodate.com. Accessed April 26, 2017.
28. Factor IX, human plasma-derived: Drug Information (Lexicomp). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at uptodate.com. Accessed April 26, 2017.
29. Afstyla Prescribing Information. Kankakee, IL: CSL Behring, LLC; May 2016. Available at http://labeling.cslbehring.com/PI/US/Afstyla/EN/Afstyla-Prescribing-Information.pdf. Accessed April 27, 2017.

30. Advate Prescribing Information. Westlake Village, CA: Baxalta US, Inc.; November 2016. Available at http://www.shirecontent.com/PI/PDFs/ADVATE_USA_ENG.pdf. Accessed April 27, 2017.
31. Adynovate Prescribing Information. Westlake Village, CA: Baxalta US, Inc., December 2016. Available at http://www.shirecontent.com/PI/PDFs/ADYNOVATE_USA_ENG.pdf. Accessed April 27, 2017.
32. Eloctate Prescribing Information. Cambridge, MA: Biogen, Inc., January 2017. Available at https://www.eloctate.com/Pdfs/full-prescribing-information.pdf. Accessed April 27, 2017.
33. Helixate FS Prescribing Information. Whippany, NJ: Bayer HealthCare LLC; May 2016. Available at http://labeling.cslbehring.com/PI/US/HelixateFS/EN/HelixateFS-Prescribing-Information.pdf. April 27, 2017.
34. Hemofil M Prescribing Information. Westlake Village, CA: Baxalta US, Inc.; February 2016. Available at https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=b8953ff7-3bba-4a0b-a486-f26fb81f05d9&type=display. Access April 27, 2017.
35. Koate Prescribing Information. Research Triangle Park, NC: Grifols Therapeutics, Inc.; February 2016. Available at https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=2f77d685-e382-b2e7-2414-0d3a3448688a&type=display. Accessed April 27, 2017.
36. Koate-DVI Prescribing Information. Research Triangle Park, NC: Grifols Therapeutics, Inc.; August 2012. Available at http://www.koate-dviusa.com/filebin/pdf/New_July2013_57210_Kedrion_PI_prf.pdf. Accessed April 27, 2017.
37. Kogenate FS with Vial Adapter Prescribing Information. Whippany NJ: Bayer HealthCare LLC; May 2016. Available at http://labeling.bayerhealthcare.com/html/products/pi/Kogenate-w-vial-adapter_PI.pdf. Accessed April 27, 2017.
38. Kogenate FS with BIO-SET Prescribing Information. Whippany NJ: Bayer HealthCare LLC; May 2016. Available at http://labeling.bayerhealthcare.com/html/products/pi/Kogenate_BIO-SET_PI.pdf. Accessed April 27, 2017.
39. Kogenate FS Prescribing Information. Whippany NJ: Bayer HealthCare LLC; May 2016. Available at http://labeling.bayerhealthcare.com/html/products/pi/Kogenate_PI.pdf. Accessed April 27, 2017.
40. Kovaltry Prescribing Information. Whippany, NJ: Bayer HealthCare LLC; March 2016. Accessible at http://labeling.bayerhealthcare.com/html/products/pi/Kovaltry_PI.pdf. Accessed April 25, 2017.
41. Monoclate-P Prescribing Information. Kankakee, IL: CSL Behring, LLC; February 2014. Available at http://labeling.cslbehring.com/PI/US/Monoclate-P/EN/Monoclate-P-Prescribing-Information.pdf. Accessed April 27, 2017.
42. NovoEight Prescribing Information. Plainsboro, NJ: Novo Nordisk, Inc.; November 2016. Available at http://www.novo-pi.com/novoeight.pdf. Accessed April 27, 2017.
43. Nuwiq Prescribing Information. Hoboken, NJ: Octapharma USA, Inc.; September 2015. Available at https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=d6cb51f8-3acd-412c-93ec-41a8017dff3e&type=display. Accessed April 27, 2017.
44. Obizur Prescribing Information. Westlake Village, CA: Baxter Healthcare Corporation; October 2014. Available at http://www.shirecontent.com/PI/PDFs/OBIZUR_USA_ENG.pdf. Accessed April 27, 2017.
45. Recombinate Prescribing Information. Westlake Village, CA: Baxalta US, Inc.; December 2010. Available at http://www.shirecontent.com/PI/PDFs/RECOMBINATE_USA_ENG.pdf. Accessed April 27, 2017.
46. Xyntha Prescribing Information. Philadelphia, PA: Wyeth Pharmaceuticals, Inc.; October 2014. Available at http://labeling.pfizer.com/showlabeling.aspx?id=496. Accessed April 27, 2017.
47. Factor VIII, human plasma-derived: Drug Information (Lexicomp). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at uptodate.com. Accessed April 27, 2017.

48. Factor VIII, recombinant human: Drug Information (Lexicomp). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at uptodate.com. Accessed April 27, 2017.
49. Factor VIII, recombinant human with Fc fusion; and factor VIII, recombinant human without Fc fusion: Drug Information (Lexicomp). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at uptodate.com. Accessed April 27, 2017.
50. Factor VIII, recombinant human pegylated: Drug Information (Lexicomp). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at uptodate.com. Accessed April 27, 2017.
51. Factor VIII, recombinant porcine: Drug Information (Lexicomp). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at uptodate.com. Accessed April 27, 2017.
52. Feiba Prescribing Information. Westlake Village, CA: Baxter Healthcare Corporation; November 2013. Accessed April 4, 2017. Available at http://www.shirecontent.com/PI/PDFs/FEIBA_USA_ENG.pdf. Accessed April 26, 2017
53. Prothrombin complex concentrate, activated, from human plasma (factor eight inhibitor bypassing activity [FEIBA]): Drug Information (Lexicomp). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at uptodate.com. Accessed April 26, 2017.
54. https://www.health.ny.gov/health_care/medicaid/redesign/2017/2017-06-06_criteria_standards.htm#iii. Accessed November 7, 2017.