BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES
SECTION: DRUGS

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CLOTTING FACTOR REPLACEMENT THERAPY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Hemophilia and von Willebrand's disease are the most common congenital bleeding disorders. The two main types of hemophilia are A and B. Hemophilia A (classic hemophilia) has low levels of clotting factor VIII, or antihemophilic factor (AHF). Hemophilia B (Christmas disease) has low levels of clotting factor IX.

AHF is an endogenous glycoprotein necessary for blood clotting and hemostasis. It is a cofactor that is necessary for factor IX to activate factor X in the intrinsic pathway.

The main treatment for hemophilia is replacement of clotting factor VIII (for hemophilia A) or clotting factor IX (for hemophilia B). Administration of clotting factors is indicated for hemophilia when a bleeding episode arises (demand treatment) or when bleeding is anticipated or likely (prophylactic treatment).

Hemophilia A and B are classified as mild, moderate or severe, depending on the amount of clotting factor VIII or IX in the blood.

Mild hemophilia	5 – 40 percent of normal clotting factor
Moderate hemophilia	1 – 5 percent of normal clotting factor
Severe hemophilia	Less than 1 percent of normal clotting factor

CLOTTING FACTOR REPLACEMENT THERAPY (cont.)

Criteria:

- FDA-approved dosages of the following clotting factor replacement therapies are considered ***medically necessary*** for individuals with hemophilia A:

  1. Advate®
  2. Alphanate®
  3. Corifact™
  4. Feiba NF®
  5. Feiba VH®
  6. Helixate FS®
  7. Hemofil M®
  8. Humate-P®
  9. Koate-DVI®
  10. Kogenate® FS
  11. Kogenate® FS with BioSet
  12. Monarc-M™
  13. Monoclate-P®
  14. Recombinate
  15. Refacto®
  16. Xyntha®

- FDA-approved dosages of the following clotting factor replacement therapies are considered ***medically necessary*** for individuals with hemophilia B:

  1. Alphanine SD®
  2. Alprolix™
  3. Bebulin VH®
  4. BeneFix®
  5. Feiba NF®
  6. Feiba VH®
  7. Mononine®
  8. Profilnine SD

- FDA-approved dosages of the following clotting factor replacement therapies are considered ***medically necessary*** for individuals with von Willebrand's disease:

  1. Alphanate®
  2. Humate-P®
  3. Wilate®

CLOTTING FACTOR REPLACEMENT THERAPY (cont.)

Criteria: (cont.)

- FDA-approved dosage of Kcentra® is considered ***medically necessary*** for urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA, e.g., warfarin) therapy in adults with acute major bleeding.

- FDA-approved dosage of NovoSeven® RT is considered ***medically necessary*** for the following indications:

  1. Bleeding episodes and peri-operative management in adults and children with hemophilia A or B with inhibitors
  2. Bleeding episodes and peri-operative management in adults with acquired hemophilia
  3. Congenital Factor VII (FVII) deficiency
  4. Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets

- FDA-approved dosage of RiaSTAP® is considered ***medically necessary*** for treatment of acute bleeding episodes in individuals with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.

- FDA-approved dosage of Rixubis is considered ***medically necessary*** for the following indications:

  1. Control and prevention of bleeding episodes in adults with hemophilia B
  2. Perioperative management in adults with hemophilia B
  3. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults with hemophilia B

- FDA-approved dosage of Tretten® is considered ***medically necessary*** for routine prophylaxis for bleeding in adult and pediatric individuals with congenital Factor XIII A-subunit deficiency.

Resources:

1. Advate®. Package Insert. Accessed 09/12/2013.

2. Alphanate®. Package Insert. Accessed 09/12/2013.

3. Alphanine SD®. Package Insert. Accessed 09/12/2013.

4. Alprolix™. Package Insert. Accessed 08/14/2014.

CLOTTING FACTOR REPLACEMENT THERAPY (cont.)

Resources: (cont.)

5. Bebulin VH®. Package Insert. Accessed 09/12/2013.
6. BeneFix®. Package Insert. Accessed 09/12/2013.
7. Corifact™. Package Insert. Accessed 09/12/2013.
8. Feiba NF®. Package Insert. Accessed 09/12/2013.
9. Feiba VH®. Package Insert. Accessed 09/12/2013.
10. Helixate FS®. Package Insert. Accessed 09/12/2013.
11. Hemofil M®. Package Insert. Accessed 09/12/2013.
12. Humate-P®. Package Insert. Accessed 09/12/2013.
13. Kcentra®. Package Insert. Accessed 09/12/2013.
14. Koate-DVI®. Package Insert. Accessed 09/12/2013.
15. Kogenate® FS. Package Insert. Accessed 09/12/2013.
16. Kogenate® FS with BioSet. Package Insert. Accessed 09/12/2013.
17. Monarc-M™. Package Insert. Accessed 09/12/2013.
18. Monoclate-P®. Package Insert. Accessed 09/12/2013.
19. Mononine®. Package Insert. Accessed 09/12/2013.
20. National Heart Lung and Blood Institute. What is Hemophilia? Accessed 09/12/2013.
21. NovoSeven® RT. Package Insert. Accessed 08/12/2014.

CLOTTING FACTOR REPLACEMENT THERAPY (cont.)

Resources: (cont.)

22. Profilnine® SD. Package Insert. Accessed 09/12/2013.

23. Recombinate®. Package Insert. Accessed 09/12/2013.

24. Refacto®. Package Insert. Accessed 09/12/2013.

25. Riastap®. Package Insert. Accessed 09/12/2013.

26. Rixubis. Package Insert. Accessed 08/14/2014.

27. Tretten®. Package Insert. Accessed 08/14/2014.

28. Wilate®. Package Insert. Accessed 09/12/2013.

29. Xyntha®. Package Insert. Accessed 09/12/2013.