



# CIGNA HEALTHCARE COVERAGE POSITION

**Subject Anti-Inhibitor Coagulant Complex Vapor Heated (Feiba® VH)**

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### INSTRUCTIONS FOR USE

Coverage Positions are intended to supplement certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Positions are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Position. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Positions. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Positions and; 4) the specific facts of the particular situation. Coverage Positions relate exclusively to the administration of health benefit plans. Coverage Positions are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2008 CIGNA

## Coverage Position

**CIGNA HealthCare covers Anti-Inhibitor Coagulant Complex Vapor Heated (Feiba® VH) as medically necessary when ANY of the following criteria are met:**

- treatment of spontaneous or surgical interventions bleeding in hemophilia A and B patients with inhibitors
- non-hemophiliac patients with acquired inhibitors to Factors VIII, XI, and XII

## General Background

Hemophilia A is a deficiency in factor VIII (FVIII) caused by a genetic mutation on the X chromosome. Hemophilia B is a deficiency in factor IX and is clinically indistinguishable from hemophilia A. Factor assays are used to confirm a diagnosis. Most patients with severe hemophilia are managed at home and are rarely admitted to the hospital for severe bleeding. Early and adequate treatment stops extremely painful bleeding into the joints and muscles. Inadequately treated patients become debilitated due to these bleeds and may be confined to a wheelchair as a young adult.

Feiba VH, Anti-Inhibitor Coagulant Complex, Vapor Heated, is a freeze-dried sterile human plasma fraction with Factor VIII inhibitor bypassing activity. Feiba VH contains Factors II, IX, and X, mainly non-activated, and Factor VII mainly in the activated form. The product contains approximately equal unitages of Factor VIII inhibitor bypassing activity and Prothrombin Complex Factors.

The safety and efficacy of Anti-Inhibitor Coagulant Complex has been demonstrated by two prospective clinical trials. The first, conducted by Sixma and collaborators during 1979 and early 1980, was a randomized double-blind study comparing the effect of Anti-Inhibitor Coagulant Complex and Prothromplex (a nonactivated prothrombin complex concentrate) in 15 patients with hemophilia A and inhibitors to Factor VIII. A total of 150 bleeding episodes (primarily joint and musculoskeletal plus a few mucocutaneous) were treated. A single dose of 88 units per kg of body weight was used uniformly for treatments with Anti-Inhibitor Coagulant Complex. The study showed that, based on subjective patient evaluation, Anti-Inhibitor Coagulant Complex was fully effective in 41.0% and partly effective in 24.6% of episodes (i.e., combined effectiveness of 65.6%), while Prothromplex was rated fully effective in 25.0% and partly effective in 21.4% of episodes (i.e., combined effectiveness of 46.4%).

The second study with Anti-Inhibitor Coagulant Complex was a multiclinic study conducted by Hilgartner et al. It was designed to evaluate the efficacy of Anti-Inhibitor Coagulant Complex in the treatment of joint, mucous membrane, musculocutaneous and emergency bleeding episodes such as central nervous system hemorrhages and surgical bleedings. In 49 patients with inhibitor titers of greater than five Bethesda Units (from nine cooperating hemophilia centers), 489 single doses were given for the treatment of 165 bleeding episodes. The usual dosage was 50 units per kg of body weight, repeated at 12-hour intervals (six-hour intervals in mucous membrane bleedings), if necessary. Bleeding was controlled in 153 episodes (93%). In 130 (78%) of the episodes, hemostasis was achieved with one or more infusions within 36 hours. Of these, 36% were controlled with one infusion within 12 hours. An additional 14% of episodes responded after more than 36 hours.

Of the 489 single doses, only 18 (3.7%) caused minor transient reactions in recipients. Ten out of 49 patients (20%) showed a rise in their inhibitor titers. In five of these patients (10%), the rise was tenfold or more. However, of these ten patients, three had received Factor VIII or Factor IX concentrates within two weeks prior to treatment with Anti-Inhibitor Coagulant Complex. These anamnestic rises have not been observed to interfere with the efficacy of Anti-Inhibitor Coagulant Complex.

Response may differ from patient to patient with no correlation to the patient's inhibitor titer. Response may also vary between different types of hemorrhage (e.g., joint hemorrhage vs. CNS hemorrhage). As a general guideline, a dosage range of 50 to 100 units of Feiba VH per kg of body weight is recommended. However, care should be taken to distinguish between the following four indications, all of which have undergone careful clinical evaluation:

Type of Hemorrhage	Recommended Dosage
<b>Joint Hemorrhage</b>	50 units per kg of body weight given at 12-hour intervals, which may be increased to doses of 100 units per kg of body weight at 12-hour intervals. Treatment should be continued until clear signs of clinical improvement appear, such as relief of pain, reduction of swelling or mobilization of the joint.
<b>Mucous Membrane Bleeding</b>	50 units per kg of body weight given at six-hour intervals under careful monitoring. If hemorrhage does not stop, the dose may be increased to 100 units per kg of body weight at six-hour intervals. However, two such administrations or 200 units per kg of body weight a day should not be exceeded.
<b>Soft Tissue Hemorrhage</b>	100 units per kg of body weight at 12-hour intervals are recommended. A daily dosage of 200 units per kg of body weight should not be exceeded.
<b>Other Severe Hemorrhages</b>	Severe hemorrhages, such as CNS bleedings have been effectively treated with doses of 100 units per kg of body weight at 12-hour intervals. Feiba VH may be given at six-hour intervals until clear clinical improvement is achieved.

## Summary

Feiba VH, an Anti-Inhibitor Coagulant Complex, is indicated for the control of spontaneous bleeding episodes or to cover surgical interventions in hemophilia A and B patients with inhibitors. In addition, it has been described in a few non-hemophiliacs with acquired inhibitors to Factors VIII, XI, and XII.

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## Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

### Covered when medically necessary:

CPT <sup>®</sup> * Codes	Description

HCPCS Codes	Description

ICD-9-CM Diagnosis Codes	Description

### Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description

HCPCS Codes	Description

ICD-9-CM Diagnosis Codes	Description

\*Current Procedural Terminology (CPT<sup>®</sup>) ©2007 American Medical Association: Chicago, IL.

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## References

1. Baxter Healthcare Corporation. Feiba<sup>®</sup> VH (Anti-Inhibitor Coagulant Complex Vapor Heated) package insert. Westlake Village, CA: Baxter Healthcare Corporation, April 2005.
2. Bolton-Maggs PH, Pasi KJ. Hemophilias A and B. Lancet 2003;361:1801-1809.

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7. Sjamsoedin LJ, Heijnen L, Mauser-Bunschoten EP, et al. The Effect of Activated Prothrombin-Complex Concentrate (FEIBA) on Joint and Muscle Bleeding in Patients with Hemophilia A and Antibodies to Factor VIII. *The New Engl. J. of Med*. 1981;305:717-721.