



## Recombinant Activated Factor VII for Prevention of Bleeding Unrelated to Hemophilia: Clinical and Economic Systematic Review

### Technologies and Conditions

Recombinant activated factor VII (eptacog alfa or rFVIIa) is an approved agent that controls bleeding in hemophilia (type A or B) patients with inhibitors to clotting factors.

### Issue

In practice, the use of rFVIIa has extended beyond its approved indications. The Canadian Blood Services freely distributes rFVIIa to hospitals across Canada, leaving little local incentive to control its use. This report focuses on the use of rFVIIa in high-risk patients undergoing liver transplantation, prostatectomy, cardiac surgery, or those who require a reversal of supratherapeutic anticoagulation.

### Methods and Results

To assess the implications of select off-label use of rFVIIa, a systematic review of clinical and economic evidence was performed. A formal economic evaluation and budget impact analysis was not conducted as the use of rFVIIa for the prevention of bleeding in Canada is still limited. The clinical and economic findings suggest that research to provide additional, better quality data is required.

### Implications for Decision-Making

- **The use of rFVIIa to prevent bleeding is unsupported by evidence.** Evidence for the prevention of bleeding in patients undergoing liver transplantation, prostatectomy, or cardiac surgery does not consistently suggest a benefit. The risk of adverse events after the use of rFVIIa in surgical patients is unknown. There is also no compelling evidence of cost-effectiveness.
- **Increased use is not expected.** Routine use of rFVIIa to prevent bleeding in surgical procedures is not common practice in Canada, due to concerns of thromboembolic adverse events.
- **There is a knowledge gap related to the prevention of bleeding in recipients of anticoagulants.** There is no known evidence of effectiveness when used in the prevention of bleeding in patients who have received supratherapeutic doses of anticoagulant agents.

This summary is based on a comprehensive health technology assessment available from CADTH's website ([www.cadth.ca](http://www.cadth.ca)): Murphy G, Tsakonas E, Ndegwa S, Anderson D, Barkun J, Mierzwinski-Urban M. *Recombinant Activated Factor VII for Prevention of Bleeding Unrelated to Hemophilia: Clinical and Economic Systematic Review* [Technology report number 124].

Canadian Agency for Drugs and Technologies in Health (CADTH)

600-865 Carling Avenue, Ottawa ON Canada K1S 5S8 Tel: 613-226-2553 Fax: 613-226-5392 [www.cadth.ca](http://www.cadth.ca)  
CADTH is an independent, not-for-profit organization that supports informed health care decision making by providing unbiased, reliable information about health technologies.