

## Directorate of Diagnostics & Therapeutics

# GUIDELINES FOR THE USE OF RECOMBINANT ACTIVATED COAGULATION FACTOR VIIA (NOVOSEVEN)

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## 1.0 Purpose

This guideline has been formulated to assist clinicians in the appropriate use of Recombinant Activated Coagulation Factor VIIa (NovoSeven) in cases of massive haemorrhage, which has proved unresponsive to all other methods of intervention. NovoSeven used under these conditions is an off-label use outside the terms of the drug licence, for which the Trust and the prescribing clinician must carry responsibility.

## 2.0 Area

The scope of the document is Trustwide.

## 3.0 Duties

### 3.1 Clinicians:

- Will access the guidelines via the intranet
- Will consult with the Consultant Haematologist to obtain authorisation for the laboratory to issue the product
- Will prescribe the drug appropriately and inform nursing staff that it needs to be given
- Will ensure the audit form is completed and returned to the laboratory
- Will ensure the appropriate blood tests are performed 60 minutes post administration

### 3.2 Laboratory Staff:

- Will issue the product and inform the ward that it is available (following authorisation from the Consultant Haematologist)
- Will issue an audit form with the drug for the clinician to complete
- Will ensure a replacement supply of the drug is ordered

### 3.3 Nurses:

- Will ensure the drug is collected from the blood bank issue fridge immediately it is available
- Will complete the register sheet on collection
- Will ensure the drug is administered as per the guidelines
- Will ensure that the record of administration of the drug is fated via Web View Unitcheck system

## 4.0 Actions

4.1 **Preconditions** – If the patient fulfils 2 of the conditions below, (1 from section 1 and 1 from section 2), there may be an indication to use NovoSeven. The Consultant Haematologist should be contacted for advice.

<b>Section 1</b>		
4.1.1 Post partum haemorrhage  'In all cases of massive obstetric haemorrhage, the use of recombinant factor VIIa should be considered prior to the decision to perform hysterectomy.'	Yes	No
4.1.2 Uncontrolled bleeding post-operatively	Yes	No
4.1.3 Uncontrolled bleeding due to road traffic accident	Yes	No
4.1.4 Massive bleeding in a multi-transfused patient in whom all surgical cause has been excluded  'More than 10 units of red cells should have been administered under the guidance of the Consultant Haematologist. <b>N.B.</b> If cell salvage has been used, then the re-infusion of equivalent amounts of salvaged blood.'	Yes	No
4.1.5 Bleeding and coagulopathy persists despite the use of adequate blood products.  'Adequate quantities of Platelets, FFP/ Octaplas, Cryoprecipitate and other drugs should have been administered under the guidance of the Consultant Haematologist.'	Yes	No
4.1.6 Uncontrolled bleeding due to excessive oral anticoagulants	Yes	No
4.1.7 Uncontrolled bleeding in Jehovah Witness patients in whom all surgical causes have been excluded,	Yes	No
<b>Section 2</b>		
4.1.8 The patient is still for resuscitation (No DNR (Do Not Resuscitate) order in place)	Yes	No
4.1.9 The condition of the patient is such that, in agreement with the Managing Clinician, survival of the patient is thought to be likely if the bleeding were controlled	Yes	No

**4.2 Drug dose and administration**

Approx body weight (kg)	Dose of NovoSeven required	Number of 2 mg vials
Up to 50	4 mg	2
55 – 100	8 mg	4
100 and above	12 mg	6

**4.3 Contact key personnel**

**4.3.1** Inform the on-call Consultant Haematologist – bleep via switchboard.

**4.3.2** The drug will be issued from the blood transfusion laboratory, following direct instructions from the On-call Haematologist.

**4.4 Authorisation of PCC**

**4.4.1** The Consultant Haematologist will need to be consulted prior to the release of any NovoSeven. The patient's approximate weight and INR should be available before contacting the Consultant Haematologist.

**4.4.2** The decision to administer NovoSeven should be made following discussion and approval with the Consultant Haematologist.

**4.5 Additional information****4.5.1 Payment:**

- The directorate to whom the patient belongs will honour payment for the drug
- The drug will be ordered and paid for by pharmacy. Once used it will be charged to the relevant Consultant/Speciality
- If the drug is not used and date expires the cost will be recharged to the blood budget

**4.5.2 Storage:**

- One dose of NovoSeven will be stored in each of the transfusion laboratories
- The laboratory staff issuing the NovoSeven will be responsible for informing the pharmacy of the patient's details and requesting replacement product. For product issued out of hours, pharmacy should be contacted the following day
- If a second dose is required by one site immediately, this can be requested from the opposite site laboratory, and replaced as above

**4.5.3 Administration and Monitoring:**

- The injection vial is room temperature stable (up to 25°C/77°F)
- Each vial of 2mg powder should be reconstituted with the diluents supplied (1ml per 1mg), and should be used immediately
- The reconstituted product should be given as a bolus IV injection over two to five minutes
- NovoSeven should not be mixed with infusion solutions, or be given in an IV infusion
- Successful use of NovoSeven is usually seen within 60 minutes of administration, repeated, if necessary between 60 minutes and 2 hours later following further consultation with the on-call haematologist
- A coagulation screen should be performed 60 minutes after administration
- Use coagulation results to guide provision of blood products to rectify any coagulopathies
- Further transfusion should not be withheld, as the product is more effective if there is an adequate circulation delivering platelets and fibrinogen to the site of bleeding. Aim for a platelet count of >50
- Correct any known or expected acidosis or hypothermia. (Arterial pH should be >7 as rFV11a is critically pH-dependant)
- Ensure the product is dated on unit check and the relevant paperwork returned to the laboratory

**4.5.4 Risks and Benefits:**

- The thrombogenic potential of this drug is unknown – recent evidence from the manufacturers raises concerns about this especially in the elderly or patients with vascular disease or damage (the Summary of Product Characteristics has been amended to reflect this new evidence)
- NovoSeven is contraindicated in patients with a known hypersensitivity to mouse, bovine or hamster proteins
- Current evidence suggests recombinant factor VIIa is more useful in blunt trauma
- There is no evidence or known benefit to support the practice of repeating administration of NovoSeven if two doses have failed to produce a response

## 5.0 Monitoring Compliance and Effectiveness

- 5.1 Following the use of NovoSeven, the clinician responsible for the care of the patient is required to complete the audit form (DTG010A).
- 5.2 A copy of this form must be forwarded to the transfusion laboratory as soon as possible after administration of the drug, (within 24 hours), and the original copy filed in the patients notes.
- 5.3 All audit forms will be reviewed by the Hospital Transfusion Team to ensure the use of the drug complies with the policy for its administration. Any non compliance will be discussed at the Hospital Transfusion Committee.
- 5.4 Data relating to the use of NovoSeven will be kept in the transfusion laboratory as per Medicine & Healthcare products Regulatory Agency (MHRA) requirements.

## 6.0 Associated Documents

- 6.1 Policy for the Administration of Blood & Blood Components & Clinical Guidelines for the Management of Transfusion Reactions.
- 6.2 Northern Lincolnshire & Goole Hospitals NHS Foundation Transfusion of blood and blood products for the management of massive haemorrhage.
- 6.3 Northern Lincolnshire & Goole Hospitals NHS Foundation Trust Emergency Blood Stock Contingency Plan.
- 6.4 Factor VIIa (NovoSeven) Audit Form.
- 6.5 European Medicines Agency - Summary of Product Characteristics 2009 [http://emc.medicines.org.uk/medicine/21171/SPC/NovoSeven 1 mg \(50KIU\)](http://emc.medicines.org.uk/medicine/21171/SPC/NovoSeven%201mg%20(50KIU)).
- 6.6 Northern Lincolnshire & Goole Hospitals NHS Foundation Trust Management of Postpartum Haemorrhage.

## 7.0 References

- 7.1 BCSH Guidelines for the Management of Massive Transfusions <http://www.bcsguidelines.com/>
- 7.2 G. Price, J. Kaplan & G. Skowronski. Use of recombinant factor VIIa to treat life-threatening non-surgical bleeding in a postpartum patient. British Journal of Anaesthesia. 2004; 93: 298 -300.
- 7.3 The Handbook of Transfusion Medicine (2007) 4th Edition, UK Blood Transfusion Services, The Stationery Office.
- 7.4 F. Boehlen, M. Morales, P. Fontana et al. Prolonged treatment of massive postpartum haemorrhage with recombinant factor VIIa: Case report and review of the literature. BJOG 2004; 111(3): 284 -87.

- 7.5 H. Mousa & S. Walkinshaw. Major postpartum haemorrhage. Current opinion in obstetrics and gynaecology. 2001; 13(6): 595-603.
- 7.6 NovoSeven for massive, uncontrollable, life-threatening haemorrhage in non-haemophiliacs. National Board of Health, Danish Centre for Evaluation and Health Technology Assessment. 2003.
- 7.7 D.R. Spahn, M.A. Tucci & M. Makris. Is recombinant FVIIa the magic bullet in the treatment of major bleeding? British Journal of Anaesthesia. 2005; 94(5): 553-5.
- 7.8 J. Ahonen, R. Jokela. Recombinant factor VIIa in life threatening post-partum haemorrhage. British Journal of Anaesthesia. 2005; 94: 234-237.
- 7.9 U. Martinowitz, M. Michaelson. Guidelines for the use of recombinant factor VIIa in uncontrolled bleeding: a report by the Israeli multidisciplinary rVIIa task force. Journal of Thrombosis and Haemostasis 2005; 3:1-9.

## 8.0 Definitions

None.

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