CIRCULAR

Reference	:	Recombinant Activated Factor Seven
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CIRCULAR 11 of 2011: OFF-LABEL USE OF rFVIIa IN INTRACTABLE BLEEDING

In the recent past, the CMS has been asked to adjudicate on a number of disputes about the payment for the use of rFVIIa in non-haemophiliac patients who had intractable life threatening bleeding. In carefully selected clinical settings, the use of rFVIIa can be life saving. Inappropriate use of rFVIIa can be costly and even fatal. To guide this off label use of rFVIIa, case studies and guidelines have been published in the international literature. Such guidelines are lacking in South Africa. The aim of this communication is to propose a practical guideline for use of rFVIIa for the treatment of life threatening intractable bleeding in South Africa

In order to facilitate and guide the development of this guideline we have enlisted the expertise of Professor Kenneth Boffard (Trauma surgeon) and Professor Johnny Mahlangu (Clinical Haematologist) from Charlotte Maxeke Johannesburg Academic Hospital. Both Professor Boffard and Prof Mahlangu have been instrumental in the development of similar guidelines for the trauma surgery and haematology fraternity respectively

The draft CMS rFVIIa guideline is herewith attached as Annexure A (page 2)

We invite affected stakeholders to discuss this draft guideline at an open meeting at the CMS, which will be held on 18 April 2011 from 13h00 to 17h00. Interested parties must please let Ms Baanetse Selebi (b.selebi@medicalschemes.com) know if they wish to attend before 8 April 2011. Written comments and input must also be submitted to Ms Selebi by the same date

Boshoff Steenekamp
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Annexure A: Draft Guideline on the use of Recombinant Factor VIIa

CMS guideline for the use of Recombinant Activated Factor VII (rFVIIa) in non-haemophiliac patients with intractable life threatening bleeding[1]

Background

This guideline describes the use of rFVIIa as an *adjunct* to life saving intervention in patients with intractable massive bleeding

Note that the use of rFVIIa in non-haemophiliac patients constitutes off label use of the drug, and therefore places considerable risk on the clinician. This guideline does not constitute CMS policy and its use is entirely at the discretion of the treating physician and funder in relation to the patient's life threatening bleeding.

1. Eligibility criteria

rFVIIa should **only** be used in patients who meet **all** of the following criteria:

(i) ***All surgical*** bleeding must be controlled before rFVIIa is administered
(ii) There must evidence of massive blood loss or transfusion and ongoing bleeding:
    a. Loss of 2/3 of blood volume or
    b. Loss of 200 ml/hr for 5 hours or more
    c. Transfusion of 6 units of Packed cells in 2-3hrs
(iii) The haematocrit must be >24%
(iv) The platelet count must be > 50,000/mm^3
(v) The pH must be > 7.2
(vi) The temperature must be > 34° C
(vii) Calcium levels must be normal.
(viii) Fibrinogen must be > 50mg/dl
(ix) If there is DIC, this should be treated
(x) There must be prolonged "R" time on thromboelastographic testing where this testing is available

2. Blood tests required at baseline and monitoring of treatment

(i) Full blood count and platelet count
(ii) Prothrombin time (PT), Activated partial thromboplastin time (aPTT), thrombin time, International normalised ratio (INR),
(iii) Fibrinogen
(iv) Calcium
(v) Blood gas
(vi) Thromboelastogram (TEG) or Rotary Thromboelastomer (ROTEM) if available

[1] Based on the International Trauma Association guideline and the draft South African Haematology Association guidelines

3. Dose of rFVIIa

(i) Initial dose of rFVIIa to be given

a. 90-120 μg/kg body weight

b. Round up to the nearest 1.2 gm. (E.g.: a 75kg male receives 75 x 90μg = 6.75 mg. rFVIIa. Round up to 7.2 mg)

(ii) Follow up dose to be given if bleeding persists after first dose:

a. Repeat doses are the same as above

b. Maximum of ***three*** doses to be given

c. Repeat second dose after 1 hour and third dose after 3 hours from first dose.

4. Endpoints of rFVIIa administration

The first of:

a. Cessation of bleeding

OR

b. A maximum of three doses has been given during a single event of massive transfusion

5. Evaluation of treatment outcome

5.1 A treatment data collection should be completed with each treatment with rFVIIa and this should be forwarded to the medical scheme.

5.2 A registry of off label rFVIIa will be developed (*A volunteer to oversee an rFVIIa registry will be identified at the meeting*)

Annexure B: Proposed information collection sheet

Name of Patient		**ID number/D.O.B**	
Name of medical scheme		**Med scheme Number**	
Hospital		**Folder Number:**	

Treating Doctor (s) (Indicate speciality):	**Event leading to use of rFVIIa:** **Please indicate the *Date* and *Time* the event it started**	
	Describe interventions to control surgical bleeding	

Massive transfusion before rFVIIa		
Blood Products	**Number of units administered**	**Time**
Fresh frozen Plasma		
Cryoprecipitate		
Platelets		
Packed cells/ whole Blood		

Number of dose	**Time**	**Dose given**
1st		
2nd		
3rd		

Tests immediately before rFVIIa/after massive transfusion	**Results (Please attach all results)**	**Comments**
TEG with increase 'R' time if available		
Haematocrit		
Platelet count		
PH		
Temperature		
Calcium levels		
Fibrinogen		
INR/PTT		

Treatment outcome		
At the end of resuscitation	**Circle**	**Comments**
Immediately	Dead/Alive	
6 hrs	Dead/Alive	
12 Hrs	Dead/Alive	
24 Hrs	Dead/Alive	