Job Certificate

Job Info Fields

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Consult. Confirm. CONTROL with NovoSeven®

A first-line treatment to stop the bleed in acquired haemophilia A (AHA)*[1,2]

Typical bleeding pattern in AHA[3]

Skin	Deep Tissue	Mucosa	Joints	CNS
53 %	**50 %**	**32 %**	**5 %**	**1 %**

The above percentages are rounded off

Lila, 72 years old, *presented with painful swelling in one leg and extensive haematoma. Lila had no prior history of unexplained bleeding.‡*

Model is used for illustrative purposes only.

* Other first-line haemostatic treatments are also recommended.

‡ Hypothetical case.

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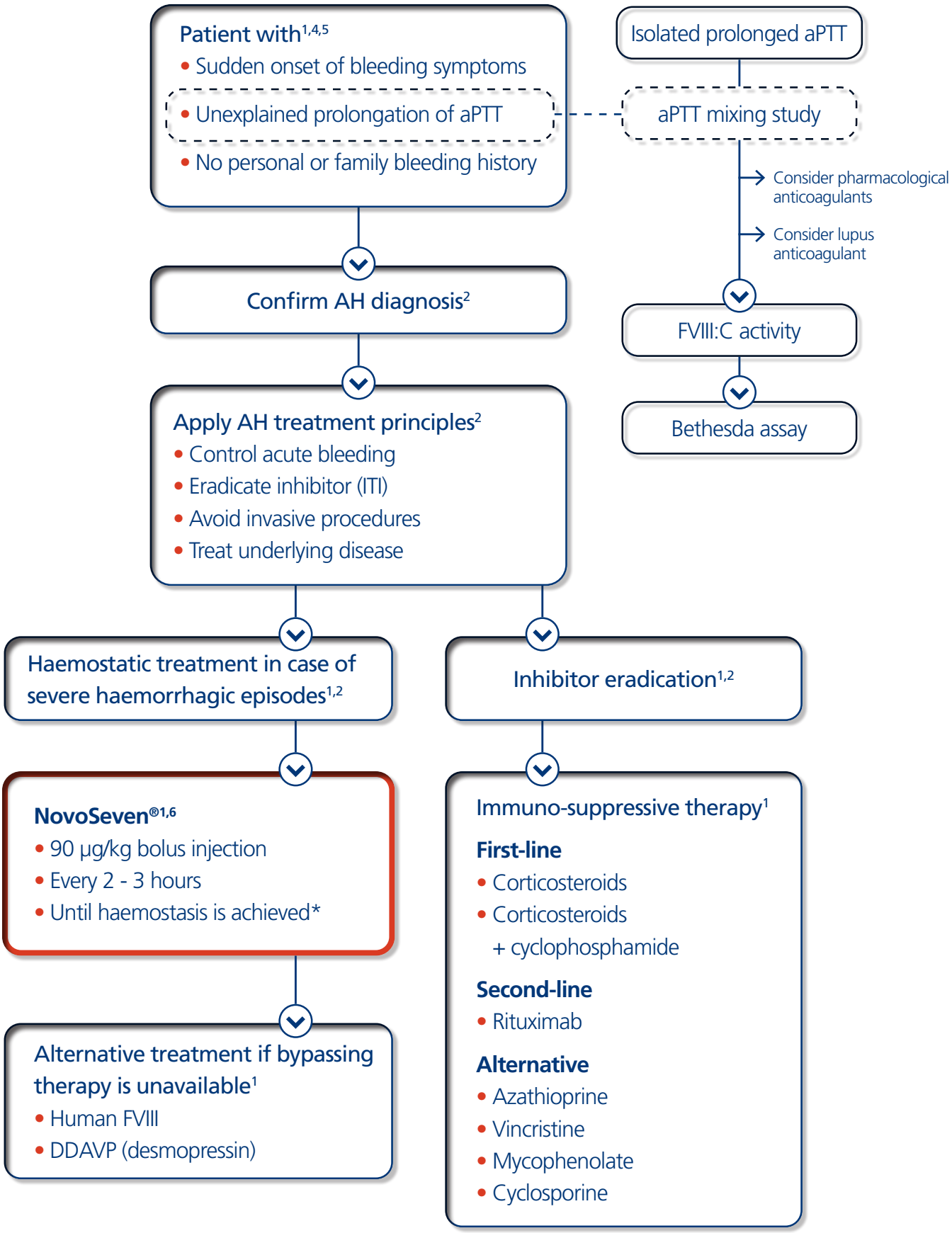
Treatment guidelines[1,2,4,5]



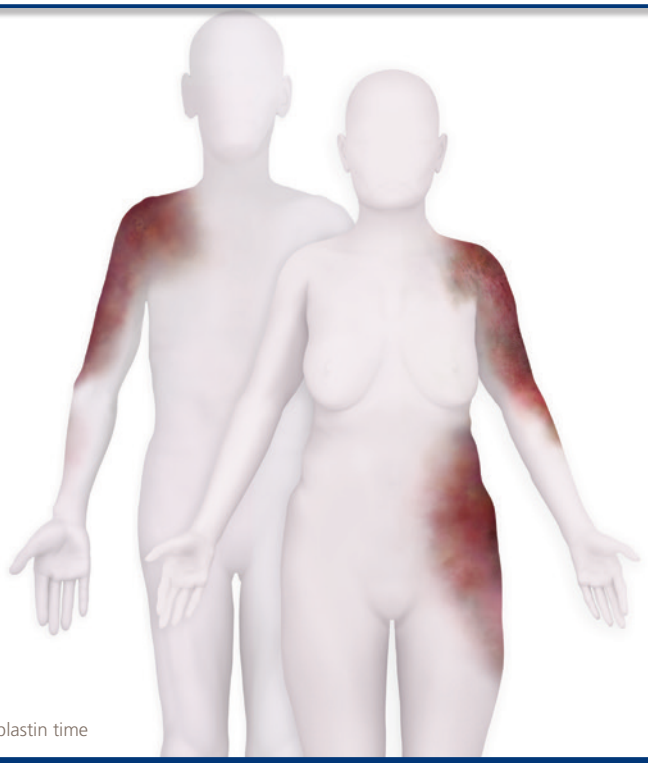
Adapted from Huth-Kuhne A, *et al.* 2009,[1] Collins P, *et al.* 2010,[2] Tiede A, *et al.* 2020[4] and Knöbl P. 2018.[5]

* Once haemostasis has been achieved, the dose interval can be increased successively to every 4, 6, 8 or 12 hours for as long as treatment is judged as being indicated.
aPTT = activated partial thromboplastin time.

Prolongation of aPTT can result from many causes of these differential diagnoses[7]

DIFFERENTIAL DIAGNOSIS	APPROPRIATE ACTION
Anticoagulants	Dependent on anticoagulant suspected, check: international normalised ratio, prothrombin, and thrombin time (Xa inhibitor requires anti-Xa assay)
Lupus anticoagulant (LA)	Consider clinical presentation Use 2+ dilute Russell's viper venom time (dRVVT) assay to confirm presence of LA
Other factor deficiencies	Conduct other factor deficiency tests
Von Willebrand disease or acquired von Willebrand syndrome	von Willebrand factor (VWF) testing, FVIII binding capacity of VWF; multimer analysis

Adapted from Tiede A, *et al.* 2014.[7]



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aPTT - activated partial thromboplastin time

Medical Aid coverage for acute bleeding related to Acquired Haemophilia in South Africa

Acquired Haemophilia is a rare but potentially life-threatening autoimmune bleeding disorder that often presents with severe bleeding and high mortality rate.[1] Because it is a life-threatening disorder, it meets the definition of an ***emergency medical condition*** *as per the regulation of Medical Scheme Act 131 of 1998.[8]*

The regulation defines an emergency medical condition as:[8]
"the sudden and unexpected onset of a health condition that requires immediate medical or surgical treatment, where failure to provide medical or surgical treatment would result in serious impairment to bodily functions or serious dysfunction of a bodily organ or part, or would place the person's life in serious jeopardy"

According to the Act on prescribed minimum benefit (PMB):[8]
Any benefit option that is offered by a medical scheme must be paid in full, without co-payment or the use of deductibles its diagnosis, treatment and care costs.

Even though the regulations of the Act promote the use of designated service providers (DSP), it also allows a patient to obtain a service from a provider other than a DSP if immediate medical or surgical treatment for a PMB was required under circumstances which reasonably preclude the patient from obtaining such treatment from a DSP.

A medical scheme may not prohibit the initiation of an appropriate intervention by a health care provider prior to receiving authorisation from the medical scheme or any other party, in respect of an emergency medical condition.[8]

References: 1. Huth-Kuhne A, *et al.* International recommendations on the diagnosis and treatment of patients with acquired hemophilia A. Haematologica 2009;94(4):566-575. **2.** Collins P, *et al.* Research article Consensus recommendations for the diagnosis and treatment of acquired hemophilia A. BMC Res Notes 2010;3:161. **3.** Knöbl P, *et al.* Demographic and clinical data in acquired A: results from the European Acquired Haemophilia Registry (EACH2). J Thromb Haemost 2012;10(4):622 -631. **4.** Tiede A, *et al.* International recommendations on the diagnosis and treatment of acquired hemophilia A. Haematologica 2020;105(7):1791-1801. **5.** Knöbl P. Prevention and Management of Bleeding Episodes in Patients with Acquired Hemophilia A. Drugs 2018;78:1861-1872. **6.** NovoSeven® approved Professional Information, January 2014. **7.** Tiede A, *et al.* Laboratory Diagnosis of Acquired Hemophilia A: Limitations, Consequences, and Challenges. Semin Thromb Hemost 2014;40(7):803 -811. **8.** MEDICAL SCHEMES ACT 131 OF 1998.

NovoSeven® 1 mg, 2 mg & 5 mg abbreviated Professional Information.
S4 NovoSeven® 1 mg, 2 mg & 5 mg. **Comp:** NovoSeven® 1 mg (corresponds to 50 KIU) contains 1 mg/vial eptacog alfa (activated); NovoSeven® 2 mg (corresponds to 100 KIU) contains 2 mg/vial eptacog alfa (activated); NovoSeven® 5 mg (corresponds to 250 KIU) contains 5 mg/vial eptacog alfa (activated). After reconstitution 1 ml solution contains 1 mg eptacog alfa (activated). **Indic.:** Treatment of pat. with haemophilia with inhib. to FVIII or FIX.; pat. suffering life or limb-threatening bleeds or requiring surgery/in home treatment setting; treatm. of bleed./prevention in pat. with congenital FVII defic. undergoing surgery; treatm. of bleeding/prevention in Glanzmann's Thrombasthenia with antibodies to GP IIb-IIIa and/or HLA. treatm. of bleed. and prevention of bleed. in pat. with acquired haemophilia. **Dosage:** NovoSeven® is for intravenous bolus admin. only. Haemophilia A or B with inhibitors: i) Serious bleed. episodes: Initial dose of 4,5 KIU (90 µg) per kg, dosing freq. should initially be every second hr. until clinical improvement is observed, if continued therapy is indicated, increase to 3 hrs for 1 - 2 days, thereafter the dose interval can be incr. to every 4, 6, 8 or 12 hrs. A major bleed. may be treated for 2 - 3 weeks. ii) Surgery/invasive procedure: Initial dose of 4,5 KIU (90 µg)/kg body wt. Dose should be repeated after 2 hrs and then 2 - 3 hrs intervals for the first 24 - 48 hrs. In major surgery, the dosage should be continued at 2 - 4 hr intervals for 6 - 7 days. The dose interval may then be increased to 6 - 8 hours for 2 wks. iii) Mild to moderate bleed. episodes: One to three inject. of 90 µg (4,5 KIU)/kg body wt. admin at 3 hr intervals, if further treatment is req. one additional dose of 90 µg/kg body wt. can be admin., one single inject. of 270 µg/kg body wt. FVII defic.: 15 - 30 µg /kg body wt. every 4 - 6 hrs until haemostasis is achieved. Glanzmann's thrombasthenia: 90 µg (range 80 -120 µg)/ kg body wt. at 2hrs interval (1,5 - 2,5 hours). Acquired haemophilia: Initial dose is 90 µg/kg body wt. with dose interval of 2 - 3 hours. Once haemostasis is achieved, dose interval can be increased to every 4, 6, 8 or 12 hours. **Contraindications:** hypersens. to active ingredient, the excipients, mouse, hamster or bovine protein. **Warnings and Special Precautions:** Arterial thromboembolic events are common if used outside the approved indications; thrombotic events or induction of DIC; hypersens; dur. of home treatm. should not exceed 24 hrs. FVII defic.: patients should be monitored for factor VII antibodies. Safety and efficacy of NovoSeven® have not been established outside the approved indications and therefore NovoSeven® is not recommended. **Side Effects:** Most frequent – Pyrexia, pruritus, urticaria and rash. The most serious adverse reaction is arterial and venous thromboembolic events. Intracardiac thrombus. Rare – Coagulopathy, nausea, headache, myocardial infarction, angina pectoris, inject. site reaction/pain, hypersensitivity, increased fibrin degrad. products, disseminated intravas. coagulation and related lab. findings including elevated levels of D-dimer and decreased levels of AT-III. **Reg. No.** NovoSeven® 1 mg – 44/8.1/0550; NovoSeven® 2 mg – 44/8.1/0551; NovoSeven® 5 mg – 44/8.1/0552. For full prescribing information, please refer to the Professional Information approved by the Medicines Regulatory Authority.

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