

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Betrixaban for preventing venous thromboembolism in people hospitalised for acute medical conditions

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of betrixaban within its marketing authorisation for preventing venous thromboembolism in people hospitalised for acute medical conditions.

Background

Venous thromboembolism is a term used to describe deep vein thrombosis and pulmonary embolism. Deep vein thrombosis is the formation of a thrombus (blood clot) in a deep vein, usually of the lower limbs. When deep vein thrombosis occurs, dislodged thrombi may travel to the lungs and this is called pulmonary embolism. Pulmonary embolism can cause sudden death, and those who survive a pulmonary embolism occasionally require intensive care and recovery can take several weeks or months. Other complications of deep vein thrombosis include post-thrombotic syndrome, a chronic disorder that may include symptoms such as pain, heaviness, swelling, cramps, itching or tingling, increased skin pigmentation and ulceration in the affected limb. In addition, chronic thromboembolic pulmonary hypertension is a rare but potentially treatable consequence of pulmonary embolism.

Venous thromboembolism has an annual incidence of approximately 1 in 1000 of the general population in England¹. This rate varies substantially with age. The risk of venous thromboembolism is significantly increased in patients who are hospitalised². Key risk factors for patients admitted to hospital include age over 60, recent immobility due to illness, prior venous thromboembolism, active cancer, obesity, sepsis and exacerbation of inflammatory illness, chest disease and heart failure.

Prevention of venous thromboembolism in patients admitted to hospital for medical care involves assessing the patient's risk of developing the condition and applying appropriate prophylactic interventions. For people considered at high risk of developing venous thromboembolism and low risk of bleeding, NICE clinical guideline 92 recommends fondaparinux sodium, low molecular weight heparin or unfractionated heparin (for patients with severe renal impairment or established renal failure). Where the risk of bleeding is higher than the risk of venous thromboembolism, the guideline recommends mechanical prophylaxis such as anti-embolism stockings, foot impulse devices, and intermittent pneumatic compression devices. NICE medical technology guidance 19 states that the geko device (a neuromuscular electrostimulation device) can be used to reduce the risk of venous

thromboembolism for people in whom it is not possible to use other methods of preventing blood clots.

The technology

Betrixaban (brand name unknown, Portola) is an anticoagulant that acts by direct inhibition of activated factor X (factor Xa). Factor Xa is a key component in the formation of blood clots. Betrixaban is administered orally.

Betrixaban does not currently have a marketing authorisation in the UK for preventing venous thromboembolism. It has been studied in a clinical trial in the hospital and post-discharge period, compared with enoxaparin, for preventing venous thromboembolism in people aged 40 years and over. Patients in the trial were hospitalised for an acute medical condition including congestive heart failure, acute respiratory failure, acute infection without septic shock, acute rheumatic disorders, and acute ischaemic stroke with lower extremity hemiparesis or hemiparalysis.

Intervention(s)	Betrixaban
Population(s)	Adults hospitalised with acute medical illness who require extended venous thromboembolism prophylaxis
Comparators	<ul style="list-style-type: none"> • fondaparinux sodium • low molecular weight heparin • unfractionated heparin (for patients with severe renal impairment or established renal failure)
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • mortality • incidence of deep vein thrombosis • incidence of pulmonary embolism • adverse effects of treatment including bleeding events • health-related quality of life.

Economic analysis	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
Other considerations	<p>Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.</p>
Related NICE recommendations and NICE Pathways	<p>Related Technology Appraisals</p> <p>None</p> <p>Related Medical Technology Guidance</p> <p>'The geko device for reducing the risk of venous thromboembolism' (2014). NICE Medical Technology Guidance 19.</p> <p>Related Guidelines:</p> <p>'Reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in patients admitted to hospital' (2010). NICE guideline 92. Update in progress, publication expected Mar 2018.</p> <p>'Venous thromboembolic diseases: the management of venous thromboembolic diseases and the role of thrombophilia testing' (2012). NICE guideline 144. Updated Nov 2015.</p> <p>Related Quality Standards:</p> <p>'VTE prevention' (2010). NICE Quality Standard 3.</p> <p>'Diagnosis and management of venous thromboembolic diseases' (2013). NICE Quality Standard 29.</p> <p>Related NICE Pathway:</p> <p>'Venous thromboembolism'. NICE Pathway.</p>
Related National Policy	<p>NHS Commissioning Board (2013) 'Commissioning for quality and innovation (CQUIN): 2013/14 guidance'. Section 8.</p>

	<p>NHS England (2013) 'NHS England Guidance for Commissioners: Commissioning Services that deliver high quality VTE prevention'.</p> <p>Department of Health (2014) 'NHS Outcomes Framework 2015-2016'. Domains 1, 2, 3, 4 and 5.</p> <p>NHS England (2015) 'NHS England National VTE Prevention Programme'.</p>
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References

1. House of Commons Health Committee (2005) '[The prevention of venous thromboembolism in hospitalised patients](#)'. Accessed October 2017
2. Scottish Intercollegiate Guidelines Network (2010) '[Prevention and management of venous thromboembolism \(quick reference guide SIGN 122\)](#)'. Accessed October 2017.