

NICE TA 287 – Rivaroxaban for treating pulmonary embolism and preventing recurrent venous thromboembolism

<p>1</p>	<p>Summary of NICE TA 287</p> <p>Rivaroxaban is recommended as an option for treating pulmonary embolism and preventing recurrent deep vein thrombosis and pulmonary embolism in adults.</p> <p>People with suspected pulmonary embolism are generally treated with immediate parenteral anticoagulation, most commonly with a low molecular weight heparin (LMWH) delivered by subcutaneous injection, and when the diagnosis has been confirmed, an oral vitamin K antagonist such as warfarin. The LMWH is continued for at least 5 days or until the patient's international normalised ratio (INR) has been within the therapeutic range for at least 24 hours, at which point it is stopped. Duration of treatment is based on individual risk of recurrent venous thromboembolism and bleeding. The usual duration of treatment in UK practice is 6 months or more.</p> <p>The recommended dosage of rivaroxaban for initial treatment of acute pulmonary embolism is 15 mg twice daily for the first 21 days followed by 20 mg once daily for continued treatment and prevention of recurrent venous thromboembolism.</p> <p>Duration of treatment recommended in the summary of product characteristics depends on bleeding risk and other clinical criteria:</p> <ul style="list-style-type: none"> • Short-term treatment (at least 3 months) is recommended for people with transient risk factors such as recent surgery and trauma. • Longer treatment is recommended for people with permanent risk factors, or idiopathic (unprovoked) deep vein thrombosis or pulmonary embolism.
<p>2</p>	<p>Number of people in Northern Ireland expected to take up service/therapy (new cases per year)</p> <p>NICE estimates that for the population of NI there will be approximately 462 patients with a PE per year are suitable for treatment with Rivaroxaban. 50% of patients will require between 3 – 12 months of treatment and 50% will need lifelong treatment. At year five this will create a prevalent pool of 368 people.</p>
<p>3</p>	<p>Costs</p> <p>The NICE model gives net costs per standard assumptions as £348k. There are no reasons at this time to believe that NI will differ significantly from these standard assumptions. NICE assumes implementation over 5 years and costs rising from £168k in year 1 to £348k in year 5.</p>

	Year 1	Year 2	Year 3	Year 4	Year 5
	£000's	£000's	£000's	£000's	£000's
Incremental Costs	168	223	271	312	348

This costing is derived from the difference between the estimated future cost (£1,044k,) of delivering treatment to this group of patients (when Rivaroxaban is an option for some of them) and the current cost (with no Rivaroxaban) of £696k,. However this cost incorporates anticipated savings of £197k from the reduction in older anti-coagulant provision and monitoring.

3.1 Drug cost per patient per annum

Drug costs per patient per annum depend on the duration of the treatment. NICE costed using the proportion who require treatment for 3 months, for 6 months, for 12 months and for greater than a year. The total drug cost is estimated as £604K for 837patients, giving an average patient cost of £722.

3.2 In year costs

There will be in-year costs of the drug as well as the continued cost of providing warfarin/Vit K and coagulation monitoring services.

The NICE costing template estimates the first year drug cost to be £263k. If commencement is on 1st January 2014, estimated in year costs will be £62k.

3.3 Infrastructure Costs per annum

NICE do not anticipate any infrastructure costs for patients on Rivaroxaban. They anticipate savings (£197k over 5 years) from current infrastructure to monitor current regime.

3.4 Cost savings and how these will be secured

Rivaroxaban is more expensive that the current treatments so overall costs will increase. However, NICE estimates some cost savings to offset the increased cost of Rivaroxaban based on the reduction in warfarin/LWMH/Vit K prescribing, monitoring and drug administration currently associated with providing patients with these existing treatments. (NICE estimate of monitoring savings is £197k) There will likely always be a need for some patients to receive older treatments and therefore there will be a continuing need for the clinics.

NICE's model estimates an overall cost of £348K (including drug costs) if the future clinical practice model is fully implemented. For the costs to be maintained at this level there will need to be a commensurate fall in the number of patients taking the older drugs with all the monitoring and administrative costs available to re-invest in rivaroxaban implementation.

<p>3.5</p>	<p>Recurrent overall cost</p> <p>The NICE costing template advises that the additional costs of implementation will be £348k over 5 years.</p> <p>However this assumes that savings will be achievable in monitoring existing warfarin treatments (c£197k) This normally is provided in GP practices and is unlikely to be cash realisable but should provide additional capacity.</p> <p>The drugs costs are forecast to be an additional cost of £557k over 5 years.</p> <table border="1" data-bbox="237 590 1057 825"> <thead> <tr> <th></th> <th>Drugs</th> <th>Admin/monitoring</th> <th>Total</th> </tr> <tr> <th></th> <th>£000's</th> <th>£000's</th> <th>£000's</th> </tr> </thead> <tbody> <tr> <td>Current Costs</td> <td>306</td> <td>391</td> <td>697</td> </tr> <tr> <td>Future Costs</td> <td>863</td> <td>182</td> <td>1045</td> </tr> <tr> <td>Additional costs</td> <td>557</td> <td>-209</td> <td>348</td> </tr> </tbody> </table>		Drugs	Admin/monitoring	Total		£000's	£000's	£000's	Current Costs	306	391	697	Future Costs	863	182	1045	Additional costs	557	-209	348
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<p>4</p>	<p>Expected implementation period</p> <p>Patients need to follow a pathway when moving from their existing anti-coagulant to Rivaroxaban. It may take a period of time to assess and transfer patients so it is likely to be a year before the cohort is implemented.</p>																				
<p>5</p>	<p>Commissioning arrangements</p> <p>Protocols for prescribing and monitoring of patients will need to be drawn up between secondary and primary care to ensure that GPs are supported in prescribing these new drugs.</p>																				
<p>6</p>	<p>Monitoring arrangements</p> <p>MMCT - review of outliers</p> <p>Primary and secondary care adherence to shared protocol / pathway (if produced).</p> <ul style="list-style-type: none"> • GP assurance returns • Trust returns to ensure drug initiated within NICE criteria 																				
<p>7</p>	<p>DHSSPS Legislative/Policy Caveats</p> <p>This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.</p>																				

