

**SPECIALISED COMMISSIONING – RESPONSE TO AMENDMENTS REQUESTED TO EVIDENCE REVIEW DURING ENGAGEMENT OR CONSULTATION**

<b>URN</b>	1770
<b>POLICY TITLE</b>	Percutaneous patent foramen ovale closure for the prevention of recurrent cerebral embolic stroke (adults aged around 60 years and under).
<b>CRG:</b>	Cardiac
<b>NPOC:</b>	Internal Medicine
<b>Date:</b>	11 April 19

<b>Description of comments during consultation</b>	<p>New evidence papers were submitted during consultation. These were:</p> <ol style="list-style-type: none"> <li>1. Cryptogenic Stroke and High-Risk Patent Foramen Ovale: The DEFENSE-PFO Trial. Lee PH, Song JK, Kim JS, Heo R, Lee S, Kim DH, Song JM, Kang DH, Kwon SU, Kang DW, Lee D, Kwon HS, Yun SC, Sun BJ, Park JH, Lee JH, Jeong HS, Song HJ, Kim J, Park SJ. J Am Coll Cardiol. 2018 May 22;71(20):2335-2342 - Included as individual RCT reported in the evidence review.</li> <li>2. Cost-effectiveness of percutaneous patent foramen ovale closure as secondary stroke prevention. Tirschwell DL, Turner M, Thaler D, Choulerton J, Marks D, Carroll J, MacDonald L, Smalling RW, Koullick M, Gu NY, Saver JL. J Med Econ. 2018 Jul;21(7):656-665 - Included as individual study within evidence review.</li> </ol>
--	--

	<p>3. Patent Foramen Ovale Closure or Anticoagulation vs. Antiplatelets after Stroke.  Mas JL, Derumeaux G, Guillon B, Massardier E, Hosseini H, Mechtouff L, Arquizan C, Béjot Y, Vuillier F, Detante O, Guidoux C, Canaple S, Vaduva C, Dequatre-Ponchelle N, Sibon I, Garnier P, Ferrier A, Timsit S, Robinet-Borgomano E, Sablot D, Lacour JC, Zuber M, Favrole P, Pinel JF, Apoil M, Reiner P, Lefebvre C, Guérin P, Piot C, Rossi R, Dubois-Randé JL, Eicher JC, Meneveau N, Lusson JR, Bertrand B, Schleich JM, Godart F, Thambo JB, Leborgne L, Michel P, Pierard L, Turc G, Barthelet M, Charles-Nelson A, Weimar C, Moulin T, Juliard JM, Chatellier G; CLOSE Investigators.  N Engl J Med. 2017 Sep 14;377(11):1011-1021</p> <ul style="list-style-type: none"> <li>- Included within the systematic reviews reported in the evidence review.</li> </ul> <p>4. Long-Term Outcomes of Patent Foramen Ovale Closure or Medical Therapy after Stroke.  Saver JL, Carroll JD, Thaler DE, Smalling RW, MacDonald LA, Marks DS, Tirschwell DL; RESPECT Investigators.  N Engl J Med. 2017 Sep 14;377(11):1022-1032.</p> <ul style="list-style-type: none"> <li>- Included within the systematic reviews reported in the evidence review.</li> </ul> <p>5. Patent Foramen Ovale Closure or Antiplatelet Therapy for Cryptogenic Stroke.  Søndergaard L, Kasner SE, Rhodes JF, Andersen G, Iversen HK, Nielsen-Kudsk JE, Settergren M, Sjöstrand C, Roine RO, Hildick-Smith D, Spence JD, Thomassen L; Gore REDUCE Clinical Study Investigators.  N Engl J Med. 2017 Sep 14;377(11):1033-1042</p> <ul style="list-style-type: none"> <li>- Included within the systematic reviews reported in the evidence review.</li> </ul>
<p><b>Action taken by Public Health lead</b></p>	<p>Suggested references were checked against the evidence review and read in full text for relevance to the PICO document and methodology.</p>

<b>Outcome</b>	<b><u>Evidence already identified during the evidence review</u></b>
----------------	--