

NHS Dorset Clinical Commissioning Group

# Closure of Patent Foramen Ovale for Migraine

## Criteria Based Access Protocol



Supporting people in Dorset to lead healthier lives

## **NHS DORSET CLINICAL COMMISSIONING GROUP**

### **CLOSURE OF PATENT FORAMEN OVALE FOR MIGRAINE CRITERIA BASED ACCESS PROTOCOL**

#### **1. INTRODUCTION AND SCOPE**

- 1.1 This Protocol applies to closure of Patent Foramen Ovale for migraine and does not apply to closure for stroke prevention.
- 1.2 The Foramen Ovale is a hole in the wall that divides the two upper chambers of the heart. The hole is present in the heart of a developing fetus but normally closes up soon after the baby is born. If it fails to close it is known as a Patent Foramen Ovale (PFO). In most people this doesn't cause any problems but some studies have suggested that there could be a link between having PFO and recurrent migraines. The procedure to close the PFO involves passing a device through a large vessel in the groin up into the heart and closing/blocking the hole in the wall of the heart.
- 1.3 Current evidence on the efficacy of percutaneous closure of Patent Foramen Ovale (PFO) for recurrent migraine is inadequate in quality and quantity. The evidence on safety shows a small incidence of well-recognised, but sometimes serious, adverse events including; device embolization and device pro-lapse (each reported in less than 1% of patients).
- 1.4 The closure of Patent Foramen Ovale for migraine is not routinely funded by NHS Dorset Clinical Commissioning Group (CCG).

#### **2. DEFINITIONS**

- 2.1 Any definitions related to this Criteria Based Access Protocol are included as a Glossary at Appendix B.

#### **3. ACCESS CRITERIA**

- 3.1 The Closure of Patent Foramen Ovale for migraine is not routinely funded by the CCG.
- 3.2 There are no clinical access criteria for this intervention. Requests for treatment can therefore only be considered on an individual patient basis where a case is made that the individual patient is clinically exceptional.

#### **4. EXCLUSIONS**

- 4.1 This Policy does not apply to closure of Patent Foramen Ovale for stroke prevention.

#### **5. CASES FOR INDIVIDUAL CONSIDERATION**

- 5.1 Should a patient not meet the criteria detailed within this protocol, the Policy for Individual Patient Treatments (which is available on the NHS Dorset Clinical Commissioning Group website or upon request), recognises that there will be

occasions when patients who are not considered for funding may have good clinical reasons for being treated as exceptions. In such cases the requesting clinician must provide further information to support the case for being considered as an exception.

- 5.2 The fact that treatment is likely to be effective for a patient is not, in itself a basis for exceptional circumstances. In order for funding to be agreed there must be some unusual or unique clinical factor in respect of the patient that suggests that they are:
- significantly different to the general population of patients with the particular condition; and
  - they are likely to gain significantly more benefits from the intervention than might be expected for the average patient with the condition

- 5.3 In these circumstances, please refer to the Individual Patient Treatment Team at the address below:

First Floor West  
Vespasian House  
Barrack Road  
Dorchester  
DT1 1TG  
Telephone no: 01305 368936  
Email: [individual.requests@dorsetccg.nhs.uk](mailto:individual.requests@dorsetccg.nhs.uk)

## **6. AUDIT AND GOVERNANCE**

- 6.1 In line with NICE guidance this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 6.2 Clinicians wishing to undertake percutaneous closure of PFO for recurrent migraine should take the following actions:
- Inform the clinical governance leads in their Trust;
  - Ensure that patients and carers understand the uncertainty about the procedures efficacy and the possibility of serious complications. Clinicians should provide them with clear written information. In addition, the use of NICE's 'Information for Patients' (NICE, 2010) is recommended.
- 6.3 Patient selection for percutaneous closure of PFO for recurrent migraine should be carried out by a neurologist or other specialist in headache followed by an interventional cardiologist.
- 6.4 Use of this procedure should be restricted to patients who are severely affected by recurrent, refractory migraines.

## **7. CONSULTATION**

- 7.1 Prior to approval from Dorset CCG's Clinical Commissioning Committee this Protocol was reviewed within the local NHS including input from commissioners, clinicians and other relevant stakeholders.
- 7.2 An Equality Impact Assessment for this Criteria Based Access Protocol is available on request.

## **8. RECOMMENDATION AND APPROVAL PROCESS**

- 8.1 This access protocol has been approved on behalf of the Clinical Commissioning Committee in line with processes agreed by the CCG's Governing Body.

## **9. COMMUNICATION/DISSEMINATION**

- 9.1 Following approval of Criteria Based Access Protocols at Clinical Commissioning Committee each Protocol will be uploaded to the CCG's Intranet, Internet and added to the next GP Bulletin.

## **10. IMPLEMENTATION**

- 10.1 There has been significant discussion with stakeholders in respect of the introduction and implementation of this new access protocol. It is therefore considered that there is no requirement for a formal implementation plan.

## **11. DOCUMENT REVIEW FREQUENCY AND VERSION CONTROL**

- 11.1 This Criteria Based Access Protocol requires a review every three years, or in the event of any changes to national guidance or when new guidance is issued.

**FREQUENTLY ASKED QUESTIONS**

**N/A**

**GLOSSARY**

**N/A**

A DOCUMENT DETAILS	
Procedural Document Number	157
Author (Name and Job Title)	Abigail James, Individual Patient Treatment Co-ordinator
Recommending Group	Individual Patient Treatment Panel
Date of recommendation	December 2016
Date of approval by CCC	1 June 2017
Version	1.0
Review frequency	Three Years
Review date	June 2020

B CONSULTATION PROCESS			
Version No	Review Date	Author and Job Title	Level of Consultation
1.0	April 2017	Michael Cross, Senior Commissioner IPT	Circulated for comment through the Medical Directors of the three Dorset acute NHS Foundation Trusts. Reviewed previously by IPT Panel including GP, Hospital Consultant, Public Health, and Patient and Public representation.

C VERSION CONTROL					
Date of recommendation	Version No	Review date	Nature of change	Approval date	Approval Committee
Dec 2016	1.0	Dec 2016	Introduction of document	June 2017	CCC

D ASSOCIATED DOCUMENTS
<ul style="list-style-type: none"> <li>Policy for individual patient treatment, NHS Dorset Clinical Commissioning Group</li> <li>Making sense of Local Access Based Protocols, NHS Dorset Clinical Commissioning Group</li> </ul>

E SUPPORTING DOCUMENTS/EVIDENCE BASED REFERENCES		
Evidence	Hyperlink (if available)	Date
NICE Guidance IPG370	<a href="https://www.nice.org.uk/guidance/ipg370">https://www.nice.org.uk/guidance/ipg370</a>	December 2010

F DISTRIBUTION LIST			
Internal CCG Intranet	CCG Internet Website	Communications Bulletin	External stakeholders
✓	✓	✓	✓