Statutory Approvals Committee – minutes

Centre 0102 (Guy's Hospital)
Pre-implantation Genetic Diagnosis (PGD) application for Fibrodysplasia Ossificans Progressiva (FOP), OMIM #135100

Thursday, 25 October 2018

Church House Westminster, Dean's Yard, Westminster SW1P 3NZ

Committee members	Margaret Gilmore (Chair) Bobbie Farsides (Deputy Chair) Anne Lampe Anthony Rutherford Ruth Wilde Emma Cave (New Member Induction - Observer)	
Members of the Executive	Dee Knoyle Bernice Ash Catherine Burwood Paula Robinson	Committee Secretary Committee Secretary (Observer) Senior Governance Manager (Observer) Head of Planning and Governance (Observer)
Specialist Adviser	Dr Mary Porteous	
Legal Adviser	Gerard Hanratty	Browne Jacobson LLP
Observers		

Declarations of interest

- Members of the committee declared that they had no conflicts of interest in relation to this item.

The committee had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members

The following papers were considered by the committee:

- Executive summary
- PGD application form
- Redacted peer review
- Relevant paper - Fibrodysplasia Ossificans Progressiva: Clinical and Genetic Aspects
- Genetic Alliance UK statement

1. Consideration of application

1.1. The committee welcomed the advice of its Specialist Adviser, Dr Mary Porteous who confirmed that the condition was as described in the papers.

1.2. The committee noted that the description in the application for PGD for Fibrodysplasia Ossificans Progressiva (FOP), OMIM #135100 is consistent with the peer review.

1.3. The committee noted that the condition being applied for is not on the list of conditions approved for PGD.

1.4. The committee noted that the Genetic Alliance opinion provided a patient perspective and supported the application.

1.5. The committee had regard to its decision tree. The committee noted that the centre is licensed to carry out PGD. The committee was also satisfied that the centre has experience of carrying out PGD and that generic patient information about its PGD programme and associated consent forms had previously been received by the HFEA.

1.6. The committee noted that the proposed purpose of testing the embryos was as set out in paragraph 1ZA(1)(b) of Schedule 2 of the Act, i.e. 'where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality'.

1.7. The committee noted that the condition is inherited in an autosomal dominant pattern which means there is a 50% chance of an embryo being affected with the condition in each pregnancy, if either parent has a relevant mutation.

1.8. The committee noted that penetrance of the condition is 100%. The condition causes bone development outside of the skeleton within skeletal muscle, ligaments and tendons. This results in pain and in patients experiencing a progressive loss of mobility which can eventually lead to difficulties breathing, speaking, eating and eventually complete immobilisation. Patients are generally wheelchair bound by the age of 30 and overall life expectancy is around 40 years of age.

1.9. The committee noted that FOP is an incurable condition and the progressive loss of mobility cannot be prevented.

1.10. The committee noted the inspectorate's request to consider whether FOP, OMIM #135100 should be approved for inclusion on the list of conditions approved for PGD. The committee agreed to consider the application on this basis.

2. Decision

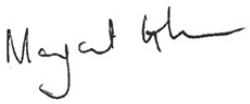
2.1. The committee considered that, in the worst case scenario Fibrodysplasia Ossificans Progressiva (FOP), OMIM #135100 is a serious condition. As muscle and connective tissue are replaced by bone, patients' joints become stiff, leading to a progressive loss of mobility requiring a wheelchair and potentially complete immobilisation. The onset of the condition is early childhood, with a mean age of onset around 5 years old. The condition is life limiting and the overall life expectancy for FOP is around 40 years. The quality of life for affected individuals is severely impacted and there is no curative treatment.

2.2. The committee had regard to its explanatory note and confirmed that, on the basis of the information presented, it was satisfied that there is a particular risk that an embryo may have the abnormality in question and that there is a significant risk, given the condition's worst symptoms, that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition. The committee was therefore satisfied that Fibrodysplasia Ossificans Progressiva (FOP), OMIM #135100 meets the criteria for testing under paragraph 1ZA(1)(b) and (2) of Schedule 2 of the Act and agreed to authorise testing.

3. Chairs signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature



Name

Margaret Gilmore

Date

27 November 2018