Statutory Approvals Committee – minutes

Centre 0102 (Guy's Hospital)

Pre-implantation Genetic Diagnosis (PGD) application for Achondrogenesis Type 2, OMIM #200610

Thursday, 25 October 2018

HFEA, 10 Spring Gardens, London, SW1A 2BU

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

Declarations of interest

- Members of the committee declared that they had no conflicts of interest in relation to this item.
- Professor Mary Porteous declared that she was the Peer Reviewer for this item and the Legal Adviser confirmed that there was no conflict of interest.

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
- Genetic Alliance UK statement
- 27 August 2015, SAC Minutes – PGD for Achondrogenesis types 1A and 1B

1. Consideration of application

1.1. The committee welcomed the advice of its Specialist Adviser, Professor 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 Achondrogenesis Type 2, OMIM #200610 is consistent with the peer review.

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

1.4. 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.

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

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 up to a 50% chance of an embryo being affected with the condition in each pregnancy, if either parent has a relevant mutation in the germline.

1.8. The committee noted the penetrance of the condition is 100%. Achondrogenesis Type 2 is a severe disorder that affects cartilage and bone development and is characterised by a small body, short limbs and other skeletal abnormalities. Affected individuals often die before birth, are stillborn or die soon after birth from respiratory failure. There are no curative treatments.

1.9. The committee noted that Achondrogenesis types 1A and 1B have been on the approved PGD condition list since August 2018, acknowledging the minutes included in the papers.

1.10. The Peer Reviewer highlighted that the condition is a very severe congenital disorder which is incompatible with life beyond infancy.

1.11. The committee noted the inspectorate’s request to consider whether Achondrogenesis Type 2, OMIM #200610, should be approved for inclusion on the PGD List. The committee agreed to consider the application on this basis.

2. Decision

2.1. The committee considered that, in the worst case scenario, Achondrogenesis Type 2, OMIM #200610, is a serious condition, which severely affects the foetus and is extremely life limiting. The condition is incompatible with life, and infants usually die before, or soon after birth. The condition severely impacts on the family.

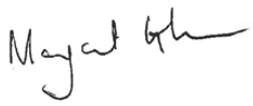
2.2. The committee had regard to its explanatory note and confirmed that, on the basis of the information presented, it was satisfied that there is a particular risk that an embryo may have the abnormality in question and that there is a significant risk, given the condition's worst symptoms, that a 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 the following conditions meet the criteria for testing under paragraph 1ZA(1)(b) and (2) of Schedule 2 of the Act and agreed to authorise testing:

- Achondrogenesis Type 2, OMIM #200610

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