Statutory Approvals Committee – minutes

Centre 0044 (The Centre for Reproductive and Genetic Health)

Pre-implantation Genetic Diagnosis (PGD) application for Renal Cell Carcinoma, Papillary 1 (RCCP1), OMIM #605074

Thursday, 25 June 2020

HFEA, 10 Spring Gardens, London, SW1A 2BU via Teleconference

Committee members	Margaret Gilmore (Chair) Emma Cave Anne Lampe Ruth Wilde	
Members of the Executive	Moya Berry Catherine Burwood	Committee Officer Licensing Manager
Specialist Adviser	Professor Mary Porteous	
Legal Adviser	Ros Foster	Brown Jacobson - LLP

Declarations of interest

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

Apologies:

- Apologies were received from Tony Rutherford.

The committee had before it:

- 9th 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
- 2019-02-28 SAC minutes, PGD for Hereditary leiomyomatosis and renal cell cancer, OMIM #150800.

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 PGD application Renal cell carcinoma, papillary, 1 (RCCP1), OMIM #605074, is consistent with the peer review.

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

1.4. The committee noted that a Genetic Alliance UK statement had not been provided on this occasion.

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 Renal cell carcinoma, papillary, 1 (RCCP1), OMIM #605074, is inherited in an autosomal dominant manner, which means there is a 50% chance of an embryo being affected by the condition in each pregnancy if either parent has a relevant mutation.

1.8. The committee noted that the penetrance of the condition is unclear but may be near 100%.

1.9. Renal cell carcinoma, papillary, 1 (RCCP1), OMIM #605074, is characterised by multiple bilateral papillary renal cell carcinomas in the kidneys. In individuals known to be at risk, screening is recommended and tumours may be detected at an asymptomatic stage. If not detected, symptoms include pain, blood loss in urine, an abdominal mass, weight loss and fatigue. Tumour metastasis can occur to other sites, notably the lungs, leading to metastatic disease and death. Life expectancy is reduced in individuals with this condition.

1.10. Treatment is not always curative and may be aggressive and involve surgery, radiotherapy, and chemotherapy.

1.11. The committee noted the executive's request to consider Renal cell carcinoma, papillary, 1 (RCCP1), OMIM #605074, 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, Renal cell carcinoma, papillary, 1 (RCCP1), OMIM #605074, is a rare and very serious condition which in the worst-case scenario may lead to premature death in early adulthood and reduced life expectancy. Treatment for the condition is often aggressive and includes chemotherapy, radiotherapy and surgery and may not always be successful. Those affected with the condition will require life-time surveillance to help minimise the risk of tumours developing. The committee considered the potentially devastating physical and psychological impact on the quality of life of those affected with the condition.

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 abnormalities in question and that there is a significant risk that a person with such an abnormality will, given the condition's worst symptoms, have or develop a serious physical disability, a serious illness or any other serious medical condition.

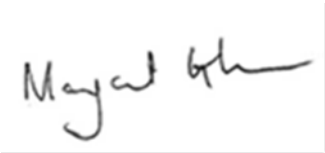
2.3. The committee was therefore satisfied that the following condition meets the criteria for testing under paragraph 1ZA(1)(b) and (2) of Schedule 2 of the Act. The committee agreed to authorise testing for:

- Renal cell carcinoma, papillary, 1 (RCCP1), OMIM #605074

3. Chairs signature

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

Signature



Name
Margaret Gilmore

Date
23 July 2020