SCHEDULE 2 – THE SERVICES

A. Service Specifications

1. Service name	Fertility and endocrine restoration using cryopreserved ovarian tissue
2. Service specification number	1867 230903
3. Date published	18/09/2023
4. Accountable Commissioner	NHS England england.npoc-womenandchildren@nhs.net

5.	**Population and/or geography to be served**
5.1	**Population Covered** All ages This service specification covers the provision of fertility and endocrine restoration for service users who have cryopreserved ovarian tissue and are in premature ovarian insuffiency (POI). It is one of three service specifications that describe an integrated single fertility preservation and restoration programme. The other two service specifications cover: - • Fertility preservation service for service users with ovarian tissue who are at high/very high risk of infertility and cannot store mature eggs • Fertility preservation for service users with testicular tissue who are at high/very high risk of infertility and cannot store sperm The fertility and endocrine restoration service specification does not include the restoration of testicular tissue as unlike ovarian tissue restoration, it is not currently clinically available for males.
5.2	**Minimum population size** Fertility and endocrine restoration are delivered by a hospital based specialised team capable of the management, oversight and optimal integration of care for service users with co-morbidities that could be as a result of their underlying diagnosis or original treatment regimen that led to infertility. The service must have specialist surgical expertise for auto-transplantation of ovarian tissue.
6.	**Service aims and outcomes**
6.1	**Service aim** The aim of the service is:

- To provide fertility and endocrine restoration treatment to service users who are infertile and have their cryopreserved ovarian tissue stored in an HTA licenced establishment.

The service will provide: -

- information and expert fertility advice to service users considering using stored ovarian tissue to restore endocrine function and fertility
- ovarian tissue auto-transplantation surgery for eligible service users
- specialist expertise, and facilities, in a designated auto-transplantation site

The service will be delivered in line with:

- National and international guidelines
- Established best practice
- Human Tissue Authority (HTA) requirements

6.2 Outcomes

NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely
Domain 2	Enhancing quality of life for people with long-term conditions
Domain 3	Helping people to recover from episodes of ill-health or following injury
Domain 4	Ensuring people have a positive experience of care
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm

Reference	Domain	Rationale	Indicator
FPS-OTC01	4,5	To understand the proportion of service users whose endocrine function is restored following auto transplantation of ovarian tissue	Proportion of service users whose endocrine function is restored following auto transplantation of tissue
FPS-OTC02	4	To understand the proportion of pregnancies resulting from auto transplanted tissue	Proportion of pregnancies resulting from auto transplanted issue
FPS-OTC03	4	To understand the proportion of live births	Proportion of live births

The service will complete/upload data for all listed quality metrics to the national Specialised Services Quality Dashboard (SSQD). The full version of the quality metrics and their descriptions including the numerators and denominators can be accessed at https://www.england.nhs.uk/commissioning/spec-services/npccrg/specdashboards/

7. Service description

This service provides treatment, care and counselling for service users who wish to have fertility restoration treatment. It also provides an assessment of the risks

	associated with auto-transplantation prior to the release and usage of cryopreserved ovarian tissue for the restoration of endocrine function and egg production. Ovarian tissue contains immature eggs within primordial follicles. Ovarian tissue cryopreservation (OTC) is a fertility preservation technique for service users who are at high/very high risk of infertility, due to the destruction of the primordial follicles by treatments such as chemotherapy, pelvic radiotherapy, total oophorectomy, hormone, or novel compounds (e.g., immunotherapy) and who were not able to store mature eggs. A service user, who has ovarian tissue stored, can use their cryopreserved ovarian tissue to restore ovarian function when they wish to have children. The tissue is auto transplanted onto the remaining ovary which results in a return of endocrine function and egg production. There have been more than 200 babies born from auto-transplantation of stored ovarian tissue worldwide, including in the UK.
7.1	**Service model** Auto-transplantation is a specialised procedure and will be undertaken in centres with a team capable of the management and oversight of the service. Due to the interdependence between the services, the clinical elements of the service must be hospital based to ensure optimal integration of care and management of co-morbidities, such as cardiac or other problems that could result from the underlying diagnosis or original treatment regimen that led to infertility. The service requires coordinated care between the Fertility Preservation Hub Team and the Tissue Establishment (TE) services involved with the initial storage of the service user's tissue and the auto-transplant team (ATT) who will provide an evaluation of tissue safety, surgery for tissue auto transplantation and follow up care. (See the service specification link in section 7.9 for fertility preservation services for service users with ovarian tissue who are at high/very high risk of infertility and cannot store mature eggs.) The ATT team will -: • Provide leadership, specialist fertility expertise, information and oversight in line with HTA licence regulations • Have the necessary expertise required to counsel patients about fertility treatment options including the risks and benefits of auto–transplantation of stored ovarian tissue and the risks of residual malignant cells within the tissue • Have access to an expert group of fertility and onco-fertility, specialists including members of the Hub team with knowledge of the patient's original disease and treatment to confirm the key investigations required to establish eligibility of the service user and safety of the ovarian tissue for transplantation • Have a Third-Party Agreement (TPA) with the HTA Human Application licensed Tissue Establishment where the cryopreserved ovarian tissue is stored. This will cover, storage, testing, thawing. release and distribution and disposal of ovarian tissue for auto-transplantation.

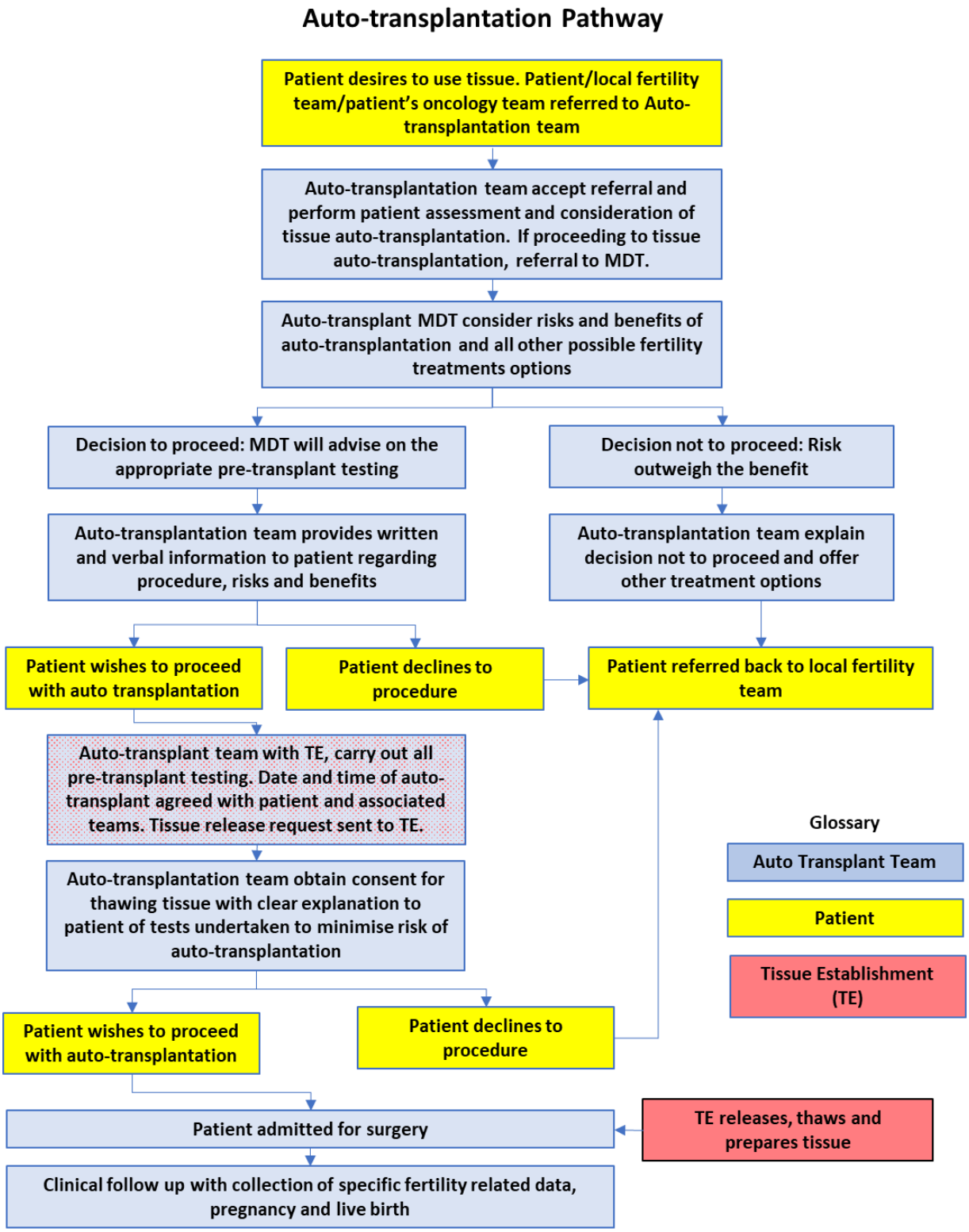
- Have specialist expertise for surgical auto-transplantation of ovarian tissue
- Have procedures for obtaining informed consent for release processing, testing, distribution, and disposal of ovarian tissue in accordance with HTA Licence requirements.
- Provide post-transplant care and follow-up in line with published protocols
- Provide psychological support and counselling for patients going through auto-transplantation treatment
- Have arrangements in place to have access to national and international expertise from centres with established programmes.
- Have arrangements in place for obtaining patient feedback to inform service evaluation.
- Have arrangements in place to use job planning, appraisal, and revalidation to ensure all members of the team are appropriately trained and competent to carry out their designated roles.

The Tissues Establishment

The tissue establishment must:

- Operate in compliance with the HTA Quality and Safety Standards and hold a Human Tissue Authority Human Application (HTA HA) Sector Licence for procurement, processing, testing, storage, distribution, and disposal of ovarian tissue.
- Have the capacity to respond to clinical demand such that cases are not delayed or deferred.
- Have in place quality assurance measures agreed with the ATT to demonstrate quality of tissue processing and storage which will be reported and audited by the ATT at least annually.
- Have in place quality assurance measures agreed with the ATT for testing and release of thawed tissue.
- Have arrangements in place to ensure that all data complies with United Kingdon Data Protection Act (UKDPA) regulations.
- Have arrangements in place to use job planning, appraisal, and revalidation to ensure all members of the team are appropriately trained and competent to carry out their designated roles.
- Have arrangements in place to keep patient records/data to ensure traceability for a minimum of 30 years after clinical use or disposal of tissue, in an appropriate and readable storage medium (including an electronic format).

7.2	**Pathways** **Overall patient pathway**



	Consent In accordance with HTA and General Medical Council (GMC) regulations a, consent for the thawing and release of ovarian tissue for transplantation must be sought prior to tissue being processed for release and auto-transplantation surgery. **Service Eligibility and Exclusion Criteria** **Eligibility criteria** Service users: • who have ovarian tissue cryopreserved in an HTA licenced establishment • who are in POI • who are medically fit for auto-transplant surgery under general anaesthesia **Exclusion criteria** Service users not included in the service specification are those: • where no ovarian tissue has been stored in an HTA licenced establishment • who have retained their fertility and endocrine function and are not in POI • where the tissue contains malignant cells and is not safe for auto-transplantation • where surgery or a general anaesthetic would carry undue risk **Transition** All healthcare services are required to deliver developmentally appropriate healthcare to patients and families. Children and young people with ongoing healthcare needs may present direct to adult services or may be required to transition into adult services from children's services. Transition is defined as a 'purposeful and planned process of supporting young people to move from children's to adults' services. Poor planning of transition and transfer can result in a loss in continuity of treatment, service users being lost to follow up, disengagement, poor self-management, and inequitable health outcomes for young people. It is therefore crucial that adult and children's NHS services, in line with what they are responsible for, plan, organise and implement transition support and care (for example, holding joint annual review meetings with the child/young person, their family/carers, the children's and adult service). This should ensure that young people are equal partners in planning and decision making and that their preferences and wishes are central throughout transition and transfer. NICE guidelines recommend that planning for transition into adult services should start by age 13-14 at the latest, or as developmentally appropriate and continue until the young person is embedded in adult services. This service covers children and young adult services and therefore addresses all transition needs of service users.
7.3	**Clinical networks** There is a requirement for providers of this service to comply with the provisions of *Schedule 2A (Clinical Networks) of the NHS Standard Contract 2022/23 The*

	Particulars. This includes meeting the requirements of the *relevant* Specialised Services Clinical Network Specification.
7.4	**Essential Staff Groups** **The ATT** • Auto-transplantation Programme Lead and Deputy responsible for the delivery of the service • Specialist fertility consultant with expertise in both cancer treatment and fertility restoration treatment options • Gynaecology consultant with a special interest in reproductive medicine/fertility • Gynaecology surgeon with appropriate laparoscopic skills • Consultant in haematology and oncology • Consultant histopathologist • Programme administrative coordinator • Data manager • Clinical nurse specialist/key worker • Counsellor • Ultra sonographer with experience in gynae/fertility scanning **The Tissue Establishment** • HTA designated Individual and deputy. • HTA licence holder contact • Quality manager • Technician(s) trained in processing and cryopreserving ovarian and testicular tissue • Technician(s) trained in thawing cryopreserved ovarian tissue. • Consultant histopathologist • Consultant microbiologist • Molecular biology and genetic expertise to assess safety of tissue • Administrative support
7.5	**Essential equipment and/or facilities** **The ATT must have** • Day care and inpatient facilities • Access to theatres for auto-transplant of ovarian tissue with facilities for sterile management of the thawed ovarian tissue • Histopathology to assess the safety and quality of the tissue for transplant • Microbiology for assessment of the microbiological safety of tissue for transplant • Molecular biology and genetic expertise to assess quality and safety of tissue for auto transplantation **The Tissue Establishment** • A facility with pharmaceutical Grade A air quality for thawing tissue on a background of Grade B air quality to minimise the risk of contamination

	• Histopathology for quality and safety assessment of tissue distributed for auto-transplantation • Microbiology for sterile testing of tissue • Environmental monitoring of processing facility
7.6	**Interdependent Service Components – Links with other NHS services** Not applicable
7.7	**Additional requirements** Not applicable
7.8	**Commissioned providers**
7.9	**Links to other key documents** NHS England Service Specification - Children's Cancer Services - Principal Treatment Centres. This service specification sets out standards for specialist cancer services including fertility preservation linked to cancer treatment that can impact on fertility. NHS England » Children's cancer services: Principal treatment centres service specification Children's cancer services; paediatric oncology shared care unit service specification NHS England » Children's cancer services: Paediatric oncology shared care unit service specification Teenage and young adult cancer services network specification NHS England » Teenage and young adult cancer clinical network specification This service specification describes the arrangements in place to ensure that service users get access to the right care, in the right place at the right time as part of a network approach to service delivery, including access to fertility treatment. Fertility preservation service for service users with ovarian tissue who are at high/very high risk of infertility and cannot store mature eggs: service specification. [Link to follow] Fertility preservation service for service users with testicular tissue who are at high/very high risk of infertility and cannot store sperm [Link to follow]