Specialist Medical and Surgical Services

Assisted Reproductive Technology Services (ART)

Service Specification

Tier 2

September 2024

Health New Zealand
Te Whatu Ora

Contents

1. Status

It is compulsory to use this nationwide service specification when purchasing this service.

MANDATORY ☑ RECOMMENDED ☒

2. Review History

Review History	Date
First Published on NSFL	2006
Amendment: clarification of reporting requirements in section10 and appendices 2, 3 and 4.	September 2014
Amendment: updated Appendix on the values to use for NNPAC reports	February 2015
Amendment: clarification to access criteria for fertility preservation	January 2016
Amendments: aligned with Service Coverage update August 2016 for access to fertility preservation, edited for consistent use of language re access, eligibility, fertility status evaluation, updated web links, reporting in Excel format.	December 2016
Amendments: aligned with Service Coverage 2018/19 requirements relating to treatment prioritisation tool, editing and clarification of clinical and reporting requirements ie mode of delivery and alcohol involved codes (FS01019 removed).	September 2018
Consideration for next Service Specification Review	Within five years
Moved to Health NZ template. Updated links for PUDD and NSFL only. Amended DHB to become District/Region where appropriate. No other changes to content made.	September 2024

Note: In September 2024 a small programme of work moved all Service Specifications to Health New Zealand branded templates. No amendments were made to the body text or content of the Service Specification, so references to DHB, Ministry of Health or other pre-2022 reforms vocabulary will still exist. A larger programme of work to review and revise all Service Specifications is planned for late 2024 to early 2025.

Contact: the Service Specification Programme Manager, Accountability, Ministry of Health, for queries re service specifications. Nationwide Service Framework Library website here.

3. Introduction

This tier two service specification for Assisted Reproductive Technology Services (the Service) must be used in conjunction with the tier one Specialist Medical and Surgical Services service specification that contains information common to this service.

When age appropriate, it is also linked to the following service specifications: tier one Services for Children and Young People service specifications and tier two Clinical Genetics Services.

The Service must comply with the Human Assisted Reproductive Technology Act 2004[1] (the HART Act).

Guidance relating to fertility preservation for young people is provided in the National Child Cancer *Network* document: Fertility Preservation Guidelines for People with Cancer a New Zealand Guideline[2].

4. Service Definition

The Service provides a range of specialist Assisted Reproductive Technology (ART) assessment and treatment services that include:

- infertility treatment arising from disease or dysfunction
- pre-implantation genetic diagnosis (PGD)
- fertility preservation before medical treatment that can damage gametes or gamete production
- advice, information services and best practice guidelines on fertility issues to primary and specialist health services.

The Service Users are people who are eligible[3] for funded treatment and meet the clinical access criteria for this Service.
The Service excludes treatment for people who are below the treatment threshold for publicly funded ART treatment, or do not meet the requirements for treatment.

5. Service objectives

5.1.1 General

The Service will:

- provide the most appropriate treatment within clinically appropriate timeframes

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[1] Human Assisted Reproductive Technology (HART) Act 2004: link http://www.legislation.govt.nz/act/public/2004/0092/latest/whole.htmlhttp:/www.legislation.govt.nz/act/public/2004/0092/latest/whole.html

[2] Fertility Preservation for People with Cancer A New Zealand Guideline: www.starship.org.nz/media/261297/fertility-preservation-for-people-with-cancer-dec-2017.pdf

[3] Being eligible gives a person a right to be considered for publicly funded health or disability services. It is not an entitlement to receive any particular service. Individuals need to meet certain clinical and other assessment criteria to receive services. The eligibility criteria for publicly funded health and disability services are prescribed by Ministerial Direction. Refer to http://www.health.govt.nz/new-zealand-health-system/eligibility-publicly-funded-health-services/guide-eligibility-publicly-funded-health-services for information on the latest eligibility criteria.

- maximise the chances of a healthy baby while limiting the incidence of untoward consequences.
- minimise complications of treatment, pregnancy, including hyper stimulation syndrome, infections, multiple pregnancy, and babies needing neonatal intensive care.
- ensure that Service Users will receive safe and reasonable Services in a manner that is respectful of their rights, minimises harm, acknowledges their cultural and individual values and beliefs, and are in accord with the Principles of the HART Act.

6. Access

6.1 Entry and Exit Criteria

6.1.1 Clinical access criteria

The clinical access criteria to the Service are:

- inability to achieve pregnancy after at least one year of unprotected intercourse, or completing 12 cycles of sperm donor insemination to attempt pregnancy, or
- a known cause of infertility [4] that prevent people from achieving or attempting pregnancy, or
- inability to carry a pregnancy to term, or
- being at risk of passing to their children a familial single gene disorder, a familial sex-linked disorder, or familial chromosomal disorder, or
- post-pubertal people who are undergoing gender transition, and post-pubertal people about to undergo publicly funded standard medical treatment that may permanently impair their fertility, and who are likely to survive that treatment and do not already have a child.

6.1.2 Fertility treatment criteria and timeframes

In all cases, the relevant guidelines and the current priority treatment criteria will apply:

- ART: use of the infertility treatment priority tool[5] and treatment threshold
- Pre-implantation Genetic Diagnosis (PGD)[6]: prioritisation criteria[7].

Each partner of a couple is treated together as 'a unit' for infertility treatment. A new relationship requires a reassessment of their eligibility and access to the Service. A reassessment of Service Users eligibility and access to treatment is needed if their circumstances have changed while they are waiting for treatment, or within a package of

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[4] Examples of known cause of infertility for early referral include: anovulation or very irregular periods (<20 or >42 days), significant tubal damage, severe endometriosis, severe male infertility

[5] The web based prioritisation tool for assisted reproductive technology is published on the National prioritisation website (password required for clinicians and administrators): www.npi.1000minds.com/

[6] To avoid transmission of familial genetic disorders as described in the Human Assisted Reproductive Technology Order 2005.

[7] The Advisory Committee on Assisted Reproductive Technology publish guidelines and advice, http://acart.health.govt.nz/publications-and-resources. There are applications of PGD that are established procedures under the Human Assisted Reproductive Technology Order 2005 also see Guidelines on Preimplantation Genetic Diagnosis with Human Leucocyte Antigen Tissue Typing published 2014. http://acart.health.govt.nz/publications-and-resources/guidelines-and-advice-issued-ecart/guidelines-preimplantation-genetic-0.

treatment: ie they are in a new relationship, or they had a live baby since they were last scored using the prioritisation tool.

Treatment timeframes: Fertility treatment should normally be commenced within 12 months of it being offered by the Service. Treatment will usually be completed within 18 months of starting the first infertility treatment package.

6.2 Fertility Preservation

The referral for fertility preservation is to be made by an appropriate specialist.

Referred individuals must be offered appropriate fertility preservation services, prior to the publicly funded oncology treatment, or similar. Fertility preservation services are provided, as clinically assessed, by the fertility specialist and referring Doctor and agreed with the Service User.

Treatment timeframes: Ovarian stimulation and oocyte, generally retrieval requires at least 10 to 17 days before the start of chemotherapy or pelvic radiotherapy.[8]

6.3 Package of Treatment

The package of infertility treatment is defined as:

- one IVF cycle/Intracytoplasmic Sperm Injection (ICSI) treatment, including subsequent transfer of any fresh or frozen embryo, until a live birth results, or no embryos remain, or
- up to four donor or intra uterine inseminations until a live birth results, or
- up to four cycles of ovulation induction using gonadotrophins until a live birth results, or
- one IVF/ICSI treatment for PGD resulting in embryos suitable for genetic testing.

Women who do not conceive in their package of treatment using IVF may access a second cycle of funded IVF if they meet the clinical requirements and achieve the prioritisation tool treatment threshold.

Where ovarian stimulation treatment is not effective, the IVF cycle should be cancelled and the woman counselled that her only treatment funded option is with a donor egg. The clinical decision should be made on a case by case basis. A cancelled IVF cycle is not a complete cycle of treatment.

6.4 Exit Criteria

The Service User exits the Service when they:

have successfully completed their treatment following a live birth, or
have used up to two packages of treatment without a live birth, or

- are below the treatment threshold, or
- no longer benefit from receiving the Service or
- are discharged/transferred with a management plan, to another Provider, or from the Service

[8] Refer to Fertility Preservation Guidelines for People with Cancer: a New Zealand Guideline. www.starship.org.nz/media/261297/fertility_preservation_for_people_with_cancer_-__a_new_zealand_guideline_april_2014final.pdf

- choose to exit the Service.

7. Co-payments

7.1 Storage

No co-payment will be sought from Service Users for any service covered by this service specification, including supplies and equipment, other than that specified below.

Service Users who receive services for infertility and/or are receiving PGD services are expected to pay for their embryo storage after 18 months of first storage.

Service Users who receive services related to fertility preservation will have their gametes/ embryos storage funded up to 10 years[9]. The 10 year storage period for embryos includes any time in which gametes used to create the embryos have been stored. The storage period of gametes and embryos also includes any time that they have been stored overseas.

8. Service Components

8.1 Processes

In addition to the generic processes in the Tier One Specialist Medical and Surgical Services service specification:

SERVICE COMPONENT	DESCRIPTION
First specialist assessment and development of a treatment plan	This includes: • initial assessment by an appropriately qualified clinician, and • confirmation that people meet the Service's access criteria and are suitable for ART treatment, or • referral back to the referring clinician and an explanation of the reason(s) to the individual/couple/their whānau, why they do not meet the criteria, or are assessed as unsuitable[10] where appropriate • discussion of treatment and management plan with Service Users, and as appropriate their whānau, including expectation, possible risks, after care arrangements, expected waiting time to receive treatment. The essential information is to be supplied in writing to the Service User. • referral for any applicable medical advice or treatment that may optimise the success or safety of treatment.

[9] The Human Assisted Reproductive Technology Act (the HART Act) amended in 2010 to clarify provisions relating to the storage and extending storage of gametes and embryos beyond the original 10-year limit. See ECART's guidelines issued by ACART, on the extended storage of gametes and embryos, to enable applications to ECART to extend the period of storage.
www.acart.health.govt.nz/system/files/documents/publications/acart-guidelines-extending-storage-gametes-embryos-2012.pdf
ECART Application Forms: www.ecart.health.govt.nz/publications-and-resources/application-forms

[10] Refer to the HART Act.

SERVICE COMPONENT	DESCRIPTION
Range of investigations and treatments	This includes: diagnostic investigations ovulation induction (OI) (includes incomplete cycles of OI that are stopped for poor response, or over-response to gonadotrophins intra uterine insemination, (IUI) including hyper stimulation in vitro fertilisation (IVF) This includes careful consideration of the number of embryos transferred in In Vitro Fertilisation (IVF) and of the degree of ovarian stimulation in all treatments. intracytoplasmic sperm injection (ICSI) including surgical sperm retrieval donor gametes and embryos (embryos should normally be used from the first oocyte pick up (OPU) cycle prior to commencing a second OPU cycle) surrogacy.
Pre-implantation genetic diagnosis	This includes PGD and related IVF for diagnosis of familial single-gene disorders, sex determination for familial sex-linked disorders, and diagnosis of familial chromosomal disorders that met the criteria for severity for established procedures under the HART Act. For individuals seeking PGD with human leukocyte antigen (HLA) tissue typing, the Guidelines on PGD with HLA tissue[11] typing apply.
Fertility Preservation	This includes: assessment and investigation retrieval, freezing and storage of gametes (eggs and sperm) embryo freezing and storage.
Peri-treatment care	Oocyte collection for IVF treatment. Sperm preparation, insemination of eggs, culture of embryos and embryo replacement for IVF/ICSI cycles. Single Embryo Transfer: transfer of a single embryo will normally be used in a public funded cycle. Transfer of two embryos may be considered where the woman has not become pregnant despite four or more transfers of single embryos, and the risk of multiple pregnancy is low. Embryo freezing (if appropriate) and embryo storage for up to 18 months. Immediate post treatment recovery including medical, nursing and other technical services as required.
Clinical follow-up	Fertility Specialist assessment of treatment effects and further treatment requirements. Review Clinic within 4 months post treatment, or as indicated. Early Pregnancy Assessment (up to 10 weeks, and referral to the Lead Maternity Carer at 8 weeks after a scan confirming viability).
Social Work and counselling services	Access to social work and counselling by specialist infertility counsellors, to address the social and psychological effects for Service Users undergoing fertility preservation treatments, infertility treatments, as well as other options such as adoption or living without children. For those people seeking PGD, provision of information relevant for informed decision making including psychosocial counselling and referral for genetic counselling. Involvement of family and whānau in counselling to meet the wishes and needs of Service Users.

[11] acart.health.govt.nz/publications-and-resources/guidelines-and-advice-issued-ecart/guidelines-preimplantation-genetic-0

SERVICE COMPONENT	DESCRIPTION
Consultation and education services	Educative services are provided to GPs and specialists concerning appropriate referral protocols and indications for ART. Consultation and advisory services are provided to GPs and specialists concerning the condition and ongoing management of the referred Service Users. Provide advice, as appropriate, to increase awareness of infertility, its prevention, and the minimisation of its impact among the general public.
Referral to other services	See section 7. Service linkages below. eg: provide support for women who have a raised Body Mass Index (BMI). Diet/nutrition and exercise support offered to women whose BMI is in the higher range (over 28) to increase the chance of a successful pregnancy. Smoking cessation services.
Gamete and embryo storage	Management of: embryo storage for up to 18 months gamete (eggs and sperm) and embryo storage for up to 10 years as part of a clinical treatment plan for fertility preservation disposal of embryos beyond 10 years of storage, if no time extension has been approved by ECART communication with Service Users who have frozen gametes or embryos, as appropriate, particularly those who are approaching the 10 year funded storage timeframe, to receive information on the disposal, or extension of storage.

8.2 Settings

The Service will be delivered in an appropriate setting to achieve the best outcomes and consider cultural appropriateness, accessibility and the most effective and efficient use of resources.
A whānau room is provided within the facility for the use of a Service User and their whānau.

8.3 Key Inputs

All health professionals must meet the Fertility Standard 8181 requirements.[12]

All other health professionals providing the Service must hold a current practising certificate applicable to their profession and will supervise all health professionals under training programmes who do not yet hold current practising certificates.

Provision of consumable supplies includes, but is not limited to, anaesthetic agents and other pharmaceuticals and disposable equipment while the Service User is in the clinic or hospital.

8.4 Support Services

[12] www.standards.govt.nz/sponsored-standards/health-care-services-standards/?utm_source=MoH&utm_medium=weblink&utm_campaign=HealthStandards

The following support services are required to enable the delivery of this Service, and are included in the price for this Service:

operating theatre, analgesic and anaesthetic services
laboratory services
counselling services- both genetic and psychosocial implications counselling
pharmaceuticals
diagnostic imaging
interpreting services, including New Zealand Sign Language (NZSL) interpreters for deaf people who communicate using NZSL.

9. Service Linkages

The Service must be well integrated with other health and support services, professional organisations and ensure that there is effective consultation, liaison and referral between services and sub-specialties. Providers will establish working arrangements or protocols that reflect the size and scope of each organisation and the degree of cooperation required between them and the Service Provider.

The Service linkages include, but are not limited to the following:

- Advisory Committee on Assisted Reproductive Technology (ACART)
- Australia New Zealand Infertility Counsellors Association (ANZICA)
- Community support groups eg, Fertility New Zealand Inc, Women's Health Action Trust
- Diet nutrition and exercise support services
- Ethics Committee on Assisted Reproductive Technology (ECART)
- Family Planning Association, Natural Fertility NZ and other accredited providers
- Fertility Nurses Association (FNA)
- Genetic Health Services NZ
- Laboratory Services/Pathology services funded through community laboratories
- Māori and Pacific Peoples health service providers
- National Travel Assistance Programme
- National Child Cancer Network
- Other Specialist services, such as clinical genetics, oncology and haematology, including paediatric oncology, gynaecology, urology, and endocrinology services.
- Primary health care services, General Practitioners, Nurse Practitioners including health education
- Scientists in Reproductive Technology (SIRT)
- Sexual Health Clinics
- Smoking cessation services.

10. Quality Requirements

The Service must comply with the quality requirements described in the Operational Policy Framework (OPF)[13] or, as applicable, Crown Funding Agreement Variations, contracts or service level agreements.
The Service provider must:

[13] The Operational Policy framework is updated annually refer to https://www.health.govt.nz/about-us/new-zealands-health-system/overview-and-statutory-framework/accountability-arrangements

- comply with all relevant legislation, regulations, statutory requirements, and guidelines from professional bodies
- hold current accreditation under the Fertility Services Standard by an auditing agency to accredit approved by Director General of Health
- have access to equipment appropriate to operate a NZ Standard 8181 Fertility Service
- deliver services in accordance with the Human Assisted Reproductive Technology Order 2005.
- comply with the quality requirements for PGD (Appendix two) and be certified by Health Cert to the NZ Fertility Standard NZS8181.

Diagnostic Laboratory services (or as applicable, individual pathology departments) are registered with International Accreditation New Zealand (IANZ[14]).

ECART approval is needed for human reproductive research, for procedures which require ethical review as set out in the HART Order ('assisted reproductive procedures'), and for extending the storage period of gametes and embryos, as set out in the HART Act.

ECART is also able to provide a non-binding ethical opinion on cases which do not require ethical review ('established procedures').

11. Purchase Units and Reporting Requirements

11.1 Purchase units

Purchase Unit (PU) Codes are defined in Health New Zelaand's Nationwide Service Framework Data Dictionary[15]. The following codes apply to this Service.

PU Code	PU Description	PU Definition	PU Unit of Measure
FS01001	Fertility Services- 1st Attendance	First attendance to a fertility specialist for specialist assessment.	Attendance
FS01024	Fertility Services- Subsequent Attendance	Follow up attendance to a fertility specialist or Medical Officer at Registrar level or above or Nurse Practitioner	Attendance
FS01002	IVF Programme- first cycle	In vitro fertilization (IVF)–first cycle- - includes ovarian stimulation, collecting and fertilizing eggs (includes blastocyst addition), and embryo transfer. Spare embryos may be frozen and stored for subsequent use.	Procedure
FS01003	Intracytoplasmic sperm injection (ICSI) Addition	Intracytoplasmic sperm injection – a single sperm injected directly into an egg for in vitro fertilization treatments	Procedure
FS01004	Donor Insemination	The insemination of donor sperm into women whose partners are infertile	Procedure

[14] www.ianz.govt.nz/about/about-ianz/
[15] https://www.tewhatuora.govt.nz/health-services-and-programmes/nationwide-service-framework-library/purchase-units

PU Code	PU Description	PU Definition	PU Unit of Measure
FS01005	Intrauterine insemination – Simple	Intrauterine technique for specially prepared sperm to be placed directly into the uterus. (Excludes hyperstimulation of the ovary FS01006).	Procedure
FS01006	Intrauterine insemination with hyper stimulation	Hyperstimulation of the ovary to produce more than one egg combined with intrauterine insemination technique using specially prepared sperm	Procedure
FS01021	Surrogacy Procedures	Surrogacy related fertility procedures	Procedure
FS01022	Donor Egg	Donor related fertility procedures including donated egg	Procedure
FS01023	Donor Embryo	Donor related fertility procedures donor embryo	Procedure
FS01008	Thawed Embryo Replacement	Transfer of additional embryos frozen at time of oocyte pickup in a following cycle	Procedure
FS01009	Ovulation Induction (OI)	Stimulation of ovaries with fertility drugs to induce mono-follicular development and allow fertilisation to occur by natural intercourse	Procedure
FS01013	Cancelled IVF Cycle	Cancelled cycle of IVF (in vitro fertilization) after gonadotrophins commenced but before egg collection	Client
FS01014	Incomplete IVF Cycle	Incomplete cycle of IVF(in vitro fertilization) resulting in no embryo to transfer or freeze	Client
FS01018	IVF standard second cycle	In Vitro Fertilization Programme (IVF) second cycle of treatment.	Procedure
FS01010	Surgical Retrieval of Sperm	Sperm obtained surgically from the epididymis or testis and then used for Intracytoplasmic sperm injection-(ICSI)	Procedure
FS01011	Sperm Freezing	Ejaculated or testicular sperm frozen for future use in fertility treatment.	Procedure
FS01030	Egg Retrieval and Freezing	Surgical retrieval and freezing of eggs	Procedure
FS01302	Annual Storage of Sperm	Annual Storage fee for frozen sperm	Client
FS01033	Annual Storage of Eggs	Annual storage fee for frozen eggs for patients whose future fertility will be compromised by impending specialist medical or surgical treatment	Client
FS02002	PGD Fertility Feasibility Test	Preimplantation genetic diagnosis (PGD) fertility feasibility test	Test
FS02003	PGD Biopsy and Testing	Preimplantation genetic diagnosis (PGD) biopsy and testing for fertility services	Procedure

Unit of Measure	Unit of Measure Definition
Attendance	Number of attendances to a clinic/department/acute assessment unit or domiciliary.
Client	Number of clients managed by the service in the reporting period (period is annual 1st July - 30th June) i.e. caseload at the beginning of

	the period plus all new cases in the period. 'Client' and 'Service User' are interchangeable.
Procedure	The number of individual operative/diagnostic/assessment procedures in the period (period is annual 1st July - 30th June).
Test	Number of separate tests purchased. For laboratory a group test is counted as one test not each individual component.

Data definitions:

Completed treatment: embryo transfer or embryo freezing for IVF, embryo transfer for frozen embryo replacement and insemination for donor insemination and intrauterine insemination, embryos suitable for genetic testing for PGD NZS8181

Ovulation induction: includes cycles stopped for over or under response to gonadotrophins.

IVF cancelled cycle: where gonadotrophins are started but the cycle is stopped before egg collection

Incomplete cycle: where egg collection occurs but there are no embryos to transfer or freeze. Reporting Requirements

12. Reporting Requirements

12.1 General

The core set of information described below will be collected and provided at the defined reporting times. This information is for the purpose of monitoring service provision, clinical auditing and to support national consistency for service development and benchmarking. Details of any additional information collected and the frequency of reporting to Sector Operations are as specified by the Funder and documented in the Provider Specific Schedule of the contract.

All reporting, except for section 10.2 Reporting to the National Non Admitted Patient Collection (NNPAC) should be forwarded to:

The Performance Reporting Team, Sector Operations
Ministry of Health
Private Bag1942
Dunedin 9054.
Email performance_reporting@moh.govt.nz.

There are four types of reporting:

- Reporting to NNPAC (monthly)
- Annual narrative quality report (to Sector Operations)
- Outcome reporting (quarterly or annual to Sector Operations)
- Wait time and indication reporting (quarterly to Sector Operations).

12.2 Reporting to NNPAC

The Service must collect and report the purchase units above to the National Non Admitted Data Collection (NNPAC) and comply with the Ministry of Health NNPAC reporting requirements for service planning and analysis purposes. Reporting to NNPAC will be monthly.

Refer to *Appendix four* for the file specification for reporting to NNPAC by fertility service providers.

12.3 Annual Narrative Quality Report

Depending on the start day of the agreement, the annual reporting will either be in July (annual financial year) or January (annual calendar year). The Service provider will forward the report to Sector Operations detailing the following:

Narrative Quality Report	
Service User Experience	Provide a summary of : • feedback received on: the quality of information provided; clarity of the explanation of the treatment; the personal support from staff; respect of privacy; and sensitivity to the Service Users' culture • education programmes provided for Service Users • referrals to other services, in particular weight loss programmes, smoking cessation services.
Complications and incidents-treatment related	• any medical complications of treatment, including hospitalisation for Ovarian Hyper Stimulation Syndrome (OHSS) • incident reporting, add severity • fetal reductions • multiple births • single embryo transfer (SET) rate.
Demonstrated relationship building	• supporting the Funders understanding of the value added services, service complexity, responding to supporting Service Users' needs, maintaining effective service linkages with Districts and other linked services • Clinical Medical Education (CME) registration • initiatives etc.
Summary of any issues	• potential service changes, trends

12.4 Outcome Reporting

Providers will collect and report: the number of live birth rates (live birth rates percentage) and multiple pregnancy rates (multiple pregnancy rate percentage) for the reporting period for each treatment listed in *Appendix Two*. This outcome reporting will be provided in an electronic format to Sector Operations (quarterly or annual reporting due dates will be agreed with the Funder and documented in the provider specific terms and conditions).

Note: The live birth rates reporting table aligns with the reporting requirements to the ANZARD database for total volumes for each reporting period for each of 1st and 2nd IVF cycle, PGD and fertility preservation services.

12.5 Wait time and indication reporting

Quarterly reported to Sector Operations due by 20 April, 20 July, 20 October, 20 January using the reporting template format in *Appendix three,* (preferably in an emailed excel spreadsheet).

12.6 Reason for using service

Report for the following purchase units: FS01001, FS01002, FS01003, FS01008, FS01013, FS01014, FS01018, the total number of each of the three reasons/indications for using the Service:

infertility (INF)
preimplantation genetic diagnosis (PGD)
fertility preservation (FPR)

12.7 Clinical indication for PGD

Report summary of clinical indications for every PGD cycle; number of PGD cycles per clinical indication.

12.8 Average wait time trend information

Report average wait time from receiving a referral to consultation for of the following purchase unit:

FS01001 Fertility Services- 1st Attendance

Report average wait time from date of acceptance for treatment (booking) to date of treatment for each of the following purchase units:

FS01030 Egg Retrieval and Freezing

FS01002* IVF Programme- first cycle (ie. all access and eligibility criteria met, being: national prioritisation score, treatment option decided, residency checked.)

FS01018* IVF standard second cycle

FS02003 PGD Biopsy and Testing.

*For both FS01002 and FS01018, the date accepted for treatment resets if the patient interrupts their waiting time (eg. is offered treatment but is not ready).

The average wait time for treatment excludes Service Users who elect to defer treatment or whose treatment is deferred for clinical reasons. Wait time is from time of booking treatment to egg collection in an IVF cycle.

13. Appendices

13.1 APPENDIX ONE Quality Requirements for Preimplantation Genetic Diagnosis

The Service Provider (the Provider) will either provide, or refer to another appropriate service, that will ensure the quality requirements of the preimplantation genetic diagnosis (PGD) services are met, as outlined below:

1. *Scope of testing*

a. The Provider will offer:

i. sex selection for familial sex-linked genetic disorders in accordance with the Human Assisted Reproductive Technology (HART) Order 2005

ii. tests for familial single gene-disorders and familial chromosomal disorders in accordance with the HART Order 2005

b. The Provider must inform patient(s) that in some instances a genetic result may not be obtained for some or all embryos.

c. The ART unit must inform patient(s) that PGD services are screening tests only and the results are not 100% accurate. (Technical limitations will never allow for complete accuracy.)

2. *Feasibility Testing*

a. Before offering a PGD treatment cycle, the Provider will undertake feasibility studies where needed for familial single-gene disorders or familial chromosomal disorders to determine:

i. whether the test is technically feasible and

ii. the degree of reliability and accuracy of the test developed.

3. *Counselling*

a. The Provider will ensure patients have had counseling by a genetic counsellor and/or a clinical geneticist prior to the commencement of treatment.

b. Counselling and information giving should address the following issues:

i. the nature of the disease and the consequences of a birth under these circumstances.

ii. the risks of a transfer of a genetic abnormality

iii. the risks of misdiagnosis with PGD

c. The reliability and accuracy of the test

i. the risk of inconclusive results due to technical issues

ii. the need for prenatal testing to confirm results

iii. the considerations relating to a PGD pregnancy if diagnosis is incorrect.

iv. the specific details and success rates associated with infertility treatment.

4. *Quality assurance*

a. The laboratory undertaking analysis of biopsied cells must undertake assurance assessments as considered appropriate for the testing being undertaken, and be certified against ISO 9001: 2000 and ISO 17025 standards or to comparable standards.

13.2 APPENDIX TWO: Live Birth and Multiple Pregnancy Rates Reporting Template

Completed treatments are reported unless otherwise specified.

Report the number of live births (live birth rates percentage) and number of multiple births (Multiple birth rate (percentage) for the preceding period for each treatment listed below:

Reporting Template for Live Birth and Multiple Pregnancy Rates				
Period (dates) of treatment:				
	Live births	**Live birth rate per purchase unit (%)**	**Multiple births**	**Multiple birth rate per live birth (%)**
IVF alone (FS01002 or FS01018)				
IVF with ICSI addition (FS01002 or FS01018 plus FS01003)				
IVF or ICSI with Donor egg addition (FS01002 or FS01018 plus FS01007)				
Thawed embryo replacement (FS01008)				
IUI with or without hyperstimulation (FS01005 plus FS01006)				
Donor insemination (FS01004)				
Ovulation induction (FS01009)				
PGD Biopsy and Testing (FS02003)				
TOTAL		(not applicable)		

13.3 APPENDIX THREE: Wait time and clinical indication reporting

Information to be reported in an excel spreadsheet, to Sector Operations using the layout/format of templates below.

Reporting template for indication				
PU Code	**PU Description**	**Reason for using service (total per reason)**		
		INF	**PGD**	**FPR**
FS01001	Fertility Services- 1st Attendance			
FS01002	IVF Programme- first cycle			
FS01003	Intracytoplasmic sperm injection (ICSI) Addition			
FS01008	Thawed Embryo Replacement			
FS01013	Cancelled IVF Cycle			
FS01014	Incomplete IVF Cycle			
FS01018	IVF standard second cycle			

Reporting template for wait times		
PU Code	**PU Description**	**Average wait time**
		Wait time from referral date (acceptance into service) to treatment
FS01001	Fertility Services- 1st Attendance	
		Wait time from date of booking to treatment
FS01030	Egg Retrieval and Freezing	
FS01002	IVF Programme- first cycle	

FS01018	IVF standard second cycle	
FS02003	PGD Biopsy and Testing	

Reporting template for Clinical indications for PGD	
Clinical Indication for PGD	Number of PGD cycles

13.4 APPENDIX FOUR: Purchase unit reporting requirements to NNPAC by fertility service providers

Clarification of fields that are to be reported when reporting purchase unit codes to NNPAC. For several fields default values have been provided for the fertility services purchase units. Rows that are grey are not relevant for fertility services and can be left blank in the reporting.

Contact Ministry of Health National Collections team for setting up the reporting.

Table is extracted from NNPAC file specification, Chapter 7 Extract file requirements, re: http://www.health.govt.nz/system/files/documents/publications/nnpac_file_specification_v5..0_doc_v5.2.pdf

Field	Type	Format	Reqd.	Notes	Default for Fertility services	Comment/clarification for Fertility services
record type	char 6	A (6)	M	'EVENT' for an add or update. 'DELETE' for a delete. Delete records may contain only key fields (client system identifier, and PMS unique identifier). No mandatory field checking will be done for other fields in DELETE records with the exception of datetime of service. Currently datetime of service must contain a valid date and time. It can be any datetime, it does not have to match the record being deleted. This will be corrected in a future release.		
event type	char 3	AAA	M	OP (outpatient), ED (emergency department). CR (community referred diagnostic) The Community Referred Diagnostic Event should only be used when the diagnostic is independent of any FSA, follow up or treatment procedure and has been ordered by the GP. Refer to 13.4 Community Referred Diagnostic Event. This field has been made mandatory for all events with Date of Service on or after 1 July 2010	OP	
health practitioner type	char 3	AAA	M	M (doctor), N (nurse), O (other)	O	Reason: many procedures involve a range of staff

Field	Type	Format	Reqd.	Notes	Default for Fertility services	Comment/clarification for Fertility services
client system identifier	char 10	A (10)	M	Validated against the external system table. New client system identifiers need to be registered with the Ministry of Health and must be associated with an extract system identifier.		Provided by MoH
pms unique identifier	varchar 14	X (14)	M	The identifier as used in the client system for this event. Leading and trailing blanks will be trimmed off in the load process.		Autonumber or existing unique event number in provider system
NHI	char 7	AAANNNN	M	Must be registered on NHI at time of file transmission.		NHI of women unless with purchase unit code for sperm retrieval, freezing etc.
facility code	char 4	XXXX	C	Must be a valid facility code. This is the code of the facility where the event took place. Mandatory if location type is Hospital Facility (i.e. 1, 2 or 3) but should be entered where available for other location types. Refer to 13.2 Events that occur outside a hospital		Provided by MoH
agency code	char 4	XXXX	M	Must be a valid agency code. This is the code of the agency paying for the service. For example, if Otago District contracts out to a private organisation Dunstan Charitable Trust, the agency is Otago District and Dunstan Charitable Trust must be submitted as the facility.		Funding DHB – see list below *
location type	Integer 2	NN	M	1 (Public Hospital), 2 (Private Hospital), 3 (Psychiatric Hospital), 4 (Other Institution), 5 (Private Residence), 6 (Other), 10 (Residential Care), 11 (Marae), 12 (Primary Care), 13 (Other Community) Refer to 13.2 Events that occur outside a hospital		Fertility Plus =1 FA, Repromed = 4

Field	Type	Format	Reqd.	Notes	Default for Fertility services	Comment/clarification for Fertility services
health specialty code	char 3	ANN	M	As for NMDS. Must be a valid health specialty code and must be active for the Date of Service	S30	Gynae = S30
service type	char 8	X (8)	M	PREADM (pre-admission), FIRST (first contact for client with condition at specialty), FOLLOWUP, CRD (community referred diagnostic)		FS01001 = First All other PUCs = FOLLOWUP
equivalent purchase unit code	char 8	X (8)	M	Is the purchase unit that would have been allocated if provided by a District as defined in the NSF data dictionary, regardless of funding. Must be a valid purchase unit code and must be active for the Date of Service. For DNA (Did Not Attend) or DNW (Did Not Wait), this is the Purchase Unit that would have been allocated had they attended or waited. Note there is a series of Nationwide Service Framework Data Dictionary Purchase Unit codes expressly for use in NNPAC for pre-admissions and subsequently admitted ED events.		Purchase units as in service specification
acc claim number	char 12	X(12)	O	Valid only if accident flag = 'Y'		N/A
accident flag	char 1	A	M	'Y' or 'N' or 'U' (unknown)	N	N/A
purchaser code	char 2	XX	M	As for NMDS. Must be a valid Principal health purchaser code and must be active for the Date of Service.	35	
attendance code	char 3	AAA	M	ATT (attended), DNA (did not attend), DNW (did not wait)	ATT	
volume	number	99999.999 (floating-point)	M	Zero if attendance code is DNA or DNW or client-based or programmed events, otherwise 1 or more if attendance code is ATT. This is not the number of events but the number of purchase units.	0 or 1	The following purchase units have a value of 0: Cancelled IVF cycle (FS01013) Incomplete IVF cycle (FS01014) Sperm storage (FS01032)

Field	Type	Format	Reqd.	Notes	Default for Fertility services	Comment/clarification for Fertility services
						egg storage (FS01033)
domicile code	char 4	AAAA	O	Must include leading zeroes. This is used for deriving the patient's District and as a data quality test to compare with the NHI domicile code.		Note: domicile code is part of Geocode
datetime of presentation	datetime	CCYY MMDD HHMM	C	The date and time a patient presents/or is presented physically to the ED department; either to the triage nurse or clerical staff, whichever comes first. Mandatory for ED events with Datetime of service on or after 1 July 2010, null for all other events		N/A (ED only)
datetime of service	datetime	CCYY MMDD HHMM	M	The date of service will be used to look up the NHI history tables to get the gender, ethnicity and domicile code of the patient at the time of the event. For ED events this is the date and time that a triage nurse/suitable ED medical professional starts the process of categorising the triage level of the incoming patient (i.e. 1 – 5). For outpatient visits the time of service should be the actual service start time if available. If not, then the booked appointment time may be used or a default time of '0000' may be sent. Refer to further notes in 13.3 ED Timestamps		Date only – 0000 for the time
datetime of first contact	datetime	CCYY MMDD HHMM	C	The date and time that the triaged patient's treatment starts by a suitable ED medical professional (could be the same time as the datetime of service if treatment is required immediately i.e. triage level 1). Mandatory for ED events with Datetime of service on or after 1 July 2010 and attendance code 'ATT', null for all other events		N/A (ED only)

Field	Type	Format	Reqd.	Notes	Default for Fertility services	Comment/clarification for Fertility services
datetime of departure	datetime	CCYYMMDDHHMM	C	The date and time of the physical departure of the patient from ED to an in-patient ward, or the time at which a patient begins a period of formal observation (whether in ED observation beds, an observation unit, or similar), or the time at which a patient being discharged from the ED to the community physically leaves the ED. Mandatory for ED events with Datetime of service on or after 1 July 2010 and attendance code 'ATT', null for all other events Refer to further notes in 13.3 ED Timestamps		N/A (ED only)
triage level	integer	N	C	From the scale of 1 – 5 Mandatory for ED events with Datetime of service on or after 1 July 2010 and attendance code 'ATT', null for all other events		
event end type code	char	AA	C	Mandatory for ED events with Datetime of service on or after 1 July 2010 Must be a valid code in the Event End Type code table.		
NMDS PMS unique identifier	varchar 14	X (14)	C	NMDS PMS unique event identifier where a patient is admitted following their emergency event. The admission may be either because a patient has been admitted to an inpatient ward or there has been an administrative admission due to the 3 hour rule (see definition of admission in the glossary to the National Collections). Mandatory for events with Datetime of service on or after 1 July 2010 and attendance code = 'ATT' and equivalent purchase unit is like ED%A.		
Funding agency code	Char	XXXX	CM	Funding agency will be reported in the new version of the load file v5.0. Mandatory for events with a purchaser code of 20, 33, 34, 35, 55, A0. Must be a valid Agency		Funding DHB – see list below *

Field	Type	Format	Reqd.	Notes	Default for Fertility services	Comment/clarification for Fertility services
				Code and must align with the Purchaser Code		
Mode of delivery					1	
Alcohol involved code						

* District Health Board code table available on http://www.health.govt.nz/nz-health-statistics/data-references/code-tables/common-code-tables/district-health-board-code-table

Agency and Funding agency code (4 digit)

011	**1011**	NLD	G00026-A	Northland
021	**1021**	NWA	G00013-C	Waitemata
022	**1022**	CAK	G00011-K	Auckland
023	**1023**	SAK	G00012-A	Counties Manakau
031	**2031**	WKO	G00027-C	Waikato
042	**2042**	LKS	G00028-E	Lakes
047	**2047**	BOP	G00031-E	Bay of Plenty
051	**2051**	TRW	G00029-G	Tairawhiti
071	**2071**	TKI	G00030-C	Taranaki
061	**3061**	HWB	G00032-G	Hawke's Bay
091	**3081**	MWU	G00033-J	Midcentral
082	**3082**	WNI	G00035-B	Whanganui
093	**3091**	CAP	G00036-D	Capital and Coast
092	**3092**	HUT	G00006-F	Hutt
093	**3093**	WRP	G00037-F	Wairarapa
101	**3101**	NLM	G00038-H	Nelson Marlborough
111	**4111**	WCO	G00039-K	West Coast
121	**4121**	CTY	G00005-D	Canterbury
123	**4123**	SCY	G00025-K	South Canterbury
160	**4160**	SRN	G02328-E	Southern

The wait time information could be collected in the local NNPAC reporting file as extra rows in the file, however this data should not be reported to NNPAC.

Below is an example for collecting data in NNPAC format:

Field	Format	Reqd.	Notes	Default for Fertility services	Comment/ clarification for Fertility services
reason for using service	AAA		Record for the following purchase units the Service User's reason / indication for using the Service: FS01001, FS01002, FS01003, FS01008, FS01013, FS01014, FS01018. Indications: INF (infertility), PGD (preimplantation genetic diagnosis), FPR (fertility preservation)		
referral/ treatment acceptance date	CCYYMMDDHHMM		Record date referred to service for: FS01001, FS01011, FS01030 Record date accepted for treatment for: FS01002, FS01018, FS02002, FS02003		Date only – 0000 for the time
wait time	days		Subtract 'treatment acceptance date' from 'datetime of service', for PUCs with 'treatment acceptance date'.		
clinical indication PGD	Free text		Report clinical indication for each PGD cycle, for PUC FS02003- PGD biopsy and testing.		