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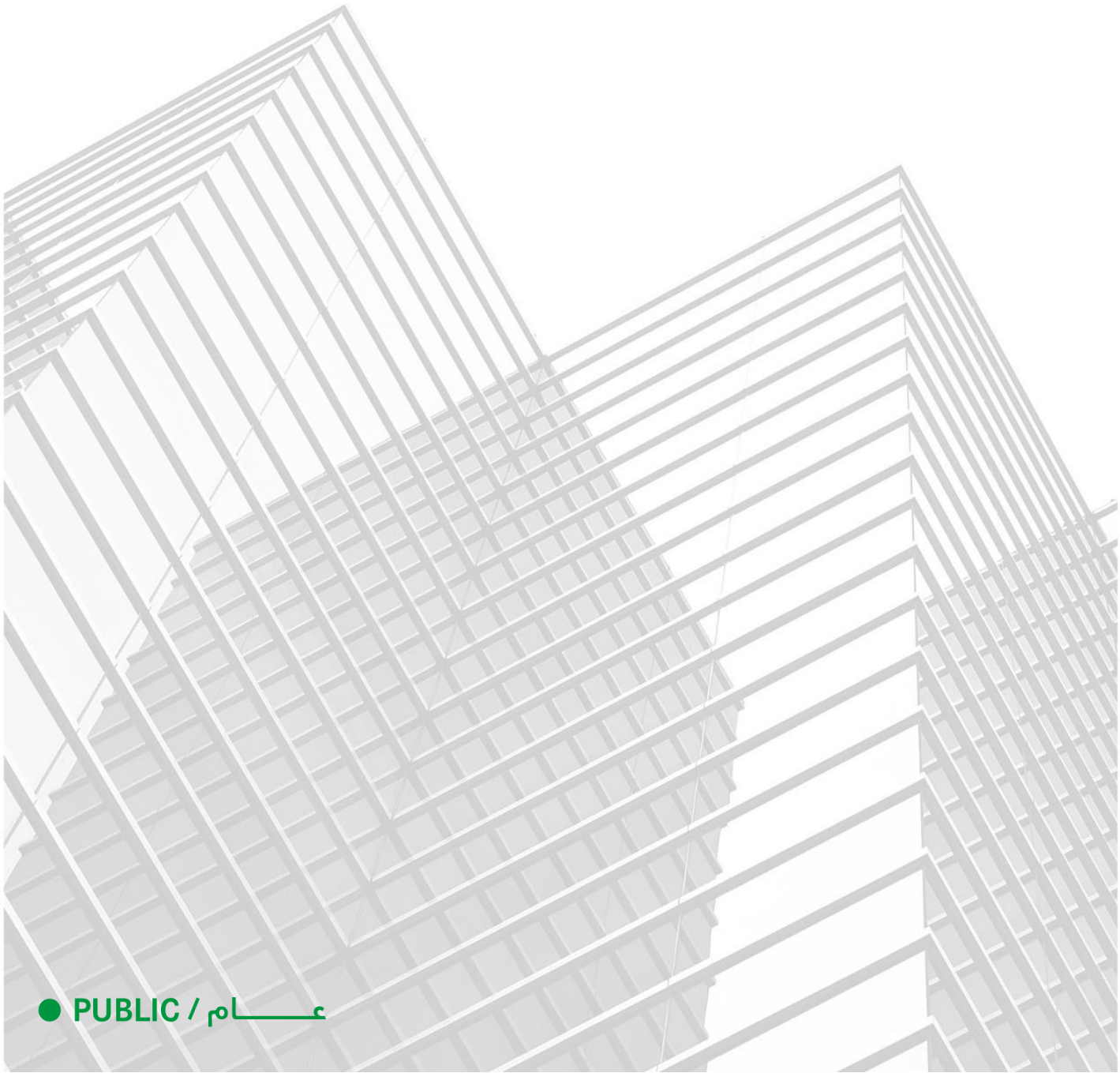
DEPARTMENT OF HEALTH

DOH Policy on THIQA Coverage for Assisted Reproductive Treatment and Services



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Applies To:	- DOH licensed Healthcare Providers of Assisted Reproductive Services. - THIQA's TPA.		
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Contact	Healthcare Payers Sector HealthSystemFinancing@doh.gov.ae		

A. Policy Purpose and Brief

This policy sets out the eligibility criteria for coverage of Assisted Reproductive Services by THIQA, the benefits that THIQA's holders are entitled to and the reimbursement packages that apply to THIQA's ART's network.

This document is not a guideline on a clinical management system. In no way does it replace the clinical judgement of the physician.

The purpose of this policy is to ensure that:

THIQA eligible patients in medical need of Assisted Reproductive Techniques, and who fulfill the legal requirements for initiating ART treatments, are covered for these treatments in accordance with evidence-based medical criteria Per Patient Per Year (PPPY);

Fertilization Centers will be reimbursed as per the package of services provided.

B. Definitions and Abbreviations

No.	Term / Abbreviation	Definition
2.1	Assisted Reproductive Techniques (ART)	ART includes any lawful treatments offered to couples experiencing reproductive problems for the purpose of establishing a pregnancy. These treatments include, but are not limited to, ovulation induction with timed intercourse, intrauterine insemination, in vitro fertilization, intracytoplasmic sperm injection, gamete cryopreservation, gamete intra fallopian transfer (GIFT).
2.2	Fertilization centres	Fertilization centres are any licensed facilities where assisted reproductive techniques are performed, including all clinical and biological procedures that are necessary to effectuate extracorporeal conception.
2.3	Infertility	Infertility is a disease of the male or female reproductive system defined by the failure to achieve a pregnancy after 12 months or more of regular unprotected sexual intercourse.1

[1] WHO https://www.who.int/news-room/fact-sheets/detail/infertility

2.4	Reduced Ovarian Reserve	A patient with a condition of low fertility where at least one of the following criteria is met: Advanced maternal age >40 years. A previous POR (≤3 oocytes with a conventional stimulation protocol). An abnormal ovarian reserve test [i.e. antral follicle count (AFC) less than 5–7 follicles or anti-Müllerian hormone (AMH) less than1.1 ng/ml]. OR Two cycles with poor ovarian response after maximum stimulation in the absence of the other criteria above.
2.5	Complete Full Cycle	Is one or more episodes of ovarian stimulation resulting in embryo transfer or more than one embryo transfer cycles originating from the same stimulation.
2.6	Incomplete Cycle	The ART cycle, which failed at any stage for any reason before oocyte or embryo freezing or embryo transfer.
2.7	Intracytoplasmic Sperm Injection (ICSI)	Procedure of injecting a spermatozoon into the cytoplasm of a mature oocyte.
2.8	Ovulation induction	A pharmacological treatment of women with anovulation or oligo-ovulation with the intention of inducing normal ovulatory cycles2. The maximum allowed trials per year of ovulation induction with gonadotropins injections is six trials.
2.9	Superovulation	A pharmacological treatment of ovulatory women with the intention of superovulation (for unexplained infertility, endometriosis etc). The maximum allowed trials per year and superovulation with gonadotropins injections is six trials.
2.10	Ovarian hyper-stimulation syndrome (OHSS)	An exaggerated systemic response to ovarian stimulation characterized by a wide spectrum of clinical and laboratory manifestations. It is classified as mild, moderate or severe according to the degree of abdominal distention, ovarian enlargement and respiratory, hemodynamic and metabolic complications3.
2.11	THIQA	Thiqa is a comprehensive health programme offered by the Abu Dhabi government to eligible UAE nationals & the like in the Emirate of Abu Dhabi.
2.12	THIQA patients	Members of the THIQA program.

[2] *https://www.who.int/reproductivehealth/publications/infertility/art_terminology.pdf*
[2] *https://www.who.int/reproductivehealth/publications/infertility/art_terminology.pdf*

C. Policy Content

3. Policy Statement

THIQA patients will be covered for Assisted Reproductive treatments where it is determined that such treatments are medically necessary and fulfill the here stated medical criteria.

4. Determination of Medical Necessity in Assisted Reproductive Treatments

4.1. The married couple have been trying for pregnancy for at least 1 year or one or both individuals have been diagnosed with infertility problems in line with definition of infertility in this Policy;

4.2. **Infertility may be diagnosed prior to one year if there are features or findings indicative of subfertility.** These include:

- 4.2.1. Oligo or amenorrhea;
- 4.2.2. Inability to have intercourse;
- 4.2.3. Previous adjuvant therapy for cancer in either partner;
- 4.2.4. History indicating an increased risk of Fallopian tube occlusion (i.e. previous pelvic infection or previous pelvic surgery);
- 4.2.5. Pelvic inflammatory disease;
- 4.2.6. Abnormality in one or more semen parameters as an indication of male factor infertility (volume <1.5 ml; pH <7.2; sperm concentration <15 million spermatozoa/ml; total sperm number: <39 million spermatozoa per ejaculate; total motility <40% motile, or <32% with progressive motility; vitality: <58% live spermatozoa; percentage of sperm with normal morphology <4%)[4];
- 4.2.7. Reduced ovarian reserve;
- 4.2.8. Men with diagnosed reproductive problems;
- 4.2.9. Cases where ART candidates are known to have chronic viral infection (e.g. HIV, Hepatitis B or Hepatitis C);
- 4.2.10. Known genetic/chromosomal disorders;

4.3. Pre-Cancer treatment Fertility Preservation: offered to married or single individuals prior to any oncology treatment due to its potential adverse effects on fertility.

4.4. Other medically necessary treatment Fertility Preservation: offered to married or single individuals prior to undergoing any medicinal regimen which could have potential adverse effects on fertility. (Refer to section 7.2.4 for the conditions.)

5. Case mix and Patient Eligibility

5.1. The preferred age range for women seeking fertility is between 18-47* years (completed years i.e. 18 years 0 days till less than 48 years 0 days). *For women aged 46 to 47 years (completed years i.e. from 46 years 0 days till less than 48 years 0 days), ART treatment could be considered if the AFC (antral follicle count only if done by a fertility expert) is equal to or above 5 (as per ESHRE Bologna criteria)

5.2. There is an exception to the lower age limit for fertility preservation (cryopreservation) in female patients diagnosed with cancer.

- 5.2.1. The patient could be less than 18 years of age.
- 5.2.2. Patient must have reached reproductive age (post-pubertal sexual maturity)
- 5.2.3. A person whose age is less than 18 years opting for ART treatment must have a substitute consent giver to sign on the application or request for the treatment.
- 5.2.4. Oncologist-approved fertility preservation documentation.
- 5.2.5. The following referral pathway must be established.

MDT (Multidisciplinary team) composition:

- Reproductive endocrinologist and infertility expert
- Oncologist
- Psychologist

[4] *WHO – World Health Organization*

5.3. BMI eligibility range for women seeking THIQA coverage for fertility treatment is from 19-40. However, women with BMI between 35-40 who are seeking fertility treatments should be:
  5.3.1. Informed of the increased risk of failure in fertility treatment and risk to pregnancy and child as a direct result of their physical condition; and
  5.3.2. Advised to consult a registered dietitian for weight management intervention for minimum of three months.

6. Covered Services

6.1. Treatment:

6.1.1. The most effective and least risk associated procedure should always be offered as a first line treatment option;
6.1.2. ART candidates known to have chronic viral infection (e.g. HIV, Hepatitis B or Hepatitis C) must be referred to DOH licensed facilities that have appropriate expertise in infectious diseases and facilities to provide investigation and specialized treatment.

6.2. Oocyte and embryo cryopreservation and pooling:

6.2.1. Freezing of healthy oocytes and embryos as clinically required is covered for the first year as part of the Bundled Package.
6.2.2. Coverage for cryopreservation for subsequent years will be on a year-by-year basis.
6.2.3. Pooling of oocytes and /or embryos before embryo transfer may be covered in cases of:
  6.2.3.1. Advanced Maternal Age (above 35 years);
  6.2.3.2. Patients with a previous POR (≤3 oocytes with a conventional stimulation protocol), or patients with an abnormal ovarian reserve test [i.e. antral follicle count (AFC) less than 5–7 follicles or anti-Müllerian hormone (AMH) less than1.1 ng/ml] or patients with two cycles with poor ovarian response after maximum stimulation in the absence of the POR and abnormal ovarian reserve criteria.
  6.2.3.3. Couple fertility preservation;
  6.2.3.4. Oncology patients;
  6.2.3.5. Genetic testing is required;
  6.2.3.6. Genetic conditions such as fragile X premutation and mosaicism for monosomy X;
  6.2.3.7. Autoimmune diseases;
  6.2.3.8. Endometriosis;
  6.2.3.9. Women who have been identified as carrying a BRCA1 or BRCA2 genetic mutation and have an increased risk of developing ovarian cancer or as a risk-reduction measure for women at very high risk of breast cancer before definitive treatment
  6.2.3.10. Young women with borderline ovarian tumors where fertility preservation is advisable.
6.2.4. Cost of excess storage time beyond 5 years or beyond the age of 47 completed years will be collected directly from patients.
6.2.5. All frozen embryos should be utilized before the start of a new fresh cycle except for patients who requires embryo pooling.
6.2.6. Clinical evidence such as radiological, laboratory results, and genetic reports should be provided for embryo pooling.
6.2.7. All frozen embryos should be utilized before the start of a new fresh cycle except for patients who requires embryo pooling.
6.2.8. Clinical evidence such as radiological, laboratory results, and genetic reports should be provided for embryo pooling.

6.3. Transfer of Embryos:

6.3.1. For patients undergoing an embryo transfer procedure, the number of embryos to be transferred should not exceed two embryos. (Appendix 2)

6.4. Medications:

6.4.1. Usage of gonadotropins injections by DOH licensed Reproductive Endocrinologists/ IVF Specialists and Consultants;
6.4.2. All medications required for fertility treatment require pre-authorization.

6.5. ICSI/IVF:

DOH laboratories licensed for IVF services should have in place written procedures approved by the nominated Director to manage the ICSI/IVF cases.

6.6. Clinical Investigations for ART Treatment:

Treatment Phase	Patient	Investigations
UAE Federal Requirements prior to handling of gametes for ART	Female and Male	HIV (I and II), Hepatitis B (Antigen / Antibody) and Hepatitis C Antibody
Recommended Baseline Investigations (To establish the diagnosis of infertility or to plan for the ART treatment)	Female	Blood type, Rhesus Factor
		CBC
		High Vaginal Swab, Syphilis, Chlamydia and Gonorrhea
		Rubella IgG
		Pap / Cervical smear
		TSH, Prolactin, AMH, FSH, LH, Estradiol, Vitamin D
		Transvaginal ultrasound
	Male	Blood type, Rhesus Factor
		Semen analysis, Syphilis
ART cycle - Investigations	Female	Estradiol, LH, FSH, Progesterone
		Ultrasound (Transvaginal or perineal or rectal or abdominal)
		Coagulation tests (PT, PTT and INR before each oocyte pickup (OPU))

6.7. Genetic Investigations:

6.7.1. Genetic investigations (i.e. Karyotyping) for certain clinical indications including the following:

6.7.1.1. Recurrent miscarriages;
6.7.1.2. Recurrent IVF implantation failure; and
6.7.1.3. Severe male factor of infertility.

6.7.2. PGT-A (PGS) test for certain clinical indications including the following:

6.7.2.1. Maternal age of >35 years old;
6.7.2.2. Advanced paternal age (>50 years old);
6.7.2.3. Severe male factor of infertility, where ICSI cycle is required (azoospermia -obstructive and non-obstructive, severe oligoastenoteratozoospermia, Klinefelter syndrome (KS), and Y-chromosome microdeletion, and men whose semen analysis does not fulfill the current World Health Organization (WHO) criteria on repeat sample analysis;
6.7.2.4. Recurrent miscarriages- two or more pregnancy losses before 24 weeks of gestation;
6.7.2.5. Recurrent IVF implantation failure- three or more failed embryo transfers involving at least four high quality embryos;
6.7.2.6. Family history of chromosome problems such as Down's syndrome; and
6.7.2.7. Reduced ovarian reserve as defined on this policy

6.7.3. Pre-implantation Genetic Diagnosis (PGT-M) can be considered for:

6.7.3.1. Patients diagnosed with an autosomal dominant or X-linked genetic disorder;
6.7.3.2. Couples who were both diagnosed as carriers of the same autosomal recessive disorder;
6.7.3.3. Patients diagnosed with mitochondrial disorders caused by mitochondrial DNA (mtDNA);
6.7.3.4. Consanguine marriage with history of single gene disorders; and
6.7.3.5. History of children with single gene disorder.

6.8. Number of Covered Cycles in relevant Bundle:

6.8.1. Maximum of six stimulations/natural cycles of egg retrieval Per Patient Per Year (PPPY) AND

6.8.2. Maximum of three embryo transfer cycles; i.e. embryo transfer episodes originating from one or more ART cycles Per Patient Per Year (PPPY).

6.9. Duration of covered bundle

6.9.1. Each bundle to be completed within 1 to 4 months.

D. Policy Roles and Responsibilities

7. Payment Authorization & Payment Bundles

7.1. Payer TPAs must comply with the THIQA's pre-authorization requirements, where appropriate, for payment for Assisted Reproductive treatments in accordance with this Policy and consistent with the Standard Provider Contract.

7.2. Payments will be bundled as follows:

7.2.1. Bundle 1- Fresh Cycle:

Is a bundle that covers a fresh cycle starting with one or more episodes of ovarian stimulation resulting in a fresh embryo transfer, including consultation, investigation, monitoring, collection of oocytes, fertilization, and oocytes and embryos cryopreservation as required.

7.2.1.1. Limit:

7.2.1.1.1. Maximum six retrievals (stimulated or natural) Per Patient Per Year (PPPY);

7.2.1.1.2. AND three embryo transfer cycles. i.e. (embryo transfer episodes originating from one or more ART cycles) Per Patient Per Year (PPPY);

7.2.1.1.3. All embryos that are normal will be transferred until all euploid embryos are exhausted, or pregnancy is established;

7.2.1.1.4. All excess embryos to be frozen at blastocyst stage;

7.2.1.1.5. All excess cryopreserved embryos to be exhausted before new fresh cycle is started.

7.2.2. Bundle 2- Embryo Storage

Is a bundle that covers embryo cryopreservation, starting with one or more episodes of ovarian stimulation resulting in embryo(s) freezing, including consultation, investigation, monitoring, collection of oocytes, and fertilization.

7.2.2.1. To be offered when:

7.2.2.1.1. Genetic testing is required;

7.2.2.1.2. The patient is at risk for OHSS;

7.2.2.1.3. High progesterone level during the follicular phase P4> 1.5ng/ml;

7.2.2.1.4. Endometrial fluid or polyp found;

7.2.2.1.5. Elective freezing.

7.2.2.2. Patient who require embryo pooling as indicated in section 6.2.2;

7.2.2.3. Limit:

7.2.2.3.1. Maximum six retrievals (stimulated or natural) PPPY;

7.2.2.3.2. Resulting embryos could be used for PGTA (Preimplantation Genetic Testing for Aneuploidy), PGTM and/or PGT-SR;

7.2.2.3.3. All normal embryos following genetic testing will be transferred until exhausted, or pregnancy is established before another bundle cycle can be started;

7.2.2.3.4. For categories 7.2.2.1.2., 7.2.2.1.3, 7.2.2.1.4, 7.2.2.1.5. all frozen embryos will be transferred until exhausted, or pregnancy is established before another Bundle 1 or Bundle 2 cycle can be started;

7.2.2.3.5. Oncology patients: Due to the urgency for treatment usually only one cycle can be done. Exception would be in cases of borderline tumors where more stimulations can take place before definitive treatment.

7.2.3. Bundle 3- Frozen Embryo Cycle

Is a bundle of a frozen cycle including consultation and monitoring then thawing one embryo or more resulting in embryo transfer.

7.2.3.1. Prerequisite of Bundle 1 or Bundle 2 and availability of existing frozen embryos.

7.2.3.2. Limit:

7.2.3.2.1. Three embryo transfer cycles. i.e. (embryo transfer episodes originating from one or more ART cycles) PPPY;

7.2.3.2.2. All embryos that are normal will be transferred until all euploid embryos are exhausted, or pregnancy is established prior to the start of another cycle;

7.2.4. Bundle 4- Egg Storage

Is a bundle that covers eggs cryopreservation to married or single individuals, starting with one or more episodes of ovarian stimulation resulting in eggs freezing, including consultation, monitoring investigation, and collection of oocytes.

7.2.4.1. To be offered Fertility preservation for:

7.2.4.1.1. Oncology patients

7.2.4.1.2. Genetic conditions such as fragile X premutation and mosaicism for monosomy;

7.2.4.1.3. Autoimmune diseases;

7.2.4.1.4. Endometriosis;

7.2.4.1.5. Women who have been identified as carrying a BRCA1 or BRCA2 genetic mutation and have an increased risk of developing ovarian cancer or as a risk-reduction measure for women at very high risk of breast cancer before definitive treatment;

7.2.4.1.6. Young women with borderline ovarian tumors where oocyte preservation is advisable. Oncology patients: Due to the urgency for treatment usually only one cycle can be done. Exception would be in cases of borderline tumors where more stimulations can take place before definitive treatment.

7.2.4.2. Limit:

7.2.4.2.1. Maximum six retrievals (stimulated or natural) per policy, per patient per year (PPPY).

7.2.5. Bundle 5- Frozen Egg Cycle

Is a bundle of a cycle starting with thawing eggs and resulting in embryo transfer, including consultation, monitoring, fertilization, and embryos cryopreservation as required.

7.2.5.1. Prerequisite of bundle 4 and availability of frozen eggs from previous cycles.

7.2.5.2. Limit:

7.2.5.2.1. Three embryo transfer cycles. i.e. (embryo transfer episodes originating from one or more ART cycles) PPPY;

7.2.5.2.2. Oncology patients: Due to the urgency for treatment usually only one cycle can be done. Exception would be in cases of borderline tumors where more stimulations can take place before definitive treatment.

7.3. Payments for services outside the bundle:

7.3.1. The following services will be covered outside the bundles:

7.3.1.1. Genetic screening of embryos - requires pre-authorization;

7.3.1.2. All medications- requires Pharmacy Benefits Approval;

7.3.1.3. Oocyte and embryo storage on yearly basis and up to 5 years OR the maximum age of 47 completed years;

7.3.2. All other ART services other than IVF and ICSI to be reimbursed as per the mandatory tariff.

7.4. Payments for incomplete cycles within the bundles

7.4.1. Successfully completed step(s) of an incomplete bundle shall be reimbursed as per the service codes specified on the DoH claims and adjudication rules.

8. Billing, Coding and Physician Documentation Information

Details on billing, coding and physician documentation can be found in the billing and adjudication rules published for ART bundled payments

E. Policy Scope of Implementation

This Policy applies to all THIQA categories and all DOH licensed ART providers within the Emirate of Abu Dhabi.

F. Enforcement and Compliance (Consequences/sanction of not applying policy by related stakeholder)

DOH-licensed ART's providers and THIQA's TPA must comply with the terms and requirements of THIQA's rules & regulations & the provisions of this Policy PPPY.

DOH may impose sanctions in relation to any breach of requirements under this Policy in accordance with the Disciplinary Regulations of the Healthcare Sector.

G. Monitoring and Evaluation (Key success factors)

DOH has put in place clear monitoring mechanisms to assess the policy.

H. Relevant Reference Documents

No.	Reference Date	Reference Name	Relation Explanation / Coding / Publication Links
1.	Jan 2023	Standard for Assisted Reproductive Technology Services and Treatment	DOH/SD/ART/1.4/2023

Note: In addition, this Policy should be read in conjunction with related Abu Dhabi and UAE laws, DOH Standards, Policies and Manuals including but not limited to:

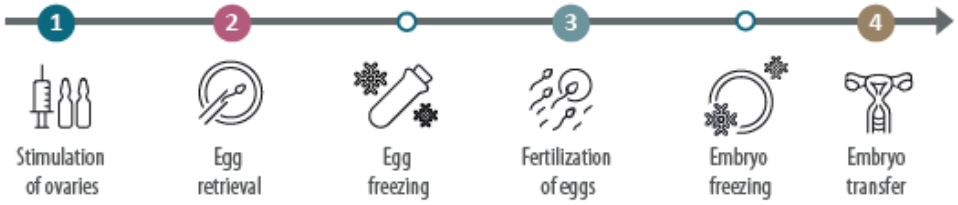
- HAAD Standard Provider Contract.
- DOH Quality Policy.
- DOH Regulator Manual.
- DOH Healthcare Provider Manual.
- DOH Health Professional Manual.
- DOH Standard on Patient Healthcare Data Privacy.
- DOH Policy on Health Information Exchange.
- Federal Law on Medical Liability.
- Federal Law on the Practice of Human Medicine.
- Federal Law on Assisted Reproduction

I.Revision List (Changes)			
Issue No.	**Revision Date**	**Clause No.**	**Revision Explanation (changes)**
1.	**8th Nov 2022**	3 Policy content, item 6.6	Revised minimum clinical investigation list
1.	**8th Nov 2022**	3 Policy content, item 5.2	Exemption to the lower age limit for cancer patients

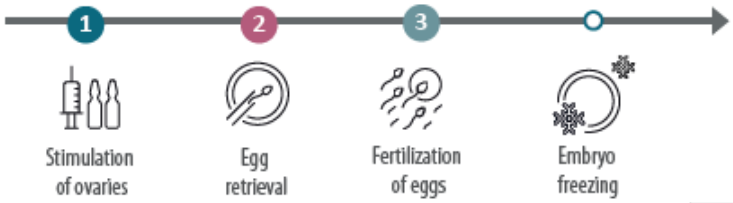
Appendices

Appendix 1: ART bundle packages

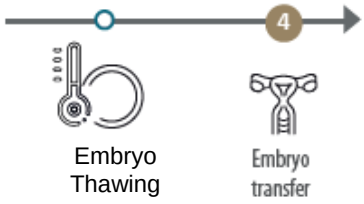
Bundle 1- Fresh Cycle



Bundle 2- Embryo Storage

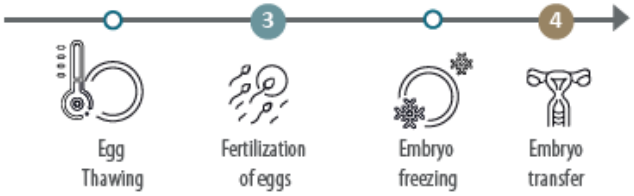


Bundle 3- Frozen Embryo Cycle



Bundle 4- Egg Storage

Bundle 5- Frozen Egg Cycle



Appendix 2: Possible contraindications for dual embryo transfer. (*Refer to clause number 6.3)

The treating clinician can consider these conditions and decide after complete clinical assessment including medical history, family history and investigations.

1. BMI less than <18 or >35
2. Short stature i.e. less than 150 cm
3. Small pelvis
4. Previous IVF success
5. Systemic diseases such as:
    - 5.1 Hypertension
    - 5.2 Diabetes
    - 5.3 Sickle cell
    - 5.4 Type 1 DM, Uncontrolled Type II DM, DM with end organ damage
    - 5.5 Chronic kidney disease
    - 5.6 Cardiopathy,
    - 5.7 Autoimmune diseases
6. High risk of developing deep vein thrombosis (DVT) like APS or ATIII deficiency or a personal history of unprovoked DVT
7. Previous history of twins
8. History of spontaneous preterm delivery
9. History of premature rupture of membranes
10. History of abnormal placentation such as placenta accreta, increta, percreta or previa
11. History of obstetrical complications or outcomes (intrauterine growth restriction, abruptio placentae, postpartum bleeding, intrauterine fetal death etc)
12. Two or more previous C-sections
13. Uterine/Mullerian anomalies such as septum, double uterus, etc.
14. Intramural fibroids >4 cm in diameter
15. Previous myomectomy of an intramural fibroid 4cm or larger
16. Patients having history for uterine surgery with opening of endometrial cavity