Australian Government Department of Health and Aged Care

Assisted Reproductive Technology Storage Funding Program

Guidelines



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Overview

The Assisted Reproductive Technology (ART) Storage Funding Program (hereafter referred to as the 'program') aims to reduce eligible patient's costs for preserving eggs, sperm, or embryos through cryostorage (freezing).

The purpose of this program is to support patients from two population groups who face extra costs associated with fertility preservation:

- people who require fertility treatment, including fertility preservation, due to a cancer diagnosis, and
- people at risk of passing on genetic conditions who have undergone pre-implantation genetic testing funded by the Medicare Benefit Schedule (MBS), as described in MBS items 13207, 73384, 73385, 73386 or 73387.

Under this program, the federal Government will make a payment to subsidise the cost of cryostorage of eggs, sperm, and embryos for eligible patients for a maximum of ten years per patient and per material stored.

This payment will be made directly to eligible ART clinics using a payment system managed by Services Australia. Patients will not receive any payment directly. Patients may not be charged out of pocket costs for cryostorage subsidised by the program.

The program has been established through an authority via the Financial Framework (Supplementary Powers) Regulations 1997 and will be administered as a demand-driven grant. The Grant Opportunity Guidelines are available from: <u>www.grants.gov.au</u>.

Please note that for the purposes of the program, applying for the grant will be done by registering with Services Australia. Please see <u>Section 3</u> for more information on the registration process.

These guidelines are intended to provide guidance to ART clinics and patients regarding details of the program. This program is not intended to alter current clinical practice or influence in any way the existing legislation, clinical guidelines and protocols that govern ART practice.

More information around the program can be found on the ART Storage Funding <u>website</u> and in the ART Storage Funding Grant Opportunity Guidelines, which will be published on <u>GrantConnect</u>.

Acknowledgements

The Department of Health and Aged Care (hereafter referred to as 'the Department') would like to thank consumer and ART sector stakeholders and clinical experts for their participation in developing the program.

1. Eligibility Requirements

1.1 Patient Eligibility

A patient is eligible for subsidised cryostorage under the program if they:

- Hold a valid Medicare card, and
- Seek cryostorage of:
 - up to two cryostorage services of different material types i.e., eggs, or sperm and embryos for fertility preservation due to a cancer diagnosis as evidenced by medical documentation, or
 - embryos for fertility preservation when there is a risk of passing on genetic conditions, and they have undergone pre-implantation genetic testing funded by the Medicare Benefit Schedule (MBS), as described in MBS items <u>13207</u>, <u>73384</u>, <u>73385</u>, <u>73386</u> or <u>73387</u> (further information <u>here</u>), and
- Consent to their ART clinic sharing their relevant personal information with the Department of Health and Aged Care and Services Australia in order to facilitate their participation in the program, as in <u>Section 5</u> of these program guidelines.

Each eligible patient can access up to a maximum of ten years of subsidised cryostorage.

CASE STUDY

Gino has cancer and is recommended to undergo fertility preservation treatment resulting in cryostorage of his sperm on 1 August 2024. Three years later, Gino is in good health and is no longer having cancer treatment, but still has sperm in cryostorage. Is Gino still eligible for the subsidy under this program?

Yes. Gino meets the eligibility requirements as there is evidence of his cancer diagnosis impacting his fertility, and his sperm sample commenced cryostorage on 1 August 2024.

Gino is eligible for the program subsidy for up to ten years or until the destruction, donation or thawing of his sperm sample (whichever comes first).

CASE STUDY

Min has melanoma in January 2024. Her fertility is not compromised during her treatment and no referral is made from her oncologist to a fertility specialist. Min chooses to freeze her eggs in April 2024 to expand her reproductive options into the future. Is Min eligible for this program?

No. Although Min did have cancer, she did not require fertility preservation as part of her cancer treatment. Her decision to place her eggs in cryostorage was due to personal choice, not due to fertility preservation treatment associated with melanoma. This means that Min is **not eligible** for this program.

In 2026, Min thaws her eggs and creates two embryos with her new partner, Felix. Felix is a carrier of a genetic disorder, so the couple decide to undergo pre-implantation genetic testing of their two embryos. As Felix is a carrier of a genetic condition, the PGT service was eligible for an MBS rebate. They use one embryo to successfully conceive a child, and elect to place the other embryo in cryostorage. Are Min and Felix eligible for this program?

Yes. Cryostorage of this embryo is eligible for funding under the program because Felix is known to be a carrier of a genetic disorder and the embryo underwent preimplantation genetic testing. Eligibility can be verified by MBS claims for items 13207, 73384, 73385, 73386 or 73387. Felix's ART clinic can submit a claim for subsidy under the program, under Felix's Medicare number.

1.2 Service Eligibility

A cryostorage service is eligible for subsidy under the program if:

- the cryostorage service commenced on or after 1 July 2023, and
- it is a cryostorage service for eggs, sperm or embryos provided by an eligible ART clinic (see <u>Section 1.3</u>), and
- it is a cryostorage service provided to an eligible patient (see Section 1.1), and
- the cryostorage subsidy limit of ten years has not been exceeded (see <u>Section 4.1</u>), and
- the patient has not been charged any additional, out-of-pocket costs for the cryostorage service (see <u>Section 1.5</u>), and
- the cryostorage service is not partly or fully subsided under any other Commonwealth, state or territory funded cryostorage service or program (see <u>Section</u> <u>1.5</u>), and
- it is not a duplicate cryostorage service (see <u>Section 1.5</u>).

Note that one 'cryostorage service' would include all storage samples of the same type of genetic material that are saved in one container (i.e., multiple storage of eggs from multiple cycles stored together would comprise one claim for one yearly payment under the program, and so forth).

A cryostorage service is **not** eligible for subsidy under this program if:

- it was placed into cryostorage with any facility before 1 July 2023, or
- it is a cryostorage service stored on behalf of a patient who is not eligible for the program (see <u>Section 1.1</u>), or
- the cryostorage subsidy limit of ten years has been exceeded (see Section 4.1), or
- the patient has been charged any additional, out-of-pocket costs for the cryostorage service (see <u>Section 1.5</u>), or
- the cryostorage service has been partly or fully subsided under any other Commonwealth, state or territory funded cryostorage service or program (see <u>Section</u> <u>1.5</u>), or
- it is a duplicate cryostorage service. Subsidy under this program is only available for eligible patients for up to two <u>different</u> types of cryostorage service (see <u>Section 1.5</u>).

CASE STUDY

Julia and Ahmet created several embryos. As Ahmet is a carrier of a genetic condition, they underwent MBS-rebated PGT testing before commencing cryostorage on April 1, 2023. Is this cryostorage service eligible for subsidy under this program?

No. Although Ahmet meets the patient eligibility requirements for PGT under the program, the storage service commenced **prior to 1 July 2023** which makes this cryostorage service ineligible for subsidy.

In April 2025, Julia and Ahmet complete another IVF cycle and create three embryos which also undergo MBS-rebated PGT. They decide to implant one embryo and place the remaining two into cryostorage. Is this cryostorage service eligible?

Yes. Ahmet meets the eligibility requirements because his shared embryo underwent PGT due to his being a carrier of a genetic disorder. The cryostorage service commenced after 1 July 2023, making this service eligible for the program subsidy. Only one member of the reproductive couple needs to meet the PGT eligibility for this subsidy to be provided for embryo storage.

CASE STUDY

Eddie has cancer and is recommended to undergo fertility preservation before he receives gonadotoxic treatment as part of his cancer treatment plan. Eddie has a sperm sample placed in cryostorage on 1 May 2023.

Eddie's cancer treatment plan is changed and his gonadotoxic treatment is delayed. In the meantime, his doctors recommend that another round of fertility treatment collection should be undertaken. Eddie's second sperm sample is placed into cryostorage on 1 August 2023. This second sample is placed in the same container and Eddie's ART clinic only charges him for one cryostorage service for both samples. Is this cryostorage service eligible for subsidy under the program?

Yes. Eddie's initial fertility preservation treatment resulted in sperm being placed into cryostorage prior to 1 July 2023. By itself, that service was not eligible for program subsidy.

However, because Eddie's gonadotoxic treatment schedule changed and his doctors recommended a further round of fertility treatment for clinically relevant reasons, the storage service now includes material which was placed in cryostorage after 1 July 2023. As such this cryostorage service will now be eligible for program subsidy.

Eddie is eligible for the program subsidy for up to ten years from 1 August 2023, when the eligible sperm sample was placed into cryostorage, or until the destruction, donation or thawing of the sperm samples in this container (whichever comes first).

1.3 ART Clinic Eligibility

An ART clinic is eligible for the program if they:

- hold a current licence from RTAC (Reproductive Technology Accreditation Committee),
- register with Services Australia's Organisation Register (see Section 3),
- sign a Grant Agreement with the Department (see Grant Opportunity Guidelines, published on <u>GrantConnect</u>, for more information), and
- meet all requirements detailed in these program guidelines.

1.4 Evidence of Eligibility

ART clinics must be able to provide evidence:

- that their clinic holds a current RTAC licence,
- that the patients for whom the clinic is seeking a subsidy are eligible for the program (see <u>Section 1.5</u>),
- that the cryostorage services for which the clinic is seeking a subsidy are eligible for the program (see <u>Section 1.2</u> & <u>Section 5.1</u>),
- that the clinic has not charged the patient any out-of-pocket costs for cryostorage services being subsidised under this program, and
- that the clinic has received consent from all eligible patients to seek a subsidy under this program (see <u>Section 5.2</u>).
 - Patients must consent to their personal information relating to the program being shared with Services Australia and with the Department of Health and Aged Care to facilitate claims for the subsidy to be paid on their behalf and for program assurance purposes, statistical and evaluation purposes and to inform program policies.

Examples of evidence of a patient's eligibility for the program may include:

- for cancer patients: a referral to fertility specialist from another doctor (e.g. GP, oncologist, endocrinologist, haematologist) may act as evidence of eligibility, and
- for patients at risk of passing on genetic conditions and who have undergone preimplantation genetic testing: evidence of the patient being billed for Medicare Benefits Schedule (MBS) items 13207, 73385, 73384, 73386 or 73387 may act as evidence of eligibility.

1.5 Exclusion Criteria

Exclusions to the program include:

- For the purposes of this program, cancer is considered a malignant neoplasm and excludes conditions such as benign tumours or other medical conditions where gonadotoxic treatment and fertility preservation may be required,
- Patients who undertake pre-implantation genetic testing, who are *not* known carriers of genetic conditions, are ineligible for this program. These patients will not satisfy

eligibility requirements for claiming MBS items 13207, 73385, 73384, 73386 or 73387,

- Cryostorage services for eggs, sperm or embryos which were placed in storage prior to 1 July 2023 are not eligible for subsidy under the program,
- Where a patient's cryostorage service is partly or fully subsided under any other Commonwealth, state or territory funded cryostorage service or program, it is not eligible for this program,
- Only one subsidy may be claimed per eligible patient, per storage period and per eligible cryostorage service, and
- Any cryostorage service for which an ART clinic has charged any additional, out-ofpocket costs is not eligible for subsidy under this program.

CASE STUDY

Meredith chooses to freeze her eggs in April 2022 as a personal choice to expand her reproductive options into the future. In February 2024, Meredith is diagnosed with cancer. Is she eligible for subsidy under this program?

Meredith's existing cryostorage is not eligible for subsidy under this program as the cryostorage service commenced prior to 1 July 2023.

If Meredith receives clinical advice that she now requires fertility preservation treatment due to her cancer diagnosis, resulting in cryostorage of eggs or embryos after 1 July 2023, these later samples will be eligible for subsidy under this program.

If the later eggs are placed in the same container as the earlier eggs and Meredith is only charged once for the container's cryostorage, then the whole container may be eligible for subsidy under the program. The container would be eligible from the date that the later eggs (those gathered in order to preserve fertility after her cancer diagnosis) were added.

CASE STUDY

Craig is using a state-funded public IVF cryostorage facility to store his sperm due to a cancer diagnosis and subsequent fertility preservation treatment. Craig is not being charged for this cryostorage. Can this clinic apply for subsidy under this program for Craig?

No. Patients who are receiving other publicly funded cryostorage services are not eligible for this program.

CASE STUDY

Asha is an eligible PGT patient and stored an embryo with an ART clinic in Victoria in August 2023. In January 2024, Asha moves to QLD with a new partner. She and her partner choose to create an embryo, undergo MBS-rebatable PGT testing and place their embryo into cryostorage at an ART clinic in QLD. Are both these embryo cryostorage services eligible for subsidy under this program?

No. Under the eligibility criteria outlined in <u>Section 1.1</u> and <u>Section 1.2</u>, subsidy under this program is only available for up to two <u>different</u> types of cryostorage service.

Asha will need to decide which ART clinic may claim subsidy under this program for the embryo cryostorage service they have provided her. Asha will need to pay for the other embryo cryostorage service herself.

Alternatively, Asha may choose to arrange for her embryo stored at the Victorian clinic to be transferred to the Queensland clinic, where both embryos may be able to be stored in the same container as one cryostorage service (see <u>Section 1.2</u>).

CASE STUDY

Francine and her partner have created several embryos across a few rounds of fertility preservation treatment. Francine is a carrier of a genetic condition, so she is eligible for MBS-rebated PGT testing, and all embryos are tested before being placed into cryostorage.

The embryos are stored in more than one container and are billed as more than one cryostorage service. What may Francine's ART clinic claim subsidy for from the program on her behalf?

Francine's clinic may claim subsidy for **one cryostorage service for the same type of material for each eligible patient**. So they may claim once from the program for embryo cryostorage provided to Francine.

Any additional cryostorage embryo services which Francine is receiving from the clinic may be charged to Francine as per usual practice.

2. Commencement

The program commenced on 1 July 2023 and is ongoing.

3. Subsidy Payments

3.1 Subsidy Amount

The subsidy amount is up to \$600 per year per patient and per eligible cryostorage service.

Payments of up to \$300 will be made in arrears on a 6 monthly basis. The first payment period will cover cryostorage of eligible services from 1 July to 31 December 2023. The first payments will be made in early 2024.

The payment amount will be calculated on a monthly pro-rata basis: i.e. eligible cryostorage services will be subsidised for storage from the first day of the month in which they are placed in storage, to the last day of the month in which the cryostorage service ends.

The subsidy amount will be periodically reviewed by the Department of Health and Aged Care in consultation with the sector.

The subsidy amount is subject to indexation annually on 1 July in line with the Wage Price Index (WPI).

Subsidies will be paid directly to eligible ART clinics via a payment system managed by Services Australia. No payments will be made directly to patients.

ART clinics are not permitted to charge additional out-of-pocket fees for cryostorage services that are subsidised under this program (see <u>Section 1.4</u> & <u>Section 1.5</u>).

CASE STUDY

Aliya has cancer and because of her diagnosis undergoes fertility preservation treatment to retrieve eggs which are placed in cryostorage on 15 September 2024. Aliya's ART clinic requests the program subsidy for this service but is unsure how to manage their claim for subsidy for the month of September.

Because the subsidy is paid on a monthly pro-rata basis commencing at the start of the month in question, the subsidy for this service will be paid from 1 September 2024. Aliya's ART clinic will need to lodge one claim every 6 months.

So in this case Aliya's ART clinic lodge a claim in January 2025 requesting the program subsidy be paid for Aliya for September – December 2024. They can then claim every 6 months thereafter for the full 6 month cryostorage period.

Two years later, Aliya is in good health. She thaws her eggs on 10 November 2026 and undergoes IVF treatment to create embryos. The ART clinic is unsure how to manage their claim for subsidy for Aliya for November 2026.

Because the subsidy is paid on a monthly pro-rata basis, the subsidy for this service will cease on 30 November 2026. Aliya's ART clinic can claim the final payment of the subsidy on her behalf in the next claim submission period (January 2027) and they will be paid for cryostorage from July 2026 – November 2026.

3.2 Registration of ART Clinics

To facilitate payments, ART clinics will be required to register their details with the Services Australia Organisation Register prior to making any claim for eligible cryostorage services (See <u>Section 3.3</u>).

Details required to register with the Organisation Register include the ART clinic's:

- ABN,
- Bank details,
- Address,
- Contact details such as a phone number and nominated contact person for the clinic, and
- RTAC licence number

Once they have registered, ART clinics will enter into a Grant Agreement with the Department. Initial grants will be in place until the end of FY2026-27. New grant agreements will be established to cover subsequent years.

More information on how to register can be found on the ART program <u>website</u>, in the '*ART* Storage Funding Program - Fact Sheet for Program Registration'.

More information on the Grant Opportunity and grant agreement is available in the Grant Opportunity Guidelines, which can be found on the <u>GrantConnect</u> website.

3.3 Payment of Subsidies

Payments will be made in arrears on a 6-monthly pro-rata basis.

Every 6 months, ART clinics will lodge claims with Services Australia for all eligible cryostorage services they provided over the previous 6 months.

Detailed information on the Services Australia payment mechanism and how to lodge claims will be published in late 2023.

CASE STUDY

Yumi and Dan undergo MBS-rebated PGT testing and commence cryostorage of their embryo on 1 February 2024. Because Yumi is a carrier of a genetic disorder, she is eligible for MBS pre-implantation genetic testing item <u>73385</u>, and therefore eligible for subsidy under this program. Yumi and Dan decide to thaw this embryo on 20 November 2024 and go on to conceive a baby. How does the ART clinic submit claims for subsidy for these 10 months of storage?

The clinic will submit the claim under Yumi's Medicare card number and note that she is eligible due to undergoing MBS-rebated PGT. Evidence of payment of MBS item 73385 will support the eligibility of this claim if evidence is required during post-payment compliance activities.

The ART clinic will lodge a claim for program subsidy for February 2024 – June 2024 in one claim submission period, and then for July 2024 – November 2024 in the next claim submission period. The clinic must note in the second claim that storage ceased in November 2024.

3.4 Claim process

Every 6 months, ART clinics will lodge claims with Services Australia for all eligible cryostorage services they provided over the previous 6 months. The claim must itemise each eligible cryostorage service for which the ART clinic are seeking payment of the program subsidy.

Note that each 'cryostorage service' would include all storage samples of the same type of genetic material that are saved in one container (i.e., multiple eggs from multiple cycles stored together would comprise one claim for one yearly payment of \$600, and so forth).

The first claim submissions under this program will be lodged in January 2024, for the storage period 1 July – 31 December 2023. Payment for these claims will be made in early 2024.

Services Australia will:

- validate claim submissions,
- work with ART clinics to ensure the service information in the claim is complete and correct as required,
- make payment to each ART clinic for validated storage services, and
- provide a payment statement to the ART clinic with details of payment made.

Detailed information on how to lodge claims will be published in late 2023.

3.5 Payment Statement

A payment statement will be provided to each ART clinic by Services Australia for each storage period once payments have been made to the clinic.

3.6 Queries

For questions on how to lodge claims contact: <u>ASSISTED.REPRODUCTIVE.TECHNOLOGY@servicesaustralia.gov.au</u>.

For general questions on the program or grant agreements contact: <u>Medical.Indemnity@health.gov.au</u>.

4. Cessation of Funding

4.1 Subsidy Limits

Subsidies are available for a maximum of ten years per person per material (i.e. egg, sperm, embryo). The ten years do not need to be continuous.

Patients may continue to store their materials beyond the subsidy period. In this case, storage payment arrangements will be made directly between the ART clinic and the patient.

CASE STUDY

Lissa and Kerry create an embryo with Lissa's egg and donor sperm. Lissa is a carrier of a genetic disorder, and the embryo has undergone MBS-rebated PGT, therefore she is eligible for this program. The embryo commenced cryostorage on 1 August 2024 and is thawed five years later on 1 August 2029 with the hope of conceiving a baby. Sadly, this attempt fails, and Lissa and Kerry repeat the PGT process with another embryo. This embryo also undergoes MBS-rebated PGT. It is placed into cryostorage on 1 August 2031 and is stored for 5 years. How many years of subsidy is Lissa eligible for under the program?

All eligible patients have access to a maximum of ten years cryostorage subsidy per material, under this program. The ten years do not need to be continuous.

Lissa used ten years of storage in total: two separate cryostorage services which lasted 5 years each. She had a two year 'gap' in between. The two year 'gap' in cryostorage service does not count towards Lissa's ten-year subsidy limit. Therefore, Lissa's ART clinic can claim for all ten years of embryo cryostorage.

Using donor sperm does not affect eligibility for this program in any way.

CASE STUDY

Sebastian has cancer. In January 2025 he and his partner are advised by his fertility specialist to seek cryostorage of both sperm and embryos. Sebastian requires extended cancer treatment, which is successful. 4 years later Sebastian and his partner thaw their embryos to start a family. The embryos are used to successfully conceive.

Two years later, Sebastian and his partner thaw his sperm so they may undergo IVF treatment to create more embryos. Is Sebastian eligible for a subsidy for both sperm and embryo cryostorage?

Yes. An upper limit of ten years per person per material is applied to this program. Sebastian is storing two different types of material, sperm and embryos.

Sebastian's ART clinic can enter Sebastian into the program when his materials enter cryostorage and claim the subsidy on his behalf for both the sperm and embryos every 6 months. They can claim the subsidy for the embryos for the 4 years they are in cryostorage, and for the sperm for the full 6 years that is in cryostorage.

4.2 Donation or Destruction of Genetic Material

If an eligible cryostorage service ceases due to the destruction of eggs, sperm, or embryos, the ART clinic's claim must reflect this (i.e., they may only lodge a claim for the portion of the 6-month storage period that passed before the material was destroyed).

If an eligible patient's eggs, sperm, or embryos are donated to another individual, reproductive partnership or organisation, then from the date of transfer the cryostorage service is no longer eligible for subsidies under this program and cannot be claimed by the ART clinic; unless the other individual is also eligible for the program.

4.2 Death of a patient

The death of a patient is a situation where sensitivity needs to be exercised and as such the following provisions will apply:

1. If a patient dies with one or more embryos in cryostorage, their surviving reproductive partner (the person who created the embryo with them) will become eligible for this program and subsidies may continue in their name.

If the surviving reproductive partner wishes to continue the cryostorage in their name, the ART clinic will need to:

- a. gain consent from the surviving reproductive partner to enter the program, and to share their personal information with Services Australia and the Department of Health and Aged Care, (See <u>Section 5.2</u>), then
- b. lodge claim for subsidy for this cryostorage service under the Medicare number of the surviving partner as a new patient.
- c. In this case, the ten year storage limit will renew under the surviving reproductive partner's name.

CASE STUDY

Anton has cancer and has been advised by his doctors to seek fertility preservation treatment. Anton and his partner Gabrielle create an embryo using both their genetic materials and place this embryo in cryostorage. Anton is eligible for subsidy under this program and his ART clinic claims accordingly.

Sadly, Anton dies 8 years later. Gabriella wishes to continue cryostorage of their embryo and is wondering whether the program subsidy is available to her and for how long.

Yes. Gabriella is now eligible for subsidy under this program. As she created the embryo with Anton, she is Anton's surviving reproductive partner and is now considered eligible for the program in regards to the embryo they created together.

Anton's ART clinic may now claim subsidy under the program under Gabriella's Medicare number. Gabriella is now eligible for up to ten years' storage subsidy.

- 2. If a patient dies with embryo/s, sperm or eggs in cryostorage and legal arrangements are in place for transfer of ownership to another person, subsidies may continue until the first of the below takes place:
 - a. ownership has been transferred, or
 - b. for a grace period of up to 2 years, or
 - c. until the material is donated or destroyed at the person's request, or
 - d. until the original ten year limit that applied to the deceased patient's cryostorage service is reached.

CASE STUDY

Nadia is 15 when she is diagnosed with cancer and referred for fertility preservation treatment. She undergoes egg retrieval, and her eggs are placed in cryostorage on 1 April 2024. Nadia is eligible for the program and the ART clinic submits for subsidy accordingly.

Unfortunately, Nadia dies 4 years later at the age of 19. Nadia had stipulated in her will that ownership of her eggs would be transferred to her sister, Isla. It takes 18 months for legal transfer of egg ownership to take place. Can the ART clinic continue to claim the program subsidy during this 18 month period after Nadia's death?

Yes. The program allows for the continuation of subsidy payments for a 'grace period' of up to 2 years in the case where a patient dies and transfer of ownership is taking place to a legal beneficiary.

Nadia's ART clinic can continue to claim under Nadia's Medicare number for the 18month period during which legal processes are underway to transfer ownership. Once Isla legally owns these eggs, subsidy under this program will cease.

- 3. If a patient dies with sperm or eggs in cryostorage and there are no legal arrangements in place for transfer of ownership to another person, in recognition of the time it may take for an ART clinic to become aware of the patient's death, subsidies may continue until the first of the below takes place:
 - a. for a grace period of up to one program storage period, or
 - b. until the material is donated or destroyed at the family's request, or

c. until the original ten year limit that applied to the deceased patient's cryostorage service is reached.

CASE STUDY

Eligible patient Wes has sperm in cryostorage. He dies in February 2033, and has no legal arrangements in place for transfer of ownership of the sperm he has in cryostorage. Wes's sperm has been in cryostorage for 8 years. What further subsidy is available for the deceased Wes's cryostorage service?

Wes's cryostorage service has not exceeded its ten year limit. Wes's death has triggered a **one-storage-period grace period**, which means this cryostorage service can receive subsidy under the program up to the end of the storage period in which Wes died.

In this example, the next claim submission would cover the storage period of January 2033 – June 2033. This whole storage period will be honoured, and the subsidy paid for those six months. Any subsequent claims for this cryostorage service will not be honoured.

Please note that cryostorage services may continue for any eggs, sperm or embryos which become ineligible for subsidy under the program, however payment will need to be sought from the patient/family.

5. Clinic obligations

All ART clinics registered to receive funding through the program must:

- obtain and keep a record of consent from all eligible patients to seek a subsidy under this program, detailed in <u>Section 5.2</u>,
- ensure their information in the Organisation Register remains up to date,
- maintain a RTAC Licence as evidence that they are compliant with industry requirements for providing safe and high quality cryostorage services,
- notify Services Australia within 28 calendar days if they lose their RTAC Licence,
- meet eligibility requirements detailed in <u>Section 1.3</u> and <u>Section 1.4</u>,
- ensure that none of the cryostorage services for which they claim the subsidy are subject to any exclusion criteria detailed in <u>Section 1.5</u>,
- follow the claim submission process and claim subsidies for eligible cryostorage services every 6 months detailed in <u>Sections 3.3 – 3.6</u>,
- provide a statement to each patient every 6 months once they have received subsidy payments for that patient's eligible cryostorage service/s,
- engage fully in compliance activities undertaken by the Department or agents acting on the Department's behalf, detailed in <u>Section 5.1</u>, and
- keep a copy of all documents relating to the ART Storage Funding program requirements for a minimum of 7 years.

5.1 Program compliance

The Department may undertake post-payment compliance activities at any time to ensure that ART clinics comply with these program guidelines. Program compliance activities may include a post-payment review of practice documents. If your practice is unable to provide information to support eligibility and the claims you have made, the Department may look to recover your past payments.

Registered ART clinics must willingly engage fully in compliance activities undertaken by the Department or agents acting on the Department's behalf. This includes being able to provide evidence:

- to support eligibility of their each cryostorage service for which they have claimed subsidy under this program,
- that they have an RTAC licence,
- that they have obtained consent from all eligible patients to seek the subsidy under this program for their eligible cryostorage service/s and share their relevant personal information as outlined in <u>Sections 5</u> and <u>5.2</u> and that they have kept a record of this consent for each eligible patient,
- that no additional out-of-pocket fees for storage were charged for patients subsidised under this program, and
- that they have provided statements to patients every 6 months, including details on subsidies paid by the Government for their eligible cryostorage service/s and information on how to cease the cryostorage (see <u>Section 5.2</u>).

ART clinics must also:

- provide accurate, timely information to the Department as requested through program compliance activities,
- keep a copy of all documents relating to the ART Storage Funding program requirements for a minimum of 7 years.

The Department reserves the right to recover any payments that have been inappropriately claimed.

5.2 Patient Consent and Notifications

ART clinics must obtain and keep a record of consent from all eligible patients that they may seek subsidies under this program for cryostorage services provided to that patient.

As part of this, patients must consent to their personal information relating to the program being shared with Services Australia and with the Department of Health and Aged Care to facilitate claims for the subsidy to be paid on their behalf and for program assurance purposes, statistical and evaluation purposes and to inform policy development. ART clinics must retain records of this informed patient consent for a minimum of 7 years, as per <u>Section</u> <u>5: Clinic Obligations</u>.

ART clinics must inform patients of the way their personal information will be collected and used by showing patients the ART Storage Funding Program Privacy Collection Notice

(notice), which will be available on the Department of Health and Aged Care's ART Storage Funding Program <u>website</u>.

The notice provides information on what patient information will be collected and used for the program. Patients choosing to be in the program after having read and acknowledged the notice agree to their information being collected and used in this way for the purposes of the program.

ART clinics are also required to ask patients at the end of each storage period whether they still want their eligible cryostorage service/s to remain in cryostorage. The method by which this is undertaken is a decision for each ART clinic.

ART clinics must provide a statement to the patient every 6 months once they have received the program payment, noting:

- that the federal Government paid for the cryostorage service rendered by the ART clinic,
- that \$0 is owing for this cryostorage service,
- the period of subsidised cryostorage (i.e., may be a portion of the 6 month period),
- which material/s storage was subsidised (i.e., eggs, sperm, embryo/s), and
- instructions for the patient regarding how to proceed if they no longer require the storage service/s.

6. Privacy

The privacy and security of your clinic's information and your eligible patients' personal information is important to the Services Australia and the Department and is protected by law. Services Australia collects this information for the purposes of managing your clinic's application and payments under this program.

Services Australia will share your clinic's personal information and your eligible patients' personal information with the Department for program assurance purposes, for statistical and evaluation purposes and to inform policy development. Services Australia and the Department will only share the information with other parties where you have agreed, or where the law allows or requires it.

You can find more information about the way in which Services Australia and the Department will manage your eligible patients' personal information at:

www.servicesaustralia.gov.au/privacy-policy

https://www.health.gov.au/resources/publications/privacy-policy

7. Program Evaluation

The Department of Health and Aged Care will evaluate the program as part of the quality assurance process to ensure it is achieving its intended purpose. Any future changes to the program will be reflected in updated program guidelines and stakeholders will be notified.

8. Disclaimer

While it's intended that the Australian Government will make payments as set out in these guidelines, payments are made at its sole discretion.

The Australian Government may alter arrangements for the program at any time and without notice.

The Australian Government does not accept any legal liability or responsibility for any injury, loss or damage incurred by the use of, reliance on, or interpretation of the information provided in these guidelines. You are encouraged to regularly visit the website of the Department of Health and Aged Care to check for updated information about the program. The guidelines contain links to external websites to help you find more information. You need to make your own decisions about the accuracy, currency, and reliability of information in linked websites.

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Definitions

	For the purposes of this program, an ART clinic is considered an
ART clinic	entity providing ART services to patients.
Cancer	Cancer is a large range of diseases in which some of the body's cells become defective, begin to multiply out of control, can invade and damage the area around them, and can also spread to other parts of the body to cause further damage. ¹ For the purposes of this program, cancer is considered a malignant neoplasm and excludes conditions such as benign tumours or other medical conditions where gonadotoxic treatment and fertility
Distinct cryostorage service	preservation is required.If multiple items are stored in the one container, this is consideredone cryostorage service and only one claim may be made for thiscryostorage service. If a patient goes through a subsequentprocedure to create another sample and it is clinically appropriate toadd this sample to the existing container, then this would remain onecryostorage service
Reproductive partner	For the purposes of this program, a reproductive partner is the partner of an eligible patient and is the person with whom the eligible patient has created an embryo.
Storage period	A 'cryostorage service' storage period is considered to be the time period between a sample of a patient's cryopreserved material being placed in a cryostorage container and the time when all material comprising the sample has been exhausted i.e. thawed, donated, or destroyed.

Table of Abbreviations

ART	Assisted Reproductive Technology
MBS	Medical Benefits Schedule
PGT	Pre-implantation genetic testing
RTAC	Reproductive Technology Accreditation Committee
WPI	Wage Price Index

¹ Cancer - Australian Institute of Health and Welfare (aihw.gov.au)

Medical.Indemnity@health.gov.au

All information in this publication is correct as at 8 August 2024.

