



# Pre-implantation Genetic Testing (PGT) services

Last updated: 12 July 2021

- The Australian Government announced \$95.9 million in funding for Pre-implantation Genetic Testing (PGT) listing on the Medicare Benefits Schedule (MBS) on 9 May 2021.
- Five new items will be implemented on the MBS from 1 November 2021 to support eligible Australians to access this testing.
- The five new items to be listed on the MBS include an item to test the reproductive couple for pathogenic variants (73384), one surgical item for an embryo biopsy from an at risk couple as identified by the first test (13207), and a further three items for genetic testing of the biopsied embryo(s) (73385, 73386, 73387).
- Eligibility for PGT items are restricted to patients and (if relevant) a reproductive partner with a recognised risk of having a child affected by a Mendelian or mitochondrial disorder, autosomal dominant disorder, or chromosome disorder, for which there is no curative treatment and there is a severe limitation of quality of life despite contemporary management.

## What are the changes?

From 1 November 2021 five new MBS items will be available to eligible patients, these include:

- New MBS item 73384 (pathology service), for the genetic analysis of samples from a patient and (if relevant) their reproductive partner to identify Mendelian or mitochondrial mutations, autosomal dominant mutations, or chromosomal abnormalities which place the patient at a clinical risk of having a child who develops the disorder. Eligibility for this service is dependent on:
  - there being no curative treatment for the disorder, for which there is severe limitation of quality of life despite contemporary management;
  - the service being provided for the purpose of providing an assay for PGT; and
  - the patient having had a consultation with a clinical geneticist.
- New MBS item 13207 (therapeutic procedure), for an embryo biopsy for the purpose of providing a sample for PGT, where the patient fulfils the criteria of item 73384.
- New MBS items 73385, 73386, 73387 (pathology services), where the patient meets the criteria specified in 73384, for the genetic analysis of the biopsied embryonic tissue for the purpose of providing a PGT of one (73385), two (73386), or three or more (73387) embryos.
- The MBS items have the following additional restrictions:
  - 13207, 73385, 73386, 73387 – Medicare rebates are restricted to one PGT test per embryo produced during a single Assisted Reproductive Treatment (ART) cycle.
  - 73384, 73385, 73386, 73387 – genetic tests must be requested by a specialist or consultant physician.



## Why are the changes being made?

The Medical Services Advisory Committee (MSAC) recommended public funding of PGT. Following this recommendation, the Department of Health established a PGT Working Group to assist with the significant and complex implementation issues. MSAC supported the proposed MBS items in March 2020 and subsequently the Australian Government agreed public funding of PGT as part of the 2021-22 Budget.

## What does this mean for providers/referrers/other stakeholders?

Specialists and consultant physicians will be able to request MBS funded PGT. To be eligible for Medicare rebates, laboratories providing these services must be accredited according to the pathology accreditation standards specified in the Health Insurance (Accredited Pathology Laboratories-Approval) Principles 2017.

## How will these changes affect patients?

PGT is used by couples or individuals who know they carry a serious genetic disorder (and are therefore at risk of having affected offspring). PGT is applied within the IVF process to detect specific genetic or chromosomal abnormalities prior to implantation and pregnancy. During the IVF cycle, the created embryos have a small number of cells extracted and these cells are tested for specific genetic variations.

With the implementation of these new PGT items, from 1 November 2021 couples with a high risk of having a child affected by a genetic disorder will be able to access PGT and receive a Medicare rebate. The eligibility and Medicare rebates for Medicare funded IVF services will not change under this proposal.

The genetic disorders that meet the eligibility criteria for these services must have no curative treatment and have a severe limitation of quality of life despite contemporary management. This includes, but is not limited to disorders such as:

- cystic fibrosis
- muscular dystrophy
- spinal muscular atrophy
- neurofibromatosis
- fragile X
- haemophilia
- Tay-Sachs
- thalassemia
- achondroplasia
- epidermolysis bullosa
- Huntington's
- Friedreich ataxia
- Dravet syndrome and
- ichthyosis.



Due to the complex and continuously changing field, the eligible disorders are dependent on the professional judgement of the treating practitioner.

## Who was consulted on the changes?

Consultation has been undertaken with key stakeholders, clinical experts and providers, and consumer health representatives as part of the MSAC process.

To address the concerns raised by the MSAC, the Department established a PGT Working Group in September 2018. The PGT Working Group included clinical experts from the fields of pathology, genetics and reproductive medicine as well as legal and ethical experts. The terms of reference for the Working Group included:

- defining eligibility parameters for patient population accessing proposed PGT MBS services;
- ensuring appropriate clinical expertise, clinical governance and quality of proposed MBS PGT services; and
- developing MBS item descriptors and information on appropriate fees for proposed MBS PGT services.

## How will the changes be monitored and reviewed?

PGT MBS items will be subject to MBS compliance processes and activities, including random and targeted audits which may require a provider to submit evidence about the services claimed.

Significant variation from forecasted expenditure may warrant review and amendment of the items and fees, and incorrect use of MBS items can result in penalties including the health professional being asked to repay monies that have been incorrectly received.

PGT MBS items will be reviewed by MSAC approximately 24 months post-implementation.

## Where can I find more information?

If you have a query relating to interpretation of the MBS, you should email [askMBS@health.gov.au](mailto:askMBS@health.gov.au). Subscribe to 'News for Health Professionals' on the Services Australia website to receive regular news highlights: <https://www.servicesaustralia.gov.au/organisations/health-professionals/news/all>.

If you are seeking advice in relation to Medicare billing, claiming, payments, or provider numbers, please visit the Health Professionals page on the Services Australia website or contact their Provider Enquiry Line – 13 21 50.

The MSAC Public Summary Document provides the full MSAC advice to the Minister and is available via the Department's website at <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1165.1-public>.

*This sheet is current as of the Last updated date shown above and does not account for MBS changes since that date.*