How your scheme must cover solid organ transplants

At the beginning of 2012 the Council for Medical Schemes (CMS) published a document defining solid organ transplants and clarifying the benefits covered by your medical scheme should you require this treatment. This edition of CMScript takes a closer look at solid organ transplants and your entitlements enshrined in legislation.

What is a solid organ transplant?
A solid organ transplant is defined as moving an internal organ from one body to another for the purpose of replacing the recipient's damaged or absent organ. Solid organs include the heart, liver, and kidneys. The donor can be alive, brain-dead, or medically and legally deceased.

What is covered by legislation?
A solid organ transplant is a prescribed minimum benefit (PMB) captured in the Medical Schemes Act 131 of 1998. PMB cover includes:

1. evaluating the recipient;
2. evaluating the donor (living or deceased);
3. in-hospital care of both recipient and donor, including ventilator costs in the case of either a brain-dead donor or a cadaver to make sure the organ is kept alive and functioning, harvesting (the removal of the organ from the donor’s body), transportation, preservation, and the transplant surgery itself; and
4. post-operative care and follow-up of both recipient and living donor.

Why is the recipient evaluated?
The recipient of the solid organ is evaluated by a medical professional to:

1. exclude any absolute or relative contraindication to the proposed procedure;
2. assess the suitability and degree of illness of each patient to better allocate resources and optimise survival;
3. assess whether the patient is psychologically ready to receive the transplant;
4. assess the factors that may affect after-care compliance; and
5. establish whether the intended recipient's organ failure has reached end stage in conditions where transplants are recommended only at end-stage organ failure, e.g. kidney disease.

How is a live donor evaluated?
The evaluation of a living donor consists of three phases: psychosocial assessment, compatibility assessment, and medical assessment. The search for a suitable donor usually starts with family members and widens if necessary until a match is found.

1. Psychosocial assessment
A preliminary psychological assessment is done to determine the person’s desire to donate while providing them with information on the risks associated with the procedure and all information required to give informed consent. A cooling-off period of about three months is allowed for the donor to consider their decision. A full social assessment is then conducted to evaluate possible social and financial risks which the donor may face after donation.

2. Compatibility assessment
After the donor has agreed to voluntary donate an organ and the three-month cooling-off period has passed, the second phase is to determine if the donor is compatible with the recipient. Blood type should be determined before proceeding with a medical assessment. Other compatibility tests include cross-matching (determining compatibility of blood from a donor.
to a recipient before a transfusion) and tissue-typing (a series of diagnostic tests before a transplant to determine whether the tissues of a donor and recipient are compatible).

3. Medical suitability

This phase includes the consultation with a physician to screen and exclude certain medical conditions. The medical assessment must be done by a physician who is not involved in the care of the recipient to ensure an independent opinion. The main aim of this assessment is to gauge the donor’s health, try and predict the risks associated with organ donation and the surgery itself, exclude infections and malignancy, and assess the transplantability of the organ being donated. The assessment includes consultation with various clinicians as well as diagnostic and pathology tests.

How is a cadaver or a brain-dead donor evaluated?

There is a difference between a cadaver and someone who is brain-dead.

A cadaver is a human body which is dead from a medical and legal point of view, but it remains attached to a medical ventilator and continues to receive blood and oxygen. This is done to preserve its organs.

A brain-dead donor is a donor whose cerebral (or brain stem) function has stopped working. Brain-dead donors are not dead in medical or legal terms.

The evaluation of a cadaver and brain-dead donor includes blood tests to exclude infections and determine compatibility. Certain diagnostic tests (an x-ray, Magnetic Resonance Imaging (MRI) scans, or a sonar) might be required to assess the condition of the organ.

During an evaluation, the care of brain-dead patients usually extends to a few hours after they are certified as brain-dead. The aim in providing care for a brain-dead donor before harvesting is for the organ to maintain normal blood flow and laboratory parameters, including adequate oxygen.

INCLUSION CRITERIA

What are the inclusion criteria for a recipient?

Before you or a family member can qualify to receive an organ transplant, you have to meet specific inclusion criteria:

1. Age and medical fitness

Age on its own is not a criterion for being listed but medical fitness is. An older patient (over 55 years of age) should only receive an older donor’s organ as the life expectancy of the organ should correlate with the life expectancy of the recipient. Older recipients should expect to live at least five more years after the transplant before they can be considered for a transplant.

2. HIV status

If you have the human immunodeficiency virus (HIV), you can be considered for transplants, but you should first be started on anti-retroviral treatment for at least six months before the transplant and your viral load should be less than 400 copies/ml. Patients should use the anti-retroviral correctly and comply with the use of such medicine. An HIV-positive patient may receive an organ from an HIV-positive donor.

3. Tuberculosis

Patients with TB must be treated for the disease, complete the course of treatment, and be declared cured before they can have an organ transplant.

4. Alcohol abuse and alcoholism

Alcoholics may face challenges which may affect their adherence to post-transplant treatment. The exclusion of alcoholics should be based on a psychosocial assessment and the clinical risk factors that may threaten the success of the transplant. Similarly, the exclusion of recovering alcoholics should be based on the outcome of a psychosocial evaluation and decisions made by the multidisciplinary transplant team.

5. Cancer

Patients with cancer are eligible for transplants only if their cancer is curable or in remission.

6. Non-compliance to treatment

A history of non-compliance alone may not be used to exclude you from treatment. People with a history of non-compliance should be counselled.

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to understand the requirements of treatment adherence, and supported.

7. Debilitating diseases

Sick recipients with a poor prognosis should not be considered for a transplant. They are not being unfairly discriminated against based on their illness, which would be unconstitutional and therefore illegal. Instead, they are being discriminated against fairly based on the availability of resources and overall survival rate. Diseases with poor prognosis reduce overall survival rate, and render a transplant uneconomical and unaffordable.

8. Obesity

A body mass index (BMI) above 35 may increase post-operative complications. Obesity is a relative exclusion, and patients cannot be excluded from a solid organ transplant based on obesity alone. A full risk assessment is required.

9. Immunisation

All transplant recipients must provide proof of receiving South African childhood immunisation. Otherwise, they should receive immunisation at least six weeks before the transplant. Patients should receive annual immunisations such as the flu vaccination after the transplant as well because they can get immune-compromised from the immunosuppressive medication which must be taken after the operation.

10. Approval of the transplant by a multidisciplinary team

Transplants depend on the availability of resources and the equitable distribution of organs. The decision to carry out a transplant must always be made by a multidisciplinary team experienced in transplants. The Minister of Health has accredited facilities which can perform solid organ transplants.

11. South African citizenship

The Minister of Health must approve transplants in non-South Africans.

What are the inclusion criteria for a living donor?

1. Free will and informed consent

   - The donor must understand the donation procedure, and benefits and risks associated with it.
   - The donor must be of legal age (18 or older).
   - The donor must be able to give consent.
   - The donor must give informed consent. Healthcare workers should enable the participant to make an informed decision by presenting the risks and benefits associated with organ donation.
   - The decision to donate must be independent and free of financial or social coercion.
2. Medical eligibility

- A living donor may not suffer from any mental illness as defined in Section 58 of the National Health Act 61 of 2003, nor meet any of the criteria in the Diagnostic and Statistical Manual of Mental Disorders IV of the American Psychiatric Association. (The DSM-IV is used internationally as a detailed diagnosis tool of all mental health conditions.)

- The donor must have a BMI of 18-35.

- The donor’s blood group must be compatible with the recipient’s.

- No significant signs indicating that you may react adversely to the anaesthetic, may be present.

- No bacterial, viral, fungal, or parasitic infections may be present.

- The living donor should not be pregnant.

- No diseases associated with the organ being donated may be present.

- The donor should not have any cardiovascular or neurological diseases.

- The donor must not have had cancer in the five years leading up to the donation.

- A history of substance and/or alcohol misuse is not an exclusion by itself. The multidisciplinary team should assess the donor and confirm that the problematic substance and/or alcohol misuse has stopped. Patients suffering from substance and/or alcohol misuse are not mentally competent to give consent.

What are the inclusion criteria for a cadaver and a brain-dead donor?

- Cadavers and brain-dead donors must be 70 years of age or younger.

- Premature babies (weighing less than 500g) cannot donate organs.

- No cancer may be present.

- The cadaver may not have had cancer with evident metastasis (which is when the cancer spreads to other organs or parts of the body).

- No aplastic anaemia (a condition where the bone marrow produces an insufficient amount of red blood cells or stops producing them altogether) may be present.

- No multiple organ failure may have been experienced.

- No bacterial, viral, fungal, or parasitic infections may be present.

What is harvesting?

Harvesting is the removal, preservation, and use of human organs and tissue from the bodies of cadavers and brain-dead people to be used in surgical transplants on the living.

- The living donor should not be pregnant.

- No diseases associated with the organ being donated may be present.

- The donor should not have any cardiovascular or neurological diseases.

- The donor must not have had cancer in the five years leading up to the donation.

3. Psychological eligibility

- Donors must be emotionally stable, and without any mental illness.

- Donors must be related to the recipient, emotionally and/or genetically, or they can be an unrelated “good Samaritan” or a paired donor (see sidebar for definition). Unrelated donors are subject to the approval of the Minister of Health.

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SURGERY AND IN-HOSPITAL CARE

The care for a solid organ transplant includes the surgery itself as well as post-operative recovery in hospital, all of which must be covered by your medical scheme in full. This includes all diagnostic and pathological tests, drugs, and all material required to care for the patient after the operation.

Post-operative care and follow-up

Care of donors

Post-operative care of donors includes a medical follow-up to monitor how the donor is functioning without the donated organ, to monitor the healing process, and to manage all complications associated with donation that may arise, including pain management. Donors must have access to physiotherapy and occupational therapy during recovery. Care of these patients includes all pathological and diagnostic tests, and consultations.
Care (including the management of all complications as a result of the surgery) must be provided until the donor has fully recovered.

**Care of recipients**

Care of recipients should include:

- consultations with relevant clinicians, including psychotherapists and professionals on the transplant team;
- rehabilitation by a physiotherapist and/or occupational therapist;
- radiology tests to assess the functionality of the organ;
- pathological tests to monitor potential complications due to the transplant (this includes a test to diagnose complications after the immunosuppressive drugs that must be taken after a transplant, have been taken);
- a lifetime’s supply of immunosuppressive drugs (which prevent the rejection of the transplanted organ/s);
- a lifetime’s supply of medicines to prevent and/or alleviate the side effects associated with immunosuppressive therapy; and
- pain treatment.

**Funding donor organs**

**Recipients**

Organ donation is a prescribed minimum benefit (PMB), and your medical scheme must therefore cover in full all the costs associated with the pre-surgery evaluation, the surgery itself, in-hospital care, and lifetime care, as per Regulation 8 of the Medical Schemes Act. Harvesting is paid for by the medical scheme of the recipient as part of in-hospital care.

**Living donor**

Although post-surgery care lasts only six weeks, the donor’s medical scheme must cover follow-up consultations for as long as the donor remains a member of the medical scheme. If you stop being a member of a medical scheme, you still need follow-ups, either for your own account at a private facility or at a state facility for free. These follow-ups are limited to periodic screenings for diseases associated with transplants, and do not include the management of complications detected after the six week post-operative care period.
Due to the donor and the recipient belonging to two different medical schemes, the costs associated with a transplant are divided. The donor’s medical scheme must fund the donor’s long-term follow-ups, which include the screening for diseases associated with the donated organ. This must be funded as a prescribed minimum benefit. The recipient’s scheme and the donor must inform the donor’s scheme of the donor’s intentions to donate an organ prior to proceeding with the transplant.

**Brain-dead or cadaver donor**

The cost of maintaining the body of a brain-dead or cadaver donor on a ventilator after brain death and the harvesting of the organ is covered by the recipient’s medical scheme. If the cadaver yields more than one organ for donation, the cost of keeping the cadaver donor on a ventilator and harvesting must be equally distributed amongst the recipients’ schemes. If the cadaver or brain-dead donor has donated more than one organ, the recipients’ medical schemes may enquire about the organs donated to ensure that they are appropriately billed.

There is currently no solid organ bank in South Africa, so costs associated with the storage of solid organs do not apply in this country.

**References**


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