

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State of VIRGINIA

STANDARDS FOR THE COVERAGE OF ORGAN TRANSPLANT SERVICES

The following criteria will be used to evaluate specific organ transplant requests.

§1.1 Patient Selection Criteria for Provision of Kidney Transplantation (KT). (12 VAC 30-50-540)

- A. Transplantation of the kidney is a surgical treatment whereby a diseased kidney is replaced by a healthy organ. Pre-authorization is required. The following patient selection criteria shall apply for the consideration of all approvals for coverage and reimbursement for kidney transplantation.
1. Current medical therapy has failed and patient has failed to respond to appropriate conservative management;
 2. The patient does not have other systemic disease including but not limited to the following:
 - a. reversible renal conditions;
 - b. major extra-renal complications (malignancy, systemic disease, cerebral cardio-arterial disease);
 - c. active infection;
 - d. severe malnutrition; or
 - e. pancytopenia.
 3. The patient is not in both an irreversible terminal state and on a life support system;
 4. Adequate supervision will be provided to assure there will be strict adherence to the medical regimen which is required;
 5. The KT is likely to prolong life and restore a range of physical and social function suited to activities of daily living;
 6. A facility with appropriate expertise has evaluated the patient, and has indicated willingness to undertake the procedure;
 7. The patient does not have multiple uncorrectable severe major system congenital anomalies;
 8. Failure to meet (1) through (7) above shall result in denial of pre-authorization and coverage for the requested kidney transplant procedures.

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§1.2 Facility Selection Criteria for Kidney Transplantation (KT).

- A. For medical facility to qualify as an approved Virginia Medicaid provider for performing kidney transplants, the following conditions must be met:
1. The facility has available expertise in immunology, infectious disease, pathology, pharmacology, and anesthesiology;
 2. The KT program staff has extensive experience and expertise in the medical and surgical treatment of renal disease;
 3. Transplant surgeons on the staff have been trained in the KT technique at an institution with a well-established KT program;
 4. The transplantation program has adequate services to provide specialized psychosocial and social support for patients and families;
 5. Adequate blood bank support services are present and available;
 6. Satisfactory arrangements exist for donor procurement services;
 7. The institution is committed to a program of at least 25 KTs a year;
 8. The center has a consistent, equitable, and practical protocol for selection of patients (at a minimum, the DMAS Patient Selection Criteria must be met and adhered to);
 9. The center has the capacity and commitment to conduct a systematic evaluation of outcome and cost;
 10. In addition to hospital administration and medical staff endorsement, hospital staff support also exists for such a program;
 11. The hospital has an active, ongoing renal dialysis service;
 12. The hospital has access to staff with extensive skills in tissue typing, immunological and immunosuppressive techniques;

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13. Initial approval as KT center requires performance of 25 KTs within the most recent 12 months, with a one-year survival rate of at least 90%. Centers that fail to meet this requirement during the first year will be given a one-year conditional approval. Failure to meet the volume requirement following the conditional approval will result in loss of approval.

§2.1 Patient Selection Criteria for Provision of Corneal Transplantation (CT). (12 VAC 30-50-550)

- A. Transplantation of the cornea is a surgical treatment whereby a diseased cornea is replaced by a healthy organ. While pre-authorization is not required, the following patient selection criteria shall apply for the consideration of all approvals for reimbursement for cornea transplantation.
 1. Current medical therapy has failed and will not prevent progressive disability;
 2. The patient is suffering from one of the following conditions:
 - a. Post-cataract surgical decompensation,
 - b. Corneal dystrophy,
 - c. Post-traumatic scarring,
 - d. Keratoconus, or,
 - e. Aphakia Bullous Keratopathy;
 3. Adequate supervision will be provided to assure there will be strict adherence by the patient to the long term medical regimen which is required;
 4. The CT is likely to restore a range of physical and social function suited to activities of daily living;
 5. The patient is not in both an irreversible terminal state and on a life support system;

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6. The patient does not have untreatable cancer, bacterial, fungal, or viral infection;
7. The patient does not have the following eye conditions:
 - a. Trichiasis,
 - b. Abnormal lid brush and/or function,
 - c. Tear film deficiency,
 - d. Raised transocular pressure,
 - e. Intensive inflammation, and
 - f. Extensive neo-vascularization.

§2.2 Facility Selection Criteria for Cornea Transplantation (CT).

- A. For medical facility to qualify as an approved Medicaid provider for performing corneal transplants, the following conditions must be met:
 1. The facility has available expertise in immunology, infectious disease, pathology, pharmacology, and anesthesiology;
 2. The CT program staff has extensive experience and expertise in the medical and surgical treatment of eye disease;
 3. Transplant surgeons on the staff have been trained in the CT technique at an institution with a well-established CT program;
 4. The transplantation program has adequate services to provide social support for patients and families;
 5. Satisfactory arrangements exist for donor procurement services;
 6. The institution is committed to a program of eye surgery;
 7. The center has a consistent, equitable, and practical protocol for selection of patients (at a minimum, the DMAS Patient Selection Criteria must be met and adhered to);
 8. The center has the capacity and commitment to conduct a systematic evaluation of outcome and cost;

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9. In addition to hospital administration and medical staff endorsement, hospital staff support also exists for such a program;
10. Initial approval as CT center requires performance of corneal transplant surgery, with a one-year graft survival rate of at least 75%. Centers that fail to meet this requirement during the first year will be given a one-year conditional approval. Failure to meet this requirement following the conditional approval will result in loss of approval.

§3.1 Liver, heart, lung, allogeneic and autologous bone marrow transplantation (12 VAC 30-50-560)

Patient selection criteria for provision of liver, heart, allogeneic, and autologous bone marrow transplantation

1. The following general conditions shall apply to these services;
 - a. Coverage shall not be provided for procedures that are provided on an investigational or experimental basis.
 - b. There must be no effective alternative medical or surgical therapies available with outcomes that are at least comparable.
 - c. The transplant procedure and application of the procedure in treatment of the specific condition for which it is proposed have been clearly demonstrated to be medically effective.
 - d. Prior authorization by the Department of Medical Assistance Services (DMAS) is required. The prior authorization request must contain the information and documentation as required by DMAS.
2. The following patient selection criteria shall apply for the consideration of authorization and coverage and reimbursement:

The patient selection criteria of the transplant center where the surgery is to be performed shall be used in determining whether the patient is appropriate for selection for the procedure. Transplant procedures will be pre-authorized only if the selection of the patient adheres to the transplant center's patient selection criteria, based upon review by DMAS of information submitted by the transplant team or center.

The recipient's medical condition shall be reviewed by the transplant team or program according to the transplant facility's patient selection criteria for that procedure and the recipient shall be determined by the team to be an appropriate transplant candidate. Patient selection criteria used by the transplant center shall include, but not necessarily be limited to, the following:

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- a. Current medical therapy has failed and the patient has failed to respond to appropriate therapeutic management;
- b. The patient is not in an irreversible terminal state, and
- c. The transplant is likely to prolong life and restore a range of physical and social function suited to activities of daily living.

3.2. Facility Selection Criteria for Liver, Heart, Allogeneic and Autologous Bone Marrow Transplantation

1. The following general conditions shall apply:
 - a. Procedures may be performed out-of-state only when the authorized transplant cannot be performed in the Commonwealth because the service is not available or, due to capacity limitations, the transplant cannot be performed in the necessary time period.
 - b. Criteria applicable to transplantation services and centers in the Commonwealth also apply to out-of-state transplant services and facilities.
2. To qualify for coverage, the facility must meet, but not necessarily be limited to, the following criteria:
 - a. The transplant program staff has demonstrated expertise and experience in the medical and surgical treatment of the specific transplant procedure;
 - b. The transplant surgeons have been trained in the specific transplant technique at an institution with a well-established transplant program for the specific procedure;
 - c. The facility has expertise in immunology, infectious disease, pathology, pharmacology, and anesthesiology;
 - d. The facility has staff or access to staff with expertise in tissue typing, immunological and immunosuppressive techniques;
 - e. Adequate blood bank support services are available;
 - f. Adequate arrangements exist for donor procurement services;
 - g. Current full membership in the United Network for Organ Sharing, for the facilities where solid organ transplants are performed;

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- h. Membership in a recognized bone marrow accrediting or registry program for bone marrow transplantation programs;
- i. The transplant facility or center can demonstrate satisfactory transplantation outcomes for the procedure being considered;
- j. Transplant volume at the facility is consistent with maintaining quality services;
- k. The transplant center will provide adequate psychosocial and social support services for the transplant recipient and family;

§ 3.3. High dose chemotherapy and bone marrow/stem cell transplantation (coverage for persons over 21 years of age). (12 VAC 30-50-570)

- A. Patient selection criteria for high dose chemotherapy and bone marrow/stem cell transplantation (coverage for persons over 21 years).
 - 1. The following general conditions shall apply to these services:
 - a. This must be the most effective medical therapy available yielding outcomes that are at least comparable to other therapies.
 - b. The transplant procedure and application of the procedure in treatment of the specific condition for which it is proposed have been clearly demonstrated to be medically effective.
 - c. Prior authorization by the Department of Medical Assistance Services (DMAS) is required. The prior authorization request must contain the information and documentation as required by DMAS. The nearest approved and appropriate facility will be considered.
 - 2. The following patient selection criteria shall apply for the consideration of authorization and coverage and reimbursement for individuals who have been diagnosed with lymphoma, breast cancer, or leukemia and have been determined by the treating health care provider to have a performance status sufficient to proceed with such high dose chemotherapy and bone marrow/stem cell transplant:
 - a. The patient selection criteria of the transplant center where the treatment is to be performed shall be used in determining whether the patient is appropriate for selection for the procedure. Transplant procedures will be preauthorized only if the selection of the patient adheres to the transplant center's patient selection criteria based upon review by DMAS of information submitted by the transplant team or center.

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- b. The recipient's medical condition shall be reviewed by the transplant team or program according to the transplant facility's patient selection criteria for that procedure and the recipient shall be determined by the team to be an appropriate transplant candidate. Patient selection criteria used by the transplant center shall include, but not necessarily be limited to the following:
 - (1) The patient is not in an irreversible terminal state (as demonstrated in the facility's patient selection criteria), and
 - (2) The transplant is likely to prolong life and restore a range of physical and social functions suited to activities of daily living.

- B. Facility selection criteria for high dose chemotherapy and bone marrow/stem cell transplantation for individuals diagnosed with lymphoma, breast cancer, or leukemia.
 - 1. The following general conditions shall apply:
 - a. Unless it is cost effective and medically appropriate, procedures may be performed out of state only when the authorized transplant cannot be performed in the Commonwealth because the service is not available or, due to capacity limitations, the transplant cannot be performed in the necessary time period.
 - b. Criteria applicable to transplantation services and centers in the Commonwealth also apply to out-of-state transplant services and facilities.

 - 2. To qualify for coverage, the facility must meet, but not necessarily be limited to, the following criteria:
 - a. The transplant program staff has demonstrated expertise and experience in the medical treatment of specific transplant procedure;
 - b. The transplant physicians have been trained in the specific transplant technique at an institution with a well-established transplant program for the specific procedure;
 - c. The facility has expertise in immunology, infectious disease, pathology, pharmacology, and anesthesiology;
 - d. The facility has staff or access to staff with expertise in tissue typing, immunological and immunosuppressive techniques;

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- e. Adequate blood bank support services are available;
- f. Adequate arrangements exist for donor procurement services;
- g. Membership in a recognized bone marrow accrediting or registry program for bone marrow transplantation programs;
- h. The transplant facility or center can demonstrate satisfactory transplantation outcomes for the procedure being considered;
- i. Transplant volume at the facility is consistent with maintaining quality services; and
- j. The transplant center will provide adequate psychosocial and social support services for the transplant recipient and family

12VAC30-50-580. Other medically necessary transplantation procedures that are determined to not be experimental or investigational (coverage for persons younger than 21 years). (12VAC 30-50-580)

A. Patient selection criteria for any other medically necessary transplantation procedures that are determined to not be experimental or investigational.

1. The following general conditions shall apply to these services:

- a. Coverage shall not be provided for procedures that are provided on an investigational or experimental basis.
- b. There must be no effective alternative medical or surgical therapies available with outcomes that are at least comparable.
- c. The transplant procedure and application of the procedure in treatment of the specific condition for which it is proposed have been clearly demonstrated to be medically effective and not experimental or investigational.
- d. Prior authorization by the Department of Medical Assistance Services is required. The prior authorization request must contain the information and documentation as required by DMAS.

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2. The following patient selection criteria shall apply for the consideration of authorization and coverage and reimbursement:
 - a. The patient must be under 21 years of age at time of surgery.
 - b. The patient selection criteria of the transplant center where the surgery is to be performed shall be used in determining whether the patient is appropriate for selection for the procedure. Transplant procedures will be preauthorized only if the selection of the patient adheres to the transplant center's patient selection criteria, based upon review by DMAS of information submitted by the transplant team or center.

The recipient's medical condition shall be reviewed by the transplant team or program according to the transplant facility's patient selection criteria for that procedure and the recipient shall be determined by the team to be an appropriate transplant candidate. Patient selection criteria used by the transplant center shall include, but not necessarily be limited to, the following:

- (1) Current medical therapy has failed and the patient has failed to respond to appropriate therapeutic management;
- (2) The patient is not in an irreversible terminal state, and
- (3) The transplant is likely to prolong life and restore a range of physical and social function suited to activities of daily living.

B. Facility selection criteria.

1. The following general conditions shall apply:
 - a. Procedures may be performed out of state only when the authorized transplant cannot be performed in the Commonwealth because the service is not available or, due to capacity limitations, the transplant cannot be performed in the necessary time period.
 - b. Criteria applicable to transplantation services and centers in the Commonwealth also apply to out-of-state transplant services and facilities.

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2. To qualify for coverage, the facility must meet, but not necessarily be limited to, the following criteria:
 - a. The transplant program staff has demonstrated expertise and experience in the medical and surgical treatment of the specific transplant procedure;
 - b. The transplant surgeons have been trained in the specific transplant technique at an institution with a well-established transplant program for the specific procedure;
 - c. The facility has expertise in immunology, infectious disease, pathology, pharmacology, and anesthesiology;
 - d. The facility has staff or access to staff with expertise in tissue typing, immunological and immunosuppressive techniques;
 - e. Adequate blood bank support services are available;
 - f. Adequate arrangements exist for donor procurement services;
 - g. Current full membership in the United Network for Organ Sharing, for the facilities where solid organ transplants are performed;
 - h. Membership in a recognized bone marrow accrediting or registry program for bone marrow transplantation programs;
 - i. The transplant facility or center can demonstrate satisfactory transplantation outcomes for the procedure being considered;
 - j. Transplant volume at the facility is consistent with maintaining quality services;
 - k. The transplant center will provide adequate psychosocial and social support services for the transplant recipient and family.