Benefit Coverage

<table>
<thead>
<tr>
<th>Covered Benefit for lines of business including:</th>
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<tr>
<td>Health Benefits Exchange (HBE), RIte Care (MED), Children with Special Needs (CSN), Substitute Care (SUB), Rhody Health Partners (RHP), Rhody Health Expansion (RHE), Rhody Health Options (RHO) Unity, Rhody Health Options (MMP) Integrity</td>
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<tr>
<th>Excluded from Coverage:</th>
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<td>Extended Family Planning (EFP)</td>
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Description

Transplant services include non-experimental human organ transplant of an organ or tissue from one person to another or from a cadaver. Organs that can be transplanted include heart, lung, kidney, kidney-pancreas (for members with Type 1 Diabetes only), liver, intestinal, bone marrow and stem cell.

Except as otherwise required by law, Neighborhood Health Plan of Rhode Island (Neighborhood) does not cover experimental or investigative treatment or drugs.

*Autologous transplantation* involves the transplanting of tissue from one part of the body to another, as when a person’s blood or stem cells are removed, stored, and later given back to the patient.

*Allogenic transplantation* involves transplanting of tissue or organs from one patient to another, as in the case of transplanting stem cells from donor to recipient.

Coverage Determination

Organ transplantation requires coordination of financial and clinical information to facilitate optimal outcomes. Neighborhood’s Transplant Contract Coordination Case Management program provides a framework for an organized flow of information exchange and decision making between internal departments and external parties.

Neighborhood’s expectation is that transplant facilities follow best practices to ensure the best outcomes for our members. The facility’s protocol must be submitted at the time of the transplant evaluation request.

Neighborhood’s benefit coverage determines if the type of transplant procedure identified can be considered for authorization. Industry standard ICD-9/ICD-10 Transplant Reference Guides are utilized as a guideline to determine, for covered transplant procedures, if the requested procedure is appropriate for the member’s diagnosis.

The requesting transplant facility utilizes the [Neighborhood Transplant Request Checklist](#) to prepare the required documentation for submission.
The following is a list of the more common transplants and at what point a member may be considered as a potential candidate.

**Note:** The request process starts with the receipt of the transplant checklist and the evaluation, unless it is an emergent nature.

Once review of the transplant checklist occurs; the physician advisor may request additional information and the actual approval for the evaluation takes place during this phase.

**Absolute Contraindications**
1. Advanced cardiopulmonary disease or any other life-limiting disorder not corrected by transplantation.
2. Pulmonary hypertension if pulmonary artery systolic pressure ≥50 mmHg or mean pressure of >35 mmHg
3. Uncontrolled HIV
4. Hepatocellular carcinoma patients who exceed Milan/UCSF criteria
5. Persistent alcohol/substance abuse
6. Unresolvable psychosocial issues
7. Inability to adhere to regimen
8. Any life-limiting disease process
9. Side effects of immunosuppression unacceptable to the patient

**Relative Contraindications**
1. Renal failure (excluding hepatorenal syndrome)
2. Active infection outside the hepatobiliary system
3. Advanced malnutrition
4. Severe diabetic complications
5. Morbid obesity (BMI ≥40)
6. Prior history of multiple abdominal surgeries
7. Significant irreversible neurologic dysfunction
Criteria
Neighborhood requires that this completed checklist and transplant evaluation be sent at the time of the request for authorization of the transplant.

**ALL** three (3) of the following criteria must be met for consideration of authorization of a covered transplant:

- All members being considered for a transplant are evaluated by the clinicians from the transplant facilities. This transplant evaluation is the initial request. This evaluation should include **ALL** of the following (as applicable to the organ being requested):
  - All medical and behavioral health diagnoses
  - Prior transplant history
  - Progress notes including disease progression and current status (acute/chronic, remission, etc.)
  - Facility Transplant Protocol/criteria
  - Test results
  - MELD/PELD score (Liver only)
  - Availability of donor (if applicable)
  - Behavioral health and Social Worker evaluations and protocols
  - Documentation of member adherence to medical, behavioral health and substance abuse appointments and treatment plans
  - Consults and all other evaluations
  - Facility’s smoking cessation protocol, documentation of member’s adherence to the protocol
  - Psycho-social support network

- There is evidenced based literature that supports the requested transplant procedure for the diagnoses present.
- There is evidenced based literature and clinical documentation that indicates an optimal outcome can be expected, based on the evaluation of the member's current status, adherence history and psycho-social supports.
Organ specific criteria

Liver
Liver transplant necessity for members age twelve (12) and older is based on the MELD (Model for end stage liver disease) which is a numerical scale ranging from six (6) (less ill) to forty (40) (gravely ill). The higher the score, the more likely they will become an imminent transplant candidate. PELD (Pediatric End Stage Liver Disease) is a similar scale for members less than twelve (12) years of age. Additional exception points include clinical situations which are Status I category for acute liver failure and a life expectancy of hours to a few days without a transplant. Neighborhood utilizes the Milan criteria when Hepatocellular carcinoma is present.

CONTRAINDICATIONS — Although organ allocation is centralized, criteria and contraindications to listing for liver transplantation are often transplantation center-specific. General contraindications adopted by most centers include:

1. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery
2. Acquired immunodeficiency syndrome (AIDS)
3. Malignancy outside of the liver not meeting oncologic criteria for cure
4. Hepatocellular carcinoma with metastatic spread
5. Intrahepatic cholangiocarcinoma
6. Hemangiosarcoma
7. Anatomic abnormalities that preclude liver transplantation
8. Uncontrolled sepsis
9. Acute liver failure with a sustained intracranial pressure >50 mmHg or a cerebral perfusion pressure <40 mmHg
10. Persistent nonadherence with medical care
11. Lack of adequate social support
12. For patients with alcoholic liver disease, most programs require a minimum period of abstinence of at least six months, participation in a structured rehabilitation and abstinence program, and adequate social support to help maintain sobriety.

Criteria
- Evaluation for liver transplant should be considered once a patient has hepatocellular dysfunction resulting in a MELD score ≥ 15 OR cirrhosis with an index complication such as ascites, hepatic encephalopathy, or variceal hemorrhage.
- Candidates with prior extrahepatic malignancy should have received definitive treatment with adequate tumor-free survival prior to listing for liver transplantation.
- Candidates should undergo age and risk factor-appropriate cancer screening e.g. colonoscopy, mammography, Papanicolaou smear.
- Neighborhood considers BMI ≥ 40 to be a relative contraindication to liver transplantation.
- Tobacco consumption should be prohibited in liver transplant candidates due to increased morbidity and mortality among post-hepatic transplant smokers.
☐ Alcohol abstinence must be documented for at least six months (via laboratory) and ongoing monitoring for Alcohol use/abuse must be clearly documented.

**Lung**
Facilities notify Neighborhood when the member is on the “Top 10 list” to receive a transplant, and/or if an admission date has been established.

The most common diagnoses that may result in a lung transplant include: advanced chronic obstructive pulmonary disease, emphysema due to alpha I antitrypsin deficiency, pulmonary fibrosis, primary pulmonary hypertension and cystic fibrosis. Less common diagnoses that can also lead to the need for transplantation include: sarcoidosis, lymphangioleiomyomatosis (LAM), and pulmonary Langerhans' cell histiocytosis.

**CONTRAINDICATIONS** — Contraindications to lung transplantation that are felt to be absolute or relative have been developed on the basis of consensus and expert opinion by the ISHLT.

Absolute contraindications include the following:
1. Uncontrolled or untreatable pulmonary or extrapulmonary infection
2. Active Mycobacterium tuberculosis infection
3. Malignancy in the last two years (see 'Malignancy' below)
4. Significant dysfunction of other vital organs (eg, heart, liver, kidney, brain)
5. Significant coronary heart disease not amenable to revascularization (see 'Coronary heart disease' below)
6. Uncorrectable bleeding diathesis
7. Significant chest wall/spinal deformity expected to cause severe restriction after transplantation
8. Class II or III obesity: body mass index (BMI) ≥35 kg/m² (see 'Nutritional status' below)
9. Active tobacco smoking
10. Drug or alcohol dependency
11. Unresolved psychosocial problems or noncompliance with medical therapy

**Bone Marrow (BMT)**
Facilities notify Neighborhood when the member has been scheduled for admission.

Diagnoses that may result in a BMT include Acute Myelogenous Leukemia (AML), Acute Lymphocytic Leukemia (ALL), Hodgkin’s, Multiple Myeloma and aplastic anemia.
Heart
Facilities notify Neighborhood when the member’s status changes.

Note: 1A=top of the list (heart), 1B lesser level

The following diagnoses/conditions may result in a need for a heart transplant, depending on the level of severity:

- End stage heart disease (New York Heart Association Class III or IV)
- Severe systolic or diastolic ventricular dysfunction
- Life threatening arrhythmias
- Intractable angina
- Primary cardiac tumors without metastases
- Other advanced, irreversible cardiac disease, including refractory CHF
- Congenital heart disease that is not amendable to surgical therapy including: hypoplastic left heart syndrome, single ventricle, truncus arteriosus, V canal, ebstein anomaly, Tetralogy of Fallot, transposition of the great arteries

Kidney
Facilities notify Neighborhood when the member is on the top 10 list, with donor confirmed and an admission date has been set.

Absolute contraindications — Absolute contraindications to renal transplantation include:

1. Active infections.
2. Active malignancy
3. Active substance abuse
4. Reversible renal failure
5. Uncontrolled psychiatric disease
6. Documented active and ongoing treatment nonadherence
7. A significantly shortened life expectancy. There is no universally accepted life expectancy below which an individual is ineligible for renal transplantation, although a life expectancy of less than one year post-transplant precludes the possibility of transplantation at virtually all centers. Some centers are hesitant to transplant an individual with a life expectancy of less than five years since that is generally the expected half-life of the allograft. However, in other centers, individuals with much shorter life expectancy may be eligible for transplantation, depending upon the nature of the chronic illness.

Intestine
For members with intestinal failure who have developed irreversible complications associated with the chronic use of parenteral nutrition.
Pancreas (whole organ)
Note: Individuals with diabetes (see below) may be considered:
1. for a transplantation procedure involving the pancreas alone (allogeneic/from a deceased donor),
2. for a linked* transplant of the (allogeneic/from a deceased donor) in combination with a kidney
   transplantation (allogeneic from either a live or a deceased donor), or
3. for a transplantation of islet cells (see below) of pancreatic origin (allogeneic).

*Linked pancreas and kidney transplantation refers to use of both pancreas and kidney transplantation for
individuals who have both insulin dependent diabetes mellitus (IDDM) and end stage renal disease (ESRD).
The transplantation procedures may occur simultaneously or the pancreatic transplantation may follow the
kidney transplant. The kidney being transplanted may be harvested from either a living or deceased donor.

Diagnoses that may result in a pancreas transplant include IDDM in conjunction with a history of frequent
acute and severe metabolic complications (hypoglycemia, marked hyperglycemia, and/or diabetic
ketoacidosis) despite documented compliance with insulin therapy.
Diagnoses that may result in a linked pancreas-kidney transplant include IDDM (with complications
occurring despite documented compliance with insulin therapy as described above) in conjunction with end
stage renal disease (ESRD). Individuals who are to receive the linked transplants must satisfy both the criteria
for pancreatic transplantation and kidney transplantation.

Facilities notify Neighborhood when the member is on the “Top 10 list” to receive a transplant
(or transplants), and/or if an admission date has been established.

Islet Cells
Individuals with diabetes may be considered for islet cell transplantation of allogeneic islet cells from a
deceased donor. This procedure is considered experimental and is not covered.

Individuals with pancreatitis may be considered for autologous transplantation of islet cells in conjunction
with pancreatectomy for treatment of symptoms resulting from chronic severe refractory pancreatitis. Islet
cell transplantation for treatment of pancreatitis may be covered provided that the pancreatectomy meets
coverage requirements.

Facilities notify Neighborhood when the member is on the “Top 10 list” to receive a transplant, and/or if an
admission date has been established.

Relative exclusions for the transplantation procedures involving pancreas or islet cells:
Chronic liver disease, malignancy, vascular disease, BMI >35 in type II IDDM, genitourinary structural
abnormality, substance use, treated cancer and uncontrolled hypertension.
Please access Prior Authorization forms by visiting Neighborhood’s website at www.nhpri.org.
1. Go to the section for Providers
2. Click on “Resources & FAQ’s”
3. Click on “Medical Management Request Forms”- forms are listed alphabetically by program.
Prior Authorization Forms
For assistance with prior authorizations please contact Clinical Administrative Support at 401-459-6060.
Fax authorization forms to 401-459-6023.
For More information on Coding please reference the Authorization Quick Reference Guide

Exclusions
Neighborhood does not cover experimental procedures or treatments, except as otherwise required by law. Also refer to Clinical Medical Policy “Experimental or Investigational Services.” Transplants of the face are considered experimental and therefore are not covered.

CMP Cross Reference: CMP-026 Experimental Cancer Treatment

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Effective Date: 9/30/15, 3/14/2016, 07/1/16, 7/17/17

Neighborhood reviews clinical medical policies on an annual base.

Disclaimer:
This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's coverage plan; a member’s coverage plan will supersede the provisions of this medical policy. For information on member-specific benefits, call member services. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. Neighborhood reserves the right to review and revise this policy for any reason and at any time, with or without notice.
References:


Optum ICD-9 Transplant Reference Guide, or similar.


