



## Guidance document for PM JAY package

### Renal Transplantation

Procedures covered:3

Specialty: Organ and Tissue Transplant

Package name	Procedure name	HBP 1.0 code	HBP 2.0 code	Package price (INR)	Remarks	ALOS
Renal Transplant	Transplant surgery, including donor nephrectomy	New Package	OT001A	2,15,595		7 days – donor 10-14 days - recipient
Renal Transplant	Induction	New Package	OT001B	39,526	Add-on Procedure	4-5 days
Renal Transplant	Intervention for acute rejection	New Package	OT001C	1,07,797	Add-on Procedure	1 – 4 weeks

#### Minimum qualification of the treating doctor:

**Essential:** MS/DNB/MCh in General Surgery/ Urology Surgery with Fellowship/Equivalent with 2 years training in Transplant Surgery

**Special empanelment criteria/linkage to empanelment module:** Facility should be registered as per HOTA Act (THE HUMAN ORGANS TRANSPLANTATION ACT) for intervention procedures. Care at a Tertiary Hospital. The Hospital should have the required infrastructure of transplantation like Normo-thermic perfusion system, vascular access, pre-transplant work-up, dialysis, transplant immunology (HLA & cross match), transplant pathology and post-transplant care.

#### Disclaimer:

For monitoring and administering the claim management process of **Renal transplant**, NHA shall be following these guidelines. This document has been prepared for guidance of PROCESSING TEAM and TRANSACTION MANAGEMENT SYSTEM of AB PM-JAY for the claims of procedures mentioned above. The hospitals can also refer to this document so that they have the insight on how the claims will be processed. However, this document doesn't provide any guidance on clinical and therapeutic management of patient. In that respect the hospitals and physicians may refer to any other relevant material as per the extant professional norms.

### PART I: GUIDELINES FOR CLINICIANS AND HEALTHCARE PROVIDERS

#### 1.1 Objective:

The purpose of this section is to act as a guidance & a clinical decision support tool for the clinicians in deciding the line of treatment, plan clinical management of patient and decide referral of cases to the appropriate level of care (as required) for treatment of patients under AB PM-JAY and selection of corresponding Health Benefit Package.



It will also serve as a tool for hospitals to determine and submit the mandatory documents required for claiming reimbursement of health benefit package under PMJAY.

## **1.2 Clinical key pointers:**

### **PEDIATRIC POPULATION**

Kidney transplantation is the treatment of choice for children with end-stage kidney disease (ESKD) because of its superior patient survival rate compared with chronic dialysis. In addition, it is associated with better growth and developmental outcomes. The most common cause of ESKD in children who undergo transplantation is congenital malformations of the kidney and urinary tract (40 percent), followed by glomerular disorders (25 percent) and hereditary/genetic kidney diseases (15 percent), particularly focal glomerulosclerosis in black patients.

#### **Preemptive transplantation**

Children frequently undergo **primary or preemptive** transplantation, in which transplantation is the first mode of treatment for end-stage kidney disease (ESKD).

There are some circumstances in which preemptive transplants cannot be performed or are not recommended. These include:

- Need for pretransplant nephrectomies (i.e., malignant renovascular hypertension, chronic pyelonephritis, or nephrotic syndrome with the associated complications due to hypercoagulability)
- ESKD from autoimmune disease with persistently high titres of autoantibody (ie, anti-glomerular basement membrane disease)
- Ongoing active infections
- Underlying kidney disease is still active and associated with rapidly progressive disease (ie, haemolytic uremic syndrome or crescentic glomerulonephritis)
- If the patient or his/her caregivers are not yet able to cope with the regimented care necessary for the transplant recipient as exhibited by nonadherence to his/her CKD care

#### **Contraindications**

There are contraindications to kidney transplantation in children, which include:

- Uncontrolled extrarenal malignancies
- Systemic sepsis
- Severe irreversible multisystem organ system failure not correctable by organ transplant
- Severe cardiac or pulmonary dysfunction in a patient who is not a candidate for multiorgan transplantation



- Life-threatening disorder of extrarenal origin that is not correctable by organ transplant
- Elevated levels of circulating antiglomerular basement membrane antibodies

### **Donor choice**

Graft survival is superior with a living donor versus a deceased donor allograft.

### **Pretransplant Evaluation**

Prior to kidney transplantation, it is advisable that the recipient undergo the following evaluation and preparation to reduce complications, and increase allograft and patient survival.

- Detection of anti-Human Leukocyte Antigen (HLA) antibodies to the donor
- Correction of any significant urinary tract abnormality
- Detection and treatment of any infection prior to transplantation
- Completion of routine childhood immunizations, including varicella vaccine
- Review of whether nephrectomy would be beneficial long-term

### **ADULT POPULATION**

- Renal transplantation is the treatment of choice for many patients with end stage renal failure
- Accurate immunosuppression management is critical to maintain long term transplant function and minimize complications
- There is an increased risk of infections and cancer, and both can progress rapidly as patients are immunosuppressed

## Box 2: Contraindications to renal transplantation

### Absolute

- Active infections*—Patients are suspended from the waiting list while being treated. Chronic viral infections that are controlled and have not caused severe organ failure (such as cirrhosis) are not contraindications (examples include HIV, hepatitis B, hepatitis C)
- Active cancer*—A 2-5 year period without recurrence is required before transplantation
- Active drug misuse*—If treated, it may not be a long term contraindication
- Uncontrolled psychiatric disease*—If treated, it may not be a long term contraindication
- Active non-concordance with treatment*—If demonstrable concordance is shown, patient can be put on waiting list
- Short life expectancy*—Many centres will not consider transplantation if projected survival with the renal transplant is less than five years. Major organ comorbidity (such as severe cardiac or respiratory disease) can preclude transplantation

### Relative

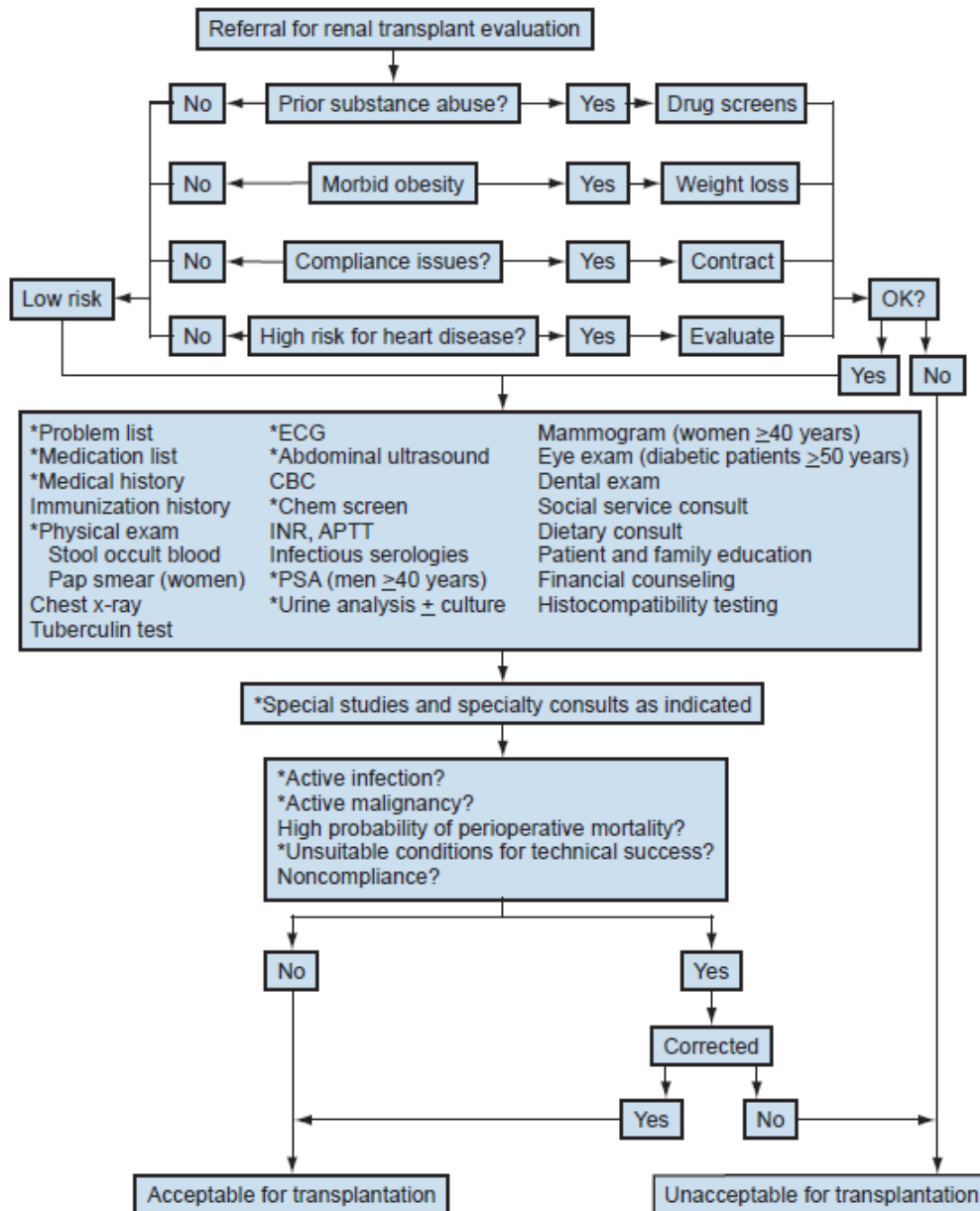
- Systemic autoimmune disease (such as vasculitis, lupus)*—Patient is monitored for disease activity and is considered when in remission
- AL amyloidosis*—Assess if disease in remission and no cardiac amyloid
- Primary hyperoxaluria*—Metabolic liver defect. Liver and kidney transplant is possible
- Cirrhosis*—May require assessment for a simultaneous liver and kidney transplant
- Obesity*—Some centres will not transplant a patient with a body mass index >35
- Recurrent disease*—Failure of previous renal transplant due to early recurrence (such as focal segmental glomerulosclerosis (FSGS))

## Matching donor and recipient

Histocompatibility antigens show remarkable polymorphism and human leukocyte antigen (HLA) matching is still very important in kidney transplantation as transplant outcome correlates with the number of HLA mismatches.

Recommendations	Strength rating
Determine the ABO blood group and the human leukocyte antigen A, B, C and DR phenotypes for all candidates awaiting kidney transplantation.	Strong
Test both the donor and recipient for human leukocyte antigen DQ. Human leukocyte antigen DP testing may be performed for sensitised patients.	Strong
Perform thorough testing for HLA antibodies before transplantation.	Strong
Perform adequate cross-match tests to avoid hyper-acute rejection, before each kidney and combined kidney/pancreas transplantation.	Strong

## Pre transplant evaluation



**Figure 47-1.** Algorithm for the evaluation of renal transplantation candidates. Circumstances may change the order in which data are obtained. APTT, activated partial thromboplastin time; CBC, complete blood cell count; ECG, electrocardiogram; INR, international normalized ratio; PSA, prostate-specific antigen. Asterisks indicate items of special significance for the urologist. (Modified from Barry JM. Current status of renal transplantation: patient evaluations and outcomes. Urol Clin North Am 2001;28:788.)

Note: 2D ECHO is a very important test needed to identify if the patient is low risk or high risk for cardiac. End stage renal disease patients who have been on dialysis for a long time invariably have high PA pressures with LVH with valvular dysfunction with poor cardiac contractility, if these findings are severe they are at a high risk of

## **LIVING-DONOR NEPHRECTOMY**

The endoscopic (laparoscopic) approach is the preferred technique for living-donor nephrectomy in established kidney transplant programs. Nevertheless, open surgery, preferably by a mini-incision approach, can still be considered a valid option, despite increased pain in the post-operative period.

Endoscopic living-donor nephrectomy (ELDN) includes:

- Pure or hand-assisted trans peritoneal laparoscopy;
- Pure or hand-assisted retroperitoneal approach;
- Laparo-Endoscopic Single Site Surgery (LESS);
- Natural Orifice Transluminal Endoscopic Surgery-assisted (NOTES);
- Laparo-Endoscopic Single Site Surgery and robotic-assisted trans peritoneal or retroperitoneal approach.

## **DONOR COMPLICATIONS**

- Infections
- Bleeding
- Cardiopulmonary risks
- Bowel injury
- Hernia at operated site
- Long -term complications

## **RECIPIENT COMPLICATIONS**

- Hemorrhage
- Arterial/Venous thrombosis
- Transplant renal artery stenosis
- Arteriovenous fistula and pseudo-aneurysms after renal biopsy
- Lymphocele
- Urinary leak
- Ureteral stenosis
- Hematuria
- Reflux and acute pyelonephritis
- Kidney stones



- Wound infection
- Incisional hernia

### **INDUCTION THERAPY**

Induction therapy is immunosuppressive therapy administered at the time of kidney transplantation to reduce the risk of allograft rejection. In general, induction strategies fall into one of two categories. The first relies upon high doses of conventional immunosuppressive agents, while the more commonly used strategy utilizes either T cell-depleting or interleukin (IL) 2 receptor-blocking antibodies in combination with lower doses of conventional agents.

Practically all kidney allograft recipients require immunosuppressive therapy to prevent rejection and loss of the allograft.

- High risk for rejection – There is substantial evidence that rabbit antithymocyte globulin (rATG)-Thymoglobulin is superior to interleukin (IL) 2 receptor antibodies and placebo among patients at high immunologic risk who are receiving concurrent immunosuppressive regimens. Given these results, administer rATG-Thymoglobulin, a lymphocyte-depleting agent, rather than an IL-2 receptor antagonist or no antibody therapy to high-risk patients undergoing kidney transplantation.
- Lower risk for rejection – Among lower-risk patients, some administer rATG-Thymoglobulin based upon evidence that rATG-Thymoglobulin produces lower acute rejection rates. However, others administer an IL-2 receptor antagonist based upon studies that have shown similar rates of acute rejection, patient and graft survival, and infection with rATG-Thymoglobulin and IL-2 receptor antagonists.

### **RENAL ALLOGRAFT DYSFUNCTION**

The most common complication of kidney transplantation is allograft dysfunction, which in some cases leads to graft loss. The causes of renal allograft dysfunction vary with the time (usually classified as immediate, early, and late period) after transplantation.

Approach to the evaluation and diagnosis of renal allograft dysfunction depends upon the timing of presentation. A diagnosis can be established in most patients by means of thorough history and physical examination, laboratory and imaging studies, and/or a renal allograft biopsy.

**Patients with allograft dysfunction immediately (<1 week) post-transplant** — Patients who develop renal allograft dysfunction within the first week post-transplant most commonly

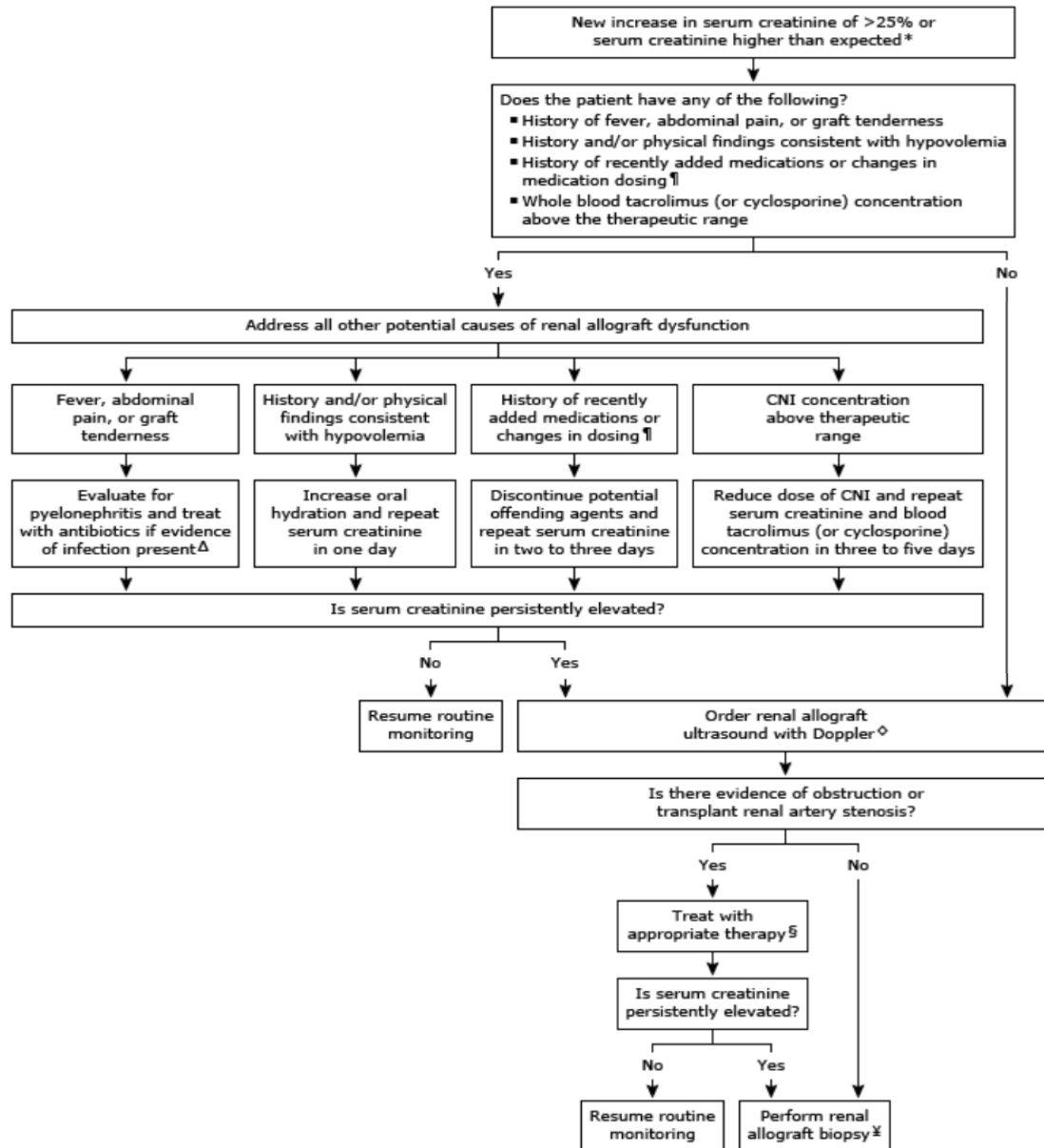


present with low urine output or failure of the serum creatinine to decrease after transplantation. Some patients (ie, those with delayed graft function [DGF]) may require dialysis in the first week after transplantation.

#### **Patients with allograft dysfunction >1week post-transplant**



## Approach to the patient with renal allograft dysfunction >1 week posttransplant



CNI: calcineurin inhibitor; ACE: angiotensin-converting enzyme; ARB: angiotensin II receptor blocker; DSA: donor-specific antibody; CMV: cytomegalovirus.

\* A serum creatinine that is higher than expected may be seen in the setting of recently transplanted patients whose serum creatinine is not decreasing as quickly as expected after transplantation.

¶ Medications of interest include ACE inhibitors and ARBs, which can be associated with prerenal acute kidney injury, and nondihydropyridine calcium channel blockers and azole antifungal agents, which interact with CNIs and can increase whole blood CNI levels.

Δ Refer to UpToDate topics on complicated urinary tract infection in kidney transplant recipients.

◇ For patients who live far away from their respective transplant centers, some centers routinely order a renal allograft ultrasound as part of the initial evaluation of renal allograft dysfunction.

§ Urinary obstruction may be treated with a ureteral stent or drainage of a perinephric fluid collection, if present. Transplant renal artery stenosis should be managed with angioplasty of the transplant renal artery.

¶ Other parts of the evaluation include measurement of a DSA level and plasma BK (polyomavirus) and CMV viral loads. Although the results of these tests do not impact the decision to perform a renal allograft biopsy, they provide additional information to establish the cause of allograft dysfunction and are used to monitor the response to therapy.

## **IMMUNOLOGICAL COMPLICATIONS**

**Acute rejection** — Acute rejection is one of the most common causes of allograft dysfunction in the early post-transplant period. It typically manifests within the first six months after transplantation but can also occur late in patients who are non-adherent to their immunosuppression regimen. Acute rejection should be suspected among all transplant recipients who present with a creatinine that is increased above the patient's usual baseline, especially if they have associated symptoms such as fever, oliguria, and graft pain or tenderness. There are two principal histologic forms of acute rejection:

- Acute T cell-mediated (cellular) rejection, which is characterized by infiltration of the allograft by lymphocytes and other inflammatory cells.
- Active (acute) antibody-mediated rejection (ABMR), the diagnosis of which requires morphologic evidence of acute tissue injury, circulating DSAs, and immunologic evidence of an antibody-mediated process (such as C4d deposition in the allograft). Cellular infiltrates may not be present.

### **Hyper-acute rejection**

Hyper-acute rejection is the most dramatic and destructive immunological attack on the graft. Prevent hyper-acute rejection by adequate ABO blood group and HLA matching of donor and recipients.

### **Treatment of T-cell mediated acute rejection**

- Use steroid bolus therapy as first-line treatment for T-cell mediated rejection in addition to ensuring adequate baseline immunosuppression.
- In severe or steroid-resistant rejection, use intensified immunosuppression, high-dose steroid treatment, and eventually T-cell depleting agents.

### **Treatment of antibody mediated rejection**

- Treatment of antibody mediated rejection should include antibody elimination.

### 1.3 Mandatory documents- For healthcare providers:

Following documents should be uploaded by the concerned hospital staff at the time of pre-authorization and claims submission

Mandatory document	Transplant surgery, including donor nephrectomy	Induction	Intervention for acute rejection
<b>i. At the time of Pre-authorization</b>			
a. Clinical notes with planned line of management	Yes	Yes	Yes
b. Documentation of indication for induction	--	Yes	--
c. NOTTO (National organ and tissue transplant organization) ID of the recipient and / donor	Yes	--	--
d. Donor work-up summary sheet	Yes	--	--
e. Recipient work-up summary sheet	Yes	--	--
f. Cross-match report with donor and recipient photo-ID proof	Yes	--	--
g. Undertaking signed by donor (in living donor transplant)	Yes	--	--
h. Hospital authorization letter on recipient and donor with details of the surgery	Yes	Yes	--
i. Digital Subtraction Angiography (DSA)	--	--	Yes
j. Biopsy	--	--	Yes
<b>ii. At the time of claim submission</b>			
a. Detailed Indoor case papers (ICPs)	Yes	Yes	Yes
b. Detailed Procedure / Operative notes	Yes	Yes	Yes
c. Clinical photograph	Yes	--	--
d. Investigation reports (if done)	Yes	Yes	Yes
e. Details of the drug and dosage used for induction	--	Yes	--
f. Details of the drug and dosage used for treatment rejection	--	--	Yes
g. Detailed discharge Summary	Yes	Yes	Yes

## **PART II: GUIDELINES FOR PROCESSING TEAM**

**2.1 Objective:** To provide guidance to the pre-authorization and claims processing team in ascertaining the medical necessity of procedure carried out vis a vis the patient's medical condition as evidenced by supporting documents/investigation reports etc, in deciding the



admissibility and quantum of claim and compliance with mandatory documents by the hospital.

## **2.2 Following mandatory documents to be diligently reviewed by the pre-auth / claims processing personnel:**

### **2.2.1 At the time of pre-authorization processing- For pre-authorization processing doctor (PPD):**

- a. Clinical notes – all vitals, detailed history, symptoms, signs, physical examination, indication for surgery, planned line of treatment, and advice for admission?
- b. Were the following documents available – NOTTO ID, donor/recipient work-up summary sheet/cross-match report, informed consent of donor (in living donor transplant), hospital authorization letter?
- c. Were DSA and biopsy reports submitted (if applicable)?

### **2.2.2 At the time of claim processing- For claims processing doctor (CPD):**

- a. Are the detailed ICPs with daily vitals and treatment details (including drug and dosage for induction/treatment rejection – if applicable)?
- b. Are the detailed procedure / Operative Notes available?
- c. Is the Discharge summary with follow-up advise at the time of discharge?

## **PART III: GUIDELINES FOR TRANSACTION MANAGEMENT SYSTEM (TMS)**

**3.1 Objective:** To enable setting up of cross check mechanisms/rule engines within the IT platform (TMS) to ensure compliance with STGs and to prevent fraud / abuse of the Health Benefit Package.

**3.2 Below mentioned are the scenarios where a provision would be built in TMS for pop-ups:**

- I. Is the hospital registered under HOTA/NOTTO ACT? Yes
- II. Has the hospital transplant committee approved the case? Yes
- III. Is the patient suffering from end stage kidney disease and/or not responding to dialysis? Yes
- IV. Documentation of no absolute contraindications for doing the procedure? Yes
- V. Is the Donor medically fit to undergo the Transplant Donor Nephrectomy?

Till the time the functionality is being developed, the processing doctors shall check the above manually.

## **References**



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