

## Guidance document for processing PM-JAY packages

### Critical Care Neonatal Package

Procedures covered: 1

Specialty: Neo-natal Care

Package name	Procedures name	HBP 1.0 code	HBP 2.0 code	Package price (INR)
<p>Critical Care Neonatal Package: Babies with birthweight of &lt;1200 g or Babies of any birthweight with at least one of the following conditions:</p> <ul style="list-style-type: none"> <li>• Severe Respiratory Failure requiring High Frequency Ventilation or inhaled Nitric Oxide (iNO)</li> <li>• Multisystem failure requiring multiple organ support including mechanical ventilation and multiple inotropes</li> <li>• Critical congenital heart disease</li> </ul> <p>Mother's stay and food in the hospital for breastfeeding, family centred care and (Kangaroo Mother Care) KMC is mandatory and included in the package rate</p>	<p>Critical Care Neonatal Package: Babies with birthweight of &lt;1200 g or Babies of any birthweight with at least one of the following conditions:</p> <ul style="list-style-type: none"> <li>• Severe Respiratory Failure requiring High Frequency Ventilation or inhaled Nitric Oxide (iNO)</li> <li>• Multisystem failure requiring multiple organ support including mechanical ventilation and multiple inotropes</li> <li>• Critical congenital heart disease</li> </ul> <p>Mother's stay and food in the hospital for breastfeeding, family centred care and (Kangaroo Mother Care) KMC is mandatory and included in the package rate</p>	M300005	MN005A	7,000

**ALOS:** 30-45 days

**Minimum qualification of the treating doctor:**

**Essential:** DM/DNB/Equivalent (in Neonatology) and other specialty referral based on diagnosis

**Special empanelment criteria/linkage to empanelment module:** Care at Tertiary Hospital

**Disclaimer:**

For monitoring and administering the claim management process of **Critical Care Neonatal Package**, 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 PMJAY 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:

### • **Babies with birthweight of <1200 g**

#### **Elements of a Protocol for Standardizing Care of the Extremely Low Birth Weight (ELBW):**

- **Prenatal consultation**
  - Parental education
  - Determining parental wishes when viability is questionable
  - Defining limits of parental choice; need for caregiver-parent teamwork
- **Delivery room care**
  - Define limits of resuscitative efforts
  - Respiratory support
  - Low tidal volume ventilation strategy
  - Prevention of heat and water loss
  - Early surfactant therapy
- **Ventilation strategy**
  - Low tidal volume, short inspiratory time
  - Avoid hyperoxia and hypocapnia
  - Early surfactant therapy as indicated
  - Define indications for high-frequency ventilation
- **Fluids**
  - Early use of humidified incubators to limit fluid and heat losses
  - Judicious use of fluid bolus therapy for hypotension
  - Careful monitoring of fluid and electrolyte status
  - Use of double-lumen umbilical venous catheters for fluid support
- **Nutrition**
  - Initiation of parenteral nutrition shortly after birth
  - Early initiation of trophic feeding with maternal milk
  - Advancement of feeding density to provide adequate calories for healing and growth
- **Cardiovascular support**
  - Maintenance of blood pressure within standard range
  - Use of dopamine for support as indicated
  - Corticosteroids for unresponsive hypotension
- **PDA**
  - Avoidance of excess fluid administration

- Consider medical therapy when hemodynamically significant PDA is present
- Consider surgical ligation after failed medical therapy
  - **Infection control**
- Scrupulous hand hygiene, use of bedside alcohol gels
- Limiting blood drawing, skin punctures
- Protocol for CVL insertion and care, minimize dwell time
- Minimal entry into CVLs, no use of fluids prepared in NICU

PDA, patent ductus arteriosus; CVL, central venous line; NICU, newborn intensive care unit.

### • **Severe Respiratory Failure requiring High Frequency Ventilation or inhaled Nitric Oxide (iNO)**

**High-frequency ventilation (HFV)** is an important adjunct to conventional mechanical ventilation in newborns. High frequency oscillatory ventilation (HFOV) is a type of mechanical ventilation that uses a constant distending pressure (mean airway pressure [MAP]) with pressure variations oscillating around the MAP at very high rates (up to 900 cycles per minute).

#### **At present HFOV is only indicated as a rescue therapy:**

- Failure of conventional ventilation in the term infant (Persistent Pulmonary Hypertension of the Newborn [PPHN], Meconium Aspiration Syndrome [MAS])
- Air leak syndromes (pneumothorax, pulmonary interstitial emphysema [PIE])
- Failure of conventional ventilation in the preterm infant (severe RDS, PIE, pulmonary hypoplasia) or to reduce barotrauma when conventional ventilator settings are high

#### **Initial settings on HFOV**

##### **Optimal lung volume strategy**

(aim to maximise recruitment of alveoli).

- Set MAP 2-3 cmH<sub>2</sub>O above the MAP on conventional ventilation
- MAP in 1-2 cmH<sub>2</sub>O steps until oxygenation improves
- Set frequency to 10 Hz

Consider recruitment manoeuvres after discussion with consultant

##### **Low volume strategy**

(aim to minimise lung trauma)

- Set MAP equal to the MAP on conventional ventilation
- Set frequency to 10 Hz
- Adjust amplitude to get an adequate chest wall vibration.

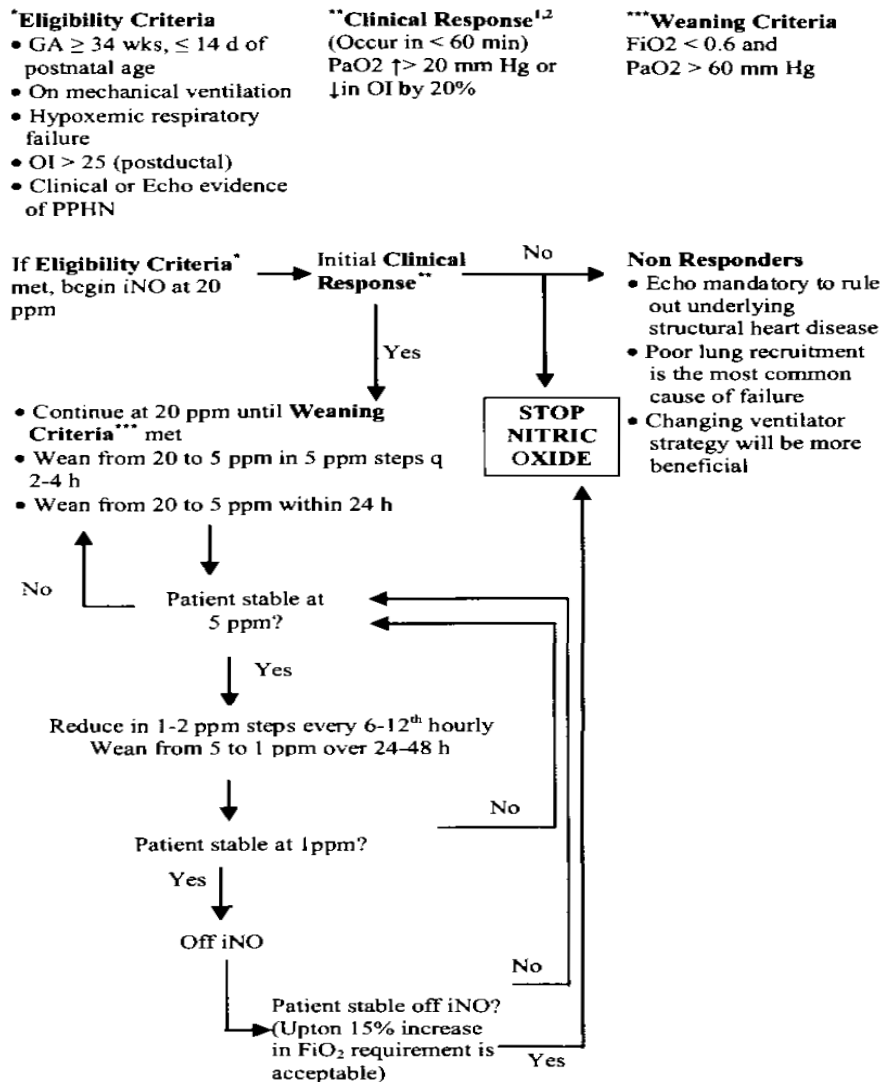
**Inhaled nitric oxide (iNO)** is a selective pulmonary vasodilator used in management of term and near-term neonates with hypoxemic respiratory failure and Persistent pulmonary hypertension (PPHN).

#### **Indications:**

Candidates satisfying all the following criteria are eligible

- GA  $\geq 34$  wks
- $\leq 14$  d of postnatal age
- On mechanical ventilation
- Hypoxemic respiratory failure (PaO<sub>2</sub> <50 mm Hg on FiO<sub>2</sub> of 1.0 with PaCO<sub>2</sub> <50 mm Hg)
- Post ductal OI  $\geq 25$  [OI = (MAP x FiO<sub>2</sub>) / PaO<sub>2</sub>]

- Clinical and/or Echocardiographic evidence of PPHN. Need for Echocardiography prior to initiation of treatment.



### • Multisystem failure requiring multiple organ support including mechanical ventilation and multiple inotropes

Multiple organ failure (MOF) is a clinical syndrome characterized by the failure of two, or more, organs which are unable to maintain homeostasis without intervention. Described causative factors for MODS in the neonatal period are sepsis, shock due to any cause, tissue hypoperfusion, prematurity, hypoxic ischemic encephalopathy, necrotizing enterocolitis (NEC), surgery, congenital heart disease and others.

MODS has also been classified as:

- primary (or early) MODS: where organ dysfunctions occur in the first 7 days of illness and can be directly attributable as a consequence of the primitive illness;
- secondary (or late) MODS: where organ dysfunctions develop after 7 days of illness as a consequence of the host responses.

### Clinical features

The clinical presentation of MODS can vary widely, depending on the primary causes, nature, number and severity of the organ systems involved. Dysfunction in at least two organ systems is, by definition, diagnostic for MODS.

### Treatment and Prevention

MODS is less a syndrome to be treated than a complication to be prevented. Pre-MODS conditions should be promptly identified and treated. General measures that should be considered to reduce the progression of the inflammation and MODS are summarized below.

General measures that should be considered to reduce the progression of the inflammation and multiple organ dysfunction syndrome (MODS) in the newborn.

- Provide adequate initial resuscitation (ABCD)
- Treat shock: fluid resuscitation (up to 60 ml/kg of isotonic saline IV in the first hour, if necessary to attain normal capillary refill and blood pressure), inotropes (Dopamine  $\pm$  Dobutamine) in fluid refractory shock, epinephrine, vasodilators, iNO, ECMO or CRRT
- Prevent and correct hypoxemia
- Treat infections: antimicrobial agents (early empiric followed by conversion to infection-specific, with best MIC, antibiotics), removal of known focus of infection, selective decontamination of the digestive tract
- Monitor organ functions: cardiac and pulmonary (pre- and post-ductal pulse oxymetry, invasive or non-invasive blood pressure, arterial blood gas analysis, continuous ECG, serial Doppler echocardiography for evaluating PDA, ventricular function, cardiac output, PPHN, SVC flow), renal (urine output, eGFR/GFR, renal ultrasound), liver function, cerebral function (EEG, CFM, cerebral ultrasound, NIRS), metabolic (glucose, electrolytes, acid base balance), hemocoagulation
- Assess etiology for specific treatment (e.g. congenital heart disease, hypoxic ischemic encephalopathy, NEC, inborn errors of metabolism, adrenal insufficiency, hypothyroidism, primitive single organ failure)
- Avoid fluid overload: diuretics or renal replacement/dialysis
- Avoid lung overdistension: lung protective ventilation strategies (HFOV, volume guarantee with adequate tidal volumes)
- Avoid hyperglycemia/hypoglycemia: insulin, maintenance solution with D10
- Correct other metabolic imbalances
- Avoid malnutrition and microbial gut imbalance: early enteral nutrition, parenteral nutrition (to provide adequate caloric intake and nitrogen balance)
- Consider need for blood products: follow available guidelines for red packet cells (after resuscitation lower hemoglobin target could be considered), fresh-frozen plasma (bleeding due to DIC, liver failure or Vitamin K deficiency) and platelets transfusion
- Consider sedation/analgesia (in ventilated infant, to reduce metabolic expenditure)
- Monitor drug toxicity (drug clearances could be impaired during MODS)

ABCD: airway, breathing, circulation, drugs; CRRT: continuous renal replacement therapy; PDA: patent ductus arteriosus; PPHN: persistent pulmonary hypertension of the newborn; SVC: superior vena cava; NIRS near-infrared spectroscopy; NEC: necrotizing enterocolitis; DIC: disseminated intravascular coagulation.

### • Critical congenital heart disease

((Respective detailed PMJAY guidance documents can be reviewed for more information))

Critical Congenital Heart disease (CHD), defined as cardiac lesions requiring surgical or catheter-based interventions in infancy. While majority of neonates with Critical CHD are symptomatic and are identified soon after birth, a significant proportion remains undetected until after discharge.

### Some specific Critical CHDs

- Coarctation of the aorta
- Double-outlet right ventricle
- d-Transposition of the great arteries
- Ebstein anomaly
- Hypoplastic left heart syndrome
- Interrupted aortic arch
- Pulmonary atresia (with intact septum)
- Single ventricle
- Total anomalous pulmonary venous return
- Tetralogy of Fallot
- Tricuspid atresia
- Truncus arteriosus

### Possible Physical Symptoms of Critical CHDs

- Problems breathing
- Pounding heart
- Weak pulse
- Very pale or blue skin color
- Poor feeding
- Very sleepy

### Newborn Screening for Critical CHDs is Done

Newborn screening for critical CHDs involves a simple bedside test called pulse oximetry. Screening is done when a baby is at least 24 hours of age, or as late as possible if the baby is to be discharged from the hospital before 24 hours of age.

### Definitive management of common CHDs (6)

<b>Correction possible</b>	<b>Only multistage surgical palliation possible (Early BT shunt/PDA stent for severe hypoxemia and early PA band for non-resolving heart failure to prepare for future cavo-pulmonary connection)</b>
<b>Neonatal Intervention</b> <ul style="list-style-type: none"> <li>• Balloon atrial septostomy for TGA with intact ventricular septum</li> </ul> <b>Neonatal surgical repair</b>	<ul style="list-style-type: none"> <li>• Single ventricle physiology</li> <li>• Double-outlet right ventricle</li> <li>• Tricuspid atresia</li> <li>• Hypoplastic left heart syndrome</li> </ul>

<ul style="list-style-type: none"> <li>Severe Coarctation of the aorta</li> <li>Total anomalous pulmonary venous return</li> <li>Transposition of the great arteries</li> </ul> <p><b>Surgery/intervention during infancy</b></p> <ul style="list-style-type: none"> <li>Truncus arteriosus</li> <li>Tetralogy of Fallot (TOF) and TOF physiology (Severe hypoxia warrants surgical Blalock Taussig shunt or percutaneous stenting of right ventricular outflow tract (RVOT) to improve saturation)</li> </ul> <p><b>Surgery during childhood</b></p> <ul style="list-style-type: none"> <li>Ebstein anomaly</li> </ul>	
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### 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	Critical Care Neonatal Package
<b>i. At the time of Pre-authorization</b>	
Clinical notes including evaluation findings and planned line of management	Yes
<p><b><u>Babies with birthweight of &lt;1200 g</u></b></p> <p><b>Mandatory</b></p> <p>Ballard scoring to determine maturity</p> <p>Birth weight</p> <p>Gestation age</p> <p>Respiratory support - Silverman score need for Surfactant/Chest X-ray/CPAP/MV</p> <p>Retinopathy of Prematurity (ROP) screening</p> <p>Neurosonogram</p> <p>Caffeine administration documentation</p> <p><b>Optional (based on Etiology)</b></p> <p>Total Parenteral Nutrition (TPN) – based on availability</p> <p>2D ECHO (Patent Ductus Arteriosus)</p> <p>Need for NSG – ventricular dilatation</p> <p>Need for PDA closure – Paracetamol/Ibuprofen</p> <p>Abdominal X-ray (Necrotizing Enterocolitis)</p> <p>Septic screen (Sepsis)</p> <p>Total Serum Bilirubin (Jaundice)</p> <p>Complete Blood count (anemia of prematurity)</p>	Yes



Serum Calcium/Electrolytes/Alkaline Phosphatase /Parathyroid hormone – (osteopenia of prematurity) Hearing assessment Thyroid profile	
<b><u>Severe Respiratory Failure requiring High Frequency Ventilation or inhaled Nitric Oxide (iNO)</u></b> <b>Mandatory</b> Chest X-ray while on conventional ventilator Arterial Base Gas (ABG) and settings while of conventional ventilator 2D ECHO (for iNO)	Yes
<b><u>Multisystem failure requiring multiple organ support including mechanical ventilation and multiple inotropes</u></b> <b>Mandatory</b> Chest X-ray Blood pressure Renal function test Liver Function test Serum lactate Arterial Blood Gas (ABG) Urine output Level of consciousness (Volpe`s score) Sepsis screen Need for inotropes Need for Mechanical Ventilation <b>Optional</b> Central venous pressure lactate dehydrogenase (LDH) Serum D-dimer Serum Ferritin Electroencephalogram (EEG) 2D ECHO (functional) Need for dialysis	Yes
<b><u>Critical congenital heart disease</u></b> <b>Mandatory</b> Pulse-oximetry screening 2D ECHO <b>Optional</b> Hyperoxia test Chest X-ray Electrocardiogram (ECG) Need for prostaglandin	Yes
<b>ii. At the time of claim submission</b>	



Detailed Indoor case papers (ICPs)	Yes
<b><u>Babies with birthweight of &lt;1200 g</u></b> Birth weight documentation	Yes
<b><u>Severe Respiratory Failure requiring High Frequency Ventilation or inhaled Nitric Oxide (iNO)</u></b> Chest X-ray/ABG	Yes
<b><u>Multisystem failure requiring multiple organ support including mechanical ventilation and multiple inotropes</u></b> Documentation of Indication for requirement mechanical ventilation and multiple inotropes	
<b><u>Critical congenital heart disease</u></b> 2D ECHO report	Yes
Detailed Procedure notes and indication (if any)	Yes
Detailed discharge summary	Yes

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

### **PART III: GUIDELINES FOR IT**

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:

• **Babies with birthweight of <1200 g**

- Was birth weight at admission < 1200gm documented? Yes/Not Applicable
- Was there a documentation of surfactant administration (optional)? Yes/Not Applicable

• **Severe Respiratory Failure requiring High Frequency Ventilation or inhaled Nitric Oxide (iNO)**

- Was ABG/2DECHO indicative of requirement of High Frequency Ventilation/iNO? Yes/Not Applicable

• **Multisystem failure requiring multiple organ support including mechanical ventilation and multiple inotropes**

- Were the investigations ABG/Serum Lactate/Chest X-ray/Sr Creatinine/Liver Function tests confirming the diagnosis? Yes/Not Applicable
- Was the indication for Mechanical Ventilation and Multiple inotropes documented? Yes/Not Applicable



### • **Critical congenital heart disease**

- a. Did 2D ECHO document any structural defects? Yes/Not Applicable

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

### **References**

1. Aufieri R, Picone S, Paolillo P. Multiple organ failure in the newborn. J Pediatr Neonat Individual Med. 2014;3(2):e030254. doi: 10.7363/030254
2. Sourabh Dutta, Praveen Kumar. The PGI NICU Handbook of Protocols. Fourth Edition. 2010.
3. John P. Cloherty, et al. Manual of Neonatal Care. Wolters Kluwer. Eighth Edition. 2015.
4. <http://www.adhb.govt.nz/newborn/guidelines/respiratory/hfov/hfov.htm>
5. <https://www.cdc.gov/ncbddd/heartdefects/cchd-facts.html>
6. Ramesh Agarwal, Ashok Deorari, Vinod K Paul, et al. AIIMS Protocols in Neonatology. Volume I & II. Second Edition. 2019.
7. Standard Treatment Guidelines. A Manual for Medical Practitioners. Health & Family Welfare Department. Government of Tamil Nadu. 2010