

## **Annex B: Pilot Implementation Program for Pediatric Home APD**

### **I. Background and Rationale**

Automated Peritoneal Dialysis (APD) is widely used in pediatric end-stage kidney disease (ESKD). Key practice statements and infection-prevention updates are available from ISPD and related bodies. Evidence for superiority of APD versus CAPD on patient-centered outcomes remains mixed; APD provides logistical and lifestyle benefits (e.g., daytime freedom), but HRQoL differences versus CAPD may be small in short windows. This pilot focuses on feasibility and real-world signals for adequacy, HRQoL, volume status, and healthcare utilization over 3 months.

Given the PhilHealth Z Package for Home APD, there is a need to optimally utilize home APD for pediatric patients in our local setting.

### **II. Objectives**

To establish a pediatric home automated peritoneal dialysis (APD) implementation protocol.

### **III. Scope**

Prospective, multicenter, pragmatic pilot cohort of pediatric PD patients managed with APD under the PhilHealth pilot reimbursement package. Duration: 3 months of follow-up per participant; preliminary report after completion.

Comparators: Within-person pre–post comparison (baseline vs. 3 months). For patients switching from CAPD to APD during the pilot, capture a 4–8-week baseline on CAPD if available. For patients already on APD, use prior 3 months as baseline where feasible.

Setting: Government hospitals participating in the PhilHealth pilot; coordination via the National Kidney and Transplant Institute.

### **IV. Population for the Pilot Study**

#### **A. Inclusion Criteria:**

1. Age < 19 years old (18 y/o and 364 days)
2. CKD stage 5 (ESKD) on PD ( $\geq 6$  months CAPD)
3. Clinically stable (no active peritonitis, tunnel/exit infection)
4. Absence of known or suspected allergy to PD solution

5. Completed APD training and competency check by certified trainer (Attending Nephrologist/Nurse Trainer can issue a certificate attesting that they have completed training and know how to operate the APD machine at home)
6. Baseline PET showing a High or high-average transporter (PET done within 6 months from enrollment)
7. With a KT/V exam not more than 1 year from enrollment
8. Functional PD catheter, exit site healed (at least  $> / = 6$  months post insertion)
9. Has completed PD initiation in an accredited health facility or accredited PD Z benefit provider
10. Able to comply with regular follow-ups (monthly or more frequent as advised by the AP) during the entire study period, failure to follow up means disqualification from the Pilot – return of machine is necessary

#### B. Exclusion Criteria

1. Active/recent peritonitis ( $<30$  days)
2. Recent abdominal surgery/hernia not yet healed ( $</=3$ months)
3. Uncontrolled BP/volume overload (BP  $>/=160$  systolic, presence of anasarca)
4. Severe heart failure (NYHA III–IV) (for this pilot study) (*Note: for this PILOT Implementation Program only*)
5. Refractory UF failure requiring HD (er or hospital admission for fluid overload  $</=$  three (3) months)
6. Unsafe home setting (no power, poor sanitation, no caregiver)
7. Anticipated kidney transplant within pilot window or modality switch to HD for non-medical reasons ( $<$  or  $= 3$  months)
8. Active peritonitis at enrollment (may enroll after resolution ( $>/=4$  weeks post peritonitis)
9. Any condition precluding reliable follow-up within the 3-month pilot

### V. **Monitoring Parameters for the Pilot Implementation Program for Pediatric Home APD**

#### A. Clinical Parameters:

1. Primary Clinical Outcome: Change in dialysis adequacy from baseline to 3 months (weekly Kt/Vurea; optionally total weekly creatinine clearance).
2. Key Secondary Clinical Outcomes:
  - a. Hospital/ER utilization: number of all-cause hospitalizations; dialysis-related ER visits during study versus prior 3 months.
  - b. Fluid status: change in overhydration by clinical composite score (weight)  $\pm$  bioimpedance spectroscopy (BIS) (baseline and after 3 months)

- c. Safety: peritonitis rate, exit-site infection rate, catheter malfunction, therapy discontinuation, other patient safety incidents
- d. APD prescription patterns: cycler, nightly duration, cycles, fill volume (mL/m<sup>2</sup> or mL/kg), last fill, dialysate concentrations, icodextrin use.

**B. Patient-Centered Parameters**

- 1. Patient satisfaction
- 2. Adequate training received and result of competency assessment
- 3. Willingness to continue home-based APD after the pilot

**C. Economic Parameters**

- 1. Direct cost (e.g. equipment, supplies, medical, nursing support)
- 2. Indirect cost (e.g. emergency visits, hospitalizations, complications, transportation)
- 3. Out of pocket cost (patient perspective)

**D. Operational Parameters**

- 1. Equipment availability and maintenance issues
- 2. Compliance to documentary requirements for reimbursement claims
- 3. Claims processing time and denial rates

**VI. Sample Size (Pilot Rationale)**

This is an implementation pilot. While the ideal number of patients may depend on each site's capacity and available resources, participating HFs may enroll a minimum of two (2) and a maximum of three (3) patients during the pilot period.

**VII. Enrollment Algorithm (Text Flow)**

- Step 1 : Screen pediatric PD patients against APD pilot inclusion/exclusion list.
- Step 2 : Confirm stable PD access and absence of active peritonitis (or deferred until resolution).
- Step 3 : Obtain consent from parent/guardian and assent from the child (age-appropriate).
- Step 4 : Baseline assessments (demographics, medical history, PD history, adequacy, volume status, prior 3-month utilization).
- Step 5 : Initiate/continue APD per treating nephrologist; capture APD prescription details.
- Step 6 : Monthly safety check-ins; capture any hospital/ER events.
- Step 7 : End-of-study assessments at Month 3; evaluate outcomes; prepare a preliminary report.

## VIII. Timelines

| <b>Milestone</b>                         | <b>Week 1</b> | <b>Week 2</b> | <b>Week 3</b> |
|--|---------------|---------------|---------------|
| Site activation & training               | ✓             |               |               |
| Enrollment & baseline data               | ✓             | —             |               |
| Monthly follow-up & safety               |               | ✓             |               |
| Endline assessments & preliminary report |               |               | ✓             |

## IX. Preliminary Report Template (End of 3 Months)

- A. Enrollment: N, by site; demographics.
- B. APD prescriptions: summary table and patterns.
- C. Primary outcome: mean  $\Delta$  Kt/V, % reaching  $\geq 1.7$ .
- D. Hospital/ER events: rate ratios pre vs during study.
- E. Volume status:  $\Delta$  in BIS/clinical indices.
- F. Safety: peritonitis and exit-site infection rates vs ISPD targets.
- G. Issues/lessons learned; recommendation re: reimbursement package.