

Agreement 13: Advanced Heart Failure Device Therapy

Parties: CardioTech Devices Inc. and Italian National Health Service **Country:** Italy **Disease Area:** End-Stage Heart Failure **Agreement Overview:** This specialized agreement addresses the high cost and uncertain outcomes associated with advanced heart failure devices, including left ventricular assist devices (LVADs) and implantable cardioverter-defibrillators with cardiac resynchronization therapy (CRT-Ds). Targeting approximately 340 patients with NYHA Class III-IV heart failure across major Italian cardiac centers, this contract creates a sustainable financing model for these expensive interventions while incentivizing appropriate patient selection and optimal post-implantation care.

Financial Structure:

- Device acquisition: €92,000 per LVAD system or €28,500 per CRT-D system
- Implementation model: 60% paid upon implantation, 40% tied to outcomes
- Outcome-based payments:
 - 15% released at 30 days with patient survival and absence of major complications
 - 15% at 6 months with functional improvement (6-minute walk test increase >50 meters)
 - 10% at 12 months with patient survival and acceptable quality of life (EQ-5D score >0.6)
- Complication penalties:
 - 30% device cost refunded for device-related infections requiring removal
 - 25% refund for device malfunction within 2 years
 - 20% refund for rehospitalization >2 times in first year for device-related issues
- Volume-based pricing: Tiered discounting of 3-12% based on annual implantation volume
- Extended warranty: Manufacturer assumes all costs for device-related issues beyond 3 years
- Budget impact protection: Maximum 15% annual growth in program expenditure
- Readmission risk-sharing: Manufacturer covers 40% of costs for unplanned readmissions within 90 days

Duration: 5 years with technology reassessment at midpoint **Special Provisions:**

- Centralized heart team evaluation for all potential device candidates
- Standardized pre-implantation frailty assessment and optimization protocol
- Comprehensive caregiver training program (minimum 32 hours)
- Dedicated VAD coordinator for each patient (continuing through device lifetime)
- Remote monitoring system with 24/7 technical support
- Home healthcare services for first 60 days post-discharge
- Palliative care integration for symptom management

- Psychological support services for patients and families
- Center of excellence certification requirements with volume minimums
- Registry participation with mandatory outcomes reporting