

Reimbursement policy of Hemopump in Belgium

BIWAC & BWGIC Videoconference 10 May 2021

Marta Moreira, MD

Attaché médecin-inspecteur INAMI/RIZIV/NIHDI

Objectives:

- To describe the reimbursement criteria of the Hemopump.
- Focus on quality of given care:
 - Right indication
 - Expertise
 - Full Medical report with detailed documentation



**MEDICAL
EXPERTISE**



Background:

Managing Patients With Short-Term Mechanical Circulatory Support

JACC Review Topic of the Week



Tim Balthazar, MD,^a Christophe Vandembrielle, MD, PhD,^{a,b} Frederik H. Verbrugge, MD, PhD,^{c,d}
 Corstiaan Den Uil, MD, PhD,^{e,f} Annemarie Engström, MD, PhD,^{e,f} Stefan Janssens, MD, PhD,^a Steffen Rex, MD, PhD,^g
 Bart Meyns, MD, PhD,^h Nicolas Van Mieghem, MD, PhD,^f Susanna Price, MD, PhD,^b Tom Adriaenssens, MD, PhD^a

TABLE 1 Overview of the Most Important Studies on Impella

First Author (Ref. #)	Year	Population	Design	Key Outcomes	Limitations
Seyfarth et al. (6)	2008	AMI-CS N = 26	RCT pVAD vs. IABP	Higher increase in cardiac index with pVAD No difference in 30-day survival for pVAD (54%) vs. IABP (54%)	Underpowered for survival analysis Single-center
Ouweneel et al. (7)	2017	AMI-CS Impella: N = 24 IABP: N = 24	RCT pVAD vs. IABP	No difference in 30-day survival for pVAD (56%) vs IABP (50%)	Underpowered Survival driven by neurological outcome
Anderson et al. (13)	2015	Right heart failure N = 30	Prospective cohort study	Improved hemodynamics 30-day survival 73.3%	No control group
O'Neill et al. (15)	2018	AMI-CS N = 15,259	Retrospective analysis	51% survival to explantation Large variability in survival between centers Higher survival when RHC was used Higher survival in pre-PCI pVAD group	Retrospective No control group
Ogunbayo et al. (44)	2018	Non-AMI-CS pVAD: N = 1,414; IABP: N = 16,619	Retrospective analysis	pVAD associated with lower survival than IABP	Retrospective Indication bias
Anderson et al. (14)	2018	Right heart failure N = 60	Retrospective analysis	30-day survival: 72%	Retrospective No control group
Basir et al. (10)	2019	AMI-CS N = 171	Retrospective analysis	Survival to explant: 72% High adherence to specific shock protocol	Retrospective No control group
Schrage et al. (8)	2019	AMI-CS N = 237 (matched pairs)	Retrospective analysis with patient matching to IABP-Shock trial population	No difference in 30-day survival for pVAD (51.5%) vs. IABP (53.6%) More bleeding, vascular complications, and sepsis in pVAD patients	Retrospective
Amin et al. (5)	2019	Impella-supported PCI Impella and shock: N = 1,792; IABP and shock: N = 22,558	Retrospective analysis with propensity matching	Higher costs and more bleeding associated with pVAD use Significant variation in costs and outcome between centers	Not specifically investigating cardiogenic shock
Tehrani et al. (11)	2019	Mixed etiology N = 204	Retrospective before/after study investigating effect of team-based approach including Impella	Significant increase in 30-day survival after implementation of protocol (47% to 58% to 77%)	Not study on pVAD device as such Retrospective Indication bias
Karami (12)	2020	Mixed etiology pVAD: N = 90; ECMO: N = 38	Retrospective analysis	No difference in 30-day survival for pVAD (47%) vs. ECMO (51%) Lower complication rate in pVAD group	Retrospective Indication bias
Dhruva et al. (9)	2020	AMI-CS N = 1680 (matched pairs)	Retrospective analysis with propensity matching	Lower in-hospital survival in pVAD group (55%) vs. IABP (65.9%)	Retrospective High survival IABP group suggests selection bias
Helgestad et al. (45)	2020	AMI-CS Impella: N = 40 (matched pairs); IABP: N = 40 (matched pairs)	Retrospective analysis with propensity matching	Higher 30-day survival in pVAD group (60%) vs. control (32.5%) No difference in survival in IABP group vs. control	Retrospective IABP and Impella not directly compared

Evolution code 159331 – 159342 from the Implants reimbursement list:



Context: lack of robust medical evidence



Code 159331-159342:



- Single use pump for temporary univentricular support in heart failure has to fulfill a number of reimbursement conditions.

<https://ondpanon.riziv.fgov.be/IRREQPublic/nl>

<https://ondpanon.riziv.fgov.be/IRREQPublic/fr>

Primary criteria of the reimbursement code 159331-159342:

- **ACUTE and ISOLATED** Cardiogenic Shock resistant to maximal conservative therapy.



AND/OR

- **AFTER CARDIOTOMY** in case of failure of weaning of extracorporeal circulation.

Code 159331-159342:



Every single case needs approval by the board of medical directors of the RIZIV/INAMI.

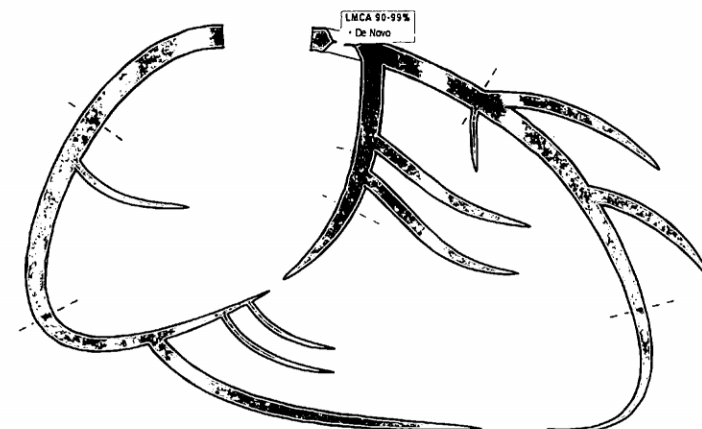
Therefore these cases need to be fully documented and described in detail.



Examples of insufficient documentation:

1. 'acute geïsoleerde cardiogene shock resistent aan maximale conservatieve therapie'

2. 'Gezien slechte biventriculaire functie met hoge inotropie en vasopressienood bij weaning cardiopulmonale bypass, werd besloten tot plaatsen Impella CP'



Documentation needed:

Comprehensible medical reporting:

- Patient history, sequence of medical events
- Cardiogenic shock etiology & timeline
- Maximal conservative medication therapy
- Hemopump placement justification
- Patient outcome information: per/post-procedural / in-hospital stay



Evolution code 159331 – 159342 from the Implants reimbursement list:



Context: lack of robust medical evidence



Clarification of code 159331-159342:

- There were discussions about the interpretation of the terminology:
 - Acute and Isolated Cardiogenic shock
- It was decided to clarify the terminology: Interpretation rule 39 (IR39).
- All Hemopump files for which reimbursement was not granted are being reviewed once again based on the IR 39.

Interpretation rule 39 terminology acute:

- The terminology 'acute' means:
 - New onset of cardiac failure or acute (sudden) exacerbation of chronic heart failure (quick manifestation or within few hours).



Interpretation rule 39 term isolated:

The terminology 'isolated' means:

- major dysfunction of the cardiac muscle and/or the cardiac valves.
- exclusion of septic, hypovolemic, obstructive or anaphylactic shock.

Cardiogenic shock is defined as a clear hemodynamic instability that persists despite maximal conservative medication therapy.

The  can be granted only under these conditions.

Important Note: the hemopump will not be reimbursed when used as prevention of cardiogenic shock in a planned high risk PCI.

CONCLUSION:



ACUTE and ISOLATED Cardiogenic Shock resistant to maximal conservative therapy.

AND/OR AFTER CARDIOTOMY in case of failure of weaning of extracorporeal circulation.

Interpretation rule 39 clarifies the acute and isolated terminology

<https://ondpanon.riziv.fgov.be/IRREQPublic/nl>

<https://ondpanon.riziv.fgov.be/IRREQPublic/fr>



Code 159331-159342:

- Pièces à usage unique d'une pompe utilisée pour un soutien univentriculaire temporaire de la fonction cardiaque déficiente. il doit **satisfait aux conditions suivantes:**
- Onderdelen voor eenmalig gebruik van een pompsysteem gebruikt voor de tijdelijke univentriculaire ondersteuning van de deficiënte hartfunctie. Moet aan **volgende voorwaarden worden voldaan:**

<https://ondpanon.riziv.fgov.be/Nomen/nl/159331/rules/numberrules>

Primary criteria for code 159331-159342:

- En cas de **choc cardiogénique isolé aigu**, résistant à une thérapie conservatrice maximale **et/ou après cardiectomie** avec impossibilité de déconnecter le bénéficiaire d'une pompe de circulation extracorporelle.
- in geval van **acute geïsoleerde cardiogene shock** resistent aan maximale conservatieve therapie **en/of na cardiectomie-ingreep** met de onmogelijkheid om de rechthebbende los te koppelen van de extracorporale circulatiepomp.

Interpretation rule 39 term ‘acute’:

- Le terme choc cardiogénique ‘aigu’ signifie que **l’insuffisance cardiaque est nouvelle ou s’ajoute à une insuffisance cardiaque chronique** où cette insuffisance cardiaque ne se **manifeste que très récemment** (en quelques heures) et rapidement.
- De term ‘acute’ cardiogene shock betekent dat het **hartfalen nieuw is of bovenop chronisch hartfalen** komt waarbij dit hartfalen **zich pas zeer recent** (binnen enkele uren) en snel manifesteert.

Regle Interpretative 39 term 'isolé':

Par choc cardiogénique 'isolé' on entend un choc dû à un **dysfonctionnement majeur du muscle cardiaque et/ou des valves cardiaques.**

Par choc et insuffisance cardiaque, on entend une **instabilité hémodynamique nette qui persiste malgré l'utilisation d'une thérapie médicamenteuse maximale.**

Pas préventif pour le déroulement difficile attendu d'une opération cardiaque.

<https://ondpanon.riziv.fgov.be/Nomen/fr/159331/rules/numberrules>

Interpretatieve regel 39 term ‘geïsoleerde’:

De term ‘geïsoleerde’ cardiogene shock betekent een shock ten gevolge van een **belangrijke dysfunctie van de hartspier en/of de hartkleppen**.

Met shock en hartfalen wordt een **duidelijke hemodynamische instabiliteit bedoeld die persisteert ondanks aanwenden van maximale medicamenteuze therapie**.

Niet preventief voor een te verwachten moeilijk verloop van een ingreep op het hart.

<https://ondpanon.riziv.fgov.be/Nomen/nl/159331/rules/numberrules>