دائـــــرة الـــصــحـــة DEPARTMENT OF HEALTH



| Health Technology Review | | |
|---------------------------------------|--|--|
| Technology Ref.: | HTA21044 | |
| Technology Name: | HTA 130 | |
| Approvals by International Bodies: | CE certificate | |
| Company name: | Horizon International Medical Supplies | |
| Agent in UAE: | Dr. Mohamad kanbour | |
| Email: | kanb@hims.ae; hims@hims.ae | |

| | HA130 Hemoperfusion disposable cartridge demonstrated benefits on | | | |
|----------------------|---|--|--|--|
| | clearance of middle uremic toxins such as B2MG and PTH and protein bound | | | |
| Short Description of | toxins. HA130 combined with conventional haemodialysis showed benefits in | | | |
| the Technology: | the complications of haemodialysis such as the uremic pruritis, sleep | | | |
| | disorders, refractory hypertension, and quality of lifeThe HA130 | | | |
| | hemoperfusion cartridge to be used on any dialysis machine | | | |

| Health Technology Assessment | Team Recommendation: |
|------------------------------|----------------------|
|------------------------------|----------------------|

Approve

Summary of Review:

It is a disposable cartridge which is added to the dialyzer used for Uraemia, maintenance haemodialysis related complications & renal failure, the product is applicable to haemodialysis patients, its absorbers Middle to macro molecular toxins of uraemia. HA130 hemoperfusion therapy provides a new solution for ESRD complications.

| Advantages | Disadvantages | |
|--|--|--|
| CE Marked Product | Lack of local cost effectiveness study | |
| In dialysis patients, hemoperfusion is considered | Further studies are required to prove the | |
| safe and effective when combined with | efficiency of the HP cartridge on haemodialysis | |
| conventional modalities. | patients | |
| Improve Quality of life for patients with Long - term haemodialysis; HP+HD joint treatment could prevent and improve long-term haemodialysis complications such as renal osteopathy, refractory skin pruritus, peripheral neuropathy, cardiovascular disease, refractory hypertension, nephro-encephalopathy, malnutrition etc. decrease morbidity of complications in long-term and short-term, prolong life span. | Risks of the technology are similar to the risks of the current practice; Complications of hemoperfusion. | |
| Enhance the efficiency of the Dialysis process | limited peer reviewed clinical trials | |
| Easy to use- Disposable | | |

• PUBLIC / م____





We recommend an **approval of using this technology** with the following conditions:

- 1. Utilizing the Cartridge as per the manufacturer & treatments guidelines & standards for haemodialysis patients .
- 2. Additional SME feedback is required from Nephrologists.
- 3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees and Patient
- 4. Provision of regular updates and reports about the product to DOH upon request.
- 5. Any other documents or information requested regarding the product and cost to finalize the approval process.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.











HA130 Use Criteria

| Question | Answer | Comments |
|--------------------|---|--|
| Which case? | haemodialysis patients; Long-term haemodialysis | |
| | and hemofiltration in blood of end-stage renal | |
| | disease (ESRD) patients | |
| Which doctors? | Nephrologists | |
| Which hospital? | Dialysis Centres- Specialized hospitals | |
| Inclusion criteria | chronic & ESRD haemodialysis patients | |
| | The hemoperfusion cartridge should be | |
| | performed in association with dialyzer by | |
| | connection in front of dialyzer, hemoperfusion | |
| | treatment time is recommended as 120-150 | |
| | mins. | |
| Exclusion criteria | Patients Allergic to dialysis equipment | As HA 130 could neither clear excess water in the uremic patient's body, nor regulate electrolyte and acid base balance, normally it was not advised to be employed alone. |

