دائــــــرة الـــصــحـــة DEPARTMENT OF HEALTH



| Health Technology Review              |                                    |  |
|---------------------------------------|------------------------------------|--|
| Technology Ref.:                      | HTA22047                           |  |
| Technology Name:                      | Y-90 RADIOEMBOLISATION             |  |
| Approvals by<br>International Bodies: | FDA approved                       |  |
| Company name:                         | CLEVELAND CLINIC ABU DHABI         |  |
| Agent in UAE:                         | FADI YOUNESS, MD                   |  |
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|                      | Y-90 RADIOEMBOLISATION OF LIVER TUMORS. THIS IS AN ESTABLISHED     |
|----------------------|--|
|                      | TREATMENT THAT IS FDA APPROVED AND USED FOR 20 YEARS. IT IS        |
| Short Description of | EMBOLIZATION PARTICLES WITH Y-90 RADIONUCLEIDE EMBEDDED IN IT. THE |
| the Technology:      | PARTICLES ARE USED TO EMBOLISE LIVER TUMORS (PRIMARY AND           |
|                      | METASTASIS). IT IS BRACHYTHERAPY LIKE INTERNAL RADIATION +         |
|                      | EMBOLLIZATION TREATMENT OF LIVER CANCERS.                          |

Health Technology Assessment Team Recommendation:

Approve

## Summary of Review:

It is a minimally Invasive, targeted therapy for Cancer in the Liver, that delivers internal radiation to hepatic tumours in the form of microspheres, can be delivered to the hepatic tumour as either a constituent of a glass microsphere, TheraSphere®, or as a biocompatible resin-based microsphere, SIR-Spheres®. The treatment used in certain patients who are not candidates for surgery or percutaneous ablation of their liver tumors. It's a palliative treatment that provides relief from symptoms but does not provide a cure for liver cancer. As with any treatment, there are risks and side effects; however, extensive measures are put in place before the procedure is done to limit the incidence of complications.

| Advantages  | Disadvantages  |
|---|--|
| FDA approved & Minimally Invasive procedure,<br>when compared to standard radiation therapy.  | The most common side effect after Y-90 radiotherapy is fatigue (feeling very tired). This can be mild or severe. It can last up to a few weeks. Other side effects include: • Poor appetite • Mild abdominal pain • Slight fever • Nausea. These symptoms should slowly go away over 1 to 2 weeks. |
| Improving Patient quality of life,<br>radioembolization can extend the life of a<br>patient with inoperable tumours from months<br>to years & improve survival rates. | It's a palliative treatment that provides relief<br>from symptoms but does not provide a cure for<br>liver cancer.   |
| Safe procedure as Several measures have been<br>put in place to limit and control the risks of  | Damage to blood vessels rarely occurs Ulcers in the stomach or duodenum if the microspheres  |

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| radioembolization, also it has been shown to be  | settle in the wrong place Infection after the                  |
| safe in combination with systemic treatments     | procedure, even after antibiotics are given.                   |
| for cancer, such as immunotherapy.               |  |
|  |  |
| Radioembolization presents fewer side effects    | Less common complications: • a build-up of                     |
| than external beam therapy, and targets the      | fluid • high levels of alkaline phosphatase                    |
| blood supply to the tumour directly.             | infection     inflammation of the pancreas                     |
|  | <ul> <li>raised blood pressure</li> <li>gallbladder</li> </ul> |
|  | inflammation • pneumonia • allergic                            |
|  | reactions • harmful effects on the kidneys.                    |
| Alternative option for patients with inoperable  |  |
| tumours, it may also allow for more curative     |  |
| options such as surgery or liver transplantation |  |

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

- 1. Using the technology by healthcare professionals in specialized medical centers for this procedure on applicable patients only.
- 2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
- 3. Provision of regular updates and reports about the product to DOH upon request.
- 4. 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.









## Population, setting and intended user for Technology "Y-90 RADIOEMBOLISATION"

## Population/ Intended User;

- Radioembolization is a therapy used to treat advanced-stage liver cancer that has either started in the liver or spread to the liver from another part of the body (metastatic).
- Treatment of primary liver tumors (Intrahepatic Cholangiocarcinoma, as well as other liver metastatic disease (NETs,Uveal Melanoma, Breast Cancer, ...) is off label.
- To be performed by:
  - Radioembolization is an outpatient treatment performed by an interventional radiologist with training in interventional oncology. The treatment is commonly performed with sedation and local anesthesia.
- Clinical Setting:
  - Hospitals
- Condition of use:
  - Y-90 to treat tumors that were initially formed in the liver or have spread (or metastasized) to the liver from another part of the body. It is a palliative treatment.
  - Radioembolization procedures are typically performed using x-ray guidance.
- Exclusion criteria:
  - Radioembolization is not recommended in cases of severe liver or kidney dysfunction, abnormal blood clotting or a blockage of the bile ducts.

