Health Technology Review	
Technology Ref.:	HTA21047
Technology Name	Caris Molecular Intelligence (CMI)
Approvals by International Bodies:	The predictive tests used in personalized medicine are overseen by two federal agencies-the FDA and the Centres for Medicare & Medicaid Services (CMS)- CE marked as an in vitro diagnostic medical device in 2015.- CARIS lab accredited by CLIA, CAP & have ISO15189:2012
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Short Description of the Technology:	MI Profile is a multi-platform, solid tumour biomarker analysis service for therapeutic decision support and clinical trials matching. Technologies used to assess DNA, RNA and Proteins include, Next-Generation Sequencing DNA/RNA (also called MI Tumour Seek), Pyro Sequencing, Fragment Analysis, Immunohistochemistry and Chromogenic in situ Hybridization.

Health Technology Assessment Team Recommendation:	**Approved**

Summary of Review:

Caris MI is predictive diagnostic tests; performs comprehensive molecular testing on the DNA, RNA and Proteins to identify the biomarkers driving a patient's tumour. This information help guide management of locally advanced or metastatic cancer and may be a powerful tool to aid oncologists in personalizing cancer therapies for their patients. Hence, improve clinical outcomes and potentially reduce health care costs & avoid harmful treatments, the lab centralized in USA and the samples sent to their lab, Caris returns the CMI report within 14 days of receiving the sample.

Advantages	Disadvantages
Precision Medicine; Treatment decisions based on CMI would represent a shift from therapy based on tumour site to a precision medicine approach based on the unique molecular characteristics of a patient's tumour.	**Risk for patient information data leak;** Patient samples sent to CARIS Lab in US.
Improve clinical outcome: Tumour profiling can help guide and identify the most effective treatment plan (individualization of cancer treatment.)	The tests results shall be ordered and interpreted **by professional genetic counsellors**

Aid in Treatment management and guidance; The test could be helpful tool for patients with certain rare cancers or other unusual circumstances.it Helps in Identifying therapies that may not have been considered and navigate among the drugs & therapies that have potential benefit.	**limited evidence** on clinical effectiveness of the test; there are currently no randomised controlled studies comparing CMI-guided treatment with non-CMI-guided treatment and no evidence on its use in children.
Enhance Patient's quality of life; Advance tumour testing could help in preventing unnecessary cost and even harmful treatments.	**Expensive** however in comparison with other available molecular profiling testing, CMI consider cheaper with high clinical benefit and impact.
The results are analysed and summarised in **one comprehensive single report**, the report include summary of important findings, Details of supporting evidence for each therapy, A list of any ongoing clinical trials that match the patient's biomarker expression profile and Appendices with full assay results.	Similar known risks of the genetic testing.

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

1. Utilize the technology for only patients who are within the inclusion criteria.
2. For Emirati population in Abu Dhabi in alignment with Emirati Genome Project.
3. Ensure the information security compliance and data privacy with UAE government law.
4. Ensure the proper Communication of Test Results and Risks.
5. Provision of regular updates and reports about the product to DOH upon request.
6. Any other documents or information requested regarding the product

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 "Caris Molecular Intelligence (CMI)"

- **Population/ Intended User**;
  - Patients with locally advanced or metastatic cancer in secondary or tertiary care settings who have no other standard care options remaining, but who are fit enough to consider further treatment (rare, aggressive, or refractory cancer patients)
- **To be ordered by**:
  - Oncologist
  - Pathologist
  - Histopathologist
- **Clinical Setting:**
  - Specialized Hospitals that have oncology department
  - cancer centers
  - Oncology institute
- **Condition of use:**
  - Patients with locally advanced or metastatic cancer**.**
- **Exclusion criteria:**
  - It is not indicated for use in de novo treatment planning because it uses a non-site-specific approach to treatment based on molecular profile, rather than exploring the use of standard care regimens by tumor site.