

Health Technology Review			
Technology Ref.:	HTA-23032		
Technology Name:	Contrast Enhanced Mammography (CEM).		
Approvals by	FDA Approval		
International Bodies:			
Company name:	General Electric Healthcare		
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	Mammography is the most reliable imaging technique for breasts, but
Short Description of the Technology:	limitations can exist due to breast density. This is especially the case in dense
	breasts where tissues may overlap. For a final diagnosis, radiologists often
	need complementary imaging, such as breast MRI. Contrast Enhanced
	Mammography / SenoBright HD offers confidence of MRI with fewer costs
	overall. An intravenous iodine injection is performed on the patient in the
	same room as the mammogram exam.

Health Technology Assessment Team Recommendation:	Approve	
Summary of Pavianus		

Summary of Review:

Contrast Enhanced Mammography is becoming a valuable tool in the diagnosis and staging of primary breast cancer. It improves the diagnostic accuracy of mammography, providing more accurate tumor sizing and identification of multifocal disease, particularly in women with denser parenchymal background patterns. Performance is equivalent to MRI and there is evidence of improved specificity, with a reduction in false-positive interpretations. Compared with MRI, it is also potentially more accessible and cheaper. CEM has the potential to detect cancers even faster, even among low risk populations, while improving the patient t experience.

Advantages	Disadvantages
studies comparing CEM and MRI showed	Main side effect is due to possible allergies
similar performance.	to contrast and to patient with Renal
	disfunction
Contrast Enhanced Mammography offers	Slightly more radiation exposure than
the confidence of MRI with fewer costs	regular mammograms
overall. An intravenous iodine injection is	
performed on the patient in the same room	
as the mammogram exam	
FDA Approved	
Perform the quick exam at the same time,	
same location, with the same equipment.	



We recommend approval this technology with the following conditions:

- 1. performed by Healthcare Professionals.
- 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.

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.

Technology Image





Population, setting and intended user for Technology "Contrast Enhanced Mammography."

Population/ Intended User.

- patients with dense breasts.
- used to evaluate breast symptoms or abnormalities seen on mammogram.
- to assess the extent of cancer in women with newly diagnosed breast cancer and to monitor response to neoadjuvant chemotherapy prior to surgery.

■ To be performed by:

Specialist mammographer/Radiographer.

Clinical Setting:

Hospitals and special mammogram centers

Condition of use:

- who has received an inconclusive result after standard mammogram being referred to MRI
- The Quality of Tumor Size Assessment

Exclusion criteria:

Do not perform CEM exam for patients with implants.