Health Technology Review	
Technology Ref.:	HTA22052
Technology Name:	NT-proBNP
Approvals by International Bodies:	CE Marked – FDA approval
Company name:	Roche Diagnostic Middle East
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Short Description of the Technology:	Immunoassay for the in vitro quantitative determination of N-terminal pro B-type natriuretic peptide in human serum and plasma. This assay is indicated as an aid in the diagnosis of individuals suspected of having congestive heart failure and detection of mild forms of cardiac dysfunction. The test also aids in the assessment of heart failure severity in patients diagnosed with congestive heart failure. This assay is further indicated for the risk stratification of patients with acute coronary syndrome and congestive heart failure, and it can also be used for monitoring the treatment in patients with left ventricular dysfunction. The test can help in the cardiovascular risk assessment of patients with type 2 diabetes mellitus. The test is further indicated to aid in the identification of patients at risk with type 2 diabetes mellitus, without known history of cardiovascular disease, to optimize cardioprotective treatment. This test can be used to identify elderly individuals at high-risk for atrial fibrillation. Test principle: Sandwich principle. Total duration of assay: 18 minutes. Test is used on Roche Immune-analysers cobas e402 and e801

Health Technology Assessment Team Recommendation:	**Approve with limitation**

Summary of Review:

NT-proBNP is a diagnostic test that detect the N-terminal proBNP (NT-proBNP) in human serum and plasma, which the gold standard biomarkers in determining the diagnosis and prognosis of heart failure. This test can be used to identify elderly individuals at high-risk for atrial fibrillation. The test is approved by FDA and CE-Marked. Roche submit the request to expand the usage of the test to help in the cardiovascular risk assessment of patients with type 2 diabetes mellitus as preventive measure. The evidence for this request is limited and may cause the increase in health cost.

Advantages	Disadvantages
Standardized diagnostic pathway for suspected heart failure as per NICE guidelines.	Limited evidence on the new indication for the test which is to help in the cardiovascular risk assessment of patients with type 2 diabetes mellitus without prior HF history
FDA Approved and CE marked device	Considering the NT-proBNP test for T2D patients with no prior HF history as preventative

	measure may cause increase in health cost.
Provided study concluded that in patients with type 2 diabetes, levels of hs-cTnT and NT-proBNP greatly improve the accuracy with which the risk of cardiovascular events or death can be estimated and may be clinically useful in this role.	Unavailability of international & local guidelines for the new indication of NT-proBNP in diabetic patients type 2 for heart failure assessment
No risk or harm on Patients and healthcare professionals	It is not approved as a routine test in type 2 DM patients by the FDA or NICE UK
Fast results (18 minutes)	Lack of cost effectiveness & comparisons study
Easy to do as it's a POINT-OF-CARE TESTING	

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

1. NT-proBNP is a standardized diagnostic tool for suspected heart failure cases.
2. Using NT-proBNP as an aid diagnostic test for diabetic patients type 2 for the diagnosis of heart failure in conjunction with the clinical information, examination and other data available to the physician.
3. To provide DOH with further evidences both Clinical efficacy and cost effectiveness study for the new induction after 6 months from the DOH date of approval.
4. To comply with DOH guidelines for the provision of cardiovascular disease management programs.
5. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
6. Provision of regular updates and reports about the product to DOH upon request.
7. 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.

Technology Image

Population, setting and intended user for Technology "NT-proBNP"

- **Population/ Intended User**;
  - NT-proBNP is indicated as an aid in the diagnosis of individuals suspected of having congestive heart failure and detection of mild forms of cardiac dysfunction.
- **To be performed by**:
  - To be ordered by healthcare professional.
- **Clinical Setting:**
  - Authorized laboratories
- **Condition of use:**
  - The test ordered for DM2 patients should be considered in conjunction with the clinical information and other data available to the physician for high risk population.
- **Exclusion criteria:**
  - Other conflicting medical issues