Health Technology Review	
Technology Ref.:	HTA21013
Technology Name:	Dexcom G6 System
Approvals by International Bodies:	NICE – UK FDA CE certification
Company name:	**Julphar pharmaceutical co.**
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Short Description of the Technology:	DexCom G6 is a Real Time continuous glucose monitoring (RT-CGM) system that consists of an implantable sensor, a transmitter and a display monitor(receiver). The sensor is inserted in the subcutaneous tissue to measure interstitial fluid (ISF) glucose level electro-chemically every 5 minutes. The system contains an algorithm (which plays a crucial role in the system's accuracy) and is factory-calibrated (i.e. does not require capillary blood glucose values to calibrate the system against the electrical signal (that is proportional to IFG glucose level)). The sensor's lifespan is 10 days, while the transmitter's life span is 3 months. The display monitor can be replaced by using a compatible mobile phone to get the CGM data displayed on it with the use of a dedicated mobile application. The system allows CGM data sharing with patient's family and healthcare team, if needed. The system is supported by a cloud- based platform (Clarity).

Health Technology Assessment Team Recommendation:	**Approved**

Summary of Review:

Dexcom G6 system it's the upgraded version of the previous technology Dexcom G4, the device intended to be an alternative to routine finger-prick blood glucose monitoring for people aged 2 and over, including pregnant women, who have type 1 or type 2 diabetes, have multiple daily injections of insulin or use insulin pumps and are self-managing their diabetes. DexCom G6 is a system consist of Sensor, transmitter, auto applicator and display device. The sensor measures the glucose level and the transmitter send the glucose data to the display device. The device is been used in UK, USA,

Advantages	Disadvantages
Efficiency: Continuously tracks glucose levels in real-time and displays results on a smartphone app or receiver device, also have alert system that can alert the patient if the blood sugar is trending high or low. (Has alarm function) hypoglycaemia alerts	**Costly:** can be expensive with or without insurance, especially as the system requires a transmitter as well as sensors that both need a prescription for purchase
Efficacy: water resistant and can measure the	**Connectivity**: the Bluetooth signal may

blood glucose up to 10 days	disconnect from your phone or insulin pump, making the data less reliable
User friendly: wearable sensor, pain-free insertion with a one-button plastic applicator device that allows for one-handed insertions	**Site Concerns**; selection & irritation, Sensor adhesion
Improve Quality of life; improve diabetes self-management, reduce severe hypoglycemic events leading to hospital admissions and hospital visits	**Data security**: The risk for Patients data information leaks
Data-sharing feature: allows of Remote viewing of data by care givers.	**The device is not suitable** for people on dialysis, or critically ill patients.
Factory calibrated – No fingerstick required - Decreased fingerstick testing	FDA did not approve the usage of the device on pregnant woman while its recommended in UK-NICE appraisals
FDA & CE certification	

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

1. To ensure the compliance with Information security regulation for patients' data.
2. The system to be used and monitored by the professional in the relevant field.
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
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

Technology Image

Population, setting and intended user for Technology "Dexcom G6 System"

- **Population/ Intended User**;
  - Type 1 and Type 2 DM (uncontrolled)
  - Gestational Diabetes (pregnancy)
  - Diabetic with High A1C, on multiple daily doses of Insulin
- **To be performed by**:
  - Self-Used
- **Clinical Setting:**
  - NA
- **Condition of use:**
  - As per the manufacturer instructions
- **Exclusion criteria:**
  - Other conflicting medical issues (the device is not intended for people on dialysis, or critically ill patients)