Health Technology Review	
Technology Ref.:	HTA22044
Technology Name:	Dry Eye treatment-Rexoneye
Approvals by International Bodies:	CE marked
Company name:	Mediclinic Al Noor
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Short Description of the Technology:	It has been known for centuries that electric currents flow throughout our body and carry the signals necessary for its operation. The heart and muscles in general contract because they are stimulated by an electric current, just as the eyes and ears allow us to see and hear because they generate and transmit electrical signals to our brain. These electrical stimuli are generated by the body itself, but others may be artificially generated and applied by biomedical tools designed for this purpose. It was recently discovered that electrical signals are able to interact with the regulation of cell behavior and homeostasis of tissues; phenomena that are the basis of many healings processes the main difficulty of artificial stimulation is to be able to generate the correct signals, that is, those able to interact with the organism to stimulate regenerative processes Rexon-Eye® is a non-invasive device that provides durable treatment for all forms of dry eye syndromes. It works by applying low-power high-frequency electric fields, capable of stimulating the metabolism and natural regeneration of cells. Rexon-Eye® treats the cause of the dry eye disease delivering long-term results. The treatment addresses all types of the dry eye syndromes, both evaporative as well as aqueous deficient, as evidenced by published studies in several subjective and objective measurements

Health Technology Assessment Team Recommendation:	**Conditional Approval**

Summary of Review:

The key technology used in Rexoneye is Quantum Molecular Resonance (QMR) technology, QMR is a technique in which low-intensity, high-frequency electric currents are administered to a biological tissue through contact electrodes, it is an in-house treatment for evaporative dry eye, where the oily layer of the tear film is insufficient to stop the watery tears from evaporating. painless and non-invasive treatment that stimulates the metabolism and natural regeneration of cells in the oil glands.

The treatment has shown initially clinical evidence to increase tear production and stabilize the tear film. This helps minimise rapid evaporation of tear fluid from the eye surface, meaning the eyes feel hydrated for much longer periods of time. Another benefit of the treatment is restoring the activity of the meibomian glands which significantly reduces the risk of further gland disease and cellular decay. QMR emits an alternating electrical signal containing a specific range of frequencies, from 4 to 16

MHz, that are the same as the molecular bonds in biological tissue.

Advantages	Disadvantages
CE marked Device	The patient may suffer from Slight blurred vision post treatment.
QMR technology used in Rexon-Eye clinically proved to be effective and safe in improving subjective and objective ocular parameters, as well as capable to normalize inflammatory markers.	The treatment duration is about 40 Minutes, it takes 20 Minutes for each eye at a time.
Non-invasive treatment, the treatment stimulates the cells to regain the natural inner balance.	The device shall be used by trained professional.
This technology has allowed injured cells to react and restore their functions in the neuro-ophthalmologic pathway.	QMR technology is new in the market with limited strong evidence about the efficacy of this treatment. Future studies will be needed to demonstrate the effectiveness of this treatment.
The treatment results are immediate and long term which result in patient satisfaction.	Lack of local cost effectiveness study
Alternative option to eye drops (artificial tears.)	

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

1. The applicant shall refer back to DOH after 6 Months from date of approval with more evidence on the clinical and cost effectiveness of the treatment for re-evaluation.
2. Using the technology by healthcare professional in specialized centers on applicable patients only.
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 "Dry Eye treatment- Rexoneye"

- **Population/ Intended User**;
  - Patients who suffer from dry eye syndromes.
- **To be performed by**:
  - By Ophthalmologists.
- **Clinical Setting:**
  - Hospitals, ophthalmology clinic.
- **Condition of use:**
  - Clinical setting.
- **Exclusion criteria:**

  Rexon Device could not be used on the following
  - Pregnant women
  - Patients carrying active implantable devices
  - Neonatal or pediatric Patients
  - Patient who undergo ocular surgeries past month