

LICENCE CONDITIONS ON THE PROVISION OF LUXTURNA (VORETIGENE NEPARVOVEC) AS A TREATMENT OPTION FOR PATIENTS

IMPOSED UNDER SECTION 13(1) OF THE HEALTHCARE SERVICES ACT 2020

1 Application

- 1.1 These licence conditions (“**LCs**”) apply to all persons that have been licensed under the Healthcare Services Act 2020 (the “**HCSA**”) (such persons referred to as “**Licensees**”).
- 1.2 A breach of these LCs may result in regulatory action being taken against Licensees under section 20 of the HCSA, including but not limited to:
- (a) suspension or revocation of the Licensee’s HCSA licence;
 - (b) shortening the term of the Licensee’s HCSA licence;
 - (c) a direction requiring the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or
 - (d) a direction requiring the Licensee to pay a financial penalty.
- 1.3 For avoidance of doubt:
- (a) the defined terms as used in these LCs shall have the meanings ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated;
 - (b) these LCs do not override a healthcare professional’s duty to make clinical decisions that are in the best interests of each patient; and
 - (c) the requirements in these LCs are without prejudice, and in addition to the requirements imposed under the HCSA as well as any Regulations and other applicable licensing conditions, directions, codes of practice made thereunder.

2 Definition

- 2.1 In these LCs, “**Luxturna**” means “Luxturna (Voretigene Neparvovec)”.

3 Restrictions on the Provision of Luxturna as a Treatment Option for Patients

3.1 A Licensee shall not provide Luxturna as a treatment option for its patients, unless the Licensee satisfies the requirements in paragraph 3.2 below.

3.2 A Licensee shall be allowed to provide Luxturna as a treatment option for its patient, provided that:

- (a) the patient has *Leber Congenital Amaurosis* or *Retinitis Pigmentosa*; and
- (b) the Licensee is licensed under the HCSA to provide an acute hospital service or an ambulatory surgical centre service under any one of the following business names:

- (1) National University Hospital;
- (2) Singapore National Eye Centre; and
- (3) Tan Tock Seng Hospital.