HTA Council Summary of Judgment

The HTAC concluded with the following findings based on its decision framework as stipulated in Republic Act 11223 or the *Universal Healthcare Act*:

Criteria	Adults Post-Ischemic Stroke
Clinical Efficacy / Effectiveness & Safety	Based on the review of clinical evidence, the relative treatment effect of cerebrolysin in combination with rehabilitation and/or standard of care (C-RS) compared to rehabilitation / SOC (RS) alone across all efficacy and safety outcomes mostly yielded non-statistically significant results (i.e., *inconclusive*). The HTA Council has therefore deemed that C-RS is **non-inferior** to RS alone for the treatment of adults post-ischemic stroke, based on moderate to very low certainty of evidence.
Cost- effectiveness	Since the clinical impact judgment is **non-inferior**, the economic evaluation was performed through cost-minimization analysis and budget impact analysis. *(Results are presented under Affordability and Viability.)*
Affordability and Viability	The estimated budget impact analysis and the costing analysis based from the computation of the HTAC showed that the government will potentially incur an additional cost of **₱25,067.25** per potential user and **₱5.15 B** for all targeted users for three years.

HTA Council Preliminary Recommendation

The HTA Council ***does not recommend government financing*** of cerebrolysin, in combination with rehabilitation, for the treatment of adults post-ischemic stroke ***through its non-inclusion in the PNF*** due to the following:

- Based on one critically low-quality review[1] (SR) that reported efficacy outcomes, it was shown that adding cerebrolysin to rehabilitation and/or SOC is clinically **non-inferior** compared to rehabilitation alone. Upon validation of quality of evidence through GRADE and ROB, the HTAD-validated GRADE ratings were generally lower than that of the SR[1].
- Based on one moderate-quality SR[2] and one high-quality SR[3], all safety outcomes were not statistically significant. Therefore, the SC deemed there **is insufficient evidence to assess** for the safety of adding cerebrolysin to rehabilitation and/or SOC.
    - Furthermore, it was found that the government will potentially incur ***additional*** costs of **₱25,067.25** per target user and an additional **₱5.15 B** for all targeted users for three years if the government will shift to this new intervention.

[1] Beghi et al (2021), [2] Strilciuc et al (2021), [3] Ziganshina et al (2020)