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Clinical Expansion: Leveraging Real-World Evidence for Optimized Patient Outcomes in Taiwan

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Renal anemia management in Taiwan has evolved within a distinct policy-driven framework under the National Health Insurance (NHI) system. Since 1995, erythropoiesis-stimulating agent (ESA) dosing has been capped at approximately 20,000 IU per month—lower than in many other healthcare systems—necessitating adaptive treatment strategies. The early adoption of intravenous iron supplementation following a national consensus in 1996 (serum ferritin <300 ng/mL and/or transferrin saturation <30%) established an iron-optimized paradigm aimed at achieving hemoglobin targets of 10–11 g/dL while minimizing ESA exposure. Real-world evidence from the Taiwan Renal Registry Data System supports this approach. In the AIM-HD study, hemoglobin levels <10 g/dL were associated with increased all-cause and cardiovascular mortality, whereas optimal outcomes were observed at ferritin levels of 300–800 ng/mL and transferrin saturation of 30–50% in hemodialysis patients. These findings, consistent across dialysis modalities, highlight the importance of balanced anemia correction. Furthermore, treatment responsiveness—reflected by the erythropoietin resistance index (ERI)—and iron regulatory pathways, particularly hepcidin-mediated iron utilization, are increasingly recognized as critical determinants of patient outcomes beyond hemoglobin targets alone. The clinical landscape is now undergoing a pivotal transition with the introduction of vadadustat in Taiwan. Following regulatory approval by the Taiwan Food and Drug Administration (TFDA) in 2024 and subsequent reimbursement for hemodialysis patients under the NHI system, vadadustat became clinically accessible in late 2025. This transition represents a shift from ESA-centered strategies toward oxygen-sensing pathway modulation. In the context of Taiwan's historically ESA-restricted environment, the adoption of HIF-

prolyl hydroxylase inhibitors offers a unique real-world model to reassess anemia management strategies, with the potential to further optimize erythropoiesis, improve iron utilization, and reduce treatment resistance. Taiwan's experience thus provides a natural clinical experiment bridging policy-driven care and next-generation therapeutics in renal anemia.

Keywords: erythropoiesis-stimulating agent, iron, HIF-prolyl hydroxylase inhibitors, vadadustat