Decision Tree – Named Patient Program vs Compassionate Use Program

Patient with an unmet clinical need

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Can the patient be treated with an authorized product for the same indication? — **YES** → **Use authorized product**

NO

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Are they eligible to participate in an on-going clinical trial for the same indication? — **YES** → **Enroll in the clinical trial**

NO

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Pre-requisite check: Is there an ongoing CT in an ICH country or ongoing MAA in the same indication? — **NO** → **Access via Named Patient Program (individual patient access) ***

YES

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Does the national regulation require treatment under a cohort pathway due to patient numbers? — **NO** → **Access via Named Patient Program (individual patient access) ***

YES

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Access via Compassionate Use Program (group-based access) *

* The above decision tree outlines the basic regulatory eligibility only. Other factors, such as patient numbers, client needs, and stakeholder engagement will also form a critical part in the final pathway decision