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Feasibility of Indication-Specific Pricing for Life Cycle Management of an Innovative Rare Disease Product

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Introduction

The feasibility to implement **indication-specific pricing for pharmaceutical products** is generally considered low in most global markets. The study explored options for **multi-indication pricing strategies** for a product launched globally, with the goal of enabling **future rare disease indication expansion**.

Objectives

The objective of this study was to evaluate **different strategic options and tactics that would enable indication-specific pricing,** for a product with the potential to launch in multiple rare diseases.

We assessed the **opportunity for new indications to establish a distinct price**, as well as options to mitigate price changes to the previously launched indications.

Methods

Primary research involved structured interviews with 40 local experts across the US, Germany, France, China and Japan. Experts were screened ensure a holistic assessment from payer, regulatory and medical billing/coding perspectives.

Additionally, **comprehensive secondary research** was conducted to evaluate the local regulatory and payer policy landscapes in each market.

Results

Based on the assessment across five markets, **establishing a dual brand** or **changing the route of administration** are considered top tactics to enable indication-specific pricing.

Feasibility Assessment by Tactic

Applicable For:

Increasing feasibility of tactics

Establishing a second brand name:

- Across most markets, **launching a new indication under a different brand name** can lead to distinct pricing negotiations, allowing for indication-specific pricing.
  - **Risk:** However, this strategy requires **securing regulatory approval of the second brand name, requiring a significant difference for the new indication** (e.g. establishing a distinct patient population, shifting from non-orphan to orphan designation, or launching with significantly different dosing).
- In China, pricing negotiations with the NRDL occur at the generic name level (chemical name + route of administration), meaning that a **new brand name alone will not enable differential pricing.**

Changing the route of administration (RoA)

- In the US, changing the RoA **enables a new NDC** and allows for a distinct price to be established.
- Although payers in Germany, France and Japan can technically grant a distinct price for a new RoA, payers are likely **to reference existing indication pricing,** meaning that pricing may not be fully decoupled from previous indications.
- However, in China, **only a significant change to the RoA** (e.g. IV to subcutaneous) can enable a distinct price, in the case that it triggers a new generic name.

Price referencing to previous indications is likely

Revising the drug formulation:

- In the US, modifying the drug formulation (e.g. adding a non-therapeutic carrier) **can allow for a distinct price point**, as it is viewed as a new product with a new NDC code.
- In Japan, a new formulation can support establishing a new price point, though payers can still **reference the price of previous indications** or conduct a foreign price adjustment for the new indication.
- Additionally, under EU law (Regulation 469 /2009), a **new formulation for an existing active substance does not qualify as a new product,** so payers in Germany and France are likely to reference previous indication pricing.

Price referencing to previous indications is likely

Adjusting the strength or concentration:

- In the US only, **changing the strength of the drug or the concentration of the vial for a new indication can establish a new NDC** and support indication-specific pricing.
- However, payers in other markets will still **formally reference the price per mg of previous indications,** when assessing a new indication launched under a different concentration.

Price referencing to previous indications is likely

Launching with a drug delivery device:

- Utilising a new drug delivery system can **lead to differential pricing in the US** as it establishes a new NDC.
- However, payers in other markets are likely to view an added drug delivery device to an existing **indication as the same value proposition** and are unlikely to grant a distinct price.

Conclusions

To achieve indication-specific pricing for innovative multi-indication therapies**, manufacturers need to thoroughly assess local payer policy landscapes**. This involves identifying the most effective strategies and tactics in each market while **carefully assessing the potential risks and financial viability associated with each, and alignment to the global strategy for the product.**

Abbreviations

RoA = Route of Administration; IV = intravenous; NDC = National Drug Code; IRA = Inflation Reduction Act; MFN = Most Favored Nation

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