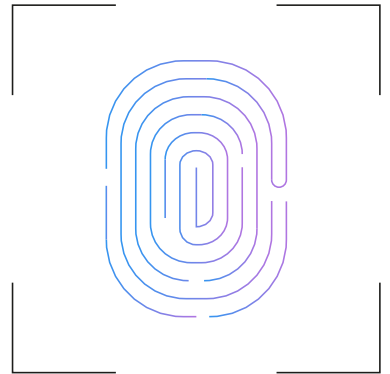


Developing a Regional Reimbursement Dossier

Case Study | Reimbursement Dossier

Developing a Regional Reimbursement Dossier to Support HTA Submissions in Latin America



Background

A biopharmaceutical company preparing to launch a rare disease therapy in Latin America required a robust regional reimbursement dossier to support market access activities. The dossier was intended to serve as a central reference for Health Technology Assessment (HTA) evaluations and pricing and reimbursement negotiations across multiple Latin American markets.

The Challenge

The client needed a clear, evidence based dossier that could support submissions across regions while remaining flexibility for country specific adaptation.

Key challenges included:

- Understanding varying HTA requirements across Latin American countries
- Identifying and addressing evidence gaps relevant to rare diseases
- Sourcing local data to support burden of disease, unmet need, and economic value
- Ensuring the regional dossier could be efficiently localized for country level use

Expert insight was required to ensure consistency, relevance, and effectiveness across markets.

The Solution

Clarivate's and HTA experts delivered a structured, regionally tailored reimbursement dossier supported by targeted evidence generation.

Key elements included:

HTA landscape review:

Assessment of HTA templates and submission requirements for key Latin American countries to ensure full alignment with local expectations.

Evidence gap analysis and literature review:

Identification of data gaps followed by targeted research to populate key sections of the dossier, including epidemiology, current treatment landscape, unmet need, and economic evidence.

Local market insights:

Incorporation of country specific data, including clinical treatment guidelines and inputs required to support economic models.

Reimbursement intelligence:

Desk research to assess recent reimbursement decisions for comparator treatments.

Localization guidance:

Strategic advice to enable affiliates to adapt the regional dossier into country specific HTA submissions.

The Results

Clarivate delivered a compelling, evidence based regional reimbursement dossier to support market access in Latin America.

Outcomes included:

- A comprehensive regional dossier suitable as a central HTA reference
- Clear articulation of the value of a rare disease treatment tailored to Latin American markets
- Evidence and guidance enabling successful localization for country level HTA submissions
- Improved readiness for pricing and reimbursement negotiations across the region

This work enabled the client to approach Latin American HTA bodies with a consistent, credible value narrative while retaining the flexibility required for localization.