Planning and Implementing a Reimbursement Submission Strategy

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Disclaimer

- This presentation will be focused on the content of reimbursement submissions rather than on the format of reimbursement submissions.

Agenda

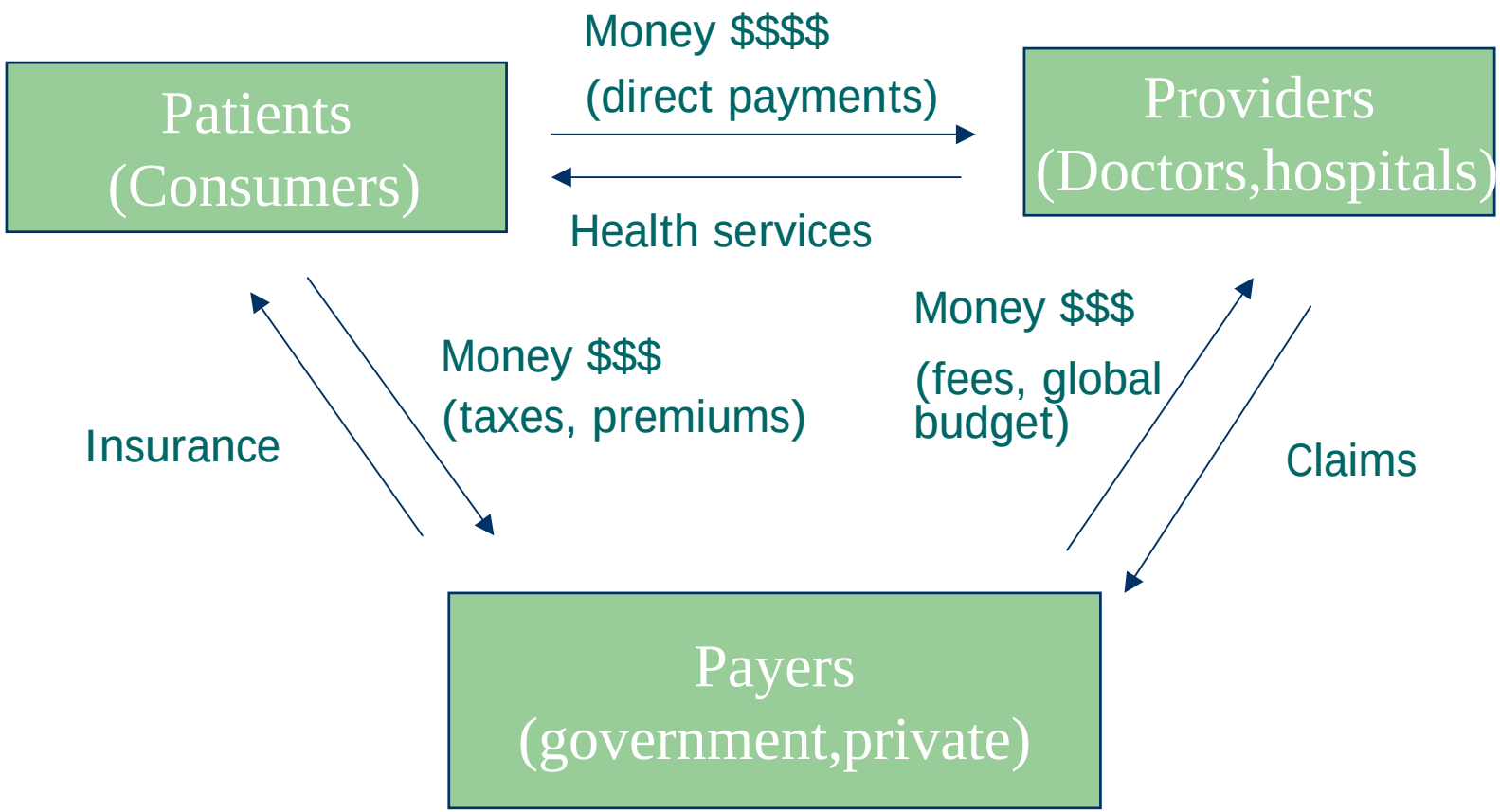
- Background
- Reimbursement process

Reimbursement Reality

"If we **do not have** the resources to do all that is technically possible, then medical care **must be limited** to what is of proven value… As we clearly **cannot afford** to do all that is technically possible, and as budgets become tighter, even medical interventions of proven value need to be **assessed according to priority**."

Hampton JR. The end of clinical freedom. BMJ 1983

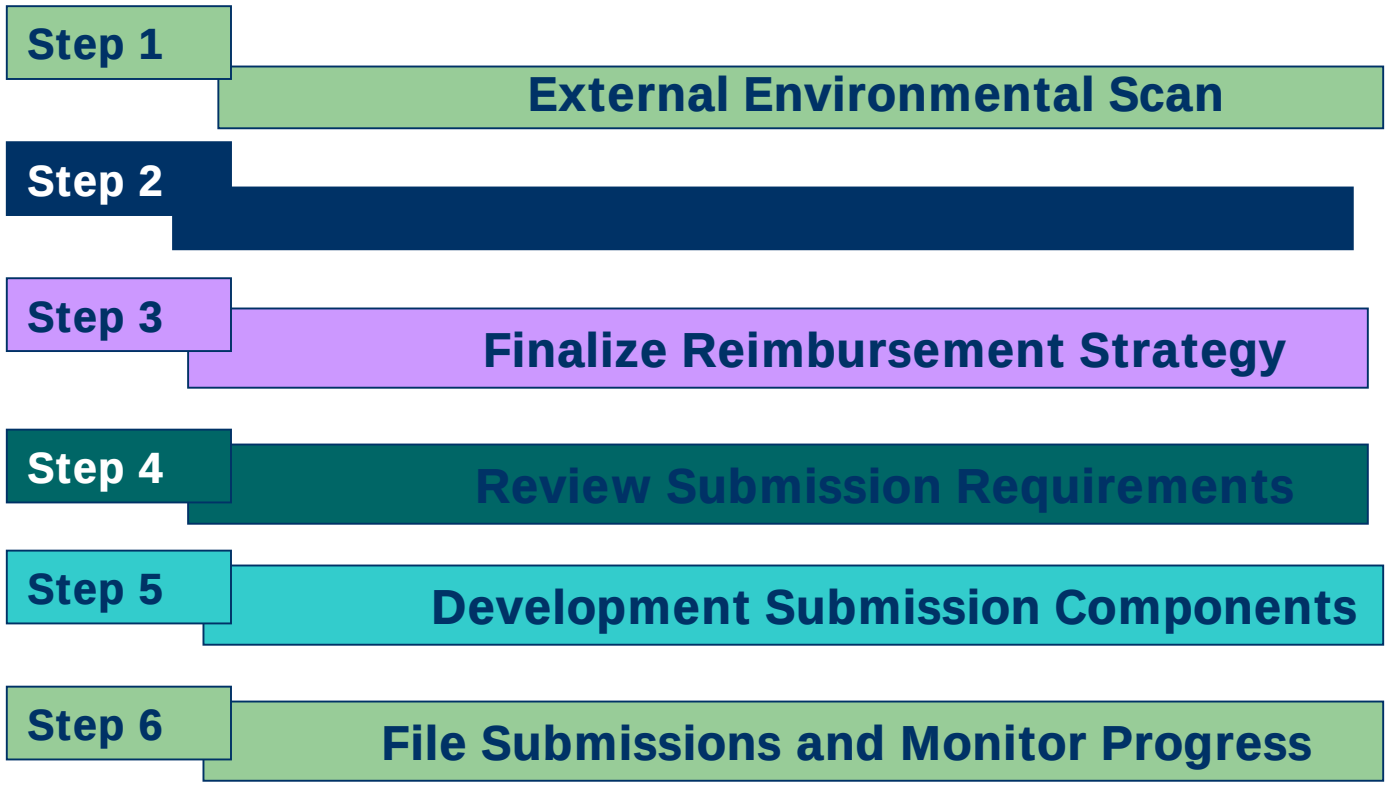
Provision of Health Care – An Imperfect Market



Basis for Evaluating Drug Therapy

- Safety: Does it do harm?
- Efficacy: Can it work under ideal circumstances?
- Effectiveness: Does it work under usual circumstances?
- Efficiency: Is it worth doing?
- Affordability: Can we afford to do it?
- Access: Is it reaching those who need it?
- Equity: Who gains and who loses?

Reimbursement Process



Step 1:
External Environmental Scan

- Objective: Understand patient demographics and therapeutic area; analyze payers that will be involved in reimbursement; review competitive landscape

- Timeframe: 12-24 months pre-NOC and ongoing

Questions to Consider

- Is reimbursement critical to commercial success?
- Who is the target audience?
  - CDR and/or provinces
  - Private payers
  - Hospital
- Is there a serious medical need?
- Is it “unmet?”
- How widespread is the disease/condition?

- Objective: Review clinical trial data. Review marketing objectives. Ensure alignment between external assessment findings and internal assessment findings.

- Timeframe: 12 - 18 months pre-NOC and ongoing

Questions to Consider

- What is the strength of the clinical data?
  - RCTs using relevant active comparators
  - Any failed or negative trials
  - Clinical significance versus statistical significance
- Is the pricing strategy aggressive?
- How much time before TPD approval/launch?
- What is the marketing strategy/expectation for the product?

Potential Product Strategies

- Create a Market
- Innovative
- Second & Better
- Profile Improvement
- Eroding Market Leader

- Line extensions, formulation changes

Step 3:
Finalize Reimbursement Strategy

- Objective: Obtain agreement from all internal stakeholders for reimbursement strategy. Identify budgets and potential suppliers (if necessary). Determine accountability; assign responsibility.

- Timeframe: 6-12 months pre-NOC

Questions to Consider

- Are marketing expectations realistic?
- Strategic alignment?
  - Marketing
  - Pricing
  - Regulatory
  - Reimbursement

Step 4: Identify Target Audience & Review Submission Requirements

- Objective: Understand requirements/needs of target audience.

- Timeframe: 6 – 12 months pre-NOC

Payer Requirements*

- CDR/Provinces/Federal plans
  - Clinical evidence, economic evaluation, BIA, Executive Summary
  - Checklists
- Pharmacy Benefit Managers
  - Clinical evidence, economic evaluation, BIA
- Hospitals
  - Clinical evidence, possibly economic evaluation, BIA from hospital perspective

CDR Requirements

Category 1

- Cover letter
- Table of Contents
- Product Monograph
- NOC
- Ability to supply letter
- Pricing Information
- Bibliography
- Letter authorizing unrestricted communication

Category 2

- Completed DNF
- BIA (if not priority review)
- CPS listing
- PAAB approved promotional materials
- CPID
- Product Patent Expiration Date

Step 5:
Develop Submission Components

- Objective: Prepare clinical summary; Conduct economic evaluation; Prepare budget impact assessments

- Timeframe: Variable

Time Frame for Submission

Activity	Time Frame
Clinical Summary	2 to 3 months
Economic Evaluation	3 to 12 months
Budget Impact Analysis	2 to 3 months
Binder Preparation & QA	1 month

- Activities can occur in parallel as long as strategy is agreed upon at start
- Generally rush of activities near the end, so planning & coordination is needed

Clinical Summary

- Disease prevalence/incidence
- Standards of Therapy/Accepted Practice
- Ease of identifying appropriate patients
- Potential for Off-label Use
- Clinical Trials – RCTs preferred
  - Active comparator preferred, although placebo-controlled may be relevant
  - Types of patients
  - Types of outcomes

Clinical summary vs. Comprehensive Summary

Remember the clinical question – “how does this drug compare (clinically) to what I’m already paying for?”

DON’T discuss preclinical trials, dose-range finding, PD & PK trials

DO discuss Phase III RCTs, generalizability issues, limitations of the trials, Phase IIIb/IV trials (planned, on-going & completed).

Economic Evaluation

- Answers the “value” question – Is it worth doing?
- Definition: A comparative analysis of alternative courses of action in terms of both their costs and consequences
- Requires technical expertise – if you have no training in this area, consider outside help
- Need to understand when its critical and when its not

Budget Impact Analysis

- Includes only drug costs
- 3 year projections
- Two approaches
  - Top down – starts with epidemiological information
  - Bottom up – starts with claims data
- Requires marketing & sales inputs
  - Market growth
  - Market capture

Step 6:
File submissions and monitor progress

- Objective: Actively monitor success of plan and respond to any questions that arise.

- Timeframe: Variable

Word of Caution

- Just because TPD views a trial as proof of safety and efficacy, don’t automatically assume that CDR or payers will accept it as proof for successful reimbursement.

  REMEMBER THEY ARE ASKING DIFFERENT QUESTIONS

Conclusion

To optimize the likelihood of successful reimbursement:

- Start early
- Resource appropriately
- Seek alignment