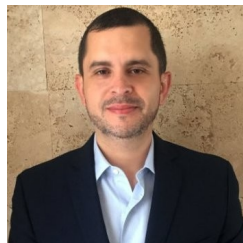


Value-Based Pricing in Colombia: The Devil Is in the Details



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PRESENTED AT:



BACKGROUND

- Value-Based Pricing (VBP) is employed to define the pricing of a technology related to its Therapeutic Value (TV), but its global experience is limited and mainly from developed countries
- In 2018, Colombia issued a VBP framework, containing six categories of therapeutic value relative to the efficacy/effectiveness and safety of new technology and its comparator or the current standard of care, as follows: I: Substantially greater, II: Greater than, III: Favorable but not as I/II, IV: Same as, V: Unfavorable and VI: Unclassifiable
- As this framework application was postponed until 2021, we aim to synthesize hurdles for implementation based on available evidence and local stakeholders' validation through surveys

METHODOLOGY

- Using the term “Value Based Pricing”, we conducted a scoping peer-reviewed and grey literature search within the last decade in MEDLINE, Google Scholar and ISPOR Digest. Two reviewers selected the relevant evidence and synthesized hurdles for VBP implementation. Case studies were created for comparison.
- A semi-structured interview with 9 local stakeholders including policymakers, HTA experts, payers, providers, patient advocates, and pharmaceutical trade association representatives were conducted to validate literature review findings and gather insights.
- A standardized questionnaire was used to validate expert’s awareness with international VBP frameworks and provide their preference (ranking) regarding: the best designed to determine VBP, the most “comprehensive” framework and the 12 elements of value as defined by the ISPOR Task Force. In addition, we asked about overall agreement with the VBP framework proposed in Colombia, additional elements that should be considered drawing from the ISPOR value flower and the key hurdles for implementation

RESULTS

We selected 44 publications including 12 countries: Australia, Belgium, Brazil, Canada, Colombia, France, Germany, Italy, Japan, Netherlands, Sweden, United Kingdom. VBP frameworks implemented in three countries (Canada, France, Germany) using similar TV categories as Colombia were used as reference for comparison and to inform the interviews.

Experts interviewed included 3 former policymakers from the HTA agency and the Ministry of Health, 1 academic with a leadership role at the local ISPOR chapter, 1 Payer, 1 Provider, 2 representatives from pharmaceutical trade associations, and 1 patient representative.

- **Awareness of VBP frameworks.** All experts were aware of the frameworks from France, Germany, and the United Kingdom. Other frameworks were acknowledged to a lesser extent (Brazil: 3, Canada:2, Australia:1, Sweden: 1) and no experts were aware of Italy, Japan or the Netherlands.
- **Top 3 “best designed” VBP frameworks.** The VBP frameworks of France and Germany were consistently ranked as either 1st or 2nd by all experts, with France being the preferred by policymaker, payer, and academic experts. The only other framework preferred as 1st or 2d was Canada by provider, industry, and patient experts. (Figure 1)
- **Top 3 “most comprehensive” VBP frameworks.** Policymakers continue favoring France and Germany as the most complete frameworks, followed by Colombia. All other stakeholders preferred Canada, followed by France and Germany in either 2nd or 3rd.
- **Top 7 elements of value.** All experts agreed that 3 elements of value should be included in VBP: quality-adjusted life-years, net costs, and adherence-improving factors. The next elements of value most voted included productivity (8/9), unmet need (8/9), better targeting (7/9) scientific spillovers (6/9).
- **VBP framework Colombia and elements of value.** 6 of the experts mentioned uncertainty about the framework ability to assess VBP as it has not yet been implemented. To strengthen the framework comprehensiveness, it was recommended the addition of cost and improved adherence as elements of value.
- **Key hurdles for implementation.** The two most recognized hurdles were the lack of agreement in the definition of value among stakeholders and methodological challenges to assess breakthrough innovations approved using early data sets. Interviews confirmed stakeholder's perception that the VBP framework narrow focus on efficacy/effectiveness and safety, may underestimate the value of new technologies, limiting its adoption

DISCUSSION

- There is uncertainty regarding the usefulness of VBP as a policy solution to achieve fair prices. Colombia's pricing and reimbursement policies have evolved during the last years including regulations setting budget caps for non-formulary health technologies, maximum reimbursement values and reference pricing that have contain costs. In this context, the prioritization of VBP has decreased as sensed by experts interviewed.
- In case this policy is deemed for implementation, additional elements of value should be added and real-life examples of VBP frameworks leveraged to improve the ability of this policy to meet its purpose.
- In Developed countries, broader approaches for VBP have not been exempt from challenges (e.g. Gene therapies), while since the COVID-19 pandemic, other elements of value (e.g. "fear of contagion" or "budget to future options") are gaining relevance

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Figure 1. Therapeutic Value (TV) categories and use of External Reference Pricing (ERP)

 FRANCE	 GERMANY	 CANADA	 COLOMBIA
There are 5 levels of TV (SMR) which is a first step in the evaluation, followed by 5 categories or levels of added therapeutic value (ASMR): 1. ASMR I: Significant or major innovation, innovative product with substantial therapeutic benefit 2. ASMR II: Important improvement in terms of efficiency or safety 3. ASMR III: Moderate improvement in terms of efficiency or usefulness 4. ASMR IV: Minor improvement in terms of efficiency or safety 5. ASMR V: Lack of improvement compared with existing options but could still be recommended for funding ERP: Yes, for ASMR I, II, or III Countries: DE, ES, IT, UK	There are 6 categories: 1. Major: Sustained and high improvement in the relevant benefit for therapy that was not previously achieved with the competitor, such as recovery from the illness, increased survival, and long-term relief of serious symptoms. 2. Considerable: Improvement in the relevant benefit for therapy, in particular the attenuation of severe symptoms, a moderate prolongation of life, and a decrease in the severity of the illness as perceived by patients. 3. Slight or minor: Moderate or slight improvement in the relevant benefit for therapy that was not previously achieved by relevant competitors, in particular a reduction in the non severe symptoms of the illness and side effects. 4. Not quantifiable: When the available evidence does not allow the quantification of the additional benefit of the therapy. 5. No added benefit 6. Benefit less than the comparator ERP: Yes, for medicines with added benefit Countries: AT, BE, CZ, DK, ES, FI, FR, GR, IE, IT, NL, PT, SE, SK, UK	There are 4 categories: 1. Breakthrough: first medicine sold in Canada that effectively treats a particular disease or effectively addresses a particular prescription. 2. Substantial improvement: a medicine that, compared with other pharmaceutical products sold in Canada, provides an important benefit in the therapeutic effects. 3. Moderate improvement: a medicine that, compared with other pharmaceutical products sold in Canada, provides a moderate benefit in the therapeutic effects 4. Slight or no improvement: a medicine that, compared with other pharmaceutical products sold in Canada, provides a slight or no benefit in the therapeutic effects. Additionally, main and secondary factors including greater efficacy/safety, disease incidence reduction, adherence, time to response, treatment duration, disability among others are considered in the evaluation of the added therapeutic benefit. ERP: Yes, for more innovative products Countries: FR, DE, IT, SE, CH, UK, US	There are 6 categories: 1. Category I: Significantly more effective and greater or similar safety than the chosen therapeutic comparator, in critical clinical outcomes. 2. Category II: More effective and greater or similar safety than the therapeutic comparator chosen in the critical clinical outcomes. 3. Category III: Relationship between safety, efficacy, or favorable effectiveness with respect to the therapeutic comparator chosen for clinical outcomes that cannot be classified in category I or II. 4. Category IV: Similar safety and effectiveness to the therapeutic comparator chosen in clinical outcomes. 5. Category V: Relationship between safety, efficacy, or unfavorable effectiveness compared with the therapeutic comparator in clinical outcomes. 6. Category VI: Unclassifiable Medicine ERP: Yes, for Categories I, II, III or V Countries: AR, AU, BR, CA, CL, DE, EC, ES, FR, IT, MX, NO, PN, PE, PT, TR, UK, US, UY, ZA,

AR: Argentina; AT: Austria; AU: Australia; BE: Belgium; BR: Brazil; CA: Canada; CH: Switzerland; CL: Chile; CZ: Czech Republic; DE: Germany; DK: Denmark; EC: Ecuador; ES: Spain; FI: Finland; FR: France; GR: Greece; IE: Ireland; IT: Italy; NL: Netherlands; PT: Portugal; SE: Sweden; SK: Slovakia; TR: Turkey; UK: United Kingdom; US: United States; UY: Uruguay; ZA: South Africa

DISCLOSURES

Opinions included in this presentation are sole the authors and do not reflect their affiliation or workplace.

ABSTRACT

OBJECTIVES: Value-Based Pricing (VBP) is employed to define the pricing of a technology related to its Therapeutic Value (TV). VBP's global experience is limited and mainly from developed countries. In 2018 Colombia issued a VBP framework, containing five TV categories relative to the technology and comparator efficacy/effectiveness and safety; I: Substantially greater; II: Greater than; III: Favorable but not as I/II; IV: Same as; V: Unfavourable; The unclassifiable will become a separate class. However, implementation was postponed until 2021. We aim to synthesize hurdles for implementation based on available evidence and validate those with local stakeholders.

METHODS: We conducted a scoping peer-reviewed and grey literature search within the last decade. Two reviewers selected the relevant evidence and synthesized hurdles for VBP implementation. Case studies were created for comparison. Interviews with local stakeholders (Policymakers, HTA experts, Patient advocates, and Trade associations) were conducted to gather insights.

RESULTS: We selected 44 publications including 12 countries. Case studies from three countries using similar TV categories (Canada, France, and Germany) were created as references. VBP has been implemented to reward innovations, improve payer's affordability, ensure patient access, and sustain health systems. Differences in the TV definition, due to the elements of the value selected and use (e.g. indication, population) were the principal hurdles identified for implementation. Our interviews confirmed stakeholder's perception that the VBP framework narrows focus on efficacy/effectiveness and safety, may underestimate the value of new technologies, limiting its adoption. In addition, concerns exist with methodological challenges to assess breakthrough innovations approved using early data sets.

CONCLUSIONS: In Developed countries, broader approaches for VBP have not been exempt from challenges (e.g. Gene therapies), while since the COVID-19 pandemic, other elements of value (e.g. "fear of contagion" or "insurance value") are gaining relevance. Stakeholders consider that Colombia's limited value set might underestimate the TV of technologies limiting patient access to life-saving technologies.