Budgetary Impact of Adding Riociguat to a US Health Plan for the Treatment of Patients with Pulmonary Arterial Hypertension or Chronic Thromboembolic Pulmonary Hypertension

Chakkarin Burudpakdee, PharmD; Anshul Shah, MS; Vijay N. Joish, PhD; Christine Divers, PhD; Avin Yaldo, PhD

BACKGROUND: Pulmonary arterial hypertension (PAH) and chronic thromboembolic pulmonary hypertension (CTEPH) are chronic, debilitating, and life-threatening conditions. Riociguat is the first and only pharmacotherapy approved by the US Food and Drug Administration (FDA) for the treatment of PAH and for CTEPH in patients who are either inoperable or have persistent pulmonary hypertension after surgery.

OBJECTIVE: To estimate the budgetary impact of adding riociguat to a US health plan’s formulary for the treatment of patients with PAH or CTEPH using a budget impact analytic model.

METHODS: A customizable, Microsoft Excel–based decision analytic tool was developed to estimate the impact of riociguat on per-member per-month (PMPM) and per-member per-year (PMPY) bases in Medicare and non-Medicare health plans. The economic impact was calculated based on 1 million insured lives, published prevalence estimates of PAH and CTEPH, pharmacotherapy-eligible patients with PAH or CTEPH, administration costs, and monitoring costs related to pharmacotherapy. The drug costs were based on wholesale acquisition costs, and the medical costs were derived from Truven Health MarketScan claims data and the Medicare 2013 Clinical Diagnostic Laboratory Fee Schedule and Physician Fee Schedule. The market share for approved treatments was based on a tracking study of physicians treating patients with PAH or CTEPH. A sensitivity analysis was used to test the model’s robustness.

RESULTS: In a hypothetical plan population of 1 million members, the model estimated that 7 patients with PAH and 2 patients with CTEPH would be suitable for pharmacotherapy. Overall, 3 patients (1 with PAH and 2 with CTEPH) were receiving riociguat in a health plan consisting of patients with commercial and with Medicare insurance coverage. The incremental PMPY and PMPM costs for providing insurance coverage for riociguat were $0.27 and $0.02, respectively, for non-Medicare and Medicare health plans. Sensitivity analyses indicated that the budget impact increased by $0.01 PMPM, with a 25% increase in base-case parameter values.

CONCLUSION: Riociguat is a first-in-class and the only FDA-approved treatment for patients with PAH or CTEPH—2 debilitating, chronic, and life-threatening conditions with poor prognosis. This drug offers health plans an effective and safe treatment option, with a minimal economic impact. The financial impact to a health plan of providing coverage for riociguat in the first year of treatment was as low as $0.02 PMPM. The real-world budget impact of riociguat needs to be measured using real-world evidence to validate our results.

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Pulmonary arterial hypertension (PAH) and chronic thromboembolic pulmonary hypertension (CTEPH), the 2 subtypes of pulmonary hypertension, are chronic, debilitating, and life-threatening conditions. Despite the differences in etiologies between PAH and CTEPH, both are primarily characterized by vascular remodeling that results in progressive right heart failure and death. Based on a recent US analysis of risk stratification in patients with PAH, the 1-, 3-, and 5-year surviv-
The existing strategies that are approved by the US Food and Drug Administration (FDA) for the treatment of PAH involve the use of prostacyclin analogs, such as treprostinil and iloprost (including inhaled, injectable, or oral prostanoids); endothelin receptor antagonists, such as ambrisentan and bosentan; and/or phosphodiesterase (PDE)-5 inhibitors. Although not approved by the FDA for PAH, calcium channel blockers, in particular L-type calcium channel blockers (eg, nifedipine), can be effective, but they are only safe for patients who respond to a one-time vasodilator challenge (ie, vasoreactive-positive patients). Despite improved outcomes with prostacyclin analogs, endothelin receptor antagonists, and PDE-5 inhibitors, PAH remains a progressive and fatal disease, with poor survival.

In patients with CTEPH, the treatment of choice is pulmonary endarterectomy; however, in 20% to 40% of patients, CTEPH is deemed to be inoperable. In addition, 10% to 20% of patients who undergo pulmonary endarterectomy have persistent or recurrent pulmonary hypertension after surgery. In these patients, there is a significant unmet need for an effective alternative treatment to surgical intervention or for a bridging therapy before pulmonary endarterectomy.

The safety and efficacy of riociguat, an oral, first-in-class soluble guanylate cyclase stimulator, have been evaluated in 2 phase 3 randomized controlled clinical trials, 1 trial in patients with PAH and 1 trial in patients with CTEPH. Riociguat has a dual mode of action of increasing the sensitivity of soluble guanylate cyclase to nitric oxide and directly stimulating the soluble guanylate cyclase independent of nitric oxide availability, which can increase hemodynamic and exercise capacity in patients with PAH.

In October 2013, riociguat was approved by the FDA for the treatment of adults with PAH (World Health Organization [WHO] Group 1) to improve exercise capacity and WHO functional class and to delay the clinical worsening, and for the treatment of patients with inoperable or with persistent or recurrent CTEPH (WHO Group 4) to improve exercise capacity and WHO functional class.

The objective of the present study was to measure the economic impact of adding riociguat to the drug formulary of a US health plan for the treatment of patients with PAH who are inoperable or who have persistent or recurrent CTEPH.

**Methods**

**Model Overview**

An interactive, Microsoft Excel–based budget impact model was developed to evaluate the per-member per-month (PMPM) and per-member per-year (PMPY) budgetary impacts of providing coverage of riociguat for pharmacotherapy-eligible patients with PAH or CTEPH.

The model has 4 major components: (1) population, which estimates the pharmacotherapy-eligible patients with PAH or CTEPH in a health plan of 1 million covered lives; (2) treatment, which distributes eligible patients across different pharmacotherapies based on best practice; (3) resource utilization, which quantifies the...
healthcare resources utilized with treatment; and (4) cost, which applies unit costs to resources to estimate the PMPM and PMPY costs of treating patients before and after adding riociguat to a health plan drug formulary.

The costs in this analysis were for the drugs, drug administration, and drug monitoring. All costs were reported in 2013 US dollars, and no discounting of future cost was taken into account. The parameter estimates and costs for all model inputs were based on the published sources.

The budget impact of riociguat was calculated as an increase in annual expenditure for treating with riociguat pharmacotherapy-eligible patients with PAH or CTEPH, in terms of the PMPM and PMPY costs, the total annual expenditure, and the cost per therapeutic class. The PMPY costs were calculated by dividing the total expenditure by the total covered lives in the plan, and the PMPM costs were calculated by further dividing the PMPY cost by 12.

The cost impact of adding riociguat was calculated from a US health plan perspective, including patients with and without Medicare coverage, over a 1-year period. The model did not make any claims of safety and/or efficacy for the therapies included in the analysis.

**Patient Population and Treatments**

Eligibility for pharmacotherapy was determined based on the American College of Cardiology Foundation/American Heart Association guidelines for PAH.1 PAH-specific pharmacotherapy is recommended for patients with negative vasoreactive status. For patients with CTEPH, pharmacotherapy is recommended for inoperable patients and for patients with residual disease after undergoing surgery.

The population estimates for pharmacotherapy-eligible patients aged ≥18 years with PAH or CTEPH who were considered in the analysis are shown in Figure 1. Because no US-specific published prevalence data for PAH and CTEPH were identified, various estimates from European registries were used to calculate the default prevalence data in patients with PAH or CTEPH.

In this model, the prevalence of PAH was estimated to be 12.5 per 1 million individuals based on an average of estimates reported in the United Kingdom and Ireland (6.6 per 1 million individuals),15 France (15 per 1 million individuals),16 and Spain (16 per 1 million individuals).17 Similarly, a prevalence of 3.2 per 1 million individuals for CTEPH was derived from a Spanish registry in the absence of US-specific data on CTEPH.17 It was assumed that all pharmacotherapy-eligible patients with PAH or CTEPH were receiving treatment and were fully adherent to the treatment and monitoring recommendations.

Based on the epidemiology of PAH and CTEPH presented in Figure 1, a plan with 1 million covered lives would
Table 1  Pharmacotherapy-Eligible Patient Distribution in a US Health Plan

<table>
<thead>
<tr>
<th>Medication class</th>
<th>Patients, without adding riociguat, N</th>
<th>Patients, with adding riociguat, N</th>
</tr>
</thead>
<tbody>
<tr>
<td>sGC stimulator monotherapy (riociguat)</td>
<td>0</td>
<td>1 with PAH, 2 with CTEPH</td>
</tr>
<tr>
<td>PDE-5 inhibitor monotherapy (sildenafil)</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>ERA monotherapy (ambrisentan/bosentan)</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>ERA + PDE-5 inhibitor (ambrisentan/bosentan + sildenafil)</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

*aBayer’s survey; data on file.*

*bModel assumption.

CTEPH indicates chronic thromboembolic pulmonary hypertension; ERA, endothelin receptor antagonist; PAH, pulmonary arterial hypertension; PDE, phosphodiesterase; sGC, soluble guanylate cyclase.

Table 2  Model Drug Cost Inputs

<table>
<thead>
<tr>
<th>Medication class</th>
<th>Monthly drug cost, WAC (2013), $</th>
</tr>
</thead>
<tbody>
<tr>
<td>sGC stimulator monotherapy (riociguat)</td>
<td>7500.00</td>
</tr>
<tr>
<td>PDE-5 inhibitor monotherapy (sildenafil)</td>
<td>90.90</td>
</tr>
<tr>
<td>ERA monotherapy (ambrisentan/bosentan)</td>
<td>6644.18</td>
</tr>
<tr>
<td>ERA + PDE-5 inhibitor (ambrisentan/bosentan + sildenafil)</td>
<td>6375.08</td>
</tr>
<tr>
<td>ERA indicates endothelin receptor antagonist; PDE, phosphodiesterase; sGC, soluble guanylate cyclase; WAC, wholesale acquisition cost.</td>
<td></td>
</tr>
</tbody>
</table>

Consist of approximately 7 patients with PAH and 2 patients with CTEPH who were eligible for pharmacotherapy.

The treatment options considered in the analysis were based on FDA-approved pharmacotherapies, including prostacyclin analogs (ie, treprostinil, iloprost), endothelin receptor antagonists (ie, ambrisentan, bosentan), and a PDE-5 inhibitor (ie, sildenafil). Combination therapies of up to 2 molecules were included in the analysis, along with the monotherapies.

The distribution of treatments was based on the results of a national survey from a tracking study of patients with PAH or CTEPH. The study was conducted in the United States in 2012 by Bayer to assess treatments that are often used in clinical practice for patients with PAH. This unpublished study included a survey of 160 US physicians who were actively involved in drug therapy decisions for the treatment of patients with PAH, as well as 800 patient records from these physicians.

The budget impact analysis was performed at the therapeutic class level; the therapeutic classes included soluble guanylate cyclases (riociguat), PDE-5 inhibitors (sildenafil), endothelin receptor antagonists (ambrisentan and bosentan), systemic prostacyclin analogs (subcutaneous treprostinil), and inhaled prostacyclin analogs (iloprost and treprostinil). Because of the rarity of PAH, and the currently low market share of PCAs, no patients were treated with prostacyclin analogs in the base-case scenario. The rest of the therapeutic classes represented approximately 81% of the PAH drug treatment market.

Table 1 shows the number of patients who received each class of medication, with and without the addition of riociguat to a US health plan. Because of the lack of FDA-approved therapies for CTEPH before the FDA approval of riociguat, it was assumed that riociguat was the only pharmacotherapy indicated for the treatment of CTEPH.

Drug Costs

The drug costs were based on the published 2013 wholesale acquisition costs (WAC), and were calculated based on the recommended dosages in the package inserts of the drugs (Table 2). The monthly cost of a PDE-5 inhibitor was based on the price of generic sildenafil, whereas the cost of endothelin receptor antagonists was an average price of ambrisentan and bosentan.

The model assumed no out-of-pocket pharmacy expenses by patients with PAH or CTEPH. Background therapy, such as anticoagulants and diuretics, were not included in the model, because these therapies were recommended for all patients who received treatment and, therefore, were nondifferential in terms of a budget impact. For drug acquisition costs, the model used only generic costs when available, and did not account for rebates and dispensing fees in the drug cost calculations.

Drug Monitoring Costs

The annual drug monitoring costs were calculated based on the FDA package insert resource requirements for drug monitoring. The annual monitoring costs for riociguat were based on 12 urine pregnancy tests (for females only) and 12 office visits. The annual monitoring costs for endothelin receptor antagonists represented the average costs for ambrisentan and bosentan; ambrisentan required 12 urine pregnancy tests and 5 hemoglobin tests, and bosentan required 12 urine pregnancy tests, 4 hemoglobin measurements, and 12 liver function tests.

The non-Medicare cost units were derived from 2012 claims data in the Truven Health MarketScan database; the Medicare cost units were derived from the Medicare 2013 Clinical Diagnostic Laboratory Fee Schedule and the Medicare 2013 Physician Fee Schedule; the costs from claims data were adjusted to 2013 dollars.

Table 3 shows the unit costs for each recommended monitoring resource, by payer. Table 4 shows the annu-
al monitoring cost per patient for each medication class, based on the unit costs and the package insert recommended frequencies.

**Sensitivity Analysis**

One-way sensitivity analysis was performed on the key model parameters to assess the robustness of the analysis. The prevalence of PAH and CTEPH, and data on riociguat’s market share were adjusted by ±25% to test the impact of base-case estimates on the budget impact results. Our base-case analysis assumed that riociguat was used as monotherapy; therefore, we also assessed the robustness of the analysis when riociguat was administered in combination with an endothelin receptor antagonist or a prostacyclin analog for patients with PAH.

In a non-Medicare plan, the costs of subcutaneous prostacyclin analog (drug costs and administration costs) were calculated to be $1178.53 in the first month and $662.56 monthly for the rest of the treatment. 19,23,24 For a Medicare plan, these costs were $1421.29 for the first month and $6423.56 monthly for the rest of the treatment. 19,23,25 The costs of inhaled prostacyclin analogs (ie, drug costs and inhalation device costs) were $18,187.59 for the non-Medicare plan 19,24,26,27 and $18,759.28 for the Medicare plan 19,25,26 for the first month and $17,043.21 monthly18,24,28 for the rest of the treatment for Medicare and non-Medicare plans separately.

**Results**

**Base-Case Analysis: Non-Medicare Plan**

Based on our model, we estimated that 7 patients with PAH and 2 patients with CTEPH were eligible for pharmacotherapy. When riociguat was added to the health plan formulary, we assumed that 1 patient with PAH switched from treatment with a PDE-5 inhibitor to riociguat, and 2 patients with CTEPH received treatment with riociguat, currently the only FDA-approved treatment for patients with CTEPH.

**Table 5** reports the total annual expenditures (drug costs and drug monitoring costs) at the therapeutic class level, with and without riociguat included on the plan formulary. Among patients with PAH or CTEPH who were receiving pharmacotherapy, the estimated total annual expenditure increased from $328,807 to $600,654 when adding riociguat to the formulary. At a per-member level, the cost impact to the health plan of adding riociguat was $0.02 PMPM and $0.27 PMPY (Table 5).

<p>| Table 3 | Payer-Specific Unit Cost of Drug Monitoring Resources |</p>
<table>
<thead>
<tr>
<th>Monitoring resource</th>
<th>Billing code</th>
<th>Unit cost, Non-Medicare, $</th>
<th>Unit cost, Medicare, $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver function test</td>
<td>80076</td>
<td>17.49</td>
<td>11.23</td>
</tr>
<tr>
<td>Urine pregnancy test</td>
<td>81025</td>
<td>16.26</td>
<td>8.70</td>
</tr>
<tr>
<td>Hemoglobin measurement</td>
<td>85018</td>
<td>5.27</td>
<td>3.26</td>
</tr>
<tr>
<td>Office visit</td>
<td>99215</td>
<td>110.67</td>
<td>142.90</td>
</tr>
</tbody>
</table>

<p>| Table 4 | Payer-Specific Per-Patient Per-Year Monitoring Costs, by Medication Class |</p>
<table>
<thead>
<tr>
<th>Medication class</th>
<th>Non-Medicare plan, $</th>
<th>Medicare plan, $</th>
</tr>
</thead>
<tbody>
<tr>
<td>sGC stimulator  (riociguat)</td>
<td>1523.10</td>
<td>1819.20</td>
</tr>
<tr>
<td>PDE-5 inhibitor (sildenafil)</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>ERA (ambrisentan/bosentan)</td>
<td>1651.73</td>
<td>1901.25</td>
</tr>
</tbody>
</table>

ERA indicates endothelin receptor antagonist; PDE, phosphodiesterase; sGC, soluble guanylate cyclase.

<p>| Table 5 | Budget Impact of Adding Riociguat for a Non-Medicare Plan |</p>
<table>
<thead>
<tr>
<th>Treatment options</th>
<th>PMPM cost, $</th>
<th>PMPY cost, $</th>
<th>Total annual expenditure, $</th>
<th>Total annual expenditure, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>sGC stimulator</td>
<td>Without riociguat 0.00</td>
<td>With riociguat 0.02</td>
<td>Without riociguat 0.00</td>
<td>With riociguat 0.27</td>
</tr>
<tr>
<td>PDE-5 inhibitor</td>
<td>Without riociguat 0.00</td>
<td>With riociguat 0.00</td>
<td>Without riociguat 0.01</td>
<td>With riociguat 0.00</td>
</tr>
<tr>
<td>ERA</td>
<td>Without riociguat 0.03</td>
<td>With riociguat 0.03</td>
<td>Without riociguat 0.32</td>
<td>With riociguat 0.32</td>
</tr>
<tr>
<td>Total</td>
<td>Without riociguat 0.03</td>
<td>With riociguat 0.05</td>
<td>Without riociguat 0.33</td>
<td>With riociguat 0.60</td>
</tr>
<tr>
<td>Incremental change in budget</td>
<td>0.02</td>
<td>0.27</td>
<td>271,847</td>
<td>—</td>
</tr>
</tbody>
</table>

ERA indicates endothelin receptor antagonist; PDE, phosphodiesterase; PMPM, per-member per-month; PMPY, per-member per-year; sGC, soluble guanylate cyclase.
Similarly, for a Medicare plan, the estimated total annual expenditure increased from $329,382 to $601,800 with the addition of riociguat to the formulary in patients with PAH or CTEPH who received pharmacotherapy (Table 6). The cost impact of adding riociguat was $0.02 PMPM and $0.27 PMPY; these amounts were similar to the results among patients in a non-Medicare plan (Table 6).

Base-Case Analysis: Medicare Plan

Similarly, for a Medicare plan, the estimated total annual expenditure increased from $329,382 to $601,800 with the addition of riociguat to the formulary in patients with PAH or CTEPH who received pharmacotherapy (Table 6). The cost impact of adding riociguat was $0.02 PMPM and $0.27 PMPY; these amounts were similar to the results among patients in a non-Medicare plan (Table 6).

Sensitivity Analysis

One-way sensitivity analysis demonstrated that the PMPM cost impact of riociguat increased by $0.01, with a 25% increase in the base-case values for the riociguat market share and the prevalence of CTEPH and PAH. The PMPM cost impact was unchanged when data parameters were decreased by 25% (Figure 2).

The combination of riociguat and an endothelin receptor antagonist or riociguat plus a subcutaneous prostanycin analog (ie, treprostinil) for the treatment of PAH resulted in a PMPM cost of $0.03 and a PMPY cost of $0.35. When riociguat was used in combination with an inhaled prostacyclin analog, the cost impact to the health plan was $0.04 PMPM and $0.48 PMPY.

Discussion

On a daily basis, patients with PAH and CTEPH may experience debilitating symptoms, such as shortness of breath, fatigue, chest discomfort, palpitations, lightheadedness, and syncope, that can impair quality of life.30,31 Furthermore, despite current treatments for patients with PAH, this condition continues to progress and is associated with poor outcomes.4 The recent FDA approval of riociguat provides a new treatment option for patients with PAH or CTEPH, with a new mechanism of action that has been shown to improve clinical outcomes.12

In this budgetary impact model, the costs of including riociguat on the formulary for patients with PAH and for patients with inoperable or with persistent or recurrent CTEPH were estimated for a hypothetical US health plan with 1 million members. Of these, an estimated 7 patients with PAH and 2 patients with CTEPH were eligible for pharmacotherapy. It was further assumed that 1 patient with PAH would switch from a PDE-5 inhibitor to riociguat, and 2 patients with CTEPH would receive treatment with riociguat. The findings from this budget impact model suggest that adding riociguat to a formulary plan, either Medicare or a non-Medicare plan, offers a new treatment option for managing patients with PAH and CTEPH, with a budget increase estimated at $0.02 PMPM and $0.27 PMPY.

To our knowledge, this is the first study to evaluate the budget impact of adding riociguat to a formulary in a US health plan.

Limitations

The results of this analysis should be interpreted in light of several study limitations. First, the findings are

<table>
<thead>
<tr>
<th>Treatment options</th>
<th>PMPM cost, $</th>
<th>PMPY cost, $</th>
<th>Total annual expenditure, $</th>
<th>Total annual expenditure, %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Without</td>
<td>With</td>
<td>Without</td>
<td>With</td>
</tr>
<tr>
<td></td>
<td>riociguat</td>
<td>riociguat</td>
<td>riociguat</td>
<td>riociguat</td>
</tr>
<tr>
<td>sGC stimulator</td>
<td>0.00</td>
<td>0.02</td>
<td>0.00</td>
<td>0.27</td>
</tr>
<tr>
<td>PDE-5 inhibitor</td>
<td>0.00</td>
<td>0.00</td>
<td>0.01</td>
<td>0.00</td>
</tr>
<tr>
<td>ERA</td>
<td>0.03</td>
<td>0.03</td>
<td>0.32</td>
<td>0.32</td>
</tr>
<tr>
<td>Total</td>
<td>0.03</td>
<td>0.05</td>
<td>0.33</td>
<td>0.60</td>
</tr>
<tr>
<td>Budget impact</td>
<td>0.02</td>
<td>0.27</td>
<td>272,418</td>
<td>—</td>
</tr>
</tbody>
</table>

ERA indicates endothelin receptor antagonist; PDE, phosphodiesterase; PMPM, per-member per-month; PMPY, per-member per-year; sGC, soluble guanylate cyclase.
specific to a disease population of patients aged ≥18 years, which reflects our epidemiology data, and these findings may not apply to all age-groups.

Furthermore, because of a lack of specific US prevalence estimates, the actual budget impact may vary for a plan with different numbers of patients with PAH and CTEPH who receive pharmacotherapy, although this may be unlikely because of the small number of patients with these diseases.

In addition, a large proportion of the incremental expenditure in our findings is associated with using riociguat for patients with CTEPH where there were no previously indicated treatments. The actual budget impact to health insurance plans may be lower if patients currently receive medications that are not indicated for CTEPH. The market share assumptions used in this model are based on a patient survey of 800 patients with PAH and CTEPH who receive pharmacotherapy, although these patients may not reflect real-world clinical practice. Because of the rarity of these diseases, and the data from the patient survey, our base-case analysis assumed that no patients received prostacyclin analogs or riociguat in combination with another therapy.

Furthermore, in our model we assumed that all patients were 100% adherent to pharmacotherapy and had stable disease over the course of treatment. The costs of drug-related adverse events, birth control, and disease complications, as well as the costs related to disease monitoring were not taken into consideration. Moreover, the model accounts for drug monitoring recommendations from package inserts that may not reflect real-world clinical practice.

Another key limitation pertains to the exclusion of member costs in the base-case scenario presented here. It was assumed that all patients had met their deductible limits and that no maximum out-of-pocket caps apply.

However, these factors are unlikely to have any significant impact on our results, because few patients are expected to be diagnosed and become eligible for pharmacotherapy in a typical health plan. The budget impact model did not account for any safety or efficacy data for any of the therapies that were included. An evaluation of the cost-effectiveness of riociguat, with outcomes expressed as change in WHO functional class and time to clinical worsening, would provide additional supportive evidence for the value of riociguat for the treatment of patients with PAH or CTEPH.

Conclusions

PAH and CTEPH are rare but chronic, progressing, and life-threatening conditions. Riociguat is the first and only pharmacotherapy approved by the FDA for the treatment of patients with either of these conditions who are either inoperable or who have persistent pulmonary hypertension after surgery.

Based on the budget impact model, the budget impact to a health plan of reimbursing the use of riociguat in the first year is projected to be $0.02 PMPM for patients with PAH or CTEPH, which translates to an increase of 82.7% in drug spending for the first year for these patients. The real-world economic impact of riociguat needs to be studied using real-world data to validate the results of this model.

Acknowledgment

The authors would like to acknowledge Mohini Sharma from Communications Symmetry for her assistance in the preparation of this manuscript.

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Author Disclosure Statement

Dr Burudpakdee was employed by Market Access Solutions when this study was conducted; Dr Shah is an employee of Market Access Solutions, LLC, which received funding from Bayer for this study; Dr Joish, Dr Divers, and Dr Yaldo are employees of Bayer HealthCare.

References

STAKEHOLDER PERSPECTIVE

Is It Time for Risk-Sharing Contracts In Specialty Pharmacy?

By Atheer A. Kaddis, PharmD
Senior Vice President, Sales and Business Development, Diplomat Specialty Pharmacy, Flint, MI

The majority of my career as a pharmacist has been spent in the managed care setting, with responsibility for co-chairing a Pharmacy and Therapeutics committee, as well as for formulary development for a large health plan. Discussions regarding risk-sharing contracts and even outcomes-based contracting have been taking place between health plans and pharmaceutical manufacturers for years, with very few contracts actually being implemented. The past 7 years of my career have been spent within a specialty pharmacy, which has allowed me to see that very little progress has been made in risk-sharing contracts for specialty pharmaceuticals. Is it time for a change?

In the article by Burudpakdee and colleagues in this issue of American Health & Drug Benefits, the authors provide information on the budgetary impact of adding a new drug, riociguat, to a health plan’s formulary for the treatment of patients with pulmonary arterial hypertension or with chronic thromboembolic pulmonary hypertension. Using a budget impact analytic model, the authors estimate that the financial impact of adding riociguat to a health plan’s formulary would only be approximately $0.02 per member per month. With such a cost, why would any health plan not add this new drug to formulary? Let us ponder this question.

PAYERS/DRUG MANUFACTURERS: Pharmaceutical manufacturer development and subsequent US Food and Drug Administration (FDA) approvals of new molecular entities (NMEs) have been impressive. As of December 11, 2014, the FDA had approved 35 NMEs this year compared with only 27 NMEs in 2013. Of the 35 new drug approvals this year, 15 were for treatment of rare diseases (diseases that affect 200,000 or fewer Americans). The previous “high” was 13 new drugs for rare diseases approved in 2012.

Although this may be beneficial to all healthcare stakeholders, patients, and society at large, there is also a cost that must be taken into consideration as new therapies coming to market—especially those for rare disease—carry a significant price tag. For example, riociguat has a monthly drug cost of $7500, based on the 2013 wholesale acquisition cost (WAC). Previously FDA-approved competitor therapies—ambrisentan and bosentan—have a monthly drug cost of $6644.13 (also based on the 2013 WAC). In addition, most health plans place specialty pharmaceuticals into a specialty tier on their formularies, and apply the same coinsurance metrics across all specialty drugs. Health plans then rely heavily on utilization management strategies to manage specialty pharmaceuticals within their formularies.
Based on the analysis by Burudpakdee and colleagues, it is my observation that riociguat presents an excellent opportunity for a risk-sharing contract between the drug manufacturer and a health plan. The reasons are that this medication has a higher monthly cost than other drugs in its category; it has a budget impact analytic model already developed, which will help forecast the financial impact on a health plan; it will probably be relegated to a coinsurance benefit design; and it will be strongly managed through utilization management strategies.

The concern that health plans will likely have is with regard to the potential overprescribing or inappropriate use of this medication. Therefore, why not put some skin into the game, and share some of the risk when there is overprescribing or inappropriate use, in exchange for lessened restrictions on this therapy? It is worth a discussion, at the very least.