

Budget Impact of Tegaserod on a Managed Care Organization Formulary

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Abstract

We sought to develop a budget impact model that assesses the economic effect of adding tegaserod for the management of irritable bowel syndrome (IBS) with constipation to the formulary of a managed care organization (MCO). The model estimates the per patient economic impact and the per member, per month (PMPM) economic impact of patients 6 months before and 6 months after the initiation of tegaserod. Resource utilization data, taken from medical and pharmacy administrative claims data, were based on a retrospective, longitudinal study of 3365 patients administered tegaserod through a large, geographically diverse MCO. Costs were estimated for 2 patient subgroups, women with IBS and other gastrointestinal (GI) diagnoses. Sensitivity analyses were performed by varying several model input parameters. The base-case model resulted in an incremental PMPM budget impact associated with the use of tegaserod of \$0.01. Total per patient budget impact (for all resources, including tegaserod) for a 6-month period was \$274.34 for women with IBS and \$301.84 for women with other GI diagnoses. Overall, 25.9% (29.0% for women with IBS group and 21.9% for women with other GI diagnoses group) of the cost of tegaserod was offset by decreases in resource utilization. Key drivers of post-tegaserod reductions in resource costs were hospital stays, outpatient office visits, emergency department visits, endoscopic procedures, and nonendoscopic procedures. Tegaserod therapy can decrease GI-related resource utilization, resulting in a significant cost-offset percentage. When the associated budget impact of adding tegaserod to its formulary is absorbed across an entire MCO population, the PMPM impact of tegaserod is small.

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Irritable bowel syndrome (IBS) is characterized by symptoms of abdominal pain or discomfort associated with altered/disturbed bowel movements.¹ IBS is highly

prevalent, with estimates in the US general population ranging from 10% to 20%.² Most people with IBS are women.³

Despite the large number of patients with IBS and the unpleasantness of its symptoms, only a small number of patients with IBS seek medical attention.⁴ Although the number of patients seeking treatment is small, IBS results in a considerable number of physician visits and pharmacologic treatments. Approximately 12% of patients who consult primary care physicians and 28% of patients who consult gastroenterologists are seeking help for symptoms of IBS.⁵

Aside from the physical and emotional toll, IBS results in a significant economic burden to society, with annual costs in the United States estimated by various studies to be \$1.7 billion to more than \$10.5 billion in direct medical costs (excluding prescription and over-the-counter drug costs) and \$20 billion for indirect costs,⁶ which result from decreased productivity at work and school.^{7,8} The economic impact of IBS is similar to or higher than that of other long-term conditions, such as hypertension, asthma, Crohn's disease, chronic liver disease, and cirrhosis.^{9,10}

Health status and health-related quality of life (QOL) of patients with IBS are poor compared with those of the general population.¹¹⁻¹⁵ Furthermore, several studies have shown that the health-related QOL of patients with IBS is similar to or lower than that of patients with other debilitating conditions, such as gastroesophageal reflux disease, asthma, migraine, diabetes mellitus, and end-stage renal disease.^{14,16}

Although most patients with IBS with constipation (IBS-C) are initially treated

with fiber supplements and other nonpharmacologic therapies,¹⁷ many do not achieve adequate clinical response to these treatments.³ Alternatives to fiber supplements are now available for the treatment of IBS. A relatively newer agent to join the armamentarium of therapies to treat gastrointestinal (GI) motility disorders is tegaserod maleate, a 5-hydroxytryptamine type 4 (5-HT₄) receptor agonist. Tegaserod maleate is the only US Food and Drug Administration–approved agent for the treatment of women with IBS-C and for the treatment of patients (men and women) younger than 65 years of age who have chronic idiopathic constipation. Tegaserod demonstrates clinical efficacy in reducing symptoms associated with IBS-C, including abdominal pain, bloating, and infrequent bowel movements. Tegaserod has a favorable safety and tolerability profile and has demonstrated efficacy in providing global symptom relief.^{18,19}

Demonstration of clinical efficacy in patients with IBS is arguably the most important criterion used by physicians and payers, such as managed care organizations (MCOs), when selecting a particular therapy. Intense scrutiny has recently been placed on MCOs with regard to coverage for select therapeutic areas. In part because of this new development, several studies have been conducted to demonstrate the overall economic impact associated with IBS.^{20,21} To date, however, no study has considered the potential budgetary impact of introducing tegaserod therapy to an MCO formulary. Therefore, we sought to develop a budget impact model in an MCO to compare GI-related resource utilization and costs 6 months before and after the initiation of tegaserod therapy for tegaserod users and nonusers. We hypothesized that the increased costs of tegaserod compared with alternative therapies would be partially offset by downstream savings related to a decrease in GI-related resource utilization engendered by the effectiveness of tegaserod.

Methods

Model Structure. The budget impact model was developed to simulate the 6-month budgetary impact of adding tegaserod to an MCO formulary. The model estimates

results for 2 patient subgroups based on patient diagnosis: women with IBS and other GI diagnoses, which include abdominal pain, intestinal disorders, GI/digestive disorders, liver/pancreatic disorders, GI surgical disorders, and GI cancer.

This budget impact model takes the simple approach of estimating the costs of the women with IBS and other GI diagnoses group before the introduction of tegaserod and the costs of women with IBS and other GI diagnoses after the introduction of tegaserod. Costs before the introduction of tegaserod were considered the burden of illness of the group of women with IBS and the other GI diagnoses group and were estimated by combining the relevant resource utilization with the costs of those resources. To determine the costs of women with IBS and GI diagnoses after the introduction of tegaserod, the burden of illness of women with IBS and GI diagnoses was adjusted by the relative impact of tegaserod on those resources.

Resource Utilization Study. Data to populate the model came from a retrospective, longitudinal resource use study of patients administered tegaserod from a large, geographically diverse MCO covering 14 million lives; medical and pharmacy administrative claims data were used to identify such patients from August 1, 2002 (launch of tegaserod), through June 30, 2003.²² The resource utilization study population consisted of 3365 patients taking tegaserod and compared the relative GI resource utilization in the 6 months after tegaserod initiation with that in the 6 months before tegaserod initiation.

Patient Population. In the budget impact model, we used a default patient population of 10 million as determined by data from the MCO that conducted the resource utilization study.

Prevalence of IBS in Women and of Other GI Diagnoses

We defined the prevalence of IBS in women as the proportion of covered lives of women who had a diagnosis of IBS. We defined the prevalence of the other GI diag-

noses subgroup as the proportion of covered lives of patients with other GI diagnoses, excluding those in the women with IBS subgroup. Prevalence rates from the aforementioned resource utilization study were 1.2% for the women with IBS subgroup and 26.7% for the other GI diagnoses subgroup, based on the observed MCO prevalence rates,²² which became the default values in the budget impact model.

For both patient subgroups, we defined the tegaserod treatment rate as the proportion of women with IBS or other GI diagnoses patients who received at least 1 prescription for tegaserod. Again, based on observed MCO treatment rates,²² we used an estimated tegaserod treatment rate of 2% for the women with IBS subgroup and 0.1% for the other GI diagnoses subgroup in the model.

We selected pharmacy and nonpharmacy resource utilization categories based on a previous classification scheme used by Longstreth and colleagues.²³ Categories and individual items were specified in an a priori manner without knowledge of the actual information in the medical and pharmacy database. The final medical resource categorization selection was reviewed, revised, and approved by an advisory team of specialists with experience in gastroenterology, functional GI disorders, and health services research.

Information on the relative impact of tegaserod on GI-related resources was obtained from the resource utilization study that assessed the following outcomes: physician office visits, hospitalizations, emergency department visits, endoscopic and nonendoscopic procedures and GI medications (IBS drugs, inflammatory bowel disease drugs, proton pump inhibitors [PPIs], promotility agents, ulcer drugs, antispasmodics, H₂ antagonists, antidiarrheals, and laxatives). Any medical resource utilization category that showed use of less than 5 per 1000 patients was considered too unstable for inclusion in the model and was set to zero.

Costs. GI-related costs for the categories of service listed above were determined by using the resource-based relative value scale for professional services and gap codes (part

of the resource-based relative value scale) for services not requiring physician intervention. Inpatient costs were determined using the 2003 payment reference average national payments rates for diagnosis-related groups, and drug costs used a 20% discount of the average wholesale price for costs.²⁴

The cost of tegaserod was based on actual utilization in the MCO. A mean of 2.27 prescriptions was filled by patients per 6 months of follow-up, with a mean of 68 days' supply.²²

Budget Impact Model Analyses. The model was developed from the perspective of an MCO. The time horizon considered for this analysis was 6 months; therefore, dollar values were not discounted. For each patient subgroup (women with IBS and other GI diagnoses), the 6-month per patient budget impact attributable to tegaserod was calculated by subtracting the post-tegaserod introduction pharmaceutical and medical GI-related costs from pre-tegaserod introduction per patient costs.

We calculated the per member, per month (PMPM) budget impact by dividing the 6-month per patient budget impact by 6, multiplying the resultant PMPM budget impact by the number of patients, and dividing by the total number of members.

We calculated a cost-offset percentage for both patient subgroups by dividing the total 6-month impact in non-tegaserod resource utilization costs by the 6-month per patient cost of tegaserod. The cost-offset percentage represented the percentage of tegaserod costs that can be offset by reductions in other resource utilization.

Sensitivity Analyses. We performed sensitivity analyses varying the inputs in the model to observe their effects on the total cost PMPM and the tegaserod cost-offset percentage.

Results

Budget Impact Analysis. The pre-tegaserod introduction of nonpharmaceutical, GI-related resource utilization default values are presented in **Table 1**.

In the budget impact model, the default 6-month cost of tegaserod was \$386.44 per

Table 1. Pre-Tegaserod Introduction of Nonpharmaceutical, GI-related Resource Use

	Women with IBS		Other GI diagnoses	
	Units per patient	Cost per unit (\$)	Units per patient	Cost per unit (\$)
Outpatient				
Office consultation	1.547	55.65	2.222	56.99
Emergency room visit	0.066	569.07	0.125	656.70
Inpatient				
Hospital stay	0.032	4676.46	0.071	5258.35
Endoscopic procedure				
Anoscopy	0.000*	25.38	0.010	25.38
Colonoscopy	0.178	365.73	0.233	350.84
Esophagoscopy	0.000*	135.37	0.000*	129.53
Laparoscopy	0.000*	375.58	0.006	439.35
Sigmoidoscopy/proctosigmoidoscopy	0.012	67.83	0.027	64.95
Small intestinal endoscopy	0.000*	232.92	0.000*	184.20
Upper GI endoscopy	0.094	245.45	0.199	248.59
Nonendoscopic procedures				
Anorectal manometry	0.000*	252.21	0.000*	288.24
Barium enema	0.020	187.07	0.032	182.48
Computed tomography, abdominal and pelvic	0.174	433.54	0.247	438.07
Enterolysis	0.000*	0.00	0.000*	913.02
Gastric emptying study	0.011	312.75	0.031	312.72
Magnetic resonance imaging, abdominal and pelvic	0.000*	703.41	0.016	974.55
Radiology, abdominal	0.066	43.06	0.107	44.49
Radiology, upper GI	0.040	154.84	0.078	139.92
Ultrasound, abdominal	0.061	142.75	0.136	146.97

*Any medical resource use category with an incidence of use by less than 5 per 1000 patients was considered too unstable for inclusion in the model and was set to zero.

GI indicates gastrointestinal; IBS, irritable bowel syndrome.

patient (Table 2). The total per patient budget impact (for all resources, including tegaserod) for a 6-month period was \$274.34 for women with IBS and \$301.84 for other GI diagnoses. This translated to a PMPM budget impact of \$0.01 for each patient group (Table 3).

Key drivers of post-tegaserod reductions in resource costs for women with IBS were hospital stays (-\$38.16), abdominal and pelvic computed tomography (-\$28.03), colonoscopy (-\$27.78), and outpatient office consultations (-\$18.20). Women with IBS realized small reductions in costs associated with emergency room visits (-\$9.65), upper GI endoscopy (-\$6.63), antispasmodics (-\$4.78), and H₂ antagonists (-\$2.64).

Key drivers of post-tegaserod reductions in resource costs for other GI diagnoses were slightly different, with key drivers of resource costs post-tegaserod consisting of hospital stays (-\$62.32), emergency department visits (-\$30.76), outpatient office consultations (-\$28.43), and abdominal and pelvic computed tomography (\$22.74). Patients with other GI diagnoses had smaller reductions in costs associated with abdomen ultrasound (-\$9.79) and upper GI endoscopy.

Overall, 25.9% (29.0% for women with IBS and 20.9% for other GI diagnoses) of the cost of tegaserod was offset by associated decreases in other resource utilization for all tegaserod patients (Figure 1).

Table 2. Six-Month Per Patient Costs

Per patient (6 months)	Women with IBS			Other GI diagnoses		
	Before introduction (\$)	After introduction (\$)	Budget impact (\$)	Before introduction (\$)	After introduction (\$)	Budget impact (\$)
Tegaserod	0.00	386.44	386.44	0.00	386.44	386.44
Other pharmacy	292.82	318.20	25.38	368.60	457.86	89.26
Outpatient	123.58	95.74	-27.84	208.52	149.33	-59.19
Inpatient	149.72	111.55	-38.16	373.90	311.58	-62.32
Endoscopic procedures	89.12	54.80	-34.32	135.60	122.96	-12.63
Nonendoscopic procedures	100.33	63.18	-37.15	174.91	135.20	-39.72
Total cost	755.57	1029.91	274.34	1261.52	1563.37	301.84

IBS indicates irritable bowel syndrome; GI, gastrointestinal.

Sensitivity Analyses. We varied the prevalence of women with IBS and other GI diagnoses to determine the effect on the 6-month tegaserod cost per patient. For each percentage increase in the prevalence rate, an equivalent PMPM percentage increase in tegaserod cost was observed. For example, when the prevalence rates for women with IBS and other GI diagnoses were increased 50% from 1.2% to 1.7% for women with IBS and from 26.7% to 40% for other GI diagnoses, the total cost PMPM increased from \$0.011 to \$0.016 for women with IBS and from \$0.009 to \$0.014 for other GI diagnoses.

Similar results were seen when varying the prevalence of women with IBS and other GI diagnoses to determine the effect on the 6-month tegaserod cost per patient. For each percentage increase in the prevalence rate, an equivalent percentage increase in tegaserod cost per patient was seen. When the tegaserod treatment rate for women with IBS was increased 50% to 3.1%, the total cost PMPM increased from \$0.011 to \$0.016. When the tegaserod treatment rate for other GI diagnoses was increased 50% from 0.067% to 0.1%, the total cost PMPM increased from \$0.009 to \$0.014.

The 6-month tegaserod cost per patient was varied to examine the effect on cost offset, and the relationship between the 2 is shown in **Figure 2** for women with IBS and in **Figure 3** for other GI diagnoses. As the tegaserod cost per patient decreases, the

cost offset increases by the same percentage. In other words, if the cost of tegaserod is reduced to half (\$193.22), the cost offset doubles to 58% for women with IBS and 43.8% for other GI diagnoses. For the cost of tegaserod to be completely (100%) offset by reductions in other resources, the tegaserod cost per patient must be decreased to \$112.09 for women with IBS and \$84.56 for other GI diagnoses. Varying the percentages of patients with women with IBS and other GI diagnoses or the tegaserod treatment rate did not affect the cost-offset percentage because all end points examined were per patient amounts.

Discussion

Our analysis indicates that introducing tegaserod to an MCO formulary can decrease GI-related medical costs in women with IBS and other GI diagnoses compared

Table 3. Budget Impact Per Patient

	Women with IBS	Other GI diagnoses
Total cost per patient (\$)	274.34	301.84
Number of patients	2380	1800
Number of members	10 million	10 million
Cost per member, per month (\$)	0.01	0.01

IBS indicates irritable bowel syndrome; GI, gastrointestinal.

with costs before the approval of tegaserod. When these GI-related resources and their associated costs are considered in addition to the cost of the drug, the impact of introducing tegaserod to an MCO formulary is small (\$0.01 PMPM). Nearly one third (29%) of the cost of tegaserod may be offset by reductions in costs in other resource use categories for women with IBS. For other GI diagnoses, more than one fifth (21.9%) of the cost of tegaserod is offset by reductions in associated resources. The results of the

model were robust, as evidenced by our discovery that varying the percentage of women with IBS and with other GI diagnoses or varying the tegaserod treatment rate did not affect the cost-offset percentage.

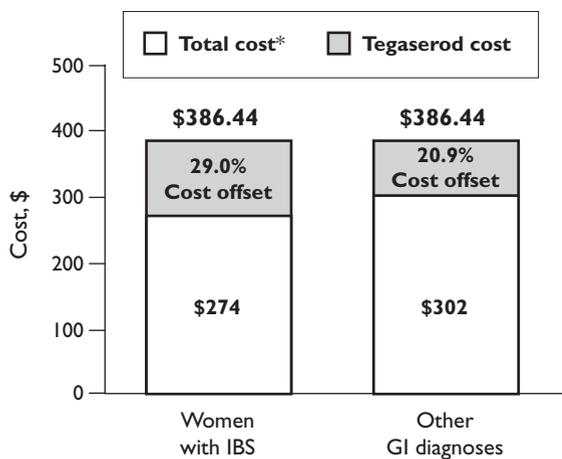
The cost of tegaserod is only partially offset by reductions in medical resources; however, because of its ability to provide multiple symptom relief, tegaserod may be a better treatment than other single-symptom options, such as laxatives and antispasmodics. Because other therapies do not target all of the symptoms associated with IBS (ie, abdominal pain, bloating, and constipation), patients may attempt to obtain relief for all of their symptoms by using multiple treatments.

This model demonstrated that introducing tegaserod in women with IBS and patients with other GI diagnoses is associated with a PMPM increase of \$0.01. This number is very small given the average MCO PMPM expenditures for other common IBS treatments, such as PPIs (\$2.55) and H₂ antagonists (\$0.23), and for medications, such as antidepressants (\$3.22), antidiabetic agents (\$1.33), contraceptive hormones (\$0.74), and antimigraine agents (\$0.44), prescribed for other prevalent conditions.²⁵

Several studies of IBS patients in the United States, including those in the managed care setting, demonstrate that IBS results in a significant economic impact.^{9,10,21,26,27} This current model demonstrates that treatment of IBS with tegaserod will help to offset some of these increased costs, using a budget impact model that is directly relevant to payers who may potentially be including this product in their formularies.

In addition to the impact on direct medical costs, tegaserod may result in other benefits not examined in this study, such as improved health-related QOL and increased productivity at work, school, and home. In particular, one study shows that indirect costs associated with lost wages and decreased productivity account for the largest proportion of the total IBS burden⁷; other studies show a substantial IBS burden in the form of indirect costs, such as medically related absenteeism.^{6,26,27} The results of these studies support the need for future

Figure 1. Cost Offset Per Patient



*Tegaserod cost minus costs associated with reduced resource utilization. IBS indicates irritable bowel syndrome; GI, gastrointestinal.

Figure 2. Sensitivity Analysis of the Effect of 6-Month Tegaserod Cost Per Patient on Cost Offset for Women with Irritable Bowel Syndrome

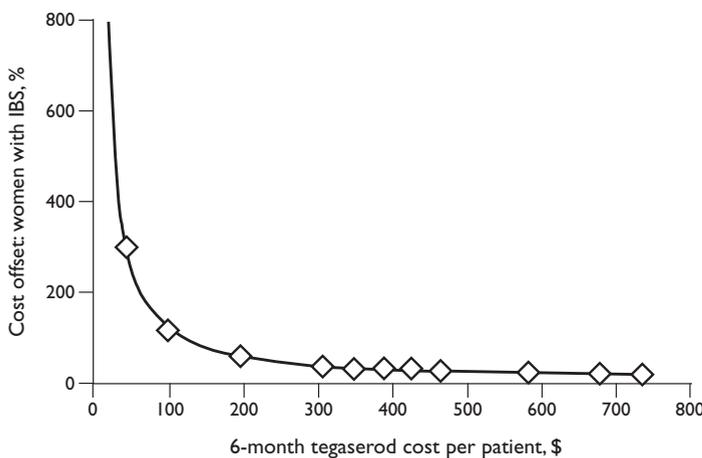
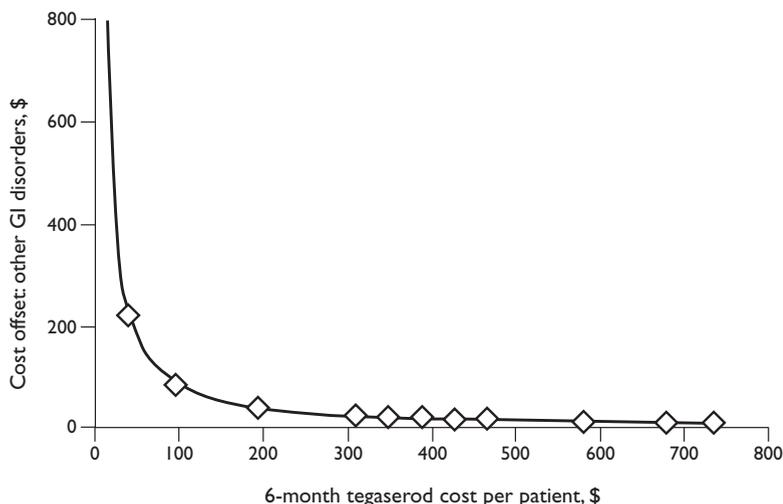


Figure 3. Sensitivity Analysis of the Effect of 6-Month Tegaserod Cost Per Patient on Cost Offset for Other Gastrointestinal Disorders



studies to assess the indirect cost benefit associated with tegaserod.

This model demonstrated that PMPM costs might increase slightly when tegaserod is introduced in women with IBS, the current indication for tegaserod. However, similar to the results of the group of women with IBS, the budget impact model also demonstrated a low PMPM cost when tegaserod was introduced in the other GI diagnoses group. Therefore, it is anticipated that future research may demonstrate the usefulness and small budget impact of tegaserod in the other GI diagnoses group, such as chronic constipation.

Although this model can be used as a tool to assess the economic impact of IBS, it is not without its limitations. First, as in any model, the accuracy of the data input into the model dictates the accuracy and credibility of the final end product of the model.^{28,29} Therefore, limitations that may affect the data from the resource use study²² include limited study duration and sample size, selection bias relative to patients chosen to be treated with tegaserod compared with other therapies, and lack of control for sampling/drug supply compared with actual filled prescriptions. Collectively, this may affect the generalizability of results. Another potential drawback of how the model is implemented is the use of national cost estimates. A model that was cus-

tomized to individual MCO plans might prove more beneficial and might provide a more accurate cost assessment for individual plans.

Conclusion

This model provides evidence that introducing tegaserod therapy in a managed care population may result in decreases in GI-related resource utilization costs and in relatively small increases in overall PMPM costs. The results of this study may be useful to any MCO considering adding tegaserod to its formulary.

In addition, this model demonstrates that a portion (25.9%) of the cost of treating with tegaserod could be offset by associated reductions in other resource categories (pharmacy, inpatient, outpatient, endoscopic, and nonendoscopic resources). When the associated budget impact is absorbed across an entire MCO population, the PMPM impact of tegaserod is very small.

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