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# Costs for Treating Patients With Ulcerative Colitis With Vedolizumab or Adalimumab Based on Endoscopic Improvement Data From the VARSITY Trial

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## Background

- Ulcerative colitis (UC) is a chronic inflammatory disease with an estimated prevalence in the USA of over 180 per 100,000 adults in 2016, showing a steady increase since 2007[1]
- Many factors contribute to the high costs associated with treating patients with UC, such as long-term use of medication, intermittent periods of hospitalization and, in more severe and uncontrolled cases, the need for colectomy[2,3]
- Endoscopic improvement has been linked to reduced colectomy rates[4,5]
- In the phase 3b, randomized, active-controlled VARSITY trial in patients with moderate to severe UC, a greater proportion of patients treated with vedolizumab experienced endoscopic improvement than those treated with adalimumab;[6] however, the cost implications of this are unknown

## Aim

- To inform decision-makers in choice of treatments, we produced a model of projected mean costs for treating patients with moderate to severe UC with either vedolizumab or adalimumab

## Methods

- We developed a Monte Carlo simulation model (**Figure 1**) using the model inputs described in **Table 1**
- Endoscopic improvement at week 52 was taken from the VARSITY trial (NCT02497469), which defined endoscopic improvement as a Mayo endoscopic sub-score of 0 or 1[6]
- The model estimated the mean cost (in US$) for a US patient from a cohort of 10,000 over a 1-year period from a payer's perspective and accounted for discontinuation of treatment due to lack of response with response defined as endoscopic improvement
- Scenarios based on the proportion of patients with endoscopic improvement were evaluated, and sensitivity analyses with inputs varying by ± 20% were performed to test model parameters

**Figure 1. Model structure**

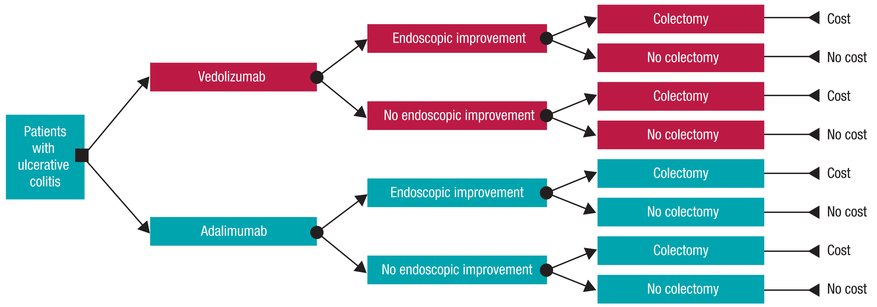


**Table 1. Model inputs**

| Input parameter | Value |
|---|---|
| **Proportion of patients with endoscopic improvement,[6] %** | |
| Vedolizumab | 39.7 |
| Adalimumab | 27.7 |
| **Proportion of surgery-free patients,[7] %** | |
| With endoscopic improvement | 96.5 |
| Without endoscopic improvement | 86.1 |
| **Drug cost per patient,* US$** | |
| With endoscopic improvement | |
| Vedolizumab† | 60,133 |
| Adalimumab‡ | 89,523 |
| Without endoscopic improvement | |
| Vedolizumab† | 22,550 |
| Adalimumab‡ | 35,809 |
| **Colectomy cost per patient,[2,§] US$** | 103,248 |

*Drug cost is presented as wholesale acquisition cost (based on Price Rx, as of April 22, 2021[9]) plus administration cost (based on the 2020 InHealth Physicians' Fee and Coding Guide[9]), including wastage.
†The model assumes intravenous administration of vedolizumab in a clinic over 30 minutes. Patients received 300 mg at day 1 and at weeks 2 and 6; patients with endoscopic improvement received 300 mg every 8 weeks from week 14.
‡The model assumes self-administration of subcutaneous adalimumab. Patients received 160 mg on day 1, 80 mg on day 15 and 40 mg on days 29 and 43; patients with endoscopic improvement received 40 mg every 14 days for the remainder of the year.
§Costs in this model reflect annual incremental costs for patients with UC undergoing colectomy. Colectomy cost was reported in 2017 US$ and was inflated to 2020 US$.
UC, ulcerative colitis.

## Results

- Mean total costs (**Figure 2**) included mean drug and colectomy costs, which were estimated to be $37,564 and $10,036 for vedolizumab, and $50,570 and $11,353 for adalimumab, respectively
- In the base case, the colectomy rate for patients treated with vedolizumab was estimated to be lower than for those treated with adalimumab (**Table 2**)
- When the proportions of patients with endoscopic improvement were equivalent for the two treatments, the probability of savings was estimated to be greater for vedolizumab versus adalimumab (**Table 2**)
- One-way sensitivity analyses demonstrated that results were most sensitive to changes in drug prices and endoscopic improvement rates (**Figure 3**)

## Summary and Conclusions

- **The high economic burden associated with UC highlights the need for cost-effective management strategies**
- **Over the course of a year, our simulation suggests a cost saving associated with the use of vedolizumab versus adalimumab**
- **Better endoscopic improvement, which resulted in lower colectomy rates, contributed to lower costs, with additional savings from lower acquisition costs with vedolizumab than with adalimumab**
- **These data highlight the economic benefit of endoscopic improvement in addition to clinical remission in managing patients with UC and may help to inform formulary decision-making**

## References

1. Ye Y, et al. *Inflamm Bowel Dis*. 2020;26(4):619-625.
2. Pilon D, et al. *CMRO*. 2020;36(8):1285-1294.
3. Lindsay JO, et al. *Aliment Pharmacol Ther.* 2015;41(11):1066-1078.
4. Ikeya K, et al. *J Crohns Colitis.* 2016;10(3):286-295.
5. Xie T, et al. *Gastroenterol Rep.* 2018;6(1):38-44.
6. Sands BE, et al. *N Eng J Med.* 2019;381(13):1215-1226.
7. Shah SC, et al. *Clin Gastroenterol Hepatol.* 2016;14(9):1245-1255.e1248.
8. Wolters Kluwer. *Price Rx.* 2021.
9. InHealth. *2020 Physicians' Fee & Coding Guide.* 2020.

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## Disclosures

Jesse Ortendahl: employee of PHAR, LLC who received consultancy funding from Takeda Pharmaceuticals U.S.A., Inc. to conduct the research described herein. Sabyasachi Ghosh: employee and holds stock/stock options at Takeda Pharmaceuticals U.S.A., Inc. Ninfa Candela: employee and holds stock/stock options at Takeda Pharmaceuticals U.S.A., Inc. Tao Fan: employee and holds stock/stock options at Takeda Pharmaceuticals U.S.A., Inc. Kandavadivu Umashankar: employee and holds stock/stock options at Takeda Pharmaceuticals U.S.A., Inc.

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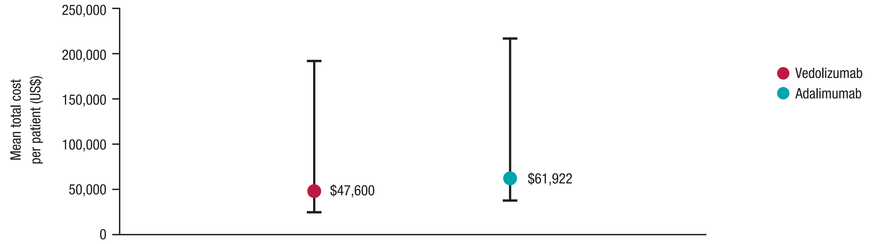
## Results (continued)

**Figure 2. Mean estimated total costs per patient treated with vedolizumab or adalimumab over 1 year were $14,322 lower for vedolizumab than for adalimumab in this model**




Error bars indicate the range across 10,000 individual simulated patients.

**Table 2. In the base case model, treatment with vedolizumab was estimated to be less expensive than treatment with adalimumab in 73.3% of patients**

| Treatment model | Proportion with endoscopic improvement, % | Colectomy rate, % | Probability of savings when treated with either drug, % |
|---|---|---|---|
| **Base case (10,000 patients)** | | | |
| Vedolizumab | 39.8 | 9.8 | 73.3 |
| Adalimumab | 27.5 | 11.5 | 26.7 |
| **Scenario 1 (1,108 patients)** | | | |
| Vedolizumab | 100 | 3.6 | 100.0 |
| Adalimumab | 100 | 3.6 | 0.0 |
| **Scenario 2 (2,874 patients)** | | | |
| Vedolizumab | 100 | 3.4 | 15.1 |
| Adalimumab | 0 | 15.8 | 84.9 |
| **Scenario 3 (1,638 patients)** | | | |
| Vedolizumab | 0 | 14.3 | 86.0 |
| Adalimumab | 100 | 3.2 | 14.0 |
| **Scenario 4 (4,380 patients)** | | | |
| Vedolizumab | 0 | 13.8 | 100.0 |
| Adalimumab | 0 | 13.8 | 0.0 |

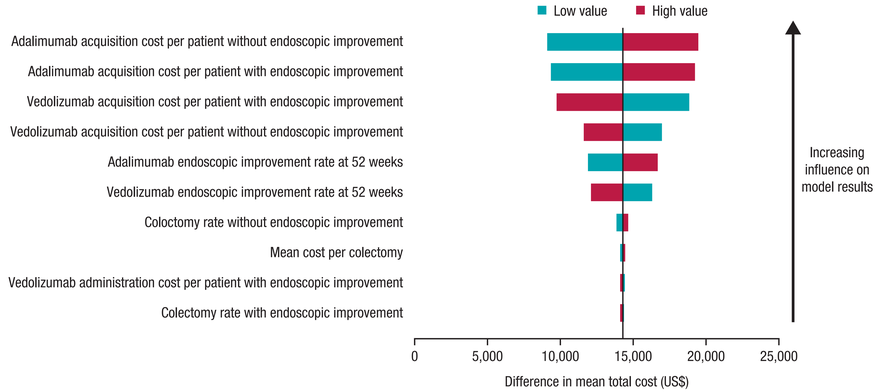



**Figure 3. Drug price and endoscopic improvement rates were the most influential parameters on model results**