Appendix

Budget Impact of Adding Vedolizumab to a Health Plan Formulary as a First-Line Biologic Option for Ulcerative Colitis and Crohn’s Disease
Michele Wilson, MSPH; Aaron Lucas, PhD, MPH; Ann Cameron, MA, PhD; Michelle Luo, PhD

This Appendix has not been edited and is provided as supplemental materials for this article, which was published in *American Health & Drug Benefits* in July 2018.

Supplementary Table 1. Dose of Biologics

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Dose and Frequency in CD</th>
<th>Dose and Frequency in UC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vedolizumab</td>
<td>Initially 300 mg repeated at week 2 and week 6, then 300 mg every 8 weeks (standard) or every 4 weeks (dose escalation)</td>
<td>Initially 300 mg repeated at week 2 and week 6, then 300 mg every 8 weeks (standard) or every 4 weeks (dose escalation)</td>
</tr>
<tr>
<td>Treatment</td>
<td>Dose and Frequency in CD</td>
<td>Dose and Frequency in UC</td>
</tr>
<tr>
<td>--------------</td>
<td>------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Infliximab</td>
<td>Initially 5 mg/kg repeated at week 2, then 5 mg/kg at week 6, then 5 mg/kg every 8 weeks; dose-escalation regimen 10 mg/kg</td>
<td>Initially 5 mg/kg repeated at week 2, then 5 mg/kg at week 6, then 5 mg/kg every 8 weeks; dose-escalation regimen 10 mg/kg</td>
</tr>
<tr>
<td>Adalimumab</td>
<td>Initially 160 mg, then 80 mg at week 2, then 40 mg every other week (standard) or 40 mg weekly (dose escalation)</td>
<td>Initially 160 mg, then 80 mg at week 2, then 40 mg every other week (standard) or 40 mg weekly (dose escalation)</td>
</tr>
<tr>
<td>Golimumab</td>
<td>N/A</td>
<td>200 mg week 0, 100 mg week 2, 100 mg every 4 weeks</td>
</tr>
<tr>
<td>Certolizumab</td>
<td>400 mg given as 2 divided doses at weeks 0, 2, and 4, then every 4 weeks</td>
<td>N/A</td>
</tr>
<tr>
<td>Ustekinumab</td>
<td>Initially 260 mg (55 kg or less); 390 mg (55 kg to 85 kg); 520 mg (more than 85 kg), and then 90 mg every 8 weeks thereafter</td>
<td>N/A</td>
</tr>
</tbody>
</table>

CD = Crohn’s disease; N/A = not applicable; UC = ulcerative colitis.
### Supplementary Table 2. Percentage of Patients on Dose-Escalation Dose

<table>
<thead>
<tr>
<th>Disease</th>
<th>Ulcerative Colitis</th>
<th>Crohn’s Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Golimumab&lt;sup&gt;a&lt;/sup&gt;</td>
<td>13.1%</td>
<td>N/A</td>
</tr>
<tr>
<td>Infliximab</td>
<td>28.9%</td>
<td>30.3%</td>
</tr>
<tr>
<td>Adalimumab</td>
<td>13.1%</td>
<td>16.7%</td>
</tr>
<tr>
<td>Vedolizumab</td>
<td>5.2%</td>
<td>5.2%</td>
</tr>
<tr>
<td>Certolizumab</td>
<td>N/A</td>
<td>34.8%</td>
</tr>
<tr>
<td>Ustekinumab</td>
<td>N/A</td>
<td>0%</td>
</tr>
</tbody>
</table>

<sup>a</sup> Golimumab was not included in the database study. As such, we assumed that the percentage of patients on a dose-escalation dose of this regimen was similar to that of adalimumab due to lack of available data.

Sources: Rubin et al. (2014)<sup>3</sup> and Khalid et al., (2016)<sup>36</sup>

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### FIGURES

**Figure Notes**

**Supplementary Figure 1.**

ADA = adalimumab; CD = Crohn’s disease; IFX = infliximab; PMPM = per member per month; VDZ = vedolizumab.

Notes: Hypothetical formulary Case 1 includes adalimumab as an existing preferred first-line treatment and infliximab as an existing preferred second-line treatment. Hypothetical formulary Case 2 includes both infliximab and adalimumab as existing preferred treatments in first and second line. Hypothetical formulary Case 3 includes infliximab as an existing...
preferred first-line treatment and adalimumab as an existing preferred second-line treatment. Ustekinumab was included as an existing preferred second-line treatment for CD patients in all cases.

**Supplementary Figure 2.**

ADA = adalimumab; CD = Crohn’s disease; IFX = infliximab; PMPM = per member per month; VDZ = vedolizumab.

Notes: Hypothetical formulary Case 1 includes adalimumab as an existing preferred first-line treatment and infliximab as an existing preferred second-line treatment. Hypothetical formulary Case 2 includes both infliximab and adalimumab as existing preferred treatments in first and second line. Hypothetical formulary Case 3 includes infliximab as an existing preferred first-line treatment and adalimumab as an existing preferred second-line treatment. Ustekinumab was included as an existing preferred second-line treatment for CD patients in all cases.

**Supplementary Figure 3.**

CI = confidence interval; PMPM = per member per month; UC = ulcerative colitis.

**Supplementary Figure 4.**

CD = Crohn’s disease; CI = confidence interval; PMPM = per member per month.
Supplementary Figure 5.
Notes: Data labels indicate total cost savings: (a) Hypothetical formulary Case 1 includes adalimumab as an existing preferred first-line treatment and infliximab as an existing preferred second-line treatment; (b) Hypothetical formulary Case 2 includes both infliximab and adalimumab as existing preferred treatments in first and second line; and (c) Hypothetical formulary Case 3 includes infliximab as an existing preferred first-line treatment and adalimumab as an existing preferred second-line treatment. Dose Esc. 1 refers to on-label dose escalation; Dose Esc. 2 refers to dose escalation for infliximab distributed between interval dose escalation and dose volume escalation during the standard interval.
Supplementary Figure 1. Medical, Drug, and Total Annual and Per-Member-Per-Month Cost Savings of Including Vedolizumab on Parity With Existing Preferred Treatments in 3 Hypothetical Formulary Cases Over 3 Years in the Ulcerative Colitis Population Only

![Graph showing cost savings with different cases.

Case 1: VDZ parity to ADA in 1st-line and IFX in 2nd-line.
Case 2: VDZ parity to both ADA and IFX in 1st-and 2nd-line.
Case 3: VDZ parity to IFX in 1st-line and ADA in 2nd-line.

Cost savings over 3 years: $1.21M, $2.39M, $3.53M for Year 1, 2, and 3 respectively.

Incremental PMPM Cost:
- Case 1: -$0.011, -$0.091, -$0.263
- Case 2: -$0.006, -$0.031, -$0.029
- Case 3: -$0.017, -$0.092, -$0.032

Legend:
- Black: Incremental PMPM medical costs
- Dashed: Incremental PMPM drug costs
- Blue: Total incremental PMPM costs

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Supplementary Figure 2. Medical, Drug, and Total Annual and Per-Member-Per-Month Cost Savings of Including Vedolizumab on Parity With Existing Preferred Treatments in 3 Hypothetical Formulary Cases Over 3 Years in the Crohn’s Disease Population Only
Supplementary Figure 3. Incremental Year 3 Per-Member-Per-Month Total Costs of Including Vedolizumab on Parity With Existing Preferred First-Line Treatments for Hypothetical Formulary Case 1 in the Ulcerative Colitis Population

Supplementary Figure 4. Incremental Year 3 Per-Member-Per-Month Total Costs of Including Vedolizumab on Parity With Existing Preferred First-Line Treatments for Hypothetical Formulary Case 1 in the Crohn’s Disease Population
Supplementary Figure 5. Sensitivity Analysis of Dose Escalation for the Combined Ulcerative Colitis and Crohn’s Disease Populations: Medical, Drug, and Total Cost Savings of Including Vedolizumab on Parity With Existing Preferred Treatments in the Hypothetical Formulary Cases

(5a) Hypothetical formulary Case 1

(5b) Hypothetical formulary Case 2

(5c) Hypothetical formulary Case 3