Cost per Responder Analysis of Guselkumab Versus Certolizumab Pegol Using Efficacy Results from Pivotal Clinical Trials in Patients with Moderate to Severe Plaque Psoriasis

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Background

- Biologic therapies are commonly used in the United States (US) to treat moderate to severe plaque psoriasis, a chronic, relapsing, inflammatory immune-mediated skin disease that has been shown to have a negative impact on patients' productivity and quality of life and to incur substantial medical care costs (Vanderpuye-Orgle et al., 2015; Brezinski et al., 2015; Jacobs et al., 2011).
- Guselkumab is an anti-interleukin-23 monoclonal antibody administered by subcutaneous injection that is indicated for the treatment of moderate to severe plaque psoriasis.
- Certolizumab pegol is Monoclonal antibody to TNF-Alpha admistered by subcutaneous injection that is indicated for the treatment of moderate to severe plaque psoriasis
- Efficacy data through week 16 from clinical trials for both products are available (VOYAGE 1 and VOYAGE 2 for guselkumab [Blauvelt et al., Reich et al., 2017] and CIMPACT for certolizumab pegol [Lebwohl et al., 2018]
- Understanding the relative value of new treatments for moderate to severe plaque psoriasis is important for insurers, health care providers, patients, and government health authorities.

Objective

- To estimate the cost per responder in the US for guselkumab relative to certolizumab pegol in the first year (induction year) of treatment based on indirect comparison of efficacy results from pivotal clinical trials (VOYAGE 1 for guselkumab and CIMPACT for certolizumab pegol).

Methods

- The calculation used to estimate the cost per responder was:
- Cost per responder =

(Per unit drug costs) × (# of doses per 52 weeks)

Percentage of patients with a response at 16 weeks (VOYAGE 1 or CIMPACT)

- Dosing was based on the Food and Drug Administration label in the first year, and the number of doses was based on a full, 52-week year for both products as shown in Table 1.

Table 1. Dosing and Pricing Inputs for Guselkumab and Certolizumab Pegol[a,b]

Biologic	Dosing	Pricing	Number of Doses in 52 Weeks Induction Year (Maintenance Year)
Guselkumab	100 mg administered by subcutaneous injection at Week 0, Week 4, and every 8 weeks thereafter	WAC per 100 mg: $10,158.52	8 (6)
Certolizumab Pegol	400 mg (given as 2 subcutaneous injections of 200 mg each) every other week. For some patients (with body weight ≤ 90 kg), a dose of 400 mg (given as 2 subcutaneous injections of 200 mg each) initially and at Weeks 2 and 4, followed by 200 mg every other week may be considered.	WAC per 400 mg: $4,044.32	26 (400 mg injections)

WAC = Wholesale Acquisition Cost.

[1]The WAC is a published list price. WAC does not contain any discounts, price concessions, or charge-backs extended to wholesalers or other end users. WAC is not intended to represent an actual sales price to customers. Wholesalers and distributors determine the actual sales price to end-user customers.

[2]WAC as of June 2018.

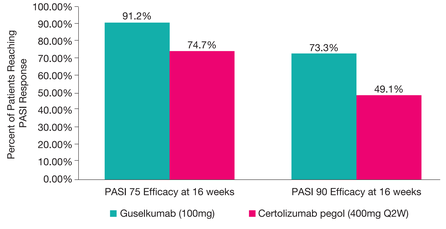
[3]A dose of 200 mg is a prescribing option for certolizumab pegol but the cost per responder analysis is based on the efficacy data for the recommended 400 mg dose.

- VOYAGE 1 (a randomized, double-blind, placebo- and active-controlled clinical trial; Blauvelt et al., 2017) and CIMPACT (a randomized, double-blind, placebo- and multiple-dose [400 mg, 200 mg] controlled trial; Lebwohl et al., 2018) were both phase 3 trials that enrolled patients with moderate to severe plaque psoriasis with similar levels of disease severity (mean Psoriasis Area and Severity Index [PASI] score 22.1 for VOYAGE 1, 20.8 for CIMPACT [400 mg dose]) and disease duration (mean 17.9 years for VOYAGE 1, 17.8 years for CIMPACT [300 mg dose]) at baseline.
- PASI 75 and PASI 90 16-week efficacy results were extrapolated to 52 weeks (assumed unchanged) and used in the induction year cost-per-responder calculation
  - Due to substantial differences in trial design and methodology for reporting results (CIMPACT trial used logistic regression and responder analysis beyond week 16 while VOYAGE 1 used non-responder imputation), week 16 PASI 90 response rates were used from each trial. Response rates were assumed to be unchanged from week 16 and extrapolated to week 52; however, this may under represent guselkumab PASI 90 results, given that response rates increased past week 16 in VOYAGE 1.
- A sensitivity analysis was conducted for patients achieving a PASI 75 response at 48 weeks. Due to differences in the way that results were reported between the two trials, the number of patients who had a response at 16 weeks was multiplied by the percentage of patients that continued to have a PASI 75 response at 48 weeks for certolizumab pegol (CIMPACT trial). This was compared to the percentage of patients with a PASI 75 response at 48 weeks for guselkumab (VOYAGE 1).
  - This methodology could not be conducted for PASI 90 due to the difference in data reporting from the CIMPACT trial (the percentage of patients with a PASI 90 response at 16 weeks who continued to have a PASI 90 response at 48 weeks was unavailable).

Results

- The first-year WAC costs (induction) were $81,268.16 (8 × $10,158.52) for guselkumab and $105,152.32 (26 × $4,044.32) for 400mg certolizumab pegol.
- Figure 1 shows the percentage of patients in the VOYAGE 1 and CIMPACT trials reaching a PASI 90 response at 16 weeks (73.3% for guselkumab and 49.1% for certolizumab pegol), and the percentage of patients reaching a PASI 75 response at 16 weeks (91.2% for guselkumab and 74.7% for certolizumab pegol)

Figure 1. Percentage of Patients Reaching PASI 75 and PASI 90 Response at 16 Weeks



- Figure 2 shows the cost-per-responder estimates for the two drugs PASI 75 and PASI 90 response rates in the induction year.
- Figure 3 shows results of the sensitivity analysis for the percentage of patients in the VOYAGE 1 and CIMPACT trials reaching a PASI 75 response at 48 weeks (87.8% for guselkumab and 73.2% for certolizumab pegol)
- For all response rates for both the base case induction year and the sensitivity analysis, the cost per responder was lower for guselkumab compared to certolizumab pegol (Figures 2 and 4).

Figure 2. Cost Per Responder for PASI 75 and PASI 90 Response Levels, Induction Year

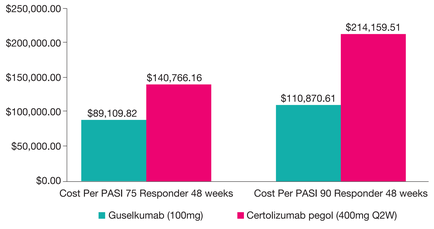


Figure 3. Sensitivity Analysis: Percentage of Patients Reaching PASI 75 at 48 Weeks

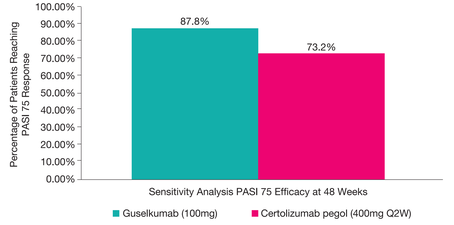
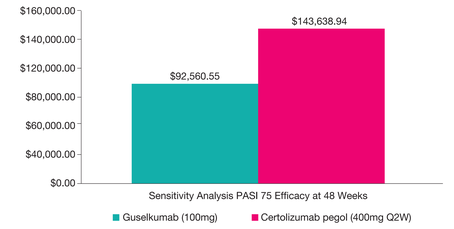


Figure 4. Sensitivity Analysis: Cost Per Responder for PASI 75, Induction Year



Limitations

- Perfect adherence was assumed for purposes of costing.
- A formal indirect comparison was not conducted; however, enrolled population characteristics appear to be similar between the two trials.
- Response rates were not adjusted for placebo response, as placebo response rates were similar and low in both trials.
- Efficacy results in the base case were assumed to be unchanged from 16 weeks to 52 weeks.
- A cost per responder analysis based on PASI 100 outcomes was not included as PASI 100 results were not available in the published CIMPACT trial results.
- All Certolizumab Pegol week 16 PASI 75 and PASI 90 response rates from CIMPACT were analyzed using a logistic regression model with fixed effects for treatment, region, and prior biologic exposure (yes/no). Results beyond week 16 were not used because they were based on a responder analysis and thus may appear inflated relative to results from the guselkumab trial.

Conclusions

- This analysis based on indirect comparison of efficacy data from the VOYAGE 1 and CIMPACT trials, demonstrates that guselkumab is a more cost-effective therapy than certolizumab pegol, with a lower cost per responder for achieving PASI 75 and PASI 90 responses in the first year of treatment among patients with moderate to severe plaque psoriasis.

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