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Cost per responder for guselkumab versus secukinumab in the United States based on a head-to-head trial of moderate to severe plaque psoriasis*

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ABSTRACT

Aims: To estimate cost per response (CPR) in the United States and number-needed-to-treat (NNT) among subjects receiving guselkumab or secukinumab for moderate to severe plaque psoriasis.

Materials and methods: Results from ECLIPSE, a double-blind, head-to-head, 48-week study of guselkumab compared with secukinumab were used to estimate 48-week, annual induction, and maintenance year CPRs for Psoriasis Area and Severity Index (PASI) 75, 90, and 100 responses for all patients and for PASI 90 response in patients according to previous systemic treatment.

Results: Week 48 PASI 90 response rates were 84.5% for guselkumab and 70.0% for secukinumab. The CPR for PASI 90 response at 48 weeks was $89,960 for guselkumab versus $110,977 for secukinumab, and for the maintenance year it was $77,109 for guselkumab versus $88,781 for secukinumab. The NNT for a PASI 90 response was 1.18 for guselkumab and 1.43 for secukinumab. CPR and NNT values were also lower for guselkumab than for secukinumab, for PASI 75 and PASI 100 for the three time periods, and for PASI 90 at 48-weeks, regardless of previous systemic treatment.

Conclusions: Results from a head-to-head study showed that, compared with secukinumab, guselkumab had lower NNTs and CPRs for PASI 75, PASI 90, and PASI 100 responses.

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1. Introduction

Moderate to severe plaque psoriasis (PsO) is a chronic, relapsing, inflammatory immune–mediated skin disease; the prevalence of PsO in adults older than 20 years of age in the United States (US) is approximately 3.2%, or more than 7.4 million people, as estimated by the National Health and Nutrition Examination Survey [1]. Estimates of the percentage of adults with PsO who have moderate to severe disease and are eligible for treatment with systemic conventional or biologic drugs range between 16.7 [2] and 18.2% [3].

Treatment of moderate to severe psoriasis with biologics has been demonstrated to be more efficacious than conventional systemic treatment. The tumor necrosis factor (TNF) alpha blockers etanercept and adalimumab have been shown to achieve better clinical responses in treating moderate to severe PsO than treatment with methotrexate [4,5]. In addition, guselkumab has been shown to be superior to adalimumab in two head-to-head clinical trials [6,7]. Moreover, guselkumab was also superior to secukinumab in achieving PASI 90 response at week 48 in a head-to-head clinical trial [8].

In the US, because psoriasis is a chronic condition and has a significant impact on health care costs, quality of life, and productivity losses [9,10], health care stakeholders making formulary and benefit design decisions are interested in long-term comparative average cost per responder and annual drug treatment costs for biologics for moderate to severe PsO. Efficacy in PsO clinical trials is typically based on the percentage improvement from baseline in the Psoriasis Area and Severity Index (PASI) score [11]. The PASI is a combined measure of the area affected by PsO and the severity of signs in those areas. Clinical improvement is commonly measured using PASI 75, PASI 90, and PASI 100 responses (75, 90, and 100% improvement from baseline, respectively). Achieving PASI 90 or PASI 100 response has been shown to be associated with greater patient quality of life than achieving a PASI 75 (or lower) response [12,13].

Dividing annual biologic cost by annual response rates for these PASI response thresholds generates a cost-per-responder (CPR) estimate for each drug and provides a relative measure of average value for different drugs. Estimates of the number needed to treat (NNT) to achieve one additional responder for each PASI response level provides a measure of the relative clinical efficacy of treatment with different drugs. In this study, CPR and NNT analyses were performed using data from the 48-week head-to-head ECLIPSE trial comparing guselkumab with secukinumab [8] (also Janssen data on file, 2019); different measures of response (PASI 75, PASI 90, and PASI 100) at week 48, after 44 weeks of systemic biologic treatment, were extrapolated to 52 and 104 weeks; biologic costs were estimated for the first 44 weeks of treatment, the first 52 weeks of treatment (induction year), and for the first maintenance year. Scenario analyses were

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*PASI 90 responses by prior treatment were presented in a poster at the 28th Congress of the European Academy of Dermatology and Venerology; October 9, 2019; Madrid, Spain. PASI 90 cost per responder values were presented in a poster at the AMCP Annual Meeting; March 25–28, 2019; San Diego, California, USA.

performed for PASI 90 responses for populations with and without prior treatment with systemic conventional drugs or biologics.

2. Materials and methods

The ECLIPSE study was a double-blind, head-to-head, 48-week study comparing guselkumab with secukinumab in patients ≥18 years of age with moderate to severe plaque PsO and a baseline PASI score ≥12 (mean PASI score was 20.0) [8]. The trial was registered on clinicaltrials.gov (identifier: NCT03090100). It was conducted with approval from formal ethics review committees at each study site, and patients signed written informed consent before study initiation [8]. The primary endpoint for the study was the proportion of patients with a PASI 90 or greater response at week 48. Secondary endpoints included the proportions of patients with PASI 75 and PASI 100 responses at week 48 and the proportions of patients with Investigator's Global Assessment (IGA) scores of 0, or 1 at 48 weeks.

Treatment in the ECLIPSE study was administered for 44 weeks for both biologics. Forty-four–week and annual drug costs were estimated based on the dosing regimens used in the ECLIPSE study, which were aligned with the dosing regimens approved by the US Food and Drug Administration (FDA) for both products. For guselkumab, the dosing regimen was 100 mg at weeks 0 and 4 and then every 8 weeks through week 44 for a total of seven doses. For the induction year estimates, we assumed one additional dose at 52 weeks. The maintenance year dosing regimen was 100 mg every 8 weeks starting at week 8 for a total of six doses. For secukinumab, the dosing regimen was 300 mg at weeks 0, 1, 2, 3, 4 and then every 4 weeks through week 44 for a total of fifteen doses. For the induction year estimates, we assumed two additional doses through week 52. The maintenance year dosing regimen was 300 mg every 4 weeks starting at week 4 through week 52 for a total of twelve doses.

Wholesale acquisition costs (WACs) for the two drugs were taken from the IBM Micromedex® RED BOOK® on August 14, 2019 [14]. Table 1 presents the induction and maintenance year dosing and pricing inputs used in the CPR analysis.

To understand CPR estimates over longer timeframes, CPR was estimated for the trial period (48-weeks), for the induction year and for the first maintenance year; it was assumed that efficacy outcomes observed at week 48 from the ECLIPSE study were maintained through week 52 in the induction year analysis and through week 104 in the maintenance year analysis. The CPR was estimated for PASI 75, PASI 90, and PASI 100 responses as the ratio between 44-week or annual drug costs for the induction and first maintenance years and the percentage of patients achieving each PASI response outcome using the following equation:

$$\text{Cost per responder} = \frac{(\text{Per unit drug costs}) \times (\#\text{ of doses per 44 weeks or induction or maintenance years})}{\text{Percentage of patients with a response at 48 weeks (ECLIPSE)}}$$

The NNT to obtain one patient with a PASI 75, PASI 90, and PASI 100 response at 48 weeks was also estimated for each drug using the following equations:

- NNT 75 = 1 ÷ percentage of patients with PASI 75 response
- NNT 90 = 1 ÷ percentage of patients with PASI90 response
- NNT 100 = 1 ÷ percentage of patients with PASI 100 response

Scenario analyses were conducted to determine the CPR and NNT for guselkumab and secukinumab in PASI 90 responders divided into subgroups depending on their previous treatment.

3. Results

3.1. Base-case analyses

PASI 90 response rates at week 48 for the overall study population were 84.5% for guselkumab and 70.0% for secukinumab. The PASI 75, PASI 90, and PASI 100 response rates observed in the study population at 48 weeks are presented in Figure 1.

The total WACs for both drugs during the 44-week trial treatment period were $76,016 for guselkumab and $77,684 for secukinumab. In the induction year, the total WACs were $86,876 for guselkumab and $88,041 for secukinumab. For the first maintenance year, the total WACs were $65,157 for guselkumab and $62,147 for secukinumab. These costs were estimated using the input values for dosing and US prices described in the Methods section (Table 1) and assuming 100% adherence and persistence with the FDA-labeled regimen.

Table 1. Dosing and unit prices and 44-week and annual drug costs in the United States for guselkumab and secukinumab: induction and maintenance years.

			Trial treatment period (44 Weeks)		Induction year (52 Weeks)		Maintenance year (52 Weeks)	
Biologic	Dosing	Pricing	Number of doses	44 week cost	Number of doses	Annual cost	Number of doses	Annual cost
Guselkumab	100 mg Administered by subcutaneous injection at week 0, week 4, and every 8 weeks thereafter[a]	WAC[b,c] per 100 mg: $10,859.46	7	$76,016.22	8	$86,875.68	6	$65,156.76
Secukinumab	300 mg dose (2 × 150 mg), at weeks 0, 1, 2, 3, 4 and then every 4 weeks thereafter[a]	WAC[b,c] per 300 mg: $5,178.91	15	$77,683.65	17	$88,041.47	12	62,146.92

WAC: wholesale acquisition cost.
[a]United States Food and Drug Administration–labeled dose; trial efficacy outcomes were measured at 48 weeks, but biologic treatment was only given through 44 weeks.
[b]The WAC is a published list price. Wholesale acquisition cost does not account for any discounts, price concessions, or charge backs extended to wholesalers or other end users. It is not intended to represent an actual sales price to customers. Wholesalers and distributors determine the actual sales price to end-user customers.
[c]Wholesale acquisition cost as of August 14, 2019. Source: IBM Micromedex® RED BOOK® [14].

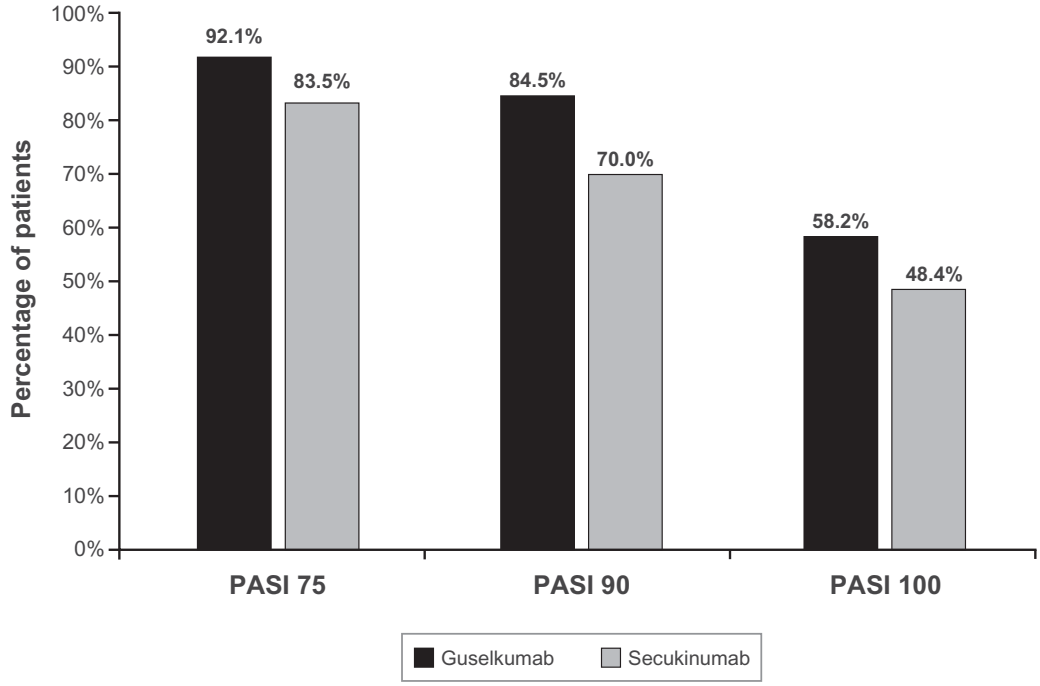

Figure 1. Percentage of patients achieving PASI 75, 90, and 100 response at 48 weeks in the ECLIPSE study[a]. PASI: Psoriasis Area and Severity Index; PsO: psoriasis. [a]The PASI was used to measure three levels of PsO improvement from baseline: PASI 75 (≥75% improvement), PASI 90 (≥90% improvement), and PASI 100 (100% improvement). *Source*: Reich et al [8]; Janssen data on file, 2019.

Table 2. Cost per responder[a] in the United States and number needed to treat: all study patients.

	Guselkumab	Secukinumab
Cost per responder (CPR) 48-week trial period		
PASI 75	$82,537	$93,034
PASI 90	$89,960	$110,977
PASI 100	$ $130,612	$160,503
Cost per responder (CPR) induction year		
PASI 75	$94,328	$105,439
PASI 90	$102,811	$125,744
PASI 100	$149,271	$181,904
Cost per responder (CPR) first maintenance year		
PASI 75	$70,746	$74,427
PASI 90	$77,109	$88,781
PASI 100	111,953	$128,403
Number needed to treat (NNT) 48-week trial efficacy endpoint and assumed value for induction or first maintenance year		
PASI 75	1.09	1.20
PASI 90	1.18	1.43
PASI 100	1.72	2.07

CPR: cost per responder; NNT: number needed to treat; PASI: Psoriasis Area and Severity Index.
[a]The PASI was used to measure three levels of PsO improvement (response) from baseline: PASI 75 (≥75% improvement), PASI 90 (≥90% improvement), and PASI 100 (100% improvement).

The CPR results are presented in Table 2 and Figure 2 (48-week trial period), Figure 3 (induction year), and Figure 4 (first maintenance year). The CPR values were lower for guselkumab than for secukinumab based on PASI 75, PASI 90, and PASI 100 response rates for the 48-week trial period, as well as for the induction and first maintenance years. For example, the PASI 90 CPR value for guselkumab for the 48-week trial period was $89,960 compared with $110,997 for secukinumab; for the induction year, the PASI 90 CPR was $102,811 for guselkumab compared with $125,774 for secukinumab; and the PASI 90 CPR value for guselkumab for the first maintenance year was $77,109 compared with $88,781 for secukinumab. Number needed to treat values were calculated using 48-week response rates and were assumed to be the same for the induction and maintenance years (Table 2). The NNTs for guselkumab were lower than those for secukinumab for all PASI responses, consistent with the superior responses observed for guselkumab at week 48 in the trial.

3.2. Scenario analyses

Subgroup analyses were generated for patients in the ECLIPSE study based on their previous psoriasis medication history [15]. Week 48 PASI 90 response rates were 81.4% for guselkumab ($n = 156$) and 64.4% for secukinumab ($n = 149$) among patients with previous biologic treatment, and 83.0% for guselkumab ($n = 276$) and 68.6% for secukinumab ($n = 287$) among patients with previous nonbiologic systemic treatment (Figure 5). The NNT and CPR values for these, as well as additional subgroups defined by type of previous biologic treatment, are shown in Tables 3 and 4. The NNT and CPR values were lower for guselkumab than for secukinumab based on PASI 90 response rates for the 48-week trial period, and for the induction and maintenance years for all previous treatment subgroups.

4. Discussion

The results of the base-case and scenario analyses for the 48-week trial period, and the induction year and first maintenance year extrapolations, indicate that the CPR and NNT outcomes were consistently more favorable for guselkumab than for secukinumab. In addition, the CPR results for PASI 90 response were also more favorable for guselkumab than for secukinumab among patients previously treated with a biologic.

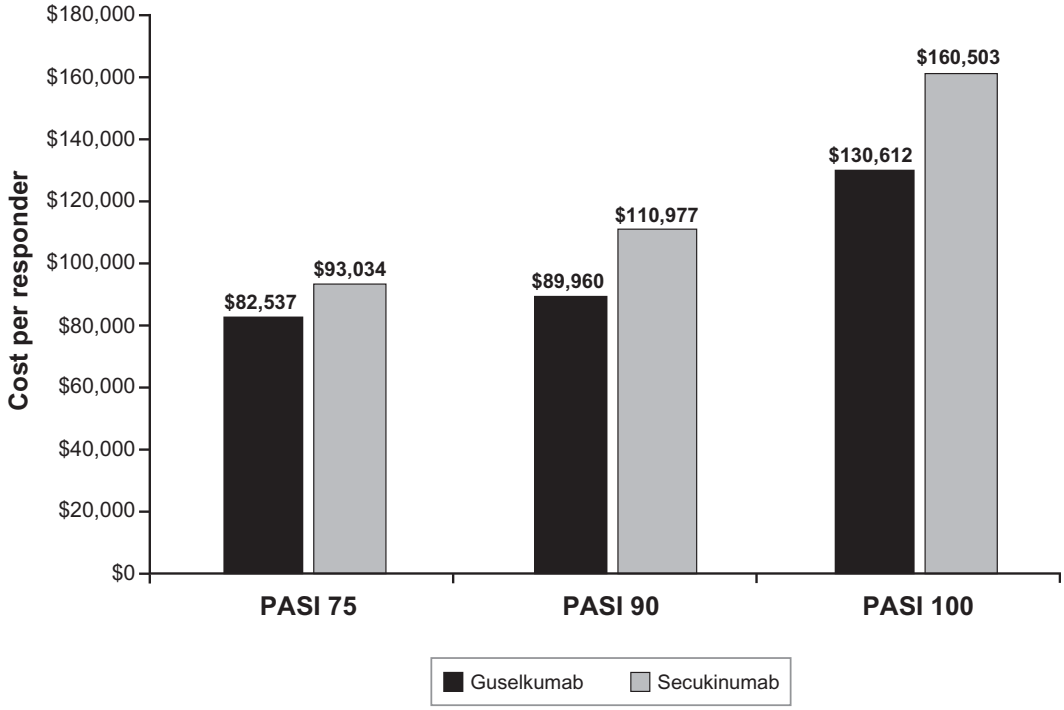

Figure 2. United States cost per responder for three PASI response levels: 48-week trial period[a]. PASI: Psoriasis Area and Severity Index. [a]Using Wholesale Acquisition Cost as of August 14, 2019. *Source*: IBM Micromedex® RED BOOK® [14].

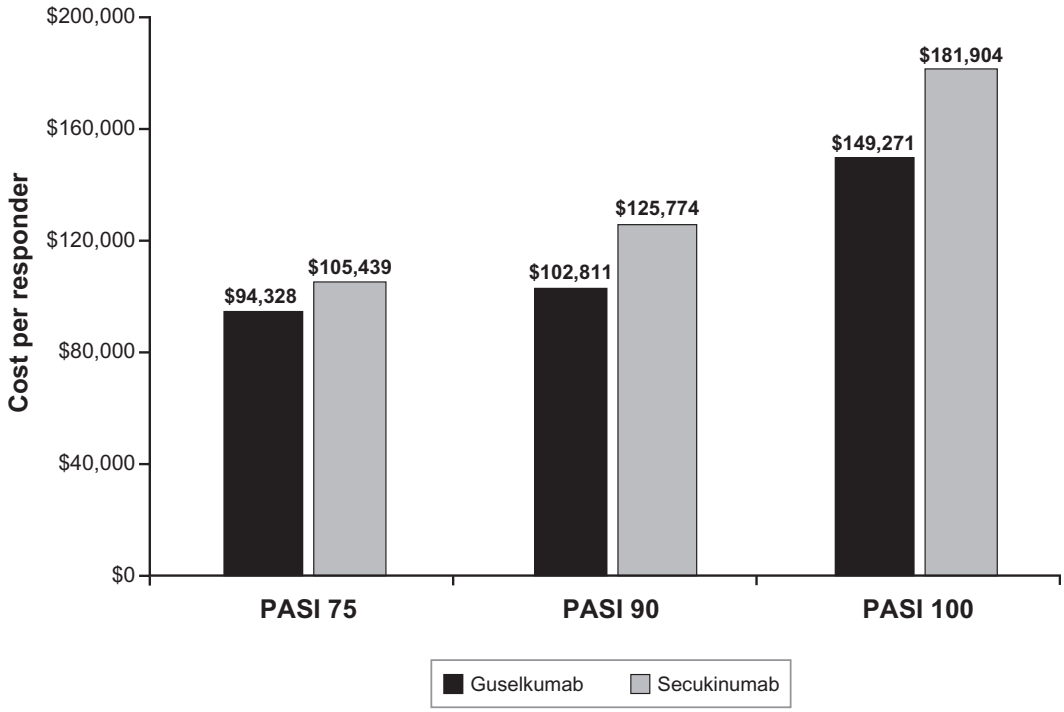

Figure 3. United States cost per responder for three PASI response levels: induction year[a]. PASI: Psoriasis Area and Severity Index.[a] Using wholesale acquisition cost as of August 14, 2019. *Source*: IBM Micromedex® RED BOOK® [14].

In a recent study, Wu et al. [16] estimated annual CPR in the US for several biologics indicated for the treatment of moderate to severe psoriasis. The annual CPR for secukinumab in the Wu et al.'s study [16] was estimated to be $75,671 for PASI 75, $108,509 for PASI 90, and $205,393 for PASI 100 responses. These estimates are based on 2017 dollars and assume a hypothetical drug discount over list price of 20%. The number of doses of secukinumab per year was not presented, and guselkumab was not included in this study. The response rates were estimated at 12–16 weeks and were assumed to be maintained at 52 weeks. The estimates of PASI response for secukinumab in that study were lower than those in the ECLIPSE study (e.g. rates for PASI 90 were 53% in Wu et al. [16] versus 70% in the ECLIPSE study [8]), but the CPRs for secukinumab were all lower

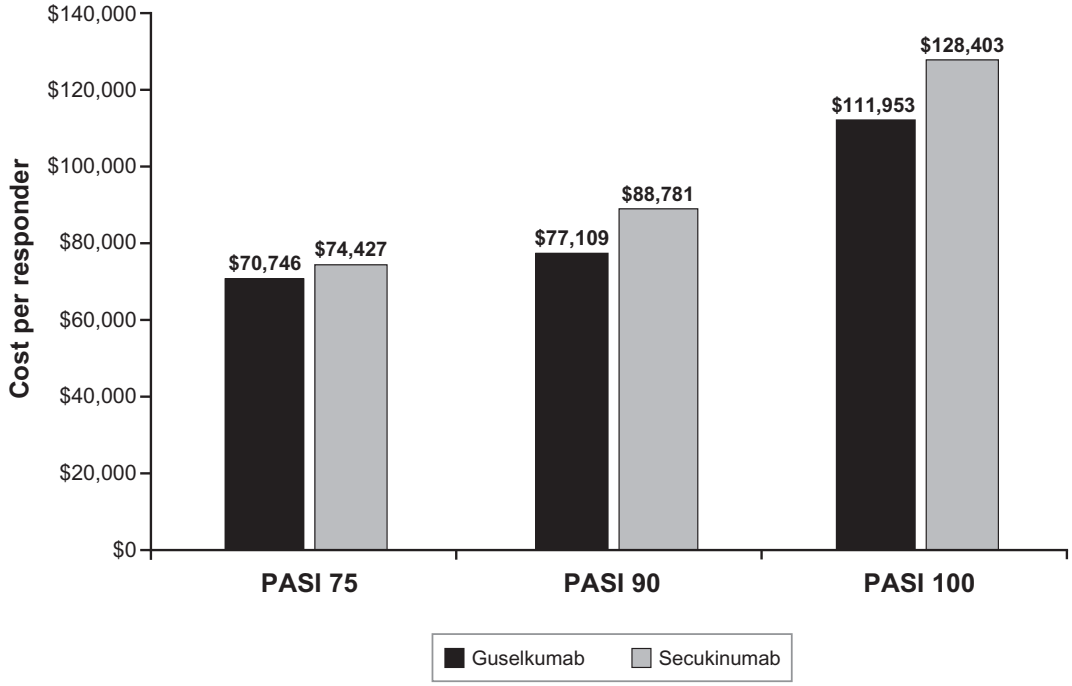

Figure 4. Cost per responder for all three PASI response levels: first maintenance year[a]. PASI: Psoriasis Area and Severity Index. [a]Using wholesale acquisition cost as of August 14, 2019. *Source*: IBM Micromedex® RED BOOK® [14].

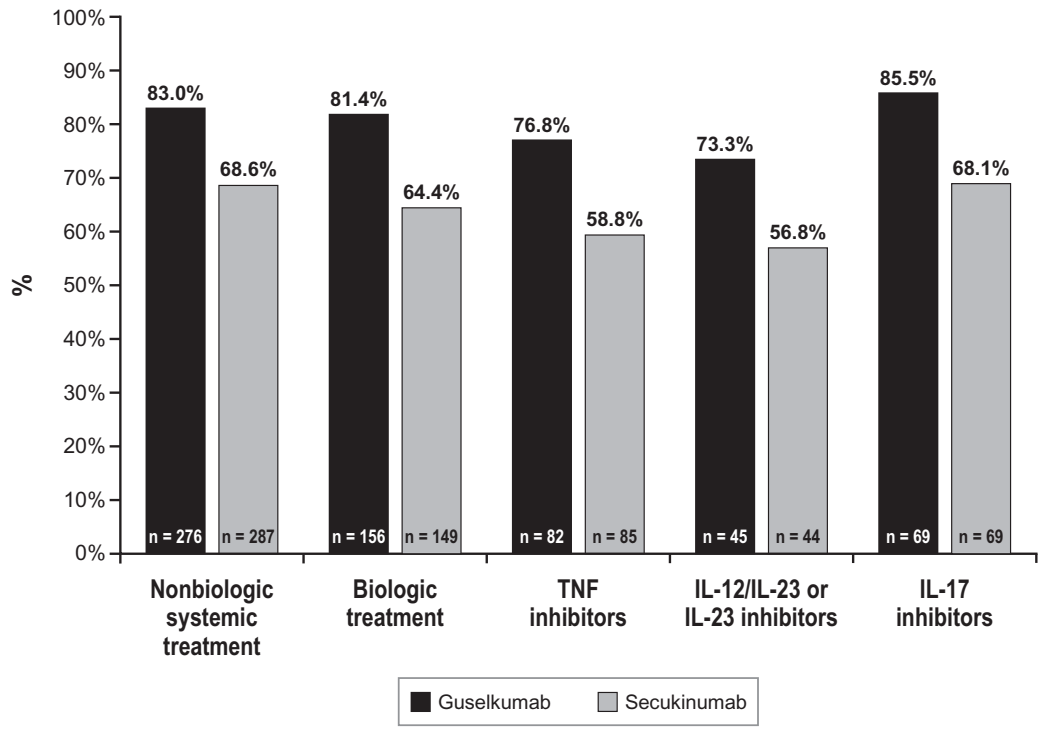

Figure 5. Percentage of patient subgroups achieving a PASI 90 response at 48 weeks by prior treatment experience[a]. PASI: Psoriasis Area and Severity Index; PsO: psoriasis. [a]The PASI was used to measure the level of PsO improvement from baseline: PASI 90 (≥90% improvement). *Source*: Blauvelt et al. [15].

than our estimates. This discrepancy is most likely due to price increases for secukinumab since 2017 and factoring in a 20% drug discount, which was not included in our estimates.

In a study comparing CPR and NNT for guselkumab and adalimumab using data from the VOYAGE 1 head-to-head trial [17], guselkumab was shown to have a lower CPR and NNT than adalimumab in both the induction and first maintenance years. The VOYAGE 1 and ECLIPSE studies differed in design (the ECLIPSE study did not have a placebo arm). The included study populations also differed in many baseline characteristics, including race, sex, duration of disease, previous treatment with biologics, PASI scores, and body surface involvement. Thus, the

Table 3. NNT according to previous psoriasis treatment in PASI 90 responders at 48 weeks: scenario analyses.

Population	Guselkumab	Secukinumab
All study population	1.18	1.43
Previous nonbiologic systemic treatment	1.20	1.46
Previous biologic systemic treatment	1.23	1.55
Previous biologic or nonbiologic systemic drug treatment	1.20	1.46
Previous treatment with TNF inhibitors	1.30	1.70
Previous treatment with IL-12/IL-23 or IL-23 inhibitors	1.36	1.76
Previous treatment with IL-17 inhibitors	1.17	1.47

IL: interleukin; NNT: number needed to treat; PASI: Psoriasis Area and Severity Index; TNF: tumor necrosis factor.
[a]Patient subgroups were not mutually exclusive; some patients had previously been treated with more than one systemic nonbiologic and/or biologic drug.

Table 4. Costs per responder according to previous psoriasis treatment among PASI 90 responders: scenario analyses.

	48-Week trial period CPR		Induction year CPR		First maintenance year CPR	
Population[a]	Guselkumab	Secukinumab	Guselkumab	Secukinumab	Guselkumab	Secukinumab
All patients	$89,960.02	$110,976.64	$102,811.46	$125,773.53	$77,108.59	$88,781.31
Previous nonbiologic systemic treatment	$91,585.81	$113,241.47	$104,669.49	$128,340.34	$78,502.12	$90,593.18
Previous biologic systemic treatment	$93,386.02	$120,626.79	$106,726.88	$136,710.36	$80,045.16	$96,501.43
Any previous systemic treatment	$91,365.65	$113,738.87	$104,417.88	$128,904.06	$78,313.41	$90,991.10
Previous treatment with TNF inhibitors	$98,979.45	$132,115.05	$113,119.38	$149,730.39	$84,839.53	$105,692.04
Previous treatment with IL-12/IL-23 or IL-23 inhibitors	$103,705.62	$136,766.99	$118,520.71	$155,002.59	$88,890.53	$109,413.59
Previous treatment with IL-17 inhibitors	$88,907.86	$114,072.91	$101,608.98	$129,282.63	$76,206.74	$91,258.33

CPR: cost per responder; IL: interleukin; PASI: Psoriasis Area and Severity Index; TNF: tumor necrosis factor.
[a]Patient subgroups were not mutually exclusive; some patients had previously been treated with more than one systemic nonbiologic and/or biologic drug.

efficacy of guselkumab and the CPR and NNT outcomes based on VOYAGE 1 are not directly comparable to those based on the ECLIPSE data.

Three US studies have presented CPR estimates for secukinumab for the induction period only for PsO [18–20]. All of these estimated CPRs are based on efficacy from only 12- to 16-week studies with cost data for the 12- to 16-week induction period only. Thus, secukinumab results from these studies are not directly comparable with those presented in our study due to differences in treatment duration covered. Moreover, given the year of publication of these studies, guselkumab was not included.

Our study has limitations that should be acknowledged. Response rates were derived from a single, head-to-head, 48-week clinical trial [8]. Our analysis also assumed that the response rates for both guselkumab and secukinumab at 48 weeks would be maintained at both 52 weeks and 104 weeks if treatment was continued as recommended in the product labels. This assumption, based on the 48-week results from the ECLIPSE trial [8], could have an impact on our results if maintenance of response over time differs between therapies. Our analysis did not account for other costs associated with biologics, such as those related to administration, monitoring, or adverse events. While this is a limitation worth noting, administration and monitoring requirements are similar for guselkumab and secukinumab, and rates and most types of adverse events were generally comparable between the guselkumab and secukinumab groups through week 48 in the ECLIPSE trial [8]. We also did not include medical care or other indirect costs associated with PsO that might change with treatment. Wholesale acquisition costs in the US were used in this model, and results may vary depending on payer-specific costs for each therapy after discounts. Lastly, we did not adjust the 48-week response rates for guselkumab and secukinumab by placebo responses at 48 weeks since a placebo arm was not included in the ECLIPSE trial.

Strengths of our study include the CPR comparison of two biologics using efficacy based on PASI 75, PASI 90, and PASI 100 response rates from a 48-week head-to-head study. Given that PsO is a chronic condition, use of 48-week or annual costs and 48-week outcomes to estimate the CPR are more illustrative of the value associated with use of biologics than monthly or short-term costs and outcomes [18–20].

5. Conclusion

In conclusion, since multiple biologic options are available for treatment of moderate to severe PsO, it is important to consider the value of each therapy. Cost per responder and NNT analyses are approaches for ranking the average value and clinical efficacy, respectively, of different treatments. In particular, annual CPR estimates presented in this study allow US decision makers to use average value as a measure of biologic drug value based on a range of PASI response levels. In this study, guselkumab was shown to have a lower CPR and was more efficacious than secukinumab for treatment of moderate to severe PsO in CPR and NNT analyses of PASI 75, PASI 90, and PASI 100 responses for 44-week, induction or maintenance year dosing based on data from the 48-week ECLIPSE study. In a scenario analysis, guselkumab compared with secukinumab was also shown to have a lower CPR and was more efficacious for PASI 90 responders among subgroups defined by previous systemic medication treatment for psoriasis.

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Author contributions

Amanda Teeple and Timothy Fitzgerald conceived and designed the study, developed the Excel model used in this analysis, interpreted the data from the model, reviewed and made extensive written contributions to the manuscript, gave approval to the final version, and agree to be accountable for all aspects of the work.

Disclosure statement

Amanda Teeple and Timothy Fitzgerald are employees of Janssen Scientific Affairs and stock holders of Johnson & Johnson the manufacturers of guselkumab.

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