

# Impact of Using Real-World Outcomes Data Versus Clinical Evidence and Published Prices in Value Assessments

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## ABSTRACT

**Background:** To assess value, industry organizations often use list prices or use gross assumptions to calculate average prices per patient or price per QALY. However, this methodology requires numerous assumptions which need to be validated and can be challenging to ascertain. A better approach may be to use fully-adjudicated net prices and real-world clinical outcomes data for value assessments. We sought to demonstrate the impact on value analyses of using list vs. net prices.

**Methodology:** Using the IBM® Access and Value Connect solution, patients in the IBM MarketScan® Commercial and Medicare Supplemental Database between 1 January 2013 through 31 December 2017 with a psoriasis diagnosis were identified. To demonstrate an example of impact on value assessments, we calculated the mean per-patient-per-month (PPPM) cost associated with apremilast and compared that to the Net Price calculation reported in the 2018 Plaque Psoriasis Condition Update by ICER, based on per-unit dosing and discount assumptions.

**Results:** We identified patients with a psoriasis diagnosis as follows: 22,928 (12 month), 29,885 (36 months), 37,354 (60 months) study periods. The adjudicated claims PPPM cost for US health plans was \$18,637 with a mean duration of exposure to apremilast of 221 days and including concomitant psoriasis medications. This is approximately \$12,000 less than the average price presented in the 2018 ICER report (\$30,807 Year 1, \$31,018 Year 2). Numerous additional differences between the real-world performance data and ICER evidence report were identified.

**Conclusions:** Our analysis found that using a fully-adjudicated net price (1) allowed direct comparison of prices amongst therapies quickly and easily and (2) facilitated a more accurate reflection of price versus value when used alongside analysis of the real-world clinical outcomes data. We recommend that net prices and real-world data be used for value assessments should incorporate the numerous data whenever possible. Value assessment organizations sets and tools available to improve transparency, accuracy and ease of analysis.

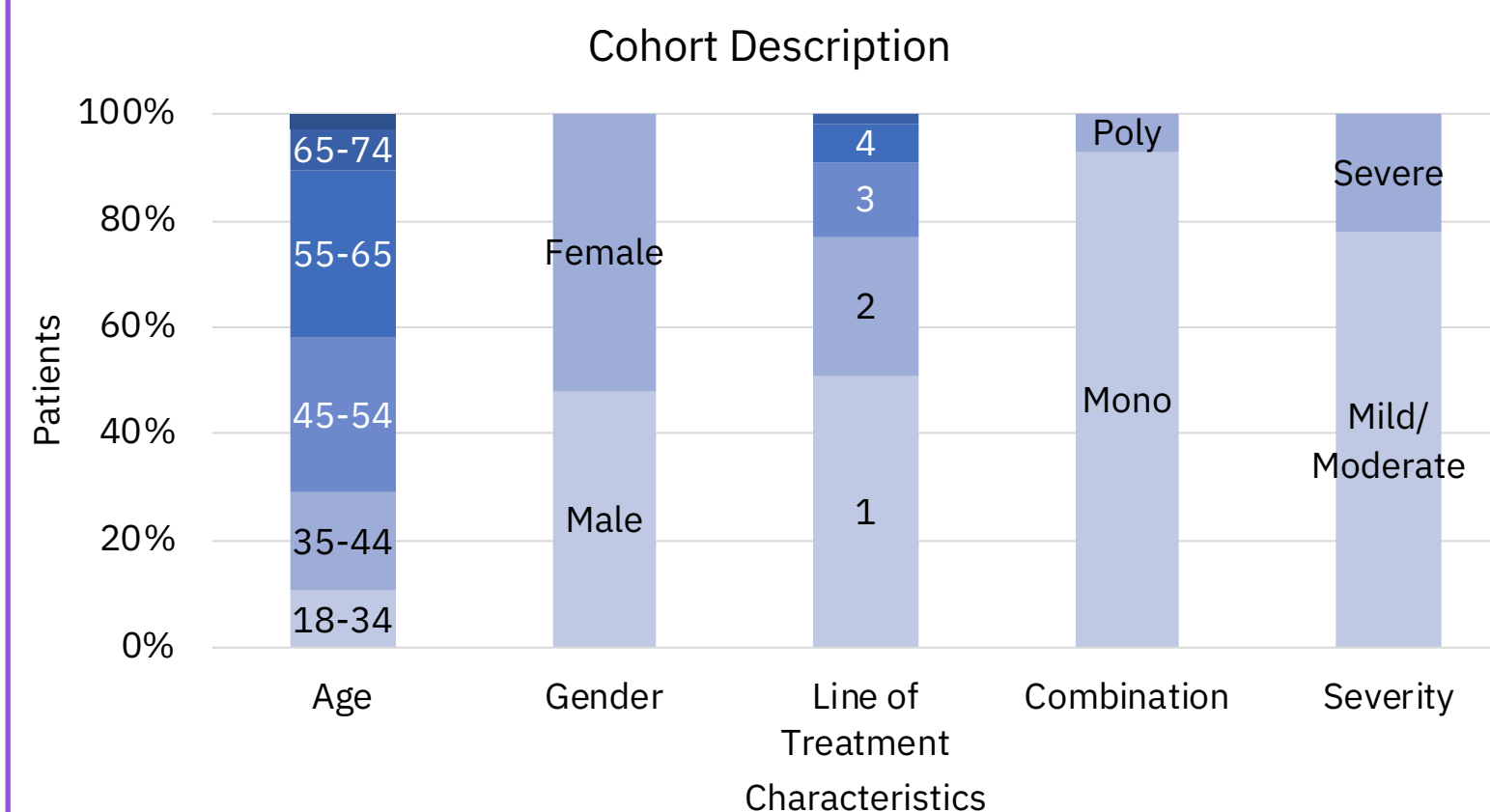
## BACKGROUND AND OBJECTIVES

- Value assessments have been gaining attention for their potential use in coverage and pricing decisions for therapeutics. While more standardized in some countries, such as the UK, the use and utility of value assessments in the US is still emerging.
- The Institute for Clinical and Economic Review has been publishing value assessments for several years, and has established a process to identify and incorporate select data.
- In this study, we sought to determine whether the use of real-world financial performance data versus assumptions compiled from secondary sources and/or not well-published would significantly impact the results of the Incremental Cost-per-QALY assessment

## METHODS

- A Psoriasis Cohort was deployed on the IBM Access and Value Connect Visual Analytics tool to quickly interrogate financial outcomes from indicated biologics and methotrexate. There cohorts were created from the IBM MarketScan Commercial and Medicare Supplemental Claims Databases from 1 January 2011 to 31 December 2017. To be included in the cohort, patients must have a psoriasis related treatment and claims indicating at least two diagnoses of psoriasis within the 12 months prior to or 30 days after treatment initiation. Only adult patients (age 18 or above at diagnosis) were considered. Patients with pregnancy related claims or diagnostic claims for HIV/AIDS, Crohn's disease, any rheumatologic diagnosis, or ankylosing spondylitis were excluded. The 12-month cohort was selected for closest comparison to ICER QALY metrics.
- The most recent ICER report on psoriasis treatments was selected and all assumptions were reviewed in depth. The methodology and inputs on price per patients and lengths on treatments were analyzed to determine whether the inputs to the model accurately reflected real-world performance data, and to inform usefulness of insights from ICER reports.
- Where possible, direct comparisons were made between model inputs from ICER and the IBM Access and Value Connect tool.

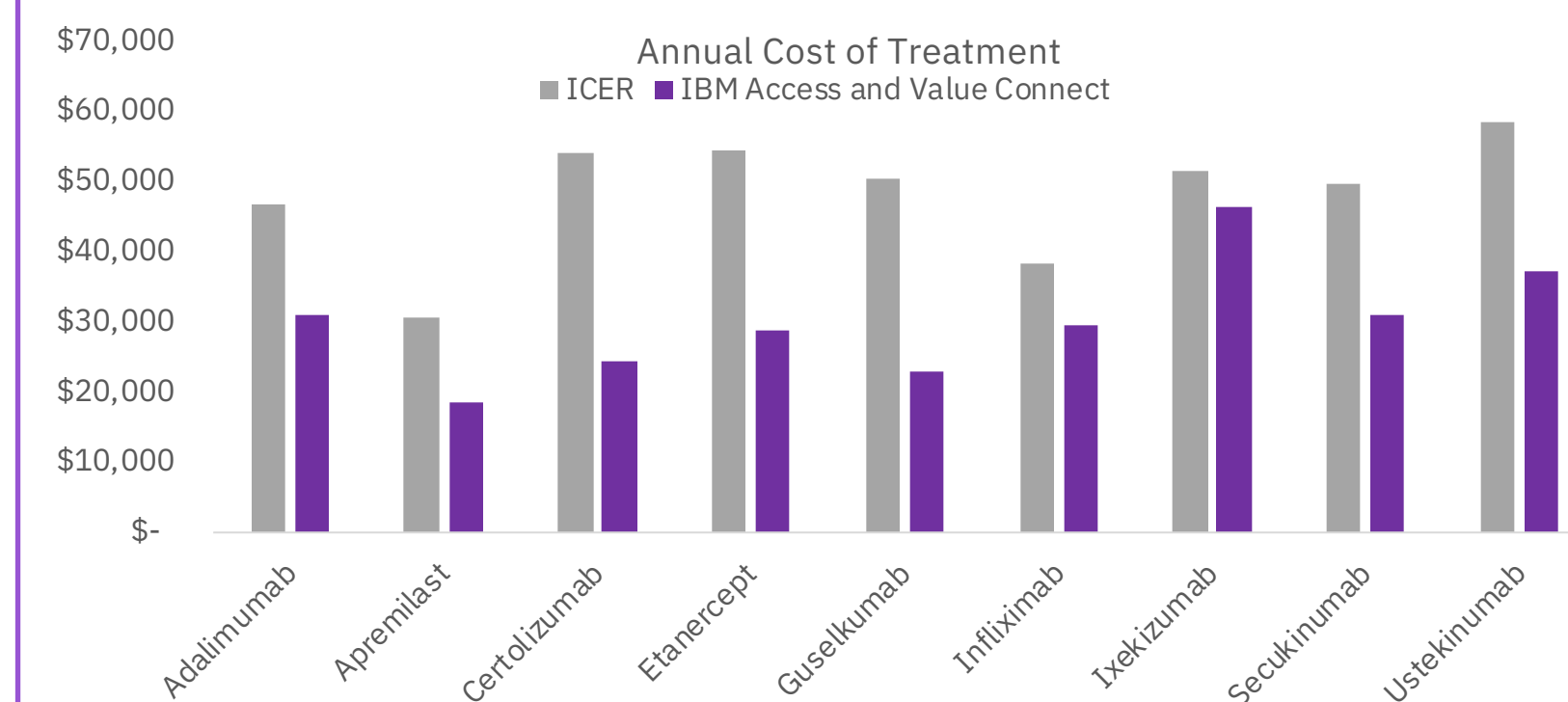
Figure 1. Cohort Description



IBM Access and Value Connect 12-Month Cohort from IBM MarketScan Commercial and Medicare Supplemental Database 1/1/2017 – 12/31/2017, selected for patients treated with indicated biologics and methotrexate for psoriasis.

## RESULTS

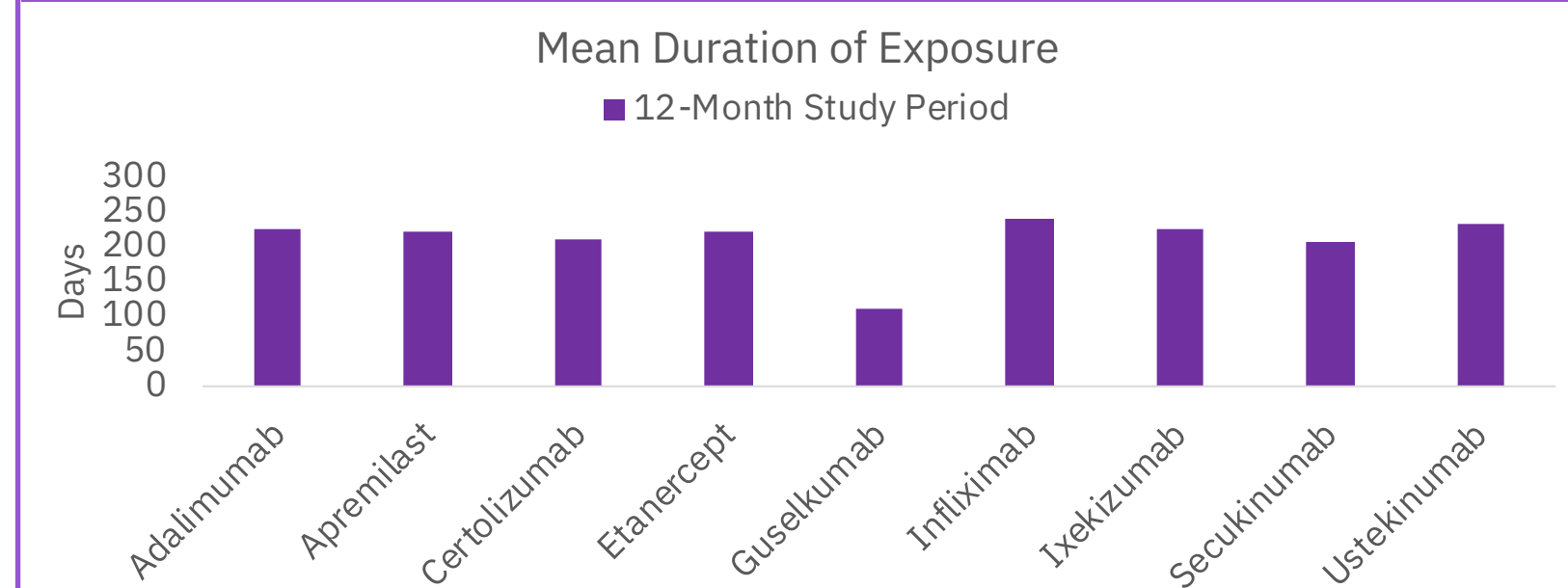
Figure 2. Comparison of Year 1 Costs by Psoriasis Treatment



ICER: Cost of First Year Treatment, Table ES6, Drug Cost Inputs  
IBM Access and Value Connect: Mean Per-Patient-Per-Month Costs times Mean Duration of Therapy by Treatment in 12-Month Cohort Study Period

- A mean difference of approximately \$14,000 per patient were observed between cost input assumptions from the ICER evaluation versus real-world performance data from IBM Access and Value Connect.
- ICER methodology uses assumptions on average weighted average costs per dose, average discount, and average adherence rates per drug, which may not reflect actual usage or rebating.
- Using fully-adjudicated claims data from the IBM MarketScan Commercial and Medicare Database incorporates filled prescription data and rebates realized on a per-patient basis.

Figure 3. Real-world Duration of Exposure of Psoriasis Treatment

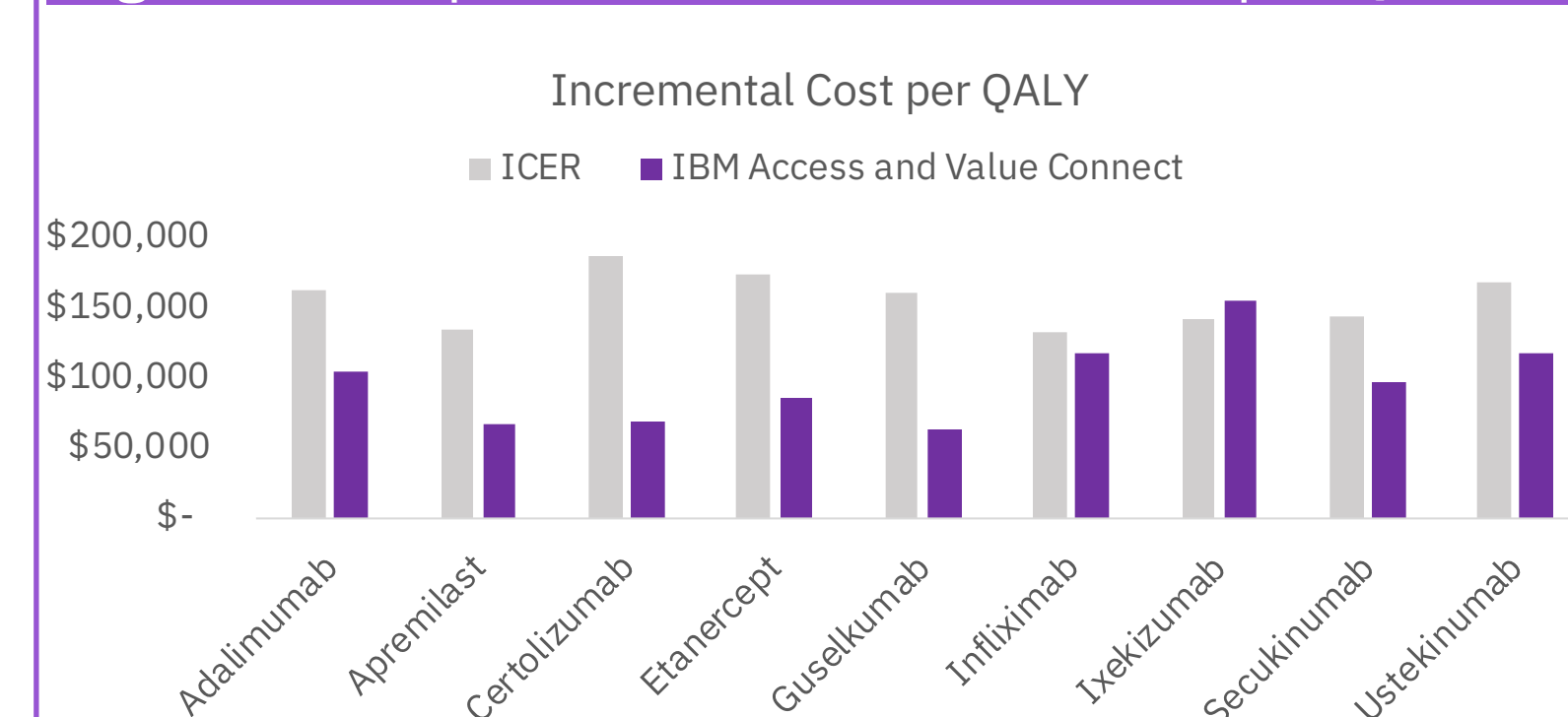


IBM Access and Value Connect: Mean Duration of Exposure for Patients in 12-Month Cohort Study Period with a Minimum Exposure of 90 days

- A mean duration of exposure of approximately 189 days was observed across all treatments in real-world data analysis. Patients duration of exposure may end due to treatment discontinuation, treatment switch, end of study period, or end of enrollment.
- ICER does not separately report assumptions on discontinuation, and states its most exhaustive data comes from Denmark, but is only reported for select treatments.
- Average duration of exposure should be explicitly considered in value assessment frameworks and based on reliable claims data, as a significant impact can be observed in mean treatment costs as a result of inaccurate duration of exposure comments.
- Further analysis is needed to differentiate the differences in duration of exposure due to discontinuation, dosing, etc., which may significantly impact value assessment results.

## RESULTS (cont.)

Figure 4. Comparison of Incremental Cost-per-QALY



ICER: Incremental Cost-Per-QALY Table ES8  
IBM Access and Value Connect: Incremental Cost-Per-QALY using Mean Year 1 Costs by Therapy and ICER QALY calculations to demonstrate impact of using fully-adjudicated net pricing.

- When using real-world financial outcomes, several treatments (apremilast, certolizumab, etanercept, guselkumab) would be acceptable at a \$100K/QALY threshold.
- Only ixekizumab was found to have a higher Incremental Cost-per-QALY using IBM Access and Value Connect per-patient price estimates.
- The mean Incremental Cost-per-QALY using IBM Access and Value Connect per-patient price estimates is approximately \$97,500 versus \$156,300 using ICER pricing assumptions, for a difference of more than \$58,000

## CONCLUSIONS

- Significant differences were observed in the assumptions made by ICER on patient pricing and duration of exposure, resulting in a large difference in the results of the incremental Cost-Per-QALY results.
- Additional analysis is warranted to determine the impact of real-world clinical outcomes on the QALY results, and the resulting impact on ICER ratios.

## REFERENCES

- IBM MarketScan Commercial and Medicare Supplemental Database.
- IBM Access and Value Connect – Psoriasis Disease Model.
- Institute for Clinical and Economic Review (ICER) Targeted Immunomodulators for the Treatment of Moderate-to-Severe Plaque Psoriasis: Effectiveness and Value Condition Update Final Evidence Report August 03, 2018.

## CONTACTS

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