Are value assessment frameworks using RWE? **A review of NICE and ICER** psoriasis assessments

Ashley Jaksa¹, Michelle Skornicki¹, Amanda R. Patrick¹ 1 Aetion, Inc., New York, NY

Background & Objective

- There is growing interest from Health Technology Assessment (HTA) agencies to utilize real-world evidence (RWE) in their decision-making.
 - » NICE (UK) is exploring how to widen their evidence base with RWE for guidance development.
 - » ICER (US) is proposing to generate RWE to fill knowledge gaps in the existing evidence, based on their 2020 framework
- Manufacturers must navigate when and how to utilize RWE in their evidence packages. In addition, HTA agencies must develop frameworks on when and how RWE will be incorporated into their processes and decision-making.
- A 2017 study¹ found that RWE is requested by HTA submission guidelines for cost, resource use, and adherence inputs in economic models, and a follow up study 2 found that RWE was more often used in cost-effectiveness analysis than comparative effectiveness analysis.
- While the use of RWE has been documented in cost-effectiveness models, the opportunity to use RWE and the actual use of RWE for cost, resource use, and adherence inputs has not been quantified
- The objective of this study is to understand the current use of RWF in HTAs and quantify the frequency of RWE use as cost, resource use, and adherence inputs/assumptions in NICE and ICER cost-effectiveness models in psoriasis.

| Table 1: Psoriasis HTAs conducted by NICE and ICER, 2018 – May 2019 | | | | |
|---|------------------|--------|-------------|--|
| Title | Reference Number | Agency | Date | |
| Certolizumab pegol for treating moderate to severe plaque psoriasis | TA574 | NICE | April 2019 | |
| Tildrakizumab for treating moderate to severe plaque psoriasis | TA575 | NICE | April 2019 | |
| Guselkumab for treating moderate to severe plaque psoriasis | TA521 | NICE | June 2018 | |
| Brodalumab for treating moderate to severe plaque psoriasis | TA511 | NICE | March 2018 | |
| Psoriasis | N/A | ICER | August 2018 | |

Methods

• Psoriasis HTAs from NICE and ICER published in 2018 - May 2019 were identified (Table 1).

- For each HTA, cost, resource use, and adherence inputs and modeling assumptions were identified from ICER's Final Evidence Reports and NICE's Final Appraisal Documents and Committee Papers, including Evidence Review Group Reports.
- The sources cited for each assumption and use of RWE were abstracted.
- Real world data sources included observational data derived from claims, electronic health records, registries, and national cost data.
- Reviews were conducted by the authors, all of whom have master's level training and hands-on experience with cost-effectiveness analysis.
- When there were discrepancies in coding, these were discussed and a consensus was reached.
- For each assumption, the authors assessed whether RWE could have been used.

| Table 2: Number of inputs and assumptions by category | | | |
|---|--|--|--|
| Assumption Category | N inputs / assumptions (N where RWE could be used) | | |
| Adherence/persistence/discontinuation | 8 (8) | | |
| Drug Cost | 10 (10) | | |
| Other healthcare costs | 9 (9) | | |

Results

- There were 28 model inputs/assumptions for cost, resource use, and adherence inputs in the 5 psoriasis HTAs evaluated (Table 2).
- RWE could have been used for all 28 inputs.
- 64% (18/28) inputs/assumptions clearly utilized RWE, while 7 inputs/assumptions did not state the source and RWE use could not be determined. Both ICER (3) and NICE (4) inputs/assumptions lacked transparency (Figure 1).
- Even when RWE was evaluated, HTA agencies requested more updated and relevant data. For example, resource use for best supportive care in multiple NICE assessments was based on a 2010 observational study of data from 2003-2008 (Figure 2).

 Inputs/assumptions sources differed between NICE and ICER assessments, but stayed consistent across NICE assessments.

• Healthcare costs were obtained from real world data sources including registry, hospital, and government data sources

 Adherence, persistence, and discontinuation assumptions were most commonly derived from registry data.



Figure 1.

Use of RWE for inputs and assumptions, by category





Figure 2.

HTA publication date and source date range for real world data assumptions

Discussion

• While RWE was used in the majority of cases, RWE was not used 100% as expected.

- ${\scriptstyle \bullet}$ Our analysis indicates that there is room for improvement, especially in transparency for input and assumption sources.
- RWF is incre

| Resource Use | 1 (1) | effectiveness models. |
|--------------|---------|--|
| Total | 28 (28) | HTAs should continue to embrace RWE, and expand its use in areas where outcomes cannot be readily captured from trial data. |
| | | Increased reliance on RWE will enhance generalizability of cost effectiveness findings, and improve efficiency of the HTA process. |
| | | As with clinical trial data, researchers need to consider the appropriateness of application of RWE and best practices for interpreting, applying and extrapolating RWE for use in HTA models. |



Conclusions

• Even in instances where RWE is accepted and preferred in HTAs, RWE is underutilized; the utility of RWE is not maximized in HTAs.

• Previous RWE submissions have been met with requests for updated data. While NICE assessments were consistent over time, more current data could have replaced older and potentially out-of-date inputs/assumptions.

• There is an opportunity for manufacturers and HTA agencies to leverage recent RWE as inputs and to justify model assumptions in value propositions to payers.

Disclosures

AJ, MS, and ARP are employees of Aetion, Inc. and have equity or stock ownership interest.

References

1 Makady A et al. Policies for Use of Real-World Data in Health Technology Assessment (HTA): A Comparative Study of Six HTA Agencies. Value Health. 2017 Apr;20(4):520-532. 2 Makady A. et al. Using Real-World Data in Health Technology Assessment (HTA) Practice: A Comparative Study of Five HTA Agencies. Pharmacoeconomics. 2018 Mar;36(3):359-368