BACKGROUND

- Biologic treatment for psoriasis is typically indicated only in moderate to severe disease and on the next step in the treatment sequence after failure of topical or immunosuppressive systemic treatment.
- Treatment sequencing for biologic therapies with different mechanisms of action is not yet standardized, and data addressing treatment strategies are sparse and often incomplete. However, in October 2010, the National Institutes of Health’s (NIH) National Psoriasis Foundation (NPf) issued new guidelines for the management of psoriasis, including a review on use of second-line biologic drug following inadequate response to the first biologic drug.

- In addition, most published economic evaluations of psoriasis treatments are based on data from randomized controlled trials that include patients with a risk of prior treatments and a risk of treatment failure. However, for such products, mechanism of action is not yet standardized, and data addressing treatment strategies are sparse and often incomplete. Published economic evaluations of psoriasis treatments are generally not included such pathways.2

OBJECTIVE

- To develop a cost-effectiveness model for use in decision analysis and the clinical decision-making pathways of payers and physicians by demonstrating the advantages of sequential biologic therapy in psoriasis and highlighting different factors between drugs.

METHODS

- A targeted literature review was conducted to identify previously published cost-effectiveness models and articles.
- The review focused on cost-effectiveness models to submit to NICE as part of the manufacturer’s submissions for reimbursement requests.

RESULTS

- The review identified four manufacturer submissions to NICE with cost-effectiveness models: etanercept and efalizumab (the York model), adalimumab, ustekinumab, and infliximab.
- No existing drugs in this class have been approved following three cost-effectiveness models and performed a critique from these submissions.

- Many previous models focused on one line of biologic therapy; however, this model is based closely on the York model. Key differences include the following:

  - The trial period lasts for 16 weeks for ustekinumab and 12 weeks for infliximab.
  - The 16-week decision-tree model structure is shown in Figure 2.

Model Structure

- A short-term decision-tree model allowable for a clinical determination of PASI response at 12 or 16 weeks after therapy initiation. In the 12- or 16-week treatment period, the model changes in response to therapies and recommendations, by following a sequence of therapies (biologic therapies) on a patient-by-patient level (as shown in Figure 2).

- The 16-week decision-tree model structure is shown in Figure 2.

Model Outcomes

- As new drugs allow some patients to achieve complete PASI clearance, a NICE model is included to incorporate this cost-effectiveness model for use in decision analysis.
- The 16-week decision-tree model structure is shown in Figure 2.

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- Following the decision tree, patients enter a semi-Markov model with a pre-defined PASI response to separate the cohort into responders and nonresponders. In this case, the model uses an option to better represent clinical practice for patients who have experience on first- and second-line biologic therapy.

- The utility weight for the active treatment state in the Markov model for each drug is calculated as a weighted average based on the drug-specific PASI response.

- Between the time points, a NICE model of disease progression is conducted for 2 to 6 weeks.

- The utility weight for the active treatment state in the Markov model for each drug is calculated as a weighted average based on the drug-specific PASI response.

Model Outcomes

- Cost-effectiveness is measured as incremental cost per quality-adjusted life-year relative to supportive care and to each of the alternative treatments.
- Automated one-way and probabilistic sensitivity analyses are conducted.

CONCLUSIONS

- The model calculates the clinical benefits, resource use, and costs over a range of time horizons, using an initial treatment period of 12 or 24 weeks and a subsequent maintenance phase where treatment is maintained in NICE responders (metaplastin response benefit).

- The primary analysis is conducted over a 12-year time horizon for the first time following the original approach taken in York model and also with the time horizon adopted by length and colleagues in the Swedish model for intermittent Enbrel versus Humira, which allows for the extrapolation of response benefit.

- Results of this study provide additional evidence to support the use of ustekinumab in patients with psoriasis.

REFERENCES

[Provide references here]