Targeted Immunomodulators for the Treatment of Moderate-to-Severe Plaque Psoriasis: Effectiveness and Value

Public Meeting – November 18, 2016
Welcome and Introduction

• The Institute for Clinical and Economic Review (ICER)

• The New England Comparative Effectiveness Public Advisory Council (New England CEPAC)
Sources of Funding (%)

- Non-profit foundations: 70%
- Life Science companies: 17%
- Insurers and Provider Groups: 9%
- Government contracts: 4%

ICER Policy Summit only
Welcome and Introduction

• Why are we here today?
  • Substantial innovation in treatment and shifts in paradigms of care for patients with psoriasis

  • Innovation often expensive, raising questions about the value and affordability of treatment options, and creating pressure on health systems and patients
Welcome and Introduction

![Price per TRx Chart](source: Leerink Research, IMS, Company Reports)
Welcome and Introduction

• Why are we here today?
  • Substantial innovation in treatment and shifts in paradigms of care for patients with psoriasis
  • Innovation often expensive, raising questions about the value and affordability of treatment options, and creating pressure on health systems and patients
  • Clinical practice, medical policies, and pricing considerations can benefit from independent reviews of evidence and public discussion
Welcome and Introduction

How was the ICER report on psoriasis treatments developed?

• Scoping with guidance from patient groups, clinical experts, manufacturers, and other stakeholders
• Internal ICER staff evidence analysis
• University of Washington cost-effectiveness modeling
• Public comment and revision
• Clinical expert report reviewers
  • Alexa B. Kimball, MD, MPH
    Professor of Dermatology, Harvard Medical School
  • Joseph F. Merola, MD, MMSc
    Director of Clinical Trials
    Co-Director, Center for Skin and Related Musculoskeletal Diseases

• How is the evidence report structured to support CEPAC voting and policy discussion?
Goal: Sustainable Access to High-Value Care for All Patients

Long-Term Value for Money

1) Level of Certainty
2) Magnitude of Added Benefit

Other Benefits or Disadvantages

Estimated Incremental cost-effectiveness

Contextual Considerations

Short-Term Affordability

Potential Budget Impact
Welcome and Introduction

What is the agenda for the day?

10:00am: Welcome and Opening Remarks
10:15am: Presentation of the Evidence
  - Evidence Review: Jeffrey Linder, MD, MPH, Harvard Medical School
  - Comparative Value: David Veenstra, PharmD, PhD, University of Washington
  - Budget Impact Analysis: Rick Chapman, PhD, MS, ICER
11:30am: Public Comments
12:15pm: Lunch
1:00pm: New England CEPAC Deliberation and Votes
2:00pm: Policy Roundtable
3:15pm: Reflections and Wrap Up
4:00pm: Meeting Adjourned
Evidence Review

Jeffrey A. Linder, MD, MPH, FACP
Associate Professor of Medicine, Harvard Medical School
Division of General Internal Medicine and Primary Care,
Brigham and Women’s Hospital
Disclosures

• **Stock:** Amgen, Biogen, and Eli Lilly

• **Former grant funding:** Astellas Pharma, Inc. and Clintrex/Astra Zeneca

• **Honoraria:** Society of Healthcare Epidemiology of America (supported by Merck)
Key Review Team Members

Anne M. Loos, MA
Shanshan Liu, MS, MPH
Topic in Context
Topic in Context: Chronic Plaque Psoriasis

• Autoimmune skin disease that causes itchy, red, scaly raised plaques
• Affects 3% of the population
• Associated with
  • Other autoimmune diseases
  • Metabolic syndrome and cardiovascular disease
  • Psoriatic arthritis: in up to 30%
• Decreased HRQL
Typical Psoriatic Plaque
Psoriatic Involvement of the Back

Involving about 10% of body surface area
Topic in Context

• Available treatments
  • *Topical Therapies*: steroids and others
  • *Older systemic therapies*: cyclosporine, MTX
  • *Phototherapy*
  • *Targeted immunomodulators*

• ~70% to 80% of patients can be managed with topical therapy
Targeted Immunomodulators

- **TNFα**: adalimumab, etanercept, infliximab
- **IL-12/23**: ustekinumab
- **IL-17A**: secukinumab, ixekizumab, brodalumab
- **PDE-4**: apremilast
Insights from Patients and Patient Groups

• Research is not patient-centered
• Patient dissatisfaction
• Challenges of Black and Hispanic patients
• Using treatments can be challenging
• Affects social functioning
• Psychological and emotional effects
• Concern about lack of access
Goal of Evidence Review

- Evaluate comparative clinical effectiveness of targeted immunomodulators
  - Focus on direct comparative data
  - Network meta-analysis for indirect comparisons

- Provide Evidence Rating
  - Magnitude of the comparative “net health benefit”
  - Certainty of the best point estimate of the net health benefit
  - Ratings from “A” to “D”, includes “I”
Evidence Review
Review Scope (PICOTS)

- **Population:** moderate-to-severe plaque psoriasis
- **Interventions:** targeted immunomodulators
- **Comparator:** placebo or TIs
- **Outcomes**
  - Psoriasis Area and Severity Index (PASI)
  - Others: physician assessments and PROs
  - Harms
- **Timing and Setting**
Literature Search

- Included: RCTs, comparative observational studies of FDA-approved regimens

1392 articles

29 key trials

8 comparative trials
Points to Know about Clinical Trials

- **Inclusion Criteria**
  - ≥18 years old
  - BSA ≥10%
  - PASI score ≥12
  - ≥6 months of plaque psoriasis diagnosis
  - candidates for phototherapy or systemic therapy

- **Prohibition of use of other treatments**
- **Comparisons mostly during induction**
Other Outcomes

- Other PASI thresholds
- PGA or IGA
- Dermatology Life Quality Index (DLQI)
- Symptom measures
  - Psoriasis Symptom Inventory
  - Psoriasis Symptom Diary
  - Specific symptoms: itch, pain, scaling
- Productivity

- Variably reported across trials
- Largely mirrored PASI 75 results
Placebo-Controlled Trials

All targeted immunomodulators had statistically significantly higher PASI 75 responses compared to placebo by the end of induction.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>PASI 75 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>5-6</td>
</tr>
<tr>
<td>Apremilast</td>
<td>29-33</td>
</tr>
<tr>
<td>Etanercept</td>
<td>40-59</td>
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<tr>
<td>Adalimumab</td>
<td>71-80</td>
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<tr>
<td>Infliximab</td>
<td>76-80</td>
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<tr>
<td>Ustekinumab</td>
<td>66-76</td>
</tr>
<tr>
<td>Secukinumab</td>
<td>76-87</td>
</tr>
<tr>
<td>Brodalumab</td>
<td>83-86</td>
</tr>
<tr>
<td>Ixekizumab</td>
<td>87-90</td>
</tr>
</tbody>
</table>
Direct Comparative Trials

**Superior to etanercept:** ustekinumab, secukinumab, and ixekizumab

**Perhaps superior to ustekinumab:** secukinumab, brodalumab, ixekizumab

<table>
<thead>
<tr>
<th>Trial</th>
<th>Treatment</th>
<th>PASI 75 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCEPT</td>
<td>Etanercept</td>
<td>57</td>
</tr>
<tr>
<td></td>
<td>Ustekinumab</td>
<td>68-74</td>
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<tr>
<td>FIXTURE</td>
<td>Etanercept</td>
<td>44</td>
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<tr>
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<td>Secukinumab</td>
<td>77</td>
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<tr>
<td>UNCOVER 2 &amp; 3</td>
<td>Etanercept</td>
<td>42-53</td>
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<td></td>
<td>Ixekizumab</td>
<td>87-90</td>
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<tr>
<td>CLEAR</td>
<td>Ustekinumab</td>
<td>79</td>
</tr>
<tr>
<td></td>
<td>Secukinumab</td>
<td>91</td>
</tr>
<tr>
<td>AMAGINE 2 &amp; 3</td>
<td>Ustekinumab</td>
<td>69-70</td>
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<td></td>
<td>Brodalumab</td>
<td>85-86</td>
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<tr>
<td>IXORA-S*</td>
<td>Ustekinumab</td>
<td>69</td>
</tr>
<tr>
<td></td>
<td>Ixekizumab</td>
<td>91</td>
</tr>
</tbody>
</table>
Network Meta-Analysis
RR of PASI 75 during induction relative to placebo
Harms

• **Induction: 10-16 weeks**
  - Serious adverse events rare: 1-2%
  - Any adverse effect: 53-69% (52% in placebo)
    - Respiratory infections: 7-14%
    - Injection reactions: 1-19%
  - **Infliximab:** higher rates of serious AEs (3%), serious infections (6%), infusion reactions (10%)

• **Long-term safety**
  - Good data and safety for TNFα-s and ustekinumab
  - 1 year of data for secukinumab, brodalumab
### ICER Evidence Ratings

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Adalimumab</th>
<th>Apremilast</th>
<th>Brodalumab</th>
<th>Etanercept</th>
<th>Infliximab</th>
<th>Ixekizumab</th>
<th>Secukinumab 300</th>
<th>Ustekinumab 45/90</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adalimumab</td>
<td>-</td>
<td>C+</td>
<td>C-</td>
<td>C+</td>
<td>C-</td>
<td>C-</td>
<td>I</td>
<td>I</td>
</tr>
<tr>
<td>Apremilast</td>
<td>C-</td>
<td>-</td>
<td>D</td>
<td>I</td>
<td>C-</td>
<td>C-</td>
<td>C-</td>
<td>C-</td>
</tr>
<tr>
<td>Brodalumab</td>
<td>C+</td>
<td>B</td>
<td>-</td>
<td>B</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>B (2)</td>
</tr>
<tr>
<td>Etanercept</td>
<td>C-</td>
<td>I</td>
<td>D</td>
<td>-</td>
<td>C-</td>
<td>D (2)</td>
<td>C- (1)</td>
<td>C- (1)</td>
</tr>
<tr>
<td>Infliximab</td>
<td>C+</td>
<td>B+</td>
<td>I</td>
<td>B+</td>
<td>-</td>
<td>I</td>
<td>I</td>
<td>C+</td>
</tr>
<tr>
<td>Ixekizumab</td>
<td>C+</td>
<td>B+</td>
<td>I</td>
<td>A (2)</td>
<td>I</td>
<td>-</td>
<td>C+</td>
<td>B+ (1)</td>
</tr>
<tr>
<td>Secukinumab 300</td>
<td>I</td>
<td>B+</td>
<td>I</td>
<td>B+ (1)</td>
<td>I</td>
<td>C-</td>
<td>-</td>
<td>C+ (1)</td>
</tr>
<tr>
<td>Ustekinumab 45/90</td>
<td>I</td>
<td>B+</td>
<td>D (2)</td>
<td>B+ (1)</td>
<td>C-</td>
<td>C- (1)</td>
<td>C- (1)</td>
<td>-</td>
</tr>
</tbody>
</table>
Controversies and Uncertainties

• Based on PASI 75
• Only 8 head-to-head comparisons
• Longer-term data variable
  • Non-standard dosing
  • Treatment durability
• Second-line targeted therapy
• Combination therapy
• Ustekinumab weight-based dosing
Other Benefits and Disadvantages

- Method of administration
  - Apremilast oral
  - Infliximab IV

- Frequency of dosing
  - BID apremilast
  - qweek adalimumab, etanercept
  - q2weeks brodalumab
  - q4w secukinumab, ixekizumab
  - q8w infliximab
  - q12w ustekinumab

- Rapid effect: infliximab
Public Comments & Summary
Public Comments Received

• Psoriasis heterogeneous with range of impacts
• Impact on Black and Hispanic patients
• Limited data on long-term effectiveness, safety
• Rigid approach to dosing
• LIBERATE trial
• Ustekinumab dosing
Summary: Evidence Review

- **All targeted immunomodulators**: superior to placebo
- **Ustekinumab**: superior to etanercept
- **Infliximab**: highly effective, little direct comparative evidence, adverse effects
- **Apremilast**: appears generally less effective than other classes
- **IL-17A inhibitors**: appear generally more effective than other classes
Comparative Value

David Veenstra, PharmD, PhD
Nathaniel Hendrix, PharmD

University of Washington
Department of Pharmacy
Pharmaceutical Outcomes Research and Policy Program
Disclosures

• David Veenstra has served as a consultant to Genentech, Jazz Pharmaceuticals, and Relypsa
• Nathaniel Hendrix has no disclosures
Objective

The aim of this analysis was to estimate the cost-effectiveness of first line treatment with a targeted drug for patients with moderate to severe plaque psoriasis.
Methods in Brief
Overall Approach

• Model parameters were estimated from the network meta-analyses described earlier in this report, as well as the published literature.

• Used a 10-year timeframe in base case analysis
Model Structure

Trial period

First drug
- PASI 90+
- PASI 75-89
- PASI 50-74
- PASI < 50

All groups may transition to a second biologic, non-targeted therapy, or death.

Death

Second drug

Non-targeted therapy
Key Model Assumptions

• Second line therapy cost average of all available targeted drugs
  • Effectiveness also averaged, minus 5%
• Non-targeted therapy a mix of no treatment, topical treatment, non-targeted systemic treatment, and phototherapy
• Subcutaneous administration by patient after first visit
Treatment Discontinuation after initial response

• Discontinuation of 1\textsuperscript{st} line therapy (all causes)
  • Adalimumab, etanercept, and infliximab: 15\%/yr
    • Assumed same for apremilast
  • Ustekinumab: 5\%/yr
    • Assumed same for secukinumab, ixekizumab, brodalumab

• Discontinuation of 2\textsuperscript{nd} line therapy (all causes)
  • Based on adalimumab, etanercept, infliximab, and ustekinumab: 15\%/yr
Drug Costs – ‘Real world’ estimates

• We estimated net prices by comparing the four-quarter (i.e., 4Q15 – 3Q16) rolling averages of both net prices* and list (WAC) prices per unit to arrive at an average discount from WAC, by class.

  • TNF-α: 30%
  • Anti-IL17a: 40%
  • Anti-IL 12/23: 15%
  • Apremilast: 20%

*Source: SSR Health, LLC
Drug cost assumptions

- Brodalumab cost estimated as average of ixekizumab and secukinumab
- Ustekinumab cost assumes 30% of patients receive higher dose based on body weight
## Drug Costs

<table>
<thead>
<tr>
<th>Drug</th>
<th>1&lt;sup&gt;st&lt;/sup&gt; year cost</th>
<th>2&lt;sup&gt;nd&lt;/sup&gt;+ year cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apremilast</td>
<td>$22,997</td>
<td>$23,172</td>
</tr>
<tr>
<td>Etanercept</td>
<td>$43,095</td>
<td>$34,416</td>
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<tr>
<td>Adalimumab</td>
<td>$37,305</td>
<td>$34,416</td>
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<tr>
<td>Infliximab</td>
<td>$35,380</td>
<td>$23,376</td>
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<tr>
<td>Ustekinumab</td>
<td>$55,376</td>
<td>$39,072</td>
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<tr>
<td>Secukinumab</td>
<td>$36,607</td>
<td>$29,268</td>
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<tr>
<td>Brodalumab*</td>
<td>[$41,009]</td>
<td>[$30,720]</td>
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<tr>
<td>Ixekizumab</td>
<td>$45,652</td>
<td>$32,172</td>
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<tr>
<td>2&lt;sup&gt;nd&lt;/sup&gt;-line therapy</td>
<td>$36,531</td>
<td>$30,828</td>
</tr>
<tr>
<td>Non-targeted therapy</td>
<td>$9,840</td>
<td>$9,840</td>
</tr>
</tbody>
</table>

*Brodalumab cost estimated
## Health State Utilities

<table>
<thead>
<tr>
<th>Health State</th>
<th>Utility Weight</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>PASI 90-100</td>
<td>0.906</td>
<td>NICE</td>
</tr>
<tr>
<td>PASI 75-89</td>
<td>0.868</td>
<td>NICE</td>
</tr>
<tr>
<td>PASI 50-74</td>
<td>0.835</td>
<td>NICE</td>
</tr>
<tr>
<td>PASI &lt;50</td>
<td>0.751</td>
<td>NICE</td>
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<tr>
<td>Second line therapy</td>
<td>0.846</td>
<td>Estimated</td>
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<tr>
<td>Non-targeted therapy</td>
<td>0.642</td>
<td>NICE</td>
</tr>
</tbody>
</table>
Model Feedback and Validation

- Feedback from manufacturers resulted in:
  - Correction of an error in drug cost
  - Inclusion of drug-specific discontinuation rates
  - Modification of average patient weight
  - Inclusion of a switching cost for second-line targeted drug
  - Added scenario analyses to assess PASI 100

- We compared our results with an independently developed (unpublished) model based on the York model framework.
  - The results from these two models were generally similar
Model Results
## Results

<table>
<thead>
<tr>
<th></th>
<th>Cost</th>
<th>QALYs</th>
<th>LYs</th>
<th>ICER vs. non-target</th>
</tr>
</thead>
<tbody>
<tr>
<td>non-targeted</td>
<td>$88,086</td>
<td>5.53</td>
<td>8.64</td>
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<tr>
<td>apremilast</td>
<td>$161,741</td>
<td>6.35</td>
<td>8.64</td>
<td>$89,610</td>
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<tr>
<td>etanercept</td>
<td>$198,519</td>
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<td>8.64</td>
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<td>adalimumab</td>
<td>$208,881</td>
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<td>8.64</td>
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<td>infliximab</td>
<td>$203,532</td>
<td>6.78</td>
<td>8.64</td>
<td>$92,715</td>
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<td>ustekinumab</td>
<td>$269,843</td>
<td>6.93</td>
<td>8.64</td>
<td>$129,904</td>
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<td>secukinumab</td>
<td>$221,704</td>
<td>7.02</td>
<td>8.64</td>
<td>$89,843</td>
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<td>brodalumab*</td>
<td>[$240,398]</td>
<td>7.15</td>
<td>8.64</td>
<td>[$94,030]</td>
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<tr>
<td>ixekizumab</td>
<td>$254,287</td>
<td>7.19</td>
<td>8.64</td>
<td>$100,389</td>
</tr>
</tbody>
</table>

*Brodalumab cost estimated*
*Results for brodalumab are tentative, as pricing is not available*
Results vs. Etanercept

<table>
<thead>
<tr>
<th>Drug</th>
<th>Incremental Cost/QALY vs. Etanercept</th>
</tr>
</thead>
<tbody>
<tr>
<td>secukinumab</td>
<td>$42,190</td>
</tr>
<tr>
<td>brodalumab</td>
<td>$61,396</td>
</tr>
<tr>
<td>ixekizumab</td>
<td>$77,686</td>
</tr>
</tbody>
</table>
Sensitivity Analysis: Ixekizumab vs. non-targeted therapy

Incremental cost-effectiveness ratio, ixekizumab vs non-targeted

- Non-targeted treatment utility (-10%, +10%)
- Price (per 80 mg) ($2,145, $3,218)
- Cost of non-targeted ($410, $1230)
- Targeted treatment utility (-5%, +5%)
- Annual prod. cost offset ($0, $4,900)
- Cost of 2L ($2,055, $3083)
- 1L d/c rate (year>1, PASI 75+) (2.5%, 10%)
- Discount rate (0%, 5%)
- PASI 75 (82%, 94%)
- d/c % to 2L (25%, 75%)
- 1L d/c rate (year 1, PASI 75+) (12%, 20%)
- 2L -> non-targeted (5%, 15%)
- Cost per clinic-adm in sub-q inj ($20.35, $30.53)
- Annual rate of severe URI (0, 0.8%)

High parameter values  Low parameter values
Sensitivity Analysis: Ixekizumab vs. Etanercept

Incremental cost-effectiveness ratio, etanercept vs ixekizumab

- Price (per 80 mg) ($2,145, $3,218)
- Price (per 100 mg) ($574, $717)
- Non-targeted treatment utility (-10%, +10%)
- Cost of non-targeted ($410, $1,230)
- Targeted treatment utility (-5%, +5%)
- d/c % to 2L (25%, 75%)
- Cost of 2L ($2,055, $3083)
- Annual prod. cost offset ($0, $4,900)
- d/c % to 2L (25%, 75%)
- 2L -> non-targeted (5%, 15%)
- PASI 75 (34%, 66%)
- ixe vs eta RR (1.62, 2.19)
- 2L -> non-targeted (5%, 15%)
- 1L d/c rate (year>1, PASI 75+) (11%, 16.5%)
- 1L d/c rate (year>1, PASI 75+) (2.5%, 10%)
- 1L d/c rate (year 1, PASI 75+) (30%, 40%)
- Cost of administration (-20%, +20%)
- PASI 75 (82%, 94%)
- 1L d/c rate (year 1, PASI 75+) (12%, 20%)
- Discount rate (0%, 5%)
- Rate of severe URI (-40%, +40%)
Other scenario/sensitivity analyses

• Including productivity cost offset led to ICERs vs. non-targeted of $68K/QALY to $110K/QALY
• Accounting for % patients achieving PASI 100 + PASI 90-99 vs. PASI 90-100 had no meaningful impact
• Lifetime time horizon results similar to base-case 10-year time horizon
Limitations

• Lack of data on effectiveness of 2nd line therapy
• Cost and utility of non-targeted therapy
• Drug cost rebates variable
• Dose increases/decreases not included
• Ustekinumab weight-based dosing effect
Summary

• Using estimated ‘real-world’ drug costs, targeted agents meet commonly accepted cost-effectiveness thresholds compared to ‘non-targeted therapy’

• The IL-17A drug class provides the greatest patient benefit despite option of 2nd line treatment following 1st line treatment with less effective drugs

• The IL-17A drug class meets commonly accepted thresholds compared to etanercept, and potentially compared to adalimumab and infliximab
Public Comments Received

• Drug WAC not reflective of real-world costs
• IV therapy has important patient impacts
• Psoriatic arthritis patients not explicitly modeled
• Use of QALYs a major concern
  • Quality of life impacts considered: mobility, self-care, usual activities, pain/discomfort and anxiety/depression
Potential Budget Impact Analysis

Rick Chapman, PhD, MS
Director of Health Economics
Institute for Clinical and Economic Review
Disclosures

I have no conflicts of interest.

Key review team members:
Varun Kumar, MSc, MPH
Dan Ollendorf, PhD
Estimated Potential Budget Impact of Brodalumab & Ixekizumab at 5 Years

<table>
<thead>
<tr>
<th></th>
<th>Number Treated</th>
<th>Weighted BI per Patient</th>
<th>Average BI per Year (millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brodalumab</td>
<td>18,375</td>
<td>$65,200</td>
<td>$239.8</td>
</tr>
<tr>
<td>Ixekizumab</td>
<td>18,375</td>
<td>$72,400</td>
<td>$266.0</td>
</tr>
</tbody>
</table>

- Neither drug approaches the budget impact threshold of $904 million for a new drug.
  - Annualized potential budget impact of brodalumab is 27% of threshold
  - Annualized potential budget impact of ixekizumab is 29% of threshold
Public Comment
Jonathan Wilcox, Patients Rising
Co-Founder and Policy Director

Conflicts of interest:

• Receipt or potential receipt of anything of monetary value, including but not limited to, salary or other payments for services such as consulting fees or honoraria in excess of $5,000

• Status or position as an officer, board member, trustee, owner or employee of a health care company, or an organization which receives more than 25% of its funding from health care companies

Patients Rising receives financial support from:

• Amgen
• Bristol-Meyers Squibb
• Celgene Corporation
• Genentech
• PhRMA
Dr. Michael Siegel, National Psoriasis Foundation
Vice President, Research Programs

Conflicts of interest:

• Status or position as an officer, board member, trustee, owner or employee of a health care company, or an organization which receives more than 25% of its funding from health care companies

The National Psoriasis Foundation receives financial support from:

• Amgen
• Abbvie
• Celgene
• Eli Lilly
• Janssen
• Leo
• Novartis
• Pfizer
• Wisconsin Pharmaceutical
• Valeant Pharmaceuticals
• Alva Amco Pharmaceuticals
Dr. Jerry Bagel, Psoriasis Treatment Center of New Jersey
Director

Conflicts of Interest:

• Receipt or potential receipt of anything of monetary value, including but not limited to, salary or other payments for services such as consulting fees or honoraria in excess of $5,000

• Manufacturer support of research in the clinical area of this meeting in which you are participating

Professional and Financial Engagements:

• Abbvie: speaker, consultant, investigator
• Novartis: speaker, consultant, investigator
• Eli Lilly: speaker, consultant, investigator
• Celgene: speaker, consultant, investigator
• Leo: speaker, consultant, investigator
• Amgen: consultant, investigator
• Sun: consultant
Public Comment: Manufacturer Representatives
Frank Zhang, Celgene
Global Head of Pricing and Market Access for I&I Franchise

Conflicts of Interest:

• Equity interests such as individual stocks, stock options or other ownership interests in excess of $10,000.

• Frank Zhang is an employee of Celgene.
Conflicts of Interest:

- Receipt or potential receipt of anything of monetary value, including but not limited to, salary or other payments for services such as consulting fees or honoraria in excess of $5,000.

- Equity interests such as individual stocks, stock options or other ownership interests in excess of $10,000.

- Bradley Stolshek is an employee of Amgen.
Conflicts of Interest:

- Receipt or potential receipt of anything of monetary value, including but not limited to, salary or other payments for services such as consulting fees or honoraria in excess of $5,000

- Equity interests such as individual stocks, stock options or other ownership interests in excess of $10,000.

- Matthew Frankel is an employee of Novartis.
Break for Lunch
Meeting will resume at 1:00PM
Voting Questions
Q1. Test Voting Question:

Which city/town in the Greater Boston area is home to the nation’s first Dunkin Donuts?

a. Dorchester  
b. Quincy  
c. Lexington  
d. Cambridge
Q1. Is the evidence adequate to demonstrate that the net health benefit of apremilast is as good as that provided by any of the TNF-α inhibitors?

Yes  No
Q2. Is the evidence adequate to distinguish the net health benefit among the IL-17 targeted drugs secukinumab, ixekizumab, and brodalumab?

Yes  No
If Q2 vote is yes…

Q3. Is the evidence adequate to demonstrate that the net health benefit of [IL-17 drugs as a class] is better than that provided by adalimumab?

Yes    No
If Q2 vote is yes…

Q4. Is the evidence adequate to demonstrate that the net health benefit of [IL-17 drugs as a class] is better than that provided by etanercept?

Yes  No
If Q2 vote is yes…

Q5. Is the evidence adequate to demonstrate that the net health benefit of [IL-17 drugs as a class] is better than that provided by infliximab?

Yes  No
If Q2 vote is no…

Q6. Is the evidence adequate to demonstrate that the net health benefit of ustekinumab is better than that provided by adalimumab?

Yes  No
Q7. Is the evidence adequate to demonstrate that the net health benefit of ustekinumab is better than that provided by etanercept?

Yes                      No
Q8. Is the evidence adequate to demonstrate that the net health benefit of ustekinumab is better than that provided by infliximab?

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<th>Yes</th>
<th>No</th>
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Q9. Given the available evidence on comparative effectiveness and incremental cost-effectiveness using estimated discounted prices for private insurers presented in the report, and taking into account other benefits, disadvantages, and contextual considerations, what is the long-term value for money of Adalimumab compared to continued non-targeted therapy?

a. High
b. Intermediate
c. Low
Q9. Given the available evidence on comparative effectiveness and incremental cost-effectiveness using estimated discounted prices for private insurers presented in the report, and taking into account other benefits, disadvantages, and contextual considerations, what is the long-term value for money of Etanercept compared to continued non-targeted therapy?

a. High  
b. Intermediate  
c. Low
Q9. Given the available evidence on comparative effectiveness and incremental cost-effectiveness using estimated discounted prices for private insurers presented in the report, and taking into account other benefits, disadvantages, and contextual considerations, what is the long-term value for money of Infliximab compared to continued non-targeted therapy?

a. High  
b. Intermediate  
c. Low
Q9. Given the available evidence on comparative effectiveness and incremental cost-effectiveness using estimated discounted prices for private insurers presented in the report, and taking into account other benefits, disadvantages, and contextual considerations, what is the long-term value for money of Ustekinumab compared to continued non-targeted therapy?

a. High
b. Intermediate
c. Low
Q9. Given the available evidence on comparative effectiveness and incremental cost-effectiveness using estimated discounted prices for private insurers presented in the report, and taking into account other benefits, disadvantages, and contextual considerations, what is the long-term value for money of Secukinumab compared to continued non-targeted therapy?

a. High
b. Intermediate
c. Low
Q9. Given the available evidence on comparative effectiveness and incremental cost-effectiveness using estimated discounted prices for private insurers presented in the report, and taking into account other benefits, disadvantages, and contextual considerations, what is the long-term value for money of Ixekizumab compared to continued non-targeted therapy?

a. High
b. Intermediate
c. Low
Q9. Given the available evidence on comparative effectiveness and incremental cost-effectiveness using estimated discounted prices for private insurers presented in the report, and taking into account other benefits, disadvantages, and contextual considerations,

what is the long-term value for money of Brodalumab compared to continued non-targeted therapy?

a. High
b. Intermediate
c. Low
Q9. Given the available evidence on comparative effectiveness and incremental cost-effectiveness using estimated discounted prices for private insurers presented in the report, and taking into account other benefits, disadvantages, and contextual considerations, what is the long-term value for money of Apremilast compared to continued non-targeted therapy?

a. High
b. Intermediate
c. Low
Q10. Given the available evidence on comparative clinical effectiveness and incremental cost-effectiveness, and taking into account other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment with [any IL-17 drug] versus etanercept?

a. High
b. Intermediate
c. Low
Policy Roundtable
# Policy Roundtable

<table>
<thead>
<tr>
<th>Joseph F. Merola, MD, MMSC</th>
<th>Paul Jeffrey, PharmD</th>
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<tbody>
<tr>
<td>Harvard Medical School</td>
<td>Univ. of Massachusetts Medical School</td>
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<tr>
<td>Brigham and Women’s Hospital</td>
<td>MassHealth (Massachusetts Medicaid)</td>
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<tr>
<th>Leah McCormick Howard, JD</th>
<th>Chris Pettit</th>
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<tr>
<td>National Psoriasis Foundation</td>
<td>Patient Advocate</td>
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<tr>
<th>Abby S. Van Voorhees, MD</th>
<th>Thomas Kowalksi, RPh</th>
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<tr>
<td>Eastern Virginia Medical School</td>
<td>Blue Cross Blue Shield of Massachusetts</td>
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New England CEPAC Reflections
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