The Role of Outcomes-Based Models for the Reimbursement of Medicines in the UK National Health Service

PMU68

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BACKGROUND

- Outcomes-based models (OBMs) can be used to link the level of reimbursement for a particular medicine to the outcomes that individual patients achieve in clinical practice.
- These innovative reimbursement models introduce financial 'risk-sharing' between manufacturers and payers, and are therefore attractive to payers as the total cost of the medicine is not incurred if the medicine does not provide the expected benefits over a certain period of time.
- By requiring specific outcomes to be pre-defined and measured as part of the scheme, OBMs also promote the use of relevant outcome measures as part of routine clinical practice. This is expected to lead to improved patient care and better-informed decisions regarding a patient's response to treatment.
- There is growing interest in the United Kingdom (UK) as to whether and how OBMs could be implemented in the National Health Service (NHS).[1,2]

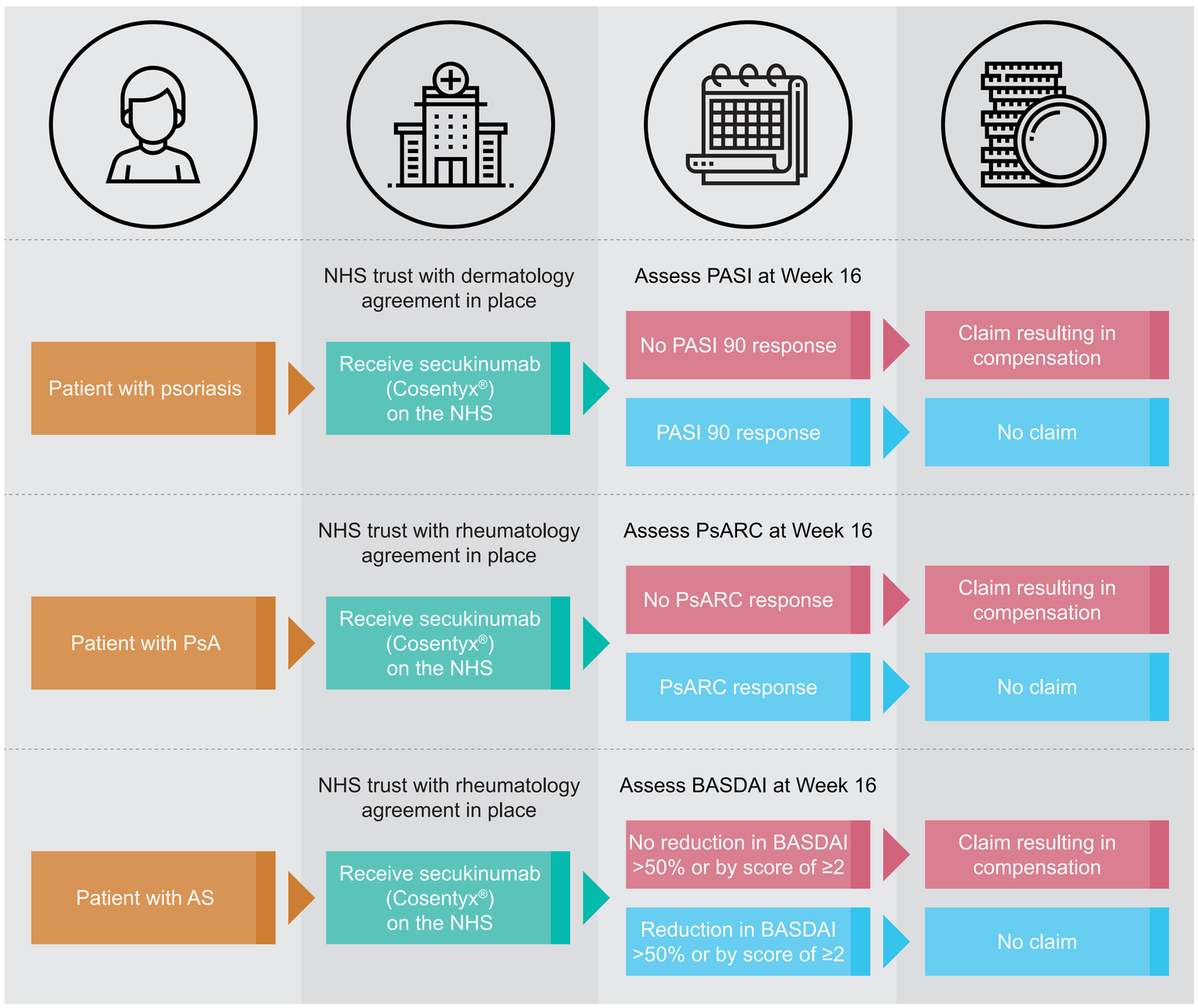
COSENTYX® PROMISE: AN EXAMPLE OUTCOMES-BASED MODEL

- Novartis UK has implemented an OBM (Cosentyx® PROMISE) for patients with psoriasis, psoriatic arthritis (PsA) and ankylosing spondylitis (AS) who are prescribed secukinumab (Cosentyx®) in the UK NHS.
- The dermatology scheme for psoriasis patients was launched in 2017 and the rheumatology scheme, which covers both PsA and AS indications, was launched in 2018.
- Since the launch of the schemes, agreements have been signed with 70 hospital trusts (38 for the dermatology scheme and 32 for the rheumatology scheme).
- As part of the OBM, Novartis UK actively encourages the monitoring of claims across each indication and is committed to ensuring that the NHS only pays for successful outcomes.

Outcomes in Psoriasis

- In the dermatology scheme, compensation is provided to the NHS if a patient fails to achieve a reduction in Psoriasis Area Severity Index score ≥90% (PASI 90) after 16 weeks of treatment **(Figure 1)**, with higher levels of compensation provided in cases where the patient also fails to achieve a reduction in PASI score ≥75% (PASI 75).
  - The PASI 90 threshold is more stringent than the PASI 75 threshold that is recommended by the National Institute for Health and Care Excellence (NICE) for assessing the response to secukinumab treatment in psoriasis.[3]
  - The aim of achieving 'clear or nearly clear' skin (as assessed by PASI 90) is an important outcome for patients receiving biologic therapies and is considered 'critical' in treatment guidelines from the British Association of Dermatologists.[4]
- Patients who are biologic-naïve and those who have failed one prior biologic are both covered by the scheme.

Figure 1. Summary of the Cosentyx® PROMISE outcomes-based model



AS: ankylosing spondylitis; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; NHS: National Health Service; PASI: Psoriasis Area Severity Index; PsA: psoriatic arthritis; PsARC: Psoriatic Arthritis Response Criteria.

- In total, 385 psoriasis patients have so far completed 16 weeks of treatment, of which 62% were biologic-naïve prior to receiving secukinumab.
- Of these 385 patients, 38 (10%) cases have resulted in compensation claims, whereas 347 (90%) cases have not resulted in a claim for compensation. The proportion of cases not requiring compensation is higher than the PASI 90 response rates reported across each of the randomised controlled trials (RCTs) of secukinumab in psoriasis that assessed PASI 90 at Week 16 **(Figure 2)**.

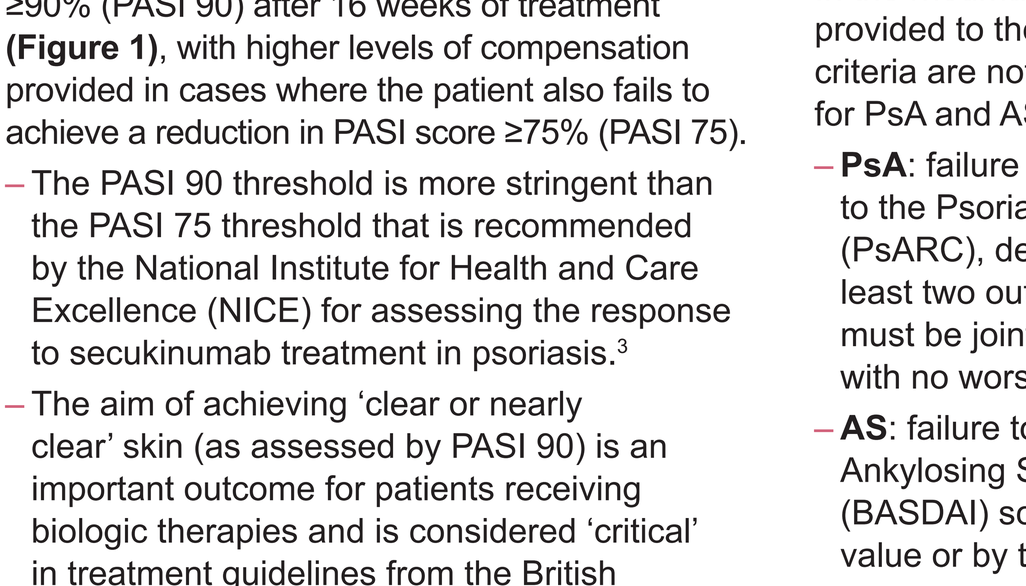
Outcomes in Psoriatic Arthritis and Ankylosing Spondylitis

- In the rheumatology scheme, compensation is provided to the NHS if the following response criteria are not met after 16 weeks of treatment for PsA and AS patients, respectively **(Figure 1)**:
  - **PsA**: failure to achieve a response according to the Psoriatic Arthritis Response Criteria (PsARC), defined as an improvement in at least two out of the four PsARC, one of which must be joint tenderness or swelling score, with no worsening in any of the other criteria;
  - **AS**: failure to achieve a reduction in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by two or more units.
- Only biologic-naïve patients with PsA or AS are covered by the current scheme.
- Compared to the dermatology scheme, fewer patients with PsA or AS have received secukinumab thus far, following the later implementation of agreements with NHS trusts for these indications.
- 131 PsA/AS patients have completed 16 weeks of treatment and of these 9 (7%) cases have resulted in a claim for compensation.

CONCLUSIONS

- Cosentyx® PROMISE demonstrates that OBMs are an innovative approach to achieving patient outcomes whilst supporting NHS financial predictability and sustainability.
- Through the compensation provided as part of the OBM, Cosentyx® PROMISE is expected to deliver value to the NHS compared to traditional payment models based on price and volume alone.
- Patients are also expected to benefit from the schemes via the use of defined measures of treatment response in clinical practice. Importantly, the outcome measures used as part of the schemes: PASI for psoriasis, PsARC for PsA, and BASDAI for AS, are consistent with those that are recommended in national treatment guidelines.[3,5,6]
- The outcomes from the dermatology scheme thus far demonstrate the 'real world' effectiveness of secukinumab, with a numerically higher proportion of psoriasis cases not resulting in compensation after 16 weeks of treatment compared to the proportion of patients achieving PASI 90 at Week 16 in the secukinumab RCTs.

Figure 2. Outcomes from the Cosentyx® PROMISE dermatology scheme and Week 16 PASI 90 response rates from the secukinumab randomised controlled trials in psoriasis



Source	n/N (%)
	No claim for compensation after 16 weeks
Cosentyx® PROMISE	347/385 (90%)
	Response at Week 16 PASI 90
ERASURE[7]	171/245 (70%)
FIXTURE[7]	234/323 (72%)
CLEAR[7]	264/334 (79%)
CLARITY[8]	423/550 (77%)

The red bar represents the proportion of cases not resulting in a claim for compensation after 16 weeks of treatment with secukinumab (Cosentyx® PROMISE) and blue bars represent the proportion of patients achieving PASI 90 at Week 16 in the secukinumab clinical trials. Results are presented from the secukinumab 300 mg treatment arm of the clinical trials, which represents the recommended licensed dose for secukinumab in plaque psoriasis.[7] PASI: Psoriasis Area Severity Index.

FOOTNOTE

The latest available outcomes from the dermatology scheme have been included in the poster. These represent more recent data compared to those presented in the abstract.

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DISCLOSURES

AH and JW are employees of Novartis Pharmaceuticals UK Limited and AY and CE were employees of Novartis Pharmaceuticals UK Limited at the time of the abstract submission.

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