Part 1 slides for public [Redacted]

NICE National Institute for Health and Care Excellence

Certolizumab pegol for treating moderate to severe plaque psoriasis [ID1060]

- 1st appraisal committee meeting

Lead team presentation

Lead team: Carlo Berti, Stephen Smith, Nigel Westwood

Chair: Sanjeev Patel

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Preview of key clinical effectiveness issues

1. What it the likely position of certolizumab pegol in the treatment pathway?
   - Is there evidence that certolizumab pegol can be used earlier in the treatment pathway that other biologic therapies?
2. Are the results from the clinical trials generalisable to the eligible population in the NHS in terms of:
   - DLQI score?
   - Previous treatment with biologic therapies?
3. Do the pooled efficacy results from the overall trial population reflect the pooled results of the subgroups where certolizumab pegol would be used in the NHS?
4. Is the network meta analysis appropriate?
5. Is there evidence that certolizumab pegol is of additional benefit during pregnancy/breastfeeding?

Disease background

- Chronic inflammatory condition characterised by flaky, scaly, itchy and red plaques on skin
- Varies in severity and distribution ranging from small patches on the elbows and knees to almost complete body coverage
- Unpredictable, relapsing and remitting course
- Associated with comorbidities such as depression, anxiety, arthritis, cardiovascular disease
- Graded as mild, moderate or severe (based on location, area affected, severity of lesions and impact on individual)
- Population:

Patient and clinical perspective – summary

Distressing and debilitating, need for a range of highly effective convenient treatments with minimal adverse reactions and impact on lifestyle

Impact of psoriasis

- can be distressing at all levels of severity
- affects all aspects of life: physical, psychological, social, financial
- topical medicines and phototherapy are inconvenient

People would like

- range of effective options (people respond differently to treatments)
- reduces symptoms immediately
- no adverse reactions
- limited impact on lifestyle
- targets high impact sites

Certolizumab pegol

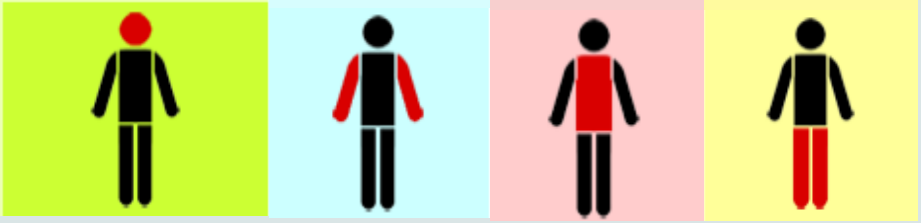
- provides an additional TNF-α inhibitor, particularly for patients with psoriatic arthritis, where this is the most effective treatment class
- can be used during pregnancy and breastfeeding as per summary of product characteristics

Measuring psoriasis severity and response

Psoriasis Area and Severity Index (PASI)

- Weighted score (0 to 72) of 4 affected areas (Head, Arms, Trunk, Legs)
  - 0 (no psoriasis); 10 (moderate); >10 (severe)
- Clinically important response defined as a 75% reduction in PASI score from baseline (PASI 75), (PASI 50, 90 and 100 are also considered in this appraisal)

	Head	Arms	Trunk	Legs
Area	○0% ○<10% ○10-29% ○30-49% ○50-69% ○70-89% ○90-100%			
Erythema (redness)	○0 ○1 ○2 ○3 ○4			
Induration (thickness)	○0 ○1 ○2 ○3 ○4			
Desquamation (scaling)	○0 ○1 ○2 ○3 ○4			



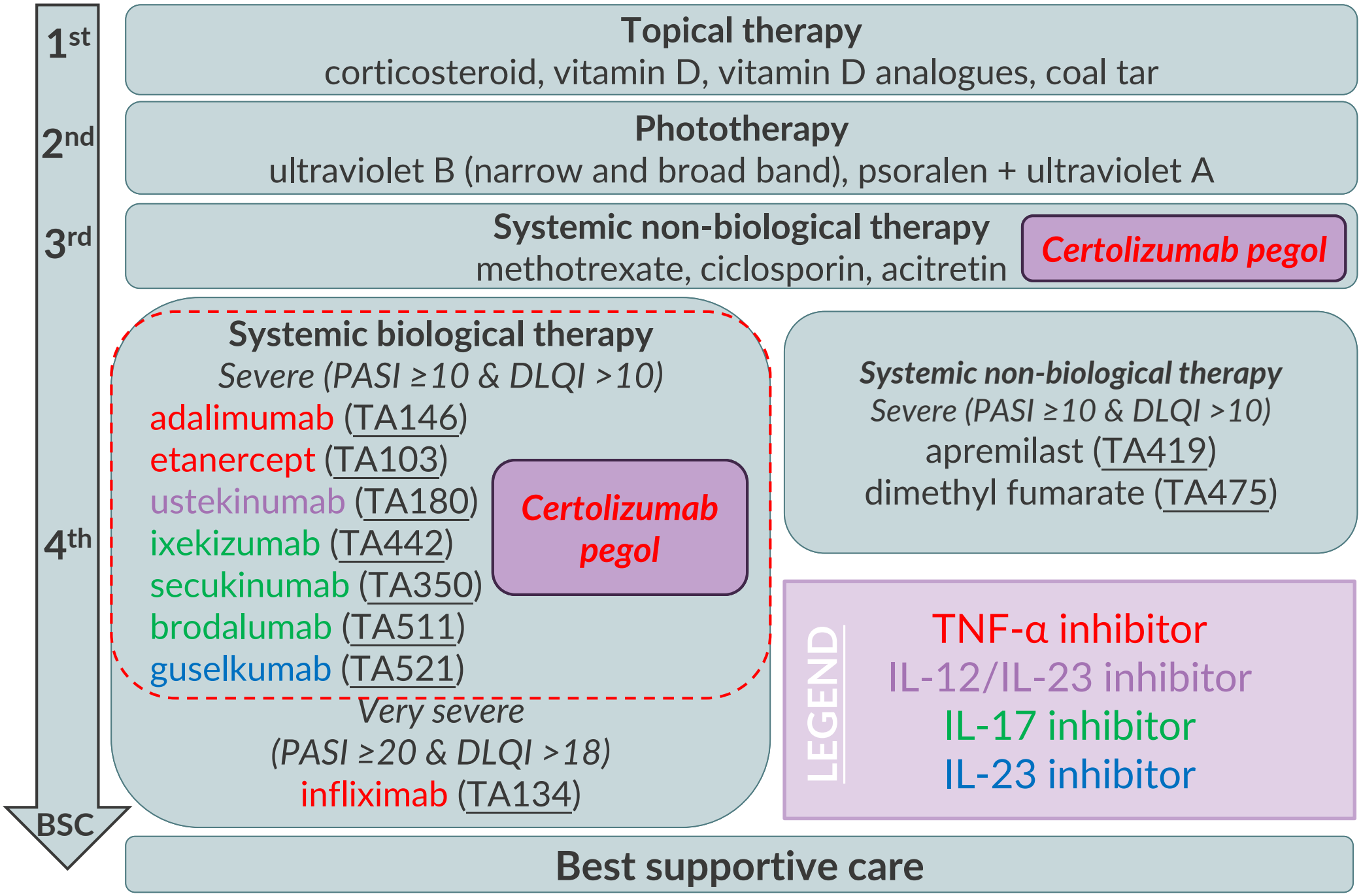
Physician Global Assessment (PGA)

- Scored physician's impression of psoriasis severity – 0 (clear) to 5 (severe)
- Clinically important response defined as a reduction to 'clear' (0) or 'minimal' (1)

Dermatology Life Quality Index (DLQI)

- 10 questions about how psoriasis affects quality of life: symptoms, feelings, daily activities, treatment etc.
  - Each question receives a response of 0-3 (3 is the worst impact); >10 DLQI (severe)
- Clinically important response defined as a 5 point reduction in DLQI

Treatment Pathway



Certolizumab pegol (Cimzia®)

Mechanism	PEGylated TNF-α inhibitor
Marketing authorisation	Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy
Administration and dose	*Loading dose:* The recommended starting dose of certolizumab pegol is 400 mg (given as 2 subcutaneous injections of 200 mg each) at weeks 0, 2 and 4. Clinical response is usually achieved within 16 weeks of treatment. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within the first 16 weeks of treatment. *Maintenance dose:* After the starting dose, the recommended maintenance dose of certolizumab pegol is 200 mg every 2 weeks. A dose of 400 mg every 2 weeks can be considered in patients with insufficient response.
List price	£357.50 per 200 mg pre-filled pen or syringe
Patient access scheme	First 12 weeks of certolizumab pegol are provided free of charge

Decision problem – population and comparators

Candidates for non-biologic systemic therapy
Population excluded in previous appraisals

NICE scope

- Systemic non-biologic therapies (including methotrexate, ciclosporin, acitretin)
- Phototherapy with or without psoralen

Excluded by company:

Phototherapy with or without psoralen

- Phototherapy not used at same position in treatment pathway as systemic non-biologic therapy

Candidates for biologic systemic therapy
Population considered in previous appraisals

NICE scope

- Approved biologic therapies
- Non-biological therapies (apremilast, dimethyl fumarate)
- Best supportive care

Excluded by company:

Apremilast and dimethyl fumarate

- Do not displace biological therapies (consistent with previous appraisals)

Infliximab

- Not 1st line biologic as recommended for very severe psoriasis

ERG: Company's exclusions seem appropriate. Notes that infliximab is included in the network meta-analysis and as a third-line biologic in the cost-effectiveness analysis

⊙ *Is the company's positioning of certolizumab pegol and choice of comparators appropriate?*

Clinical evidence overview

CIMPASI-1 (N=234) and CIMPASI-2 (N=227)

Phase III randomised, double-blind, placebo controlled trials (no sites in UK)

Primary outcomes:
- **PASI 75 at week 16**
- PGA clear or almost clear at week 16

Key secondary outcomes:
- PASI 90 at week 16
- PASI 75 at week 48
- **Health related quality of life (EQ-5D-3L)**

CIMPACT (N=559)

Phase III randomised, double-blind, parallel-group placebo- and active (etanercept) controlled trial ([redacted] UK patients)

Primary outcomes:
- PASI 75 at week 12

Key secondary outcomes:
- **PASI 75 at week 16**
- PASI 75 at week 48
- Health related quality of life (EQ-5D-3L)

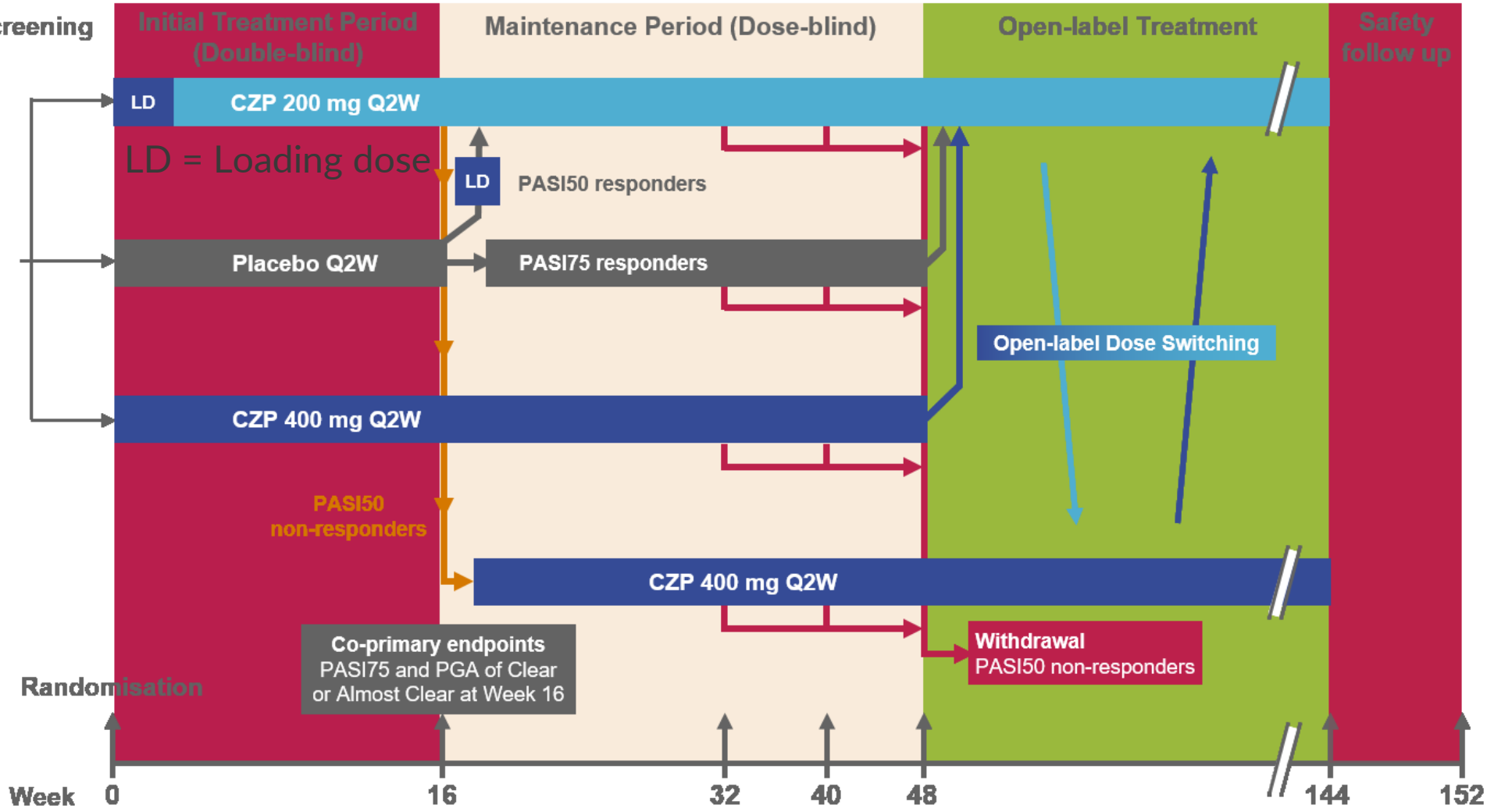
Data used in model

PASI 75 data used in Network Meta-analysis

EQ-5D-3L data used to determine utility values

All trials currently ongoing – full set of analyses will be available for week 144

CIMPASI-1 and CIMPASI-2 trial design



- CIMPACT has similar treatment phases with the following key differences:
  - Has an additional active comparator arm (etanercept)
  - Patients re-randomised in maintenance phase → not included in pooled analyses of this phase
- **ERG:** Trials well designed with low risk of bias

Baseline characteristics

	CIMPASI-1			CIMPASI-2			CIMPACT			
Characteristic	Placebo (n=51)	CZP 200 mg (n=95)	CZP 400 mg (n=88)	Placebo (n=49)	CZP 200 mg (n=91)	CZP 400 mg (n=87)	Placebo (n=57)	ETN (n=170)	CZP 200 mg (n=165)	CZP 400 mg (n=167)
Male, n (%)	35 (68.6)	67 (70.5)	60 (68.2)	26 (53.1)	58 (63.7)	43 (49.4)	34 (59.6)	127 (74.7)	113 (68.5)	107 (64.1)
PASI, mean (SD)	19.8 (7.5)	20.1 (8.2)	19.6 (7.9)	17.3 (5.3)	18.4 (5.9)	19.5 (6.7)	19.1 (7.1)	21.0 (8.2)	21.4 (8.8)	20.8 (7.7)
DLQI, mean (SD)	13.9 (8.3)	13.3 (7.4)	13.1 (6.5)	12.9 (7.3)	15.2 (7.2)	14.2 (7.2)	13.2 (7.6)	14.1 (7.4)	12.8 (7.0)	15.3 (7.3)
Concomitant psoriatic arthritis, n (%)	4 (7.8)	10 (10.5)	15 (17.0)	9 (18.4)	22 (24.2)	26 (29.9)	12 (21.1)	27 (15.9)	27 (16.4)	24 (14.4)
Treatment naïve, n (%)	15 (29.4)	29 (30.5)	27 (30.7)	13 (26.5)	26 (28.6)	24 (27.6)	[redacted]	[redacted]	[redacted]	[redacted]
Biologic naïve, n (%)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

- Lower proportion of males and higher proportion of patients with psoriatic arthritis in CIMPASI-2 (often associated with poorer outcomes)
- Trials contain treatment naïve patients – patients in NHS have non-biologic systemic therapy unless contraindicated

⊙ ***Is the patient population in the trials generalisable to NHS clinical practice?***

Pooled results and relevant subgroups

Key efficacy pools

E1
ITT
All trials
Weeks 0-16

E4
Escape population
All trials
Weeks 16-48

ERG comments

- Higher proportion of responders in CIMPASI 2 trial
- Reason for this difference unclear → Uncertain whether pooling of results appropriate because of this heterogeneity

Key outcomes

Response rates (initial period) – **Used in economic model**

Efficacy evidence for dose escalation strategy

Key subgroups

Candidates for non-biologic systemic therapy
No previous systemic therapy

Candidates for biologic systemic therapy
At least one non-biologic systemic therapy
No previous biologic therapy

Biologic exposed
At least one previous biologic therapy

Pooled results – response rates at week 16

- PASI 75 and PASI 90 response rates used in network meta analysis

Outcome	E1 pool – ITT population (CIMPASI 1/2 and CIMPACT)		
	Placebo (N = 157)	Certolizumab pegol 200 mg (N = 351)	Certolizumab pegol 400 mg (N = 342)
PASI 75, %	7.5	**74.5**	**80.1**
PASI 90, %	1.6	**44.5**	**52.2**
PGA clear/almost clear, %	2.8	54.6	63.7
DLQI score (change from baseline)	-2.4	-9.1	-10.4

Candidates for biologic systemic therapy
PASI 75 for certolizumab pegol
200 mg = [redacted] 400 mg = [redacted]

Biologic exposed
PASI 75 for certolizumab pegol
200 mg = [redacted] 400 mg = [redacted]

ERG comments:
Trials contained [redacted] patients with a DLQI score <10 (below threshold recommended by NICE in previous appraisals) → results may not be fully generalisable to patient population

⊙ ***Are the results generalisable to the NHS?***
⊙ ***Are the results for the ITT population generalisable to the key subgroups?***

Pooled results – response rates at week 16 (2)

Candidates for non-biologic systemic therapy - No previous systemic therapy

Responder rate, (%)	Placebo (n=[redacted])	CZP 200 mg (n=[redacted])	CZP 400 mg (n=[redacted])
PASI 75	[redacted]	[redacted]	[redacted]
PASI 90	[redacted]	[redacted]	[redacted]
PGA clear/almost clear	[redacted]	[redacted]	[redacted]

- Response rates from subgroup analysis of candidates for **non-biologic** therapy used in economic model as it was not possible to perform a network meta-analysis in this population

ERG comments

Not appropriate to extend population to people with no previous systemic therapy because:

- Non-biologic therapies are used 3rd line in clinical practice as much less costly than biologic therapies
- Efficacy of certolizumab pegol similar to most other biologic therapies → insufficient evidence to justify proposed positioning

⊙ ***Is the proposed positioning of certolizumab pegol for patients with no previous systemic therapy appropriate?***

Dose escalation strategy – clinical evidence

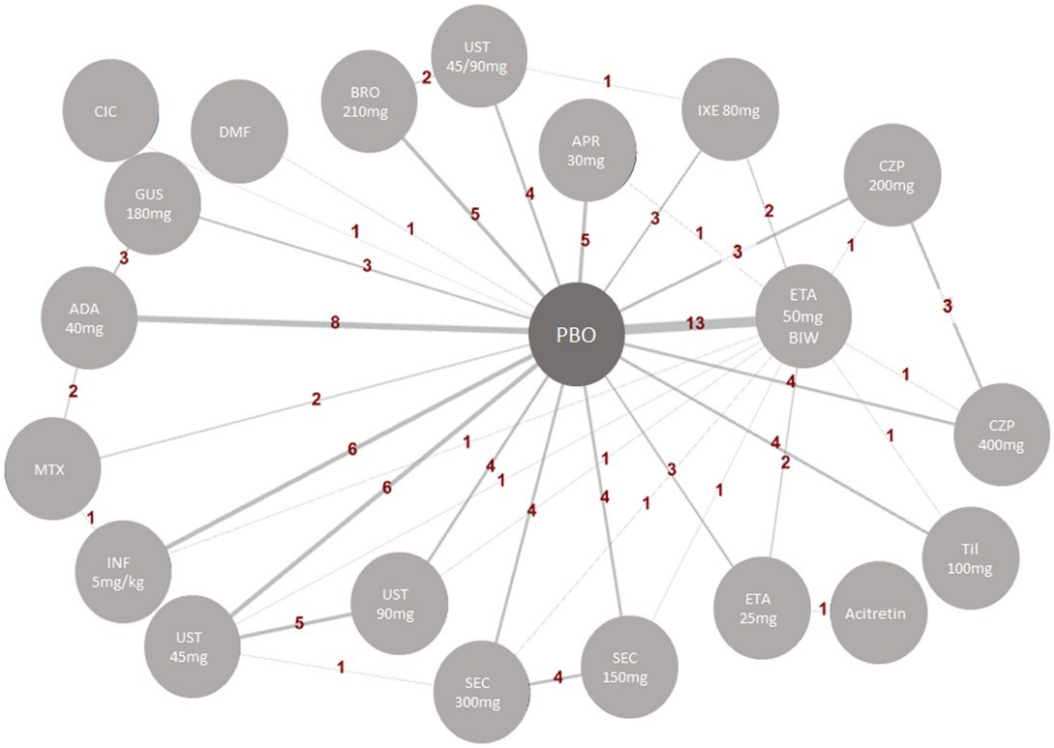
Summary of product characteristics
Dose escalation to 400 mg CZP can be considered

Evidence
Pool E4
Inadequate responders (PASI <50) re-randomised to CZP 400 mg, all trials

- Light blue line shows improvement in PASI 75 and PASI 90 response rates for patients in the clinical trials who did not have a PASI 50 response in the first 16 weeks of treatment
- Improvement in response observed over time:
  - PASI 75 response at week 32: slightly under [redacted]%
  - PASI 75 response at week 48: [redacted]%
- Company noted in response to clarification that [redacted]% of patients with a partial response (PASI 50-75) treated with certolizumab pegol achieved a PASI 75 response by week 48

⊙ *Would a dose escalation strategy for non responders be considered in clinical practice?*

Network meta-analysis (NMA)



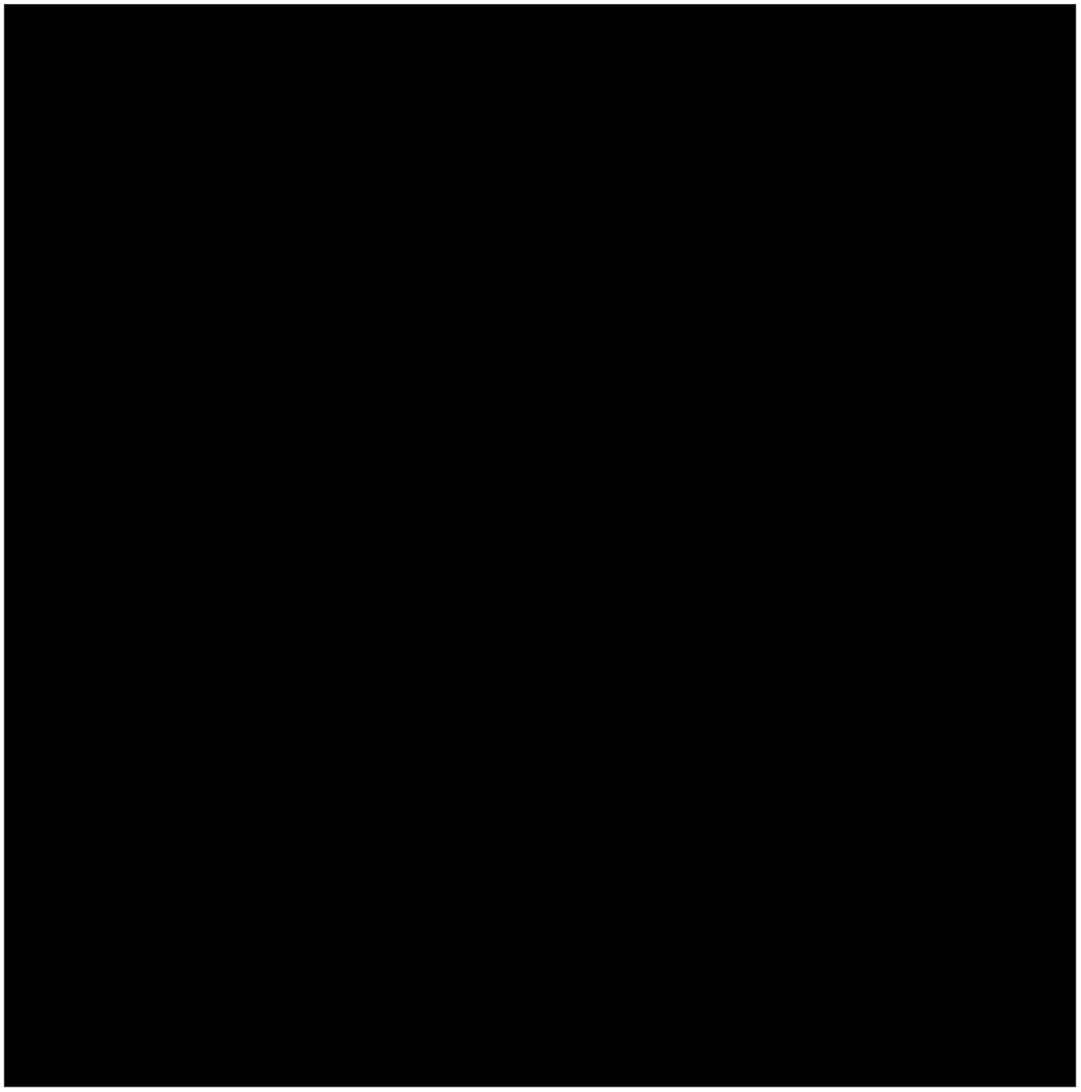
- 83 studies identified in systematic literature review, 62 included in NMA (alongside the 3 Phase III certolizumab pegol studies)
- [redacted]
- Analysis conducted for initial treatment period of 10-16 weeks
- Generates results for probability of PASI 50, 75 and 90 response
  - Used in economic model

ERG comments

- Discrepancy between PASI results for guselkumab and those in previous appraisals/clinical trial data
  - Company provided updated NMA code excluding a phase II study (X-PLORE) for guselkumab which had not been included in previous meta analyses, updated PASI results in line with those expected for guselkumab based on previous data
  - Updates to code resulted in slightly lower PASI values for certolizumab pegol and slightly higher for other treatments

Network meta-analysis: results

PASI 75 response rate



- Treatment of psoriasis with biologics is superior to placebo or standard of care (methotrexate, ciclosporin, acitretin)
- Certolizumab pegol has similar PASI 50/75/90 response rate vs most of the biologics considered
- PASI results comparable to ixekizumab NICE submission

ERG comments

- Ranking of treatments consistent with NMA undertaken by guideline development group for the British Association of Dermatologists guidelines
- Certolizumab pegol ranked lower in comparison to some biologics after company's revision to the NMA code

Certolizumab pegol during pregnancy and breastfeeding

CRIB (N=14)

Zero to minimal certolizumab pegol detected in infants at birth → suggests certolizumab pegol does not cross the placenta

CRADLE (N=17)

Zero to minimal certolizumab pegol detected in 137 breast milk samples → exposure of infants to certolizumab pegol via breast milk unlikely

Registry data (N >500)

Does not indicate a malformative effect. Too limited to conclude that there is no increased risk associated with administration during pregnancy

Summary of product characteristics (SmPC)

- Certolizumab pegol can be used in pregnancy if clinically needed
- Certolizumab pegol can be used during breastfeeding
- Wait a minimum of 5 months following the mother's last certolizumab pegol administration during pregnancy before administration of live or live-attenuated vaccines

Other biologic options (per SmPC) limited to:

- Pregnancy: adalimumab, infliximab (based on pharmacovigilance date)
- Breastfeeding: adalimumab (based on "limited information in the public literature")

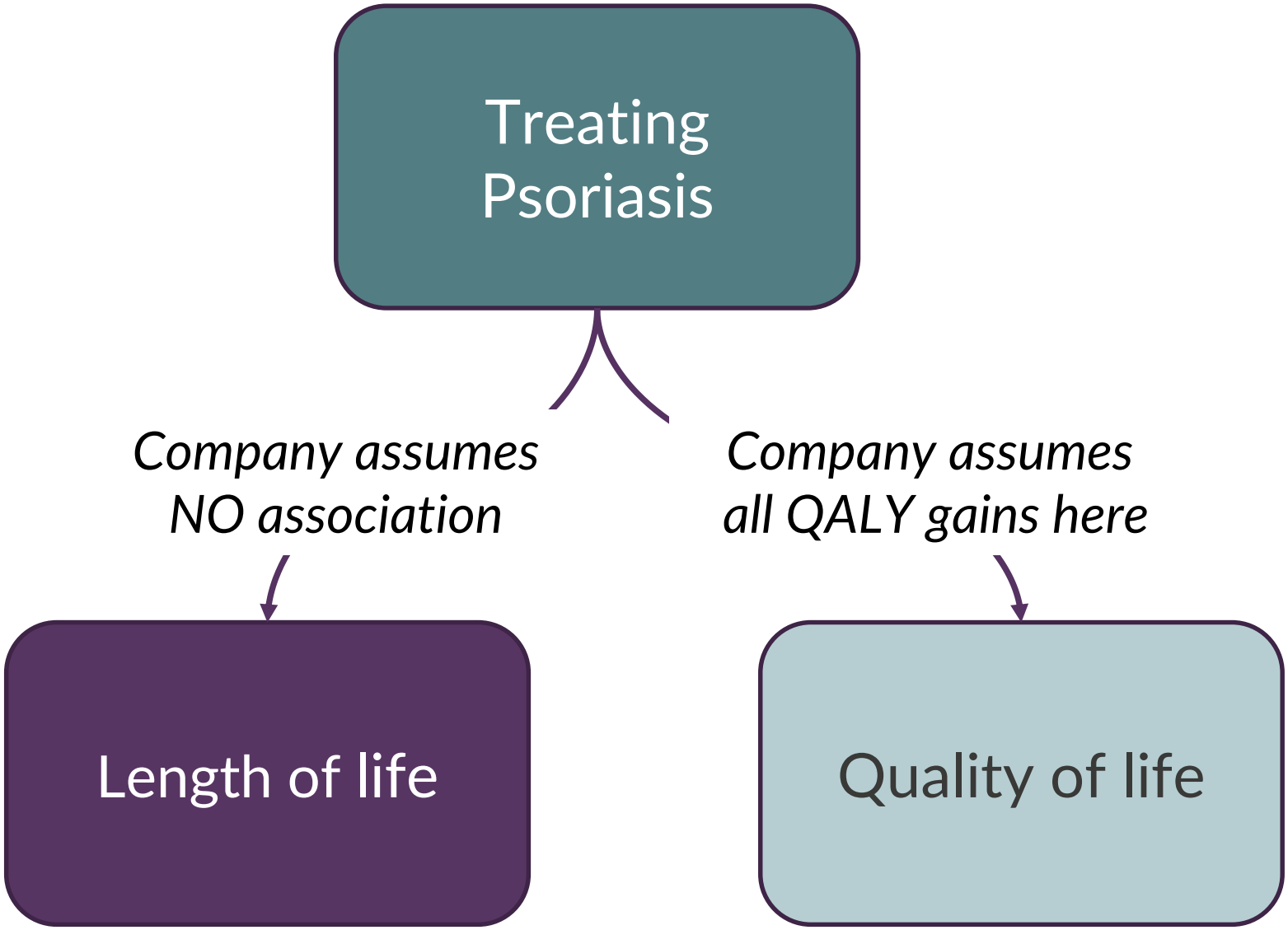
⊙ ***Does certolizumab pegol represent a "step-change" in treatments available during pregnancy?***

Cost-effectiveness

Preview of key cost effectiveness issues

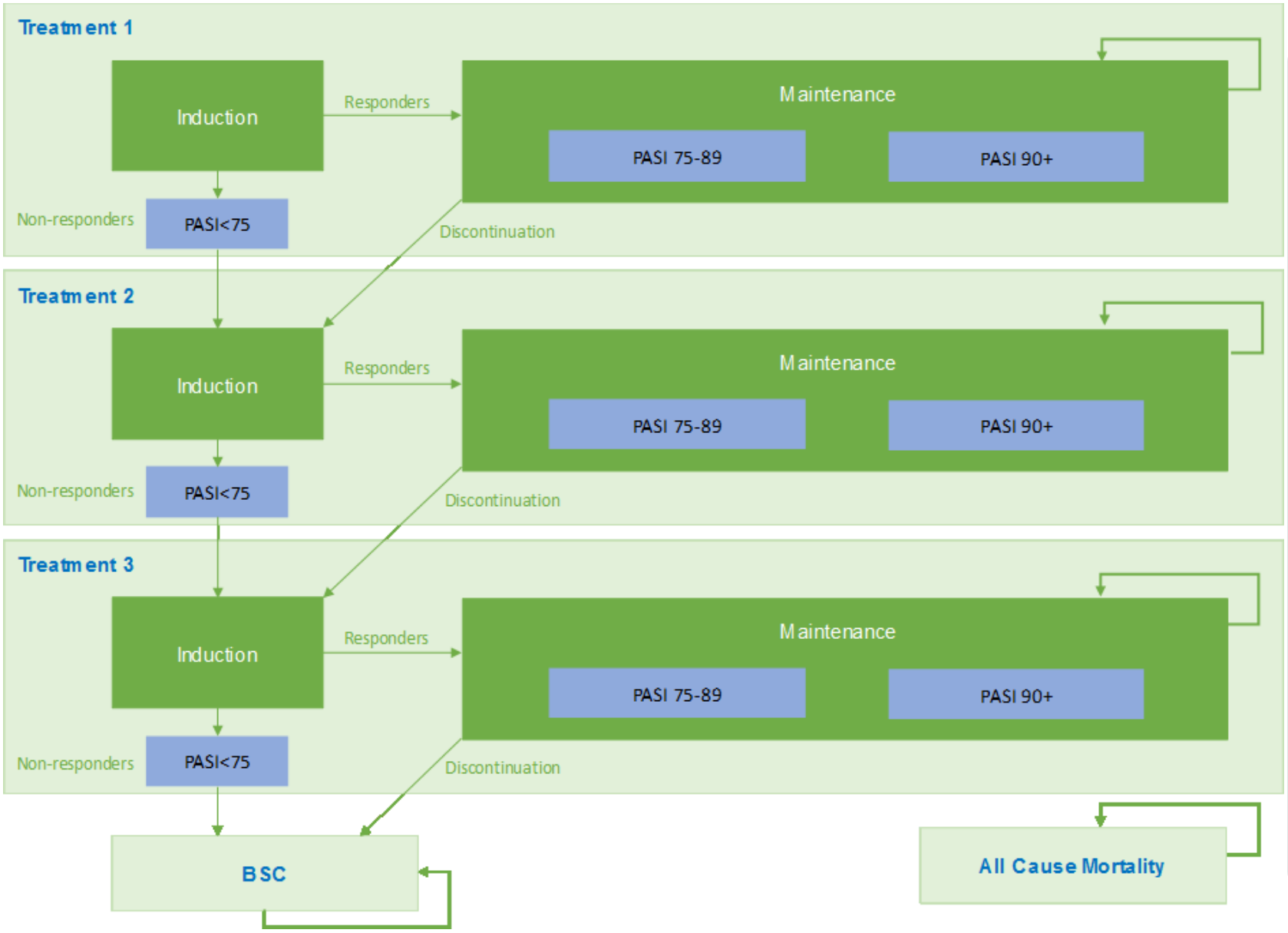
1. Is analysis of treatment sequences using ICERs or individual treatments using a net monetary benefit framework preferred?
2. What is the most appropriate comparator?
3. Is the assumption of an equivalent discontinuation rate of 20% for all biologics appropriate?
4. How should the costs of biosimilars to adalimumab be accounted for?
5. Should cost of best supportive care be modelled updated prices?
6. Should utility values be modelled by limiting population to DLQI>10 and assuming biologic utility values are the same as best supportive care?
7. Which analysis of candidates for non-biologic therapy is more appropriate, the company's comparison of treatment sequences or the ERG's comparison of certolizumab pegol 1st or 2nd line?

Where do QALY gains come from?



Increase in QALYs comes only from improvement in quality of life, rather than increasing length of life

Model structure



Key assumptions

- Lifetime time horizon
- Cycle length = 2 weeks, allows different induction periods for each treatment to be taken into account
- Treatment effect maintained with ongoing treatment
- Position of treatment does not impact effectiveness
- Discontinuation rate of 20% in maintenance period

ERG comments: model structure is consistent with the most recent NICE technology appraisals of biologics for the treatment of psoriasis

Summary of model inputs

Efficacy

PASI response rates for following groups from network meta analysis:

- PASI <50
- PASI 50 to <75
- PASI 75 to <90
- PASI 90+

Key

Consistent with previous appraisals

Partially consistent with previous appraisals

Inconsistent with previous appraisals

Quality of life

- **Best supportive care derived from EQ-5D data from all patients in certolizumab pegol phase III trials**
- **Treatment effect for all biologics derived from EQ-5D data from all patients in certolizumab pegol phase III trials**
- **Utility values for biologics > BSC so assumes an effect on HRQoL associated with treatment with biologics**

Costs and resource use

- Drug acquisition costs from BNF
- Administration costs from NHS reference costs and also include cost of training for subcutaneous injections
- Monitoring costs from NHS reference costs
- Best supportive care costs derived from Fonia et al, BNF and clinical expert opinion
- Non-responder cost from Fonia et al.
- Adverse event costs and resource use not modelled

Utility values used in the model

- Company derived utility values from the certolizumab pegol phase III clinical trials
  - Utility values for BSC derived from combined placebo arms
  - Utility values for all biologic therapies derived from combined certolizumab pegol arms
- **ERG**: restricted population to DLQI >10 to reflect population in the NHS

State	Utility value by PASI Any DLQI (company)		Utility value by PASI DLQI >10 only (ERG)	
	BSC	Biologics	BSC	Biologics
Baseline PASI	[redacted]	[redacted]	[redacted]	[redacted]
PASI <50	[redacted]	[redacted]	[redacted]	[redacted]
PASI 50–75	[redacted]	[redacted]	[redacted]	[redacted]
PASI 75–90	[redacted]	[redacted]	[redacted]	[redacted]
PASI 90–100	[redacted]	[redacted]	[redacted]	[redacted]

ERG: A possible effect on quality of life associated with treatment with biologics may be plausible. Minimal evidence has been provided to substantiate this and use of utility values from placebo arm does not reflect that **BSC is an active treatment** → ERG explored scenario using "biologics" values for patients on BSC (consistent with previous appraisals)

- ⊙ ***Should utility values be derived only from the population likely to be eligible for treatment in the NHS?***
- ⊙ ***Should utility values for biologics and best supportive care be equal?***

ERG comments – best supportive care costs

- Total annual costs of best supportive care (BSC) in company's model lower than in previous appraisals – annual cost of £3,672 compared with £5,283 in TA511 (brodalumab)
  - Driven by large difference in drug acquisition costs → sourced from BNF rather than Fonia et al. study
- ERG considers estimates calculated by company appropriate as Fonia may overestimate costs
  - 41% of costs from Fonia from fumaric acid esters, which are not considered alongside BSC in this appraisal
  - Fonia likely overestimates cost of ciclosporin
- Large impact on cost-effectiveness of biologics vs BSC – no biologic is cost effective when compared to best supportive care
- ERG implements drug costs from Fonia in line with previous appraisals in a scenario analysis

⊙ ***Are the company's assumptions regarding the cost of best supportive care more appropriate than those in previous appraisals?***

ERG comments – biosimilar costs

- Considers company has underestimated the uptake of biosimilars of infliximab and etanercept (in April 2017 the uptake of biosimilar infliximab was 80%, rather than 20%, as assumed in company submission)
  - ERG explores scenarios assuming full uptake of biosimilars
- A number of adalimumab biosimilars have been launched
  - Clinical expert opinion to ERG suggests a reduction in current list price of 30-40% could be expected
  - ERG explores scenarios with various levels of price reduction to account for adalimumab biosimilars

⊙ ***Does the ERG analysis assuming full uptake of biosimilars better reflect clinical practice?***

⊙ ***How should the cost of adalimumab biosimilars be accounted for?***

Economic analysis overview

- Company presents three sets of base case analyses
  - Candidates for systemic biologic therapy (contraindicated, intolerant or non-responsive to systemic non-biologic therapy)
  - Candidates for non-biologic therapy
  - Dose escalation (partial response to initial biologic therapy)

Cost-effectiveness results are confidential due to use of confidential patient access scheme information. Results of the company's and ERG's cost-effectiveness analyses are presented in a confidential part II of this meeting.

Company base case – candidates for biologic systemic therapy

- Company base case included treatment sequences for candidates for biological systemic therapy based on clinical expert opinion – in all sequences 2nd line therapy is followed by: infliximab → best supportive care → best supportive care
- Scenario analyses compared single treatments followed by best supportive care

Sequences	
1st line	2nd line
Certolizumab pegol (200 mg)	Ustekinumab (90 mg)
Adalimumab (40 mg)	Ustekinumab (90 mg)
Brodalumab	Ustekinumab (90 mg)
Etanercept	Ustekinumab (90 mg)
Guselkumab	Ustekinumab (90 mg)
Ixekizumab	Ustekinumab (90 mg)
Secukinumab	Ustekinumab (90 mg)
Ustekinumab (45 mg)	Adalimumab (40 mg)
Ustekinumab (90 mg)	Adalimumab (40 mg)

ERG comments – treatment sequences

- Sequences proposed by company are unlikely to reflect current practice:
  - most patients have either adalimumab or secukinumab 1st line → positioning of certolizumab pegol as first-line biologic therapy unlikely
    - launch of adalimumab biosimilars may affect practice
  - infliximab not funded for those with moderate to severe disease → unlikely to be used frequently in this population
- Most relevant comparison may be between certolizumab pegol and other TNF-α inhibitors, most notably adalimumab
- Modelling selective sequences could provide misleading cost-effectiveness estimates, especially if there are treatments in the sequences that are not cost effective

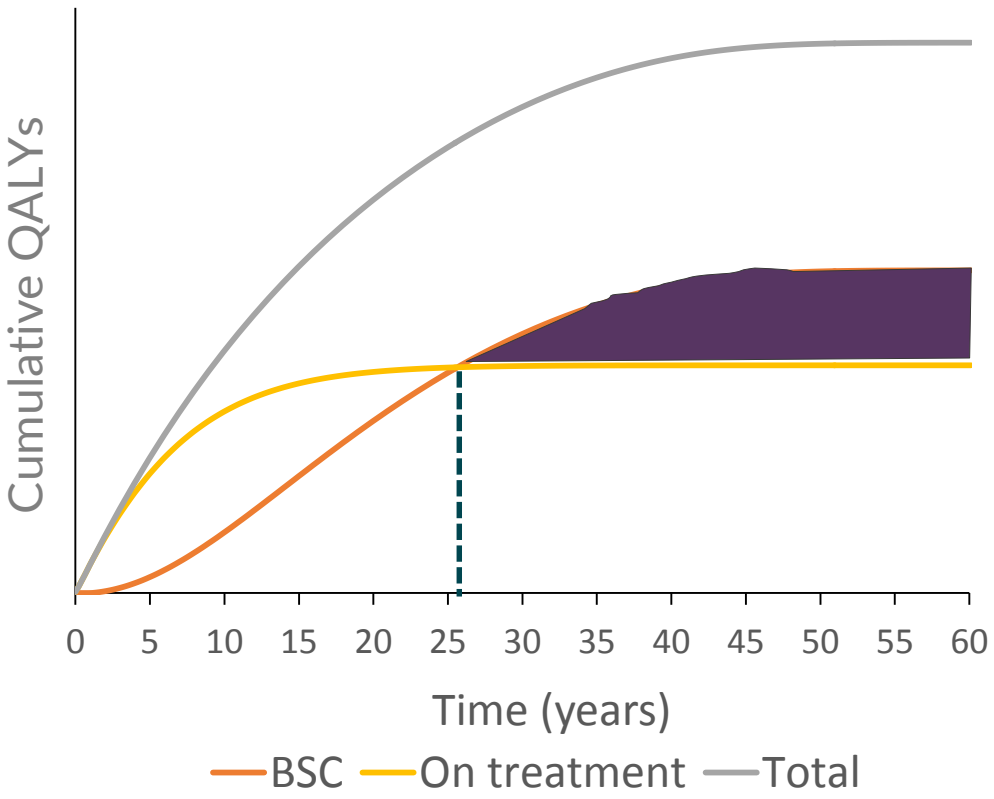
⊙ ***Do the treatment sequences presented by the company reflect clinical practice?***

ERG comments – treatment sequences

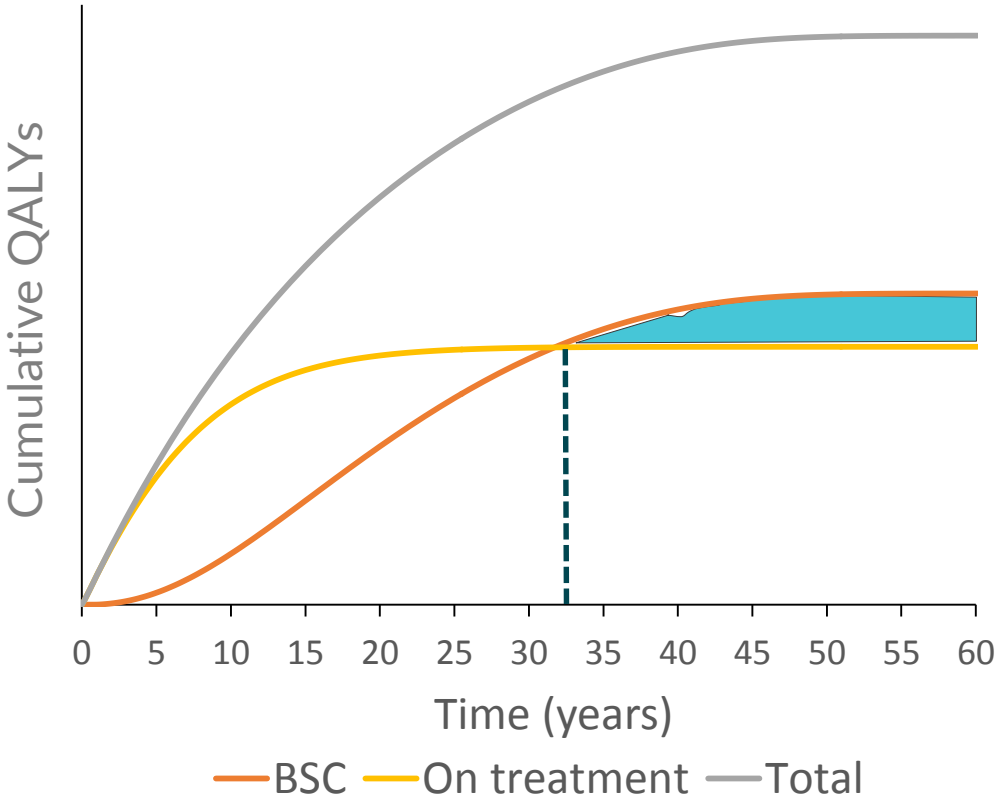
- **No comparators are cost-effective versus best supportive care** → QALYs gained on BSC are **cheaper** → sequence of drugs with lower response rates will appear more cost-effective, as patients get to BSC more quickly
- Charts compare a sequence with low response rates on left with higher on right
  - Shaded area indicates time where majority of QALYs are gained on BSC

Cumulative QALYs over time horizon

UST45 --> ADA --> INF --> BSC



BROD --> UST90 --> INF -->BSC



ERG alternative base case – Individual treatments and Net Monetary Benefit framework

Issues

- Sequences proposed by company unlikely to reflect current practice
- Sequences contain cost ineffective treatments (all biologics cost ineffective compared to BSC) → may provide misleading cost effectiveness estimates

Alternative approach

- Net monetary benefit framework assessing relative costs-effectiveness of individual biologics followed by subsequent treatment with best supportive care
- Consistent with approach taken by ERG in TA511 (brodalumab)
- Uses certolizumab as baseline to compare biologics with each other – better accounts for none of the biologics being cost-effective compared to best supportive care in company base case
- Avoids complications of negative ICERs
- ERG also present ICERs compared with best supportive care

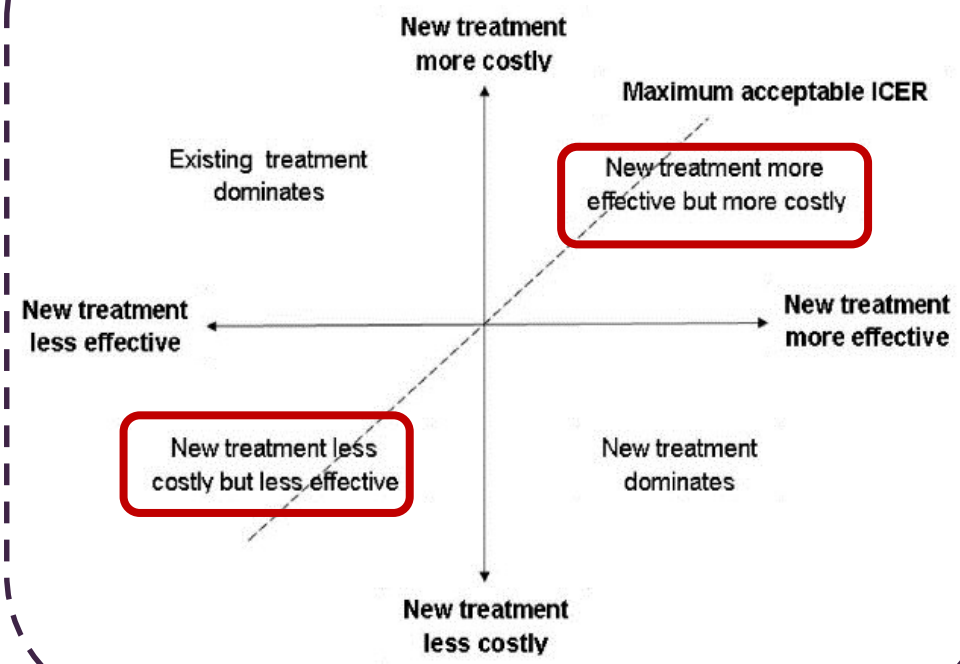
Incremental cost-effectiveness ratios (ICERs) vs net monetary benefit framework (NMB)

ICER: What is the extra cost per unit of extra benefit?

ICER decision rule: recommend technology if

Δ Costs/ Δ QALYs < threshold

But, ICER > 0 can mean:



NMB

- Value of an intervention in monetary terms at a willingness-to-pay threshold (NHS opportunity cost)
- For NMB, ICER decision rule is rearranged:

(Δ QALYs * threshold) – Δ Costs > 0

- Incremental NMB: difference in NMB between alternative interventions
- Positive incremental NMB: intervention is cost-effective compared with alternative at given willingness-to-pay threshold

ERG base case –biologic systemic therapy

- Single-line head to head comparisons using net monetary benefit framework in contrast to company's approach of treatment sequences and fully incremental analysis compared to baseline ERG base case also includes following scenarios
  - equal utilities applied to biologics and BSC with population limited to DLQI <10
  - biosimilar costs for etanercept and infliximab, adalimumab at list price
- ERG also presents several alternative base case analyses including
  - BSC costs, utility values and time horizon in line with assumptions from TA511 (brodalumab, most recent psoriasis appraisal)
  - A range of price reductions for adalimumab to account for introduction of biosimilar alternatives

Candidates for non-biologic systemic therapy

- **Company: base case:** compares standard of care (SOC) with certolizumab pegol using following treatment sequences:
  - SOC → adalimumab → ustekinumab → infliximab → best supportive care (BSC)
  - Certolizumab pegol → ustekinumab → infliximab → BSC → BSC
  - Response rates for SOC for non-biological therapy derived from pooled data from the placebo arms of the certolizumab trials. Company provided scenario analysis based on the response data derived from the systemic non-biologic therapy naïve group in the network meta analysis in response to clarification

ERG comments

- Current guidance suggests it is not appropriate to treat patients eligible for systemic non-biologic therapies with biologics
- Placebo response inappropriate as standard of care is active comparator → used response rates for methotrexate (MTX) from company's network meta analysis
  - Data unreliable due to its sample size and associated uncertainty.
- Compared use of certolizumab pegol 1st line with use of certolizumab pegol 2nd line:
  - SOC→ certolizumab pegol → BSC vs certolizumab pegol → BSC → BSC
- A more plausible analysis would model a hypothetical change in NICE guidelines and compare certolizumab pegol alongside all other available biologics

⊙ ***Are either of the company's or ERG's proposed treatment sequences appropriate?***

Innovation

- Company highlighted that
  - PEGylation extends the half-life of certolizumab pegol to approximately 14 days, increases bioavailability and enables prolonged circulation time in the blood
  - is the only biologic and synthetic targeted therapy with clinical trial data in its label that supports potential use in both pregnancy and breastfeeding in chronic inflammatory diseases
  - is available as a prefilled pen or pre-filled syringe
  - can be used to treat concomitant psoriatic arthritis, which affects approximately 30% of patients

⊙ ***Are there any benefits for certolizumab pegol not captured in the estimation of QALYs?***

Equality

- Pregnancy
  - Submission from Psoriasis Association noted that "Women of childbearing age deserve to have effective treatments available to them in order to manage their chronic condition without compromising their family plans."
- Issues raised in previous guidance
  - When using the PASI, healthcare professionals should take into account skin colour and how this could affect the PASI score, and make the clinical adjustments they consider appropriate.
  - When using the DLQI, healthcare professionals should take into account any physical, psychological, sensory or learning disabilities, or communication difficulties that could affect the responses to the DLQI and make any adjustments they consider appropriate.

⊙ ***Are there equality factors the committee should take into consideration when making its decision?***

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