Mirikizumab for treating moderately to severely active Crohn's disease

Contains CON and cPAS information. For committee only

Highly Specialised Technologies Evaluation Committee [cost comparison]

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Company: Eli Lilly

Mirikizumab for treating moderately to severely active Crohn's disease

- ✓ **Summary**
- ❑ Clinical effectiveness
- ❑ Modelling and cost effectiveness

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Summary

EAG agrees cost comparison with ustekinumab is robust, but comparison with risankizumab is uncertain

Company says mirikizumab is similarly effective and cheaper than risankizumab in its recommended population (TA888).

EAG says:

- Broadly agrees that cost comparison is appropriate
- Company's modelling approach is aligned with cost-comparison analyses in other NICE guidance for Crohn's (risankizumab TA888 and upadacitinib TA905)
- However, clinical similarity case is uncertain for the comparison with risankizumab (based on NMA)
- There is robust evidence that mirikizumab is clinically similar to ustekinumab, based on direct evidence from VIVID-1

Equalities issues: none raised by company or EAG

See supplementary appendix for technology information, decision problem and treatment pathway

Mirikizumab for treating moderately to severely active Crohn's disease

- ❑ Summary
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- ❑ Modelling and cost effectiveness

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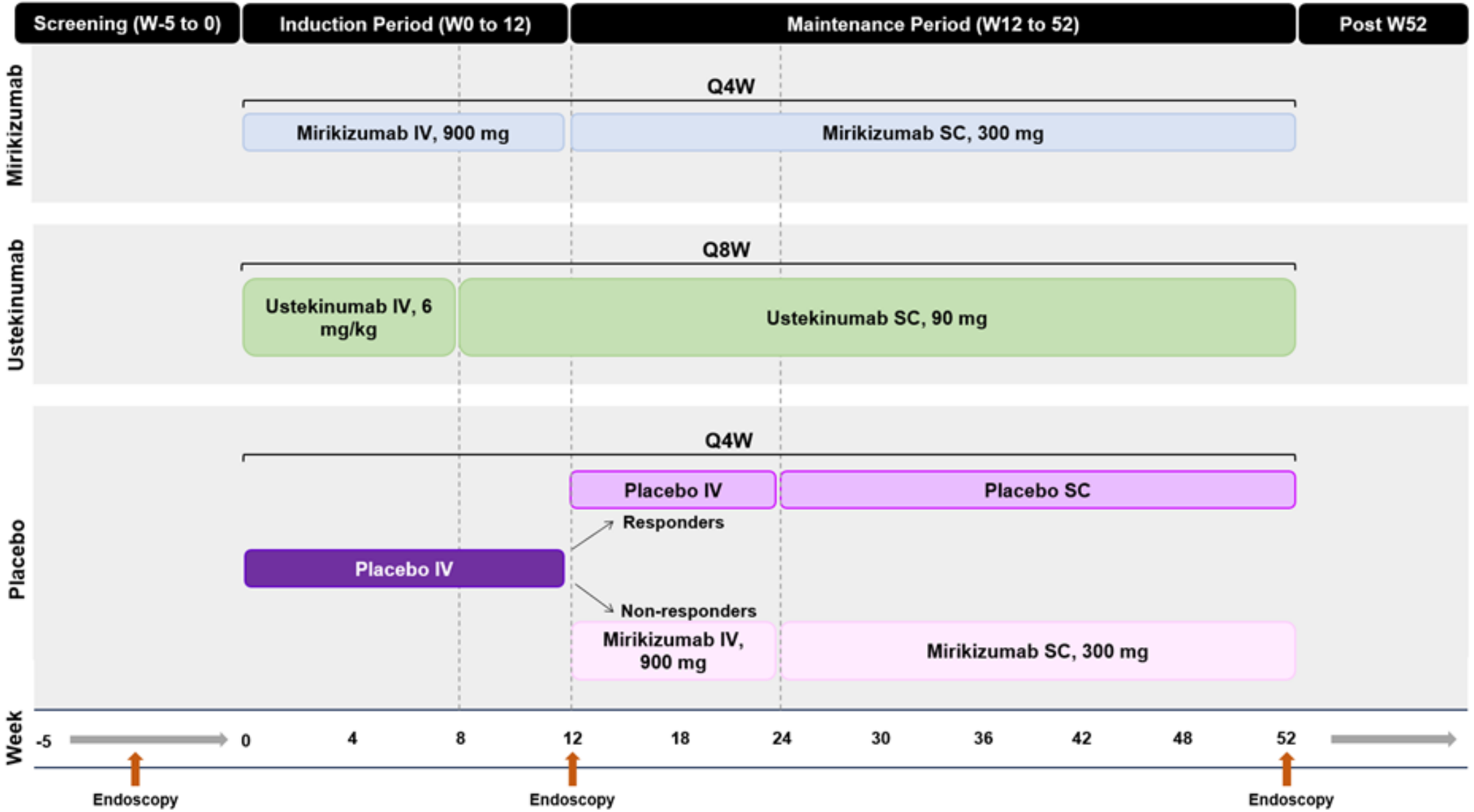
The VIVID-1 study

3 arm ‘treat through’ trial comparing mirikizumab with ustekinumab and placebo in moderate to severe Crohn’s disease



VIVID-1 trial results: mirikizumab vs. ustekinumab

EAG says direct comparison with ustekinumab shows robust non-inferiority

% achieving clinical remission (RD>0 favours mirikizumab)

Population	Miri	Ustek	Risk difference (95% CIs)
Week 12			
PAS	[redacted]	[redacted]	[redacted]
BF	[redacted]	[redacted]	[redacted]
CCF	[redacted]	[redacted]	[redacted]
Week 52			
PAS	[redacted]	[redacted]	[redacted]
BF	[redacted]	[redacted]	[redacted]
CCF	[redacted]	[redacted]	[redacted]

% achieving clinical response (RD>0 favours mirikizumab)

Population	Miri	Ustek	Risk difference (95% CIs)
Week 12			
PAS	[redacted]	[redacted]	[redacted]
BF	[redacted]	[redacted]	[redacted]
CCF	[redacted]	[redacted]	[redacted]
Week 52			
PAS	[redacted]	[redacted]	[redacted]
BF	[redacted]	[redacted]	[redacted]
CCF	[redacted]	[redacted]	[redacted]

- Mirikizumab met the criteria for non-inferiority* compared to ustekinumab at both 12 and 52 weeks for the PAS group and CCF subgroup
- For the BF subgroup, mirikizumab was non-inferior at 52 weeks. At 12 weeks, the results marginally crossed the non-inferiority margin

- Effect estimates marginally favoured mirikizumab for PAS group and both subgroups, with 95% CIs within non-inferiority margins at wk 12 and wk 52

EAG considered VIVID-1 to be a '*high-quality trial which included the relevant population, intervention, comparators and outcomes to match the NICE final scope and answer the decision problem.*'

* Based on non-inferiority margin of 10%; BF: biologic failed; CCF: conventional care failed; CDAI: Crohn's disease activity index; CI: confidence interval; MIRI: mirikizumab; PAS: primary analysis set; RD: risk difference; UST: ustekinumab.

VIVID-1 trial results: adverse events

AEs in the induction and maintenance phases

Adverse event	Intervention		
	Placebo	Mirikizumab	Ustekinumab
Induction phase			
≥1 TEAE (%)	[redacted]	[redacted]	[redacted]
≥1 Severe TEAE (%)	[redacted]	[redacted]	[redacted]
≥1 SAE (%)	[redacted]	[redacted]	[redacted]
Treatment discontinuation due to AEs (%)	[redacted]	[redacted]	[redacted]
Maintenance phase			
≥1 TEAE (%)	73.0%	78.6%	[redacted]
≥1 Severe TEAE (%)	[redacted]	[redacted]	[redacted]
≥1 SAE (%)	[redacted]	[redacted]	[redacted]
Treatment discontinuation due to AEs (%)	[redacted]	[redacted]	[redacted]

Serious treatment emergent AEs occurring in >1% patients, maintenance phase

Adverse event	Intervention		
	Placebo	Mirikizumab	Ustekinumab
Infections and infestations - n (%)	[redacted]	[redacted]	[redacted]
Gastrointestinal disorders - n (%)	[redacted]	[redacted]	[redacted]
Blood and lymphatic system disorders - n (%)	[redacted]	[redacted]	[redacted]
Hepatobiliary disorders - n (%)	[redacted]	[redacted]	[redacted]

EAG on Adverse events:

- Similar safety profiles and discontinuation rates between mirikizumab and ustekinumab
- Slightly higher % of patients had a SAE with mirikizumab during induction period (still lower than placebo). During maintenance period, % for ustekinumab and mirikizumab were similar.
- Hypersensitivity reactions were similar in induction period but higher for mirikizumab in maintenance period
- EAG's clinical experts did not highlight hypersensitivity as a major area for concern

Is mirikizumab clinically similar to ustekinumab?

SAE = serious adverse events; TEAE treatment-emergent adverse events

Network meta analysis: mirikizumab vs. risankizumab

Company performed broad NMA to inform comparison with risankizumab

- Included several comparators (adalimumab, risankizumab; upadacitinib; ustekinumab; vedolizumab and mirikizumab)
- Used adjustments to address the variation in trial designs

EAG says:

- Company's adjustment doesn't entirely remove uncertainty from trial design heterogeneity
- Each network includes interventions that aren't relevant to decision problem; don't contribute to the effect estimates for mirikizumab or risankizumab
- Additional studies introduce additional heterogeneity; can result in wider 95% CrIs for effect estimates
- Difficult to interpret the estimated relative effect estimates for mirikizumab and risankizumab
- Requested simplified ITCs including only the studies that evaluated mirikizumab or risankizumab (Bucher ITCs and unanchored matched-adjusted indirect comparisons [MAICs]
- EAG estimated the % responders (risankizumab responders calculated from NMA, mirikizumab from VIVID-1) to contextualise difference between the treatments

Further details on the network meta analysis in supplementary appendix

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CrI = credible intervals; ITC = indirect treatment comparison; NMA = network meta-analysis; OR = odds ratio;

NMA results: Induction period - mirikizumab vs. risankizumab

OR crosses 1 for all efficacy outcomes

Efficacy outcomes; induction period (OR>1 favours mirikizumab)

Outcome	NMA results OR (95% CrI)	Bucher ITC* OR (95% CrI)	EAG estimated % responders (calculated from NMA)
CCF population			
Enhanced clinical response	0.90 (0.57 to 1.40)	0.66 (0.31 to 1.36)	Miri: 60% Ris: 62% (44% to 100%)
Clinical remission	0.68 (0.38 to 1.29)	0.60 (0.27 to 1.33)	Miri: 40% Ris: 49% (38% to 100%)
Endoscopic response	0.46 (0.18 to 1.17)	0.44 (0.17 to 1.12)	Miri: 38% Ris: 57% (49% to 100%)
Endoscopic remission	0.73 (0.27, 2.00)	0.73 (0.27 to 1.96)	Miri: 22% Ris: 28% (14% to 100%)
BF population			
Enhanced clinical response	0.79 (0.48 to 1.33)	0.89 (0.50 to 1.59)	Miri: 61% Ris: 67% (50% to 100%)
Clinical remission	0.71 (0.40 to 1.23)	0.66 (0.35 to 1.23)	Miri: 36% Ris: 44% (36% to 100%)
Endoscopic response	0.84 (0.49 to 1.51)	1.18 (0.49 to 2.86)	Miri: 27% Ris: 30% (20% to 61%)
Endoscopic remission	1.63 (0.39, 11.4)	1.48 (0.31 to 7.1)	Miri: 13% Ris: 9% (1% to 22%)

Induction period

- CCF population; risankizumab was favoured numerically for all outcomes, but not statistically significant
- BF population; risankizumab was favoured numerically for all outcomes except endoscopic remission and endoscopic response, but not statistically significant

EAG says

- non-statistically significant results in ITCs reflect uncertainty rather than non-inferiority
- EAG notes differences in estimated % of responders for each outcome (e.g. 38% vs 57% for endoscopic response)

* Simplified ITC requested by EAG; BF: biologic failed; CCF: conventional care failed; CI: confidence interval; PAS: primary analysis set;

NMA results: Maintenance period – mirikizumab vs. risankizumab

Efficacy outcomes; maintenance period
(OR>1 favours mirikizumab)

Outcome	NMA results OR (95% CrI)	EAG estimated % responders (calculated from NMA)	Unanchored MAIC results* OR (95% CI)
CCF population			
Clinical remission	2.29 (0.63 to 8.29)	Miri: 72% Ris: 53% (6% to 84%)	-
BF population			
Clinical remission	1.68 (0.56 to 5.07)	Miri: 64% Ris: 51% (10% to 92%)	-
PAS population			
Clinical remission	-	-	1.777 (1.16 to 2.72)
Clinical response	-	-	2.803 (1.76 to 4.47)
Endoscopic remission	-	-	0.779 (0.51 to 1.2)
Endoscopic response	-	-	1.365 (0.90 to 2.07)

* Simplified ITC requested by EAG; BF: biologic failed; CCF: conventional care failed; PAS: primary analysis set;

Maintenance period:

- NMA results only available for clinical remission
- Mirikizumab favoured for clinical remission in both CCF and BF groups, but not statistically significant
- EAG says this reflects uncertainty rather than non-inferiority
- MAIC results only available for PAS population (not subgroups)
- MAIC results cross 1 for endoscopic outcomes; mirikizumab favoured for clinical remission and response

EAG says:

- MAIC results are uncertain due to differences in response definition and unobserved confounding
- Only those who responded to induction treatment included in MAIC for maintenance; may not reflect NHS population
- Given the uncertainty across the NMAs, Bucher ITCs and unanchored MAICs, the results do not provide robust evidence of clinical similarity in maintenance period

Clinical expert:

- No clear evidence to support using one drug over the other. Both show efficacy in the relevant populations

NMA results: adverse events

EAG says difficult to draw firm conclusions about relative safety of treatments

- Company's NMA and ITCs indicate no significant differences between treatments for induction or maintenance
- Effect estimates favoured risankizumab in induction period, but mirikizumab favoured in maintenance period
- EAG's concerns about the uncertainty of the effectiveness data also apply to outcomes relating to AEs and discontinuations; limited information to draw conclusions about relative safety of each treatment.

Adverse events and discontinuations during the induction and maintenance periods (OR<1 favours mirikizumab)

Outcome	NMA results OR (95% CrI)	Unanchored MAIC results* OR (95% CI)
Induction period		
SAEs	2.36 (0.92 to 6.67)	1.68 (0.82 to 3.44)
All-cause discontinuations	1.63 (0.52 to 5.74)	1.51 (0.64 to 3.56)
Maintenance period		
Discontinuations due to AEs	NR	0.815 (0.281 to 2.367)

Is mirikizumab clinically similar to risankizumab?

NICE

* Simplified ITC requested by EAG; AE = adverse events; NR = not reported; ITC = independent treatment comparison; SAEs = serious adverse events

Key issue: Comparators

See supplementary appendix for details of comparator TAs

Background
- Company's preferred comparator is risankizumab, EAG preferred comparator is ustekinumab
- Ustekinumab is recommended by NICE for 1L & 2L use, but mirikizumab positioned for 2L only, after TNF-αi

Company
- Risankizumab considered primary comparator based on similarities in mechanism of action and method of administration. Ustekinumab and vedolizumab included as supportive comparators.

EAG comments
- Clinical similarity is uncertain vs. risankizumab
- NMA uncertainty comes from heterogeneity of trial design; MAIC uncertainty comes from differences in response definition, unobserved confounding, and populations which don't reflect NHS use
- Robust, direct evidence that mirikizumab is clinically similar to ustekinumab; so ustekinumab preferred

Clinical expert:
- Ustekinumab (biosimilar) would likely be used before both mirikizumab and risankizumab if cost the key driver
- Mirikizumab would be used as alternative to risankizumab in anti-TNF non-response/loss of response patients

NICE Tech Team
- Cost comparison recommendations have the same positioning as the comparator and only require comparison with one NICE-recommended comparator. Risankizumab has a narrower recommendation than ustekinumab, and is the company's preferred comparator.

Which comparator will be displaced by mirikizumab?

Mirikizumab for treating moderately to severely active Crohn's disease

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- ✓ **Modelling and cost effectiveness**

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Cost-comparison modelling

- Company's cost-comparison model compares mirikizumab with risankizumab, ustekinumab and vedolizumab, assuming equal efficacy for all treatments
- Only drug acquisition costs and administration costs considered; assumed no other cost differences
- Treatment discontinuation not included
- Dose escalation was included in the model for ustekinumab and vedolizumab, but not for mirikizumab or risankizumab (to align with marketing authorisation/clinical practice)
- 3-year time horizon based on clinical expert advice in TA888 which stated that, "2 to 3 years is the reported median duration of treatment persistence with biologics"

EAG says:

- 3-year time horizon sufficient and excluding treatment discontinuation is a reasonable simplifying assumption
- Discounting should be applied (as time horizon >1yr) – EAG scenario provided, minimal impact on inc. costs
- Exclusion of AE costs for the comparison vs. ustekinumab is reasonable. For the cost-comparison of mirikizumab with risankizumab, is appropriate to capture the difference in AE costs (but problematic to do so)
- Clinical similarity of mirikizumab vs risankizumab not demonstrated; robust evidence vs ustekinumab

Clinical expert: confirmed 3-year time horizon sufficient to capture costs and benefits

Company base case results

Interventions		Total Costs (£)	Incremental costs (£)
Mirikizumab		[redacted]	-
Risankizumab*		[redacted]	[redacted]
Ustekinumab†	Low MPSC	[redacted]	[redacted]
	Mid MPSC	[redacted]	[redacted]
	High MPSC	[redacted]	[redacted]
Vedolizumab		[redacted]	[redacted]

*** Company preferred comparator**

† EAG preferred comparator

- Biosimilar treatments are available for ustekinumab. As per the NICE methods manual, the high, low and mid point MPSC prices have been used for analyses.
- When confidential prices are used for intervention and comparators, [redacted]

PAS = patient access scheme;

Company scenario analysis

Scenario	Incremental costs (£) – mirikizumab vs *(minus value = mirikizumab is cost saving)*				
	Risankizumab*	Ustekinumab†			Vedolizumab
		Low	Mid	High	
Base case	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Time horizon – 2 years *(used for RIS in TA888)*	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Time horizon – 5 years	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Vial sharing (no drug wastage) – BF population	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Treatment administration costs excluded	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Vedolizumab IV/SC 14-week induction – response to EAG CQ B7	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Vial sharing, CCF population baseline characteristics – response to EAG CQ B8	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
*** Company preferred comparator** **† EAG preferred comparator**					

Abbreviations: BF, biologic failed; CCF, conventional care failed; CQ, clarification question; EAG, External Assessment Group; IV, intravenous; SC, subcutaneous.

EAG scenario analysis

- Includes discount rate of 3.5% for costs
- EAG says minimal impact on the cost results so did not provide an EAG base case

Scenario	Incremental costs (£) – mirikizumab vs				
	Risankizumab*	Ustekinumab†			Vedolizumab
		Low	Mid	High	
Base case	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
3.5% discount rate for costs	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

*** Company preferred comparator**
† EAG preferred comparator

- When confidential prices are used for intervention and comparators, [redacted]

Supplementary appendix

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Mirikizumab (Omvoh, Eli Lilly)

Marketing authorisation	• People with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic treatment • EMA approval received Feb 2025 (MHRA approval granted April 2025 via international Recognition procedure; EMA)
Mechanism of action	• Recombinant humanised IgG4 monoclonal antibody that binds to the IL-23 cytokine
Administration	**Induction:** 900 mg by IV infusion Q4W (Weeks 0, 4 and 8). Mirikizumab 300 mg (15 ml vial; 20 mg mirikizumab per mL) is available as a concentrate for solution for infusion **Maintenance:** 300 mg by SC injection every 4 weeks after completion of induction dosing. A full maintenance dose consists of one 200 mg pre-filled pen and one 100 mg pre-filled pen. After training in SC injection technique, a patient may self-inject with mirikizumab
Price	List price per pack, induction dose (300 mg for IV infusion): £2,056.56. List price per pack, maintenance dose (1x 200 mg plus 1x 100 mg for SC injection): [redacted] Simple PAS in place for mirikizumab

Decision problem

	Final scope	Company	EAG comments
Population	Adults with moderate to severely active CD who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic treatment.	Adult patients with moderately to severely active CD, only if: • The disease has not responded well enough or lost response to a previous biological treatment or • A previous biological treatment was not tolerated, or • TNF-α inhibitors are not suitable	Matches recommendations for risankizumab in TA888 and so EAG considers this appropriate
Intervention	Mirikizumab	Mirikizumab (Induction: 900 mg by IV infusion Q4W. Maintenance: 300 mg by SC injection every 4 weeks after completion of induction dosing. Full maintenance dose from 1 200 mg pre-filled pen and 1 100 mg pre-filled pen)	N/A
Comparators	At least one of the following treatments, according to NICE guidance: • TNF-α inhibitors • Ustekinumab • Vedolizumab • Risankizumab • Upadacitinib	• Primary comparator: Risankizumab • Supportive comparators: • Ustekinumab • Vedolizumab	More robust evidence for ustekinumab to be the primary comparator, rather than risankizumab
Outcomes	• Disease activity (remission, response, relapse) • Mucosal healing • Surgery • Hospitalisation rates • Adverse effects of treatment • HRQoL	• Measures of disease activity (clinical remission and relapse, endoscopic response) • Mucosal healing (endoscopic remission, histologic remission) • Adverse Events • HRQoL (EQ-5D-5L, IBD-Q) • Bowel urgency	Appropriate

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Treatment pathway

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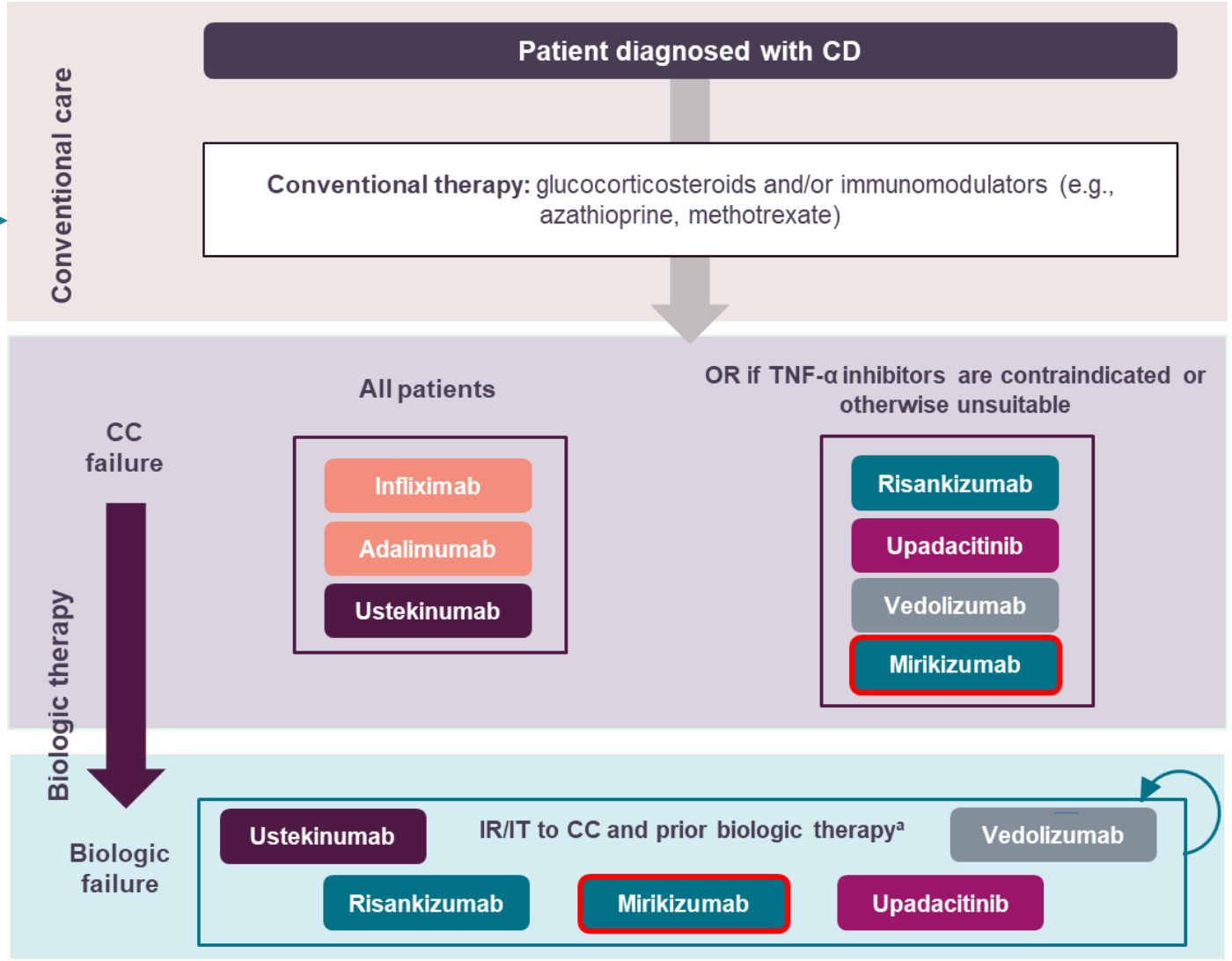
EAG clinical experts: *Conventional therapies being used less; increasingly taking biologics 1L*



Treatment choice, including switching and cycling, based on factors such as failure to respond, loss of response, previous therapies received, or contraindication or other unsuitability

From company submission

[a]Following relapse on biologic therapies, patients are switched onto an alternative biologic therapy that has not been used previously.
CD: Crohn's disease; CT: conventional therapy; IR: inadequate response; IT: intolerant; TNF-α: tumour necrosis factor-alpha.

VIVID-1 trial results: mirikizumab vs. ustekinumab

% achieving endoscopic response

Population	Miri	Ustek	Risk difference (95% CIs)
Week 12			
PAS	[redacted]	[redacted]	[redacted]
BF	[redacted]	[redacted]	[redacted]
CCF	[redacted]	[redacted]	[redacted]
Week 52			
PAS	[redacted]	[redacted]	[redacted]
BF	[redacted]	[redacted]	[redacted]
CCF	[redacted]	[redacted]	[redacted]

% achieving endoscopic remission

Population	Miri	Ustek	Risk difference (95% CIs)
Week 12			
PAS	[redacted]	[redacted]	[redacted]
BF	[redacted]	[redacted]	[redacted]
CCF	[redacted]	[redacted]	[redacted]
Week 52			
PAS	[redacted]	[redacted]	[redacted]
BF	[redacted]	[redacted]	[redacted]
CCF	[redacted]	[redacted]	[redacted]

- Percentage achieving endoscopic response was similar between mirikizumab and ustekinumab for PAS group and both subgroups at both wk 12 and wk 52
- Non-inferiority margins not used for endoscopic response, but differences between treatments non-significant
- Same patterns observed for endoscopic remission

* Based on non-inferiority margin of 10%; BF: biologic failed; CCF: conventional care failed; CI: confidence interval; PAS: primary analysis set;

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Network Meta Analysis

Outcomes and included studies

Company NMA:

- 96 studies identified, 26 considered for inclusion; 22 induction and 14 maintenance
- Following outcomes were included, for BF and CCF subgroups
  - **Induction period – efficacy and safety outcomes;** Enhanced clinical response; Clinical remission; Endoscopic response; Endoscopic remission; Serious adverse events; All-cause discontinuations.
  - **Maintenance period – efficacy outcomes;** Clinical remission.

Overview of studies included in induction NMAs

Study	Intervention	Included for CCF population?	Included for BF population?	Included for overall (mixed) population (safety)?
ADVANCE	RKZ	✓	✓	✓
CLASSIC I	ADA	✓	–	✓
Faegan 2017	RKZ	–	–	✓
GAIN	ADA	–	✓	✓
GALAXI 1	UST	✓	✓	✓
GEMINI 2	VDZ	✓	✓	✓
GEMINI 3	VDZ	✓	✓	✓
MOTIVATE	RKZ	–	✓	✓
Sandborn 2012	UST	–	✓	✓
SEAVUE	UST/ADA	✓	–	–
Targan 1997	IFX	✓	–	–
U-EXCEED	UPA	–	✓	✓
U-EXCEL Study	UPA	✓	–	✓
UNITI 1	UST	–	✓	✓
UNITI 2	UST	✓	–	✓
VIVID-1	UST/MIRI	✓	✓	✓
Watanabe 2011	ADA	✓	✓	✓
Watanabe 2020	VDZ	✓	✓	✓

ADA = adalimumab; BF - biologic failure; CCF - conventional care failure; IFX = infliximab; MIRI = mirikizumab; RKZ = risankizumab; UPA = upadacitinib; UST = ustekinumab; VED = vedolizumab.

Network Meta Analysis

Included studies

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Overview of studies included in maintenance NMAs

Study	Intervention	Maintenance period (weeks)	Study design	Included for CCF population?	Included for BF population?
ACCENT I	IFX	52	re-randomised;	✓	
CHARM	ADA	52	re-randomised	✓	✓
FORTIFY	RKZ	52	re-randomised	✓	✓
GEMINI 2	VDZ	46	re-randomised	✓	✓
IM UNITI	UST	44	re-randomised	✓	✓
SEAVUE	UST/ADA	44	treat-through	✓	
U-ENDURE	UPA	52	re-randomised	✓	✓
VISIBLE 2	VDZ	46	re-randomised	✓	✓
VIVID-1	UST/MIRI	40	treat-through	✓	✓
Watanabe 2020	VDZ	46	re-randomised	✓	✓

NOTE: In re-randomised studies, generally only induction responders continue to maintenance, while in treat-through trials both responders and non-responders proceed to maintenance

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ADA = adalimumab; BF - biologic failure; CCF - conventional care failure; IFX = infliximab; MIRI = mirikizumab; RKZ = risankizumab; UPA = upadacitinib; UST = ustekinumab; VED = vedolizumab.

Other relevant TAs

	TA888 - Risankizumab	TA905 - Upadacitinib	TA456 - Ustekinumab
Recommendation wording	Risankizumab is recommended as an option for treating moderately to severely active Crohn's disease in people 16 years and over, only if: • the disease has not responded well enough or lost response to a previous biological treatment, or • a previous biological treatment was not tolerated, or • tumour necrosis factor (TNF)-alpha inhibitors are not suitable.	Upadacitinib is recommended as an option for treating moderately to severely active Crohn's disease in adults, only if: • the disease has not responded well enough or lost response to a previous biological treatment or • a previous biological treatment was not tolerated or • tumour necrosis factor (TNF)-alpha inhibitors are contraindicated.	Ustekinumab is recommended, within its marketing authorisation, as an option for treating moderately to severely active Crohn's disease, that is, for adults who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNF-alpha inhibitor or have medical contraindications to such therapies.
TA type	Company initially submitted cost-utility model (deemed 'not suitable for decision marking'). Then submitted cost comparison	Cost comparison	Cost utility and cost comparison
Comparators	Vedolizumab	Ustekinumab and vedolizumab	Infliximab, adalimumab and vedolizumab

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