The NICE vs SMC Cost Comparison Pathways – How Similar are They?

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OBJECTIVES

- Review and compare recent FTA submitted to the NICE with the SMC cost-comparison based pathways:
  - Compare and contrast the suitability of the NICE and SMC pathways in providing fast access for patients to cost neutral or cost saving drugs.
  - Explore the use and acceptance of cost-comparison models submitted to NICE and the SMC.

BACKGROUND

- The National Institute for Health and Care Excellence (NICE) fast-track cost-comparison appraisals (FTA) process, now the "cost-comparison" pathway, aims to allow expedited reimbursement decisions for new health technologies that offer similar or better benefits at similar or reduced costs compared to approved technologies in the same indication.[1,2]
- The Scottish Medicines Consortium (SMC) effectively offers two cost-comparison pathways:
  - An abbreviated submission process, introduced as a temporary COVID-19 measure, for medicines where alternatives within the same therapeutic class are already available for the same indication.[3] The SMC are now committed to using this process long-term.[4]
  - A full SMC submission using a cost-comparison model.

METHODS

- In December 2022, the ten most recent NICE FTAs with published committee papers were identified and compared to the equivalent SMC submission (i.e. the submission for the same heath technology in the same indication).
- For each appraisal, a pre-formatted extraction grid was used to capture detailed information regarding the comparative efficacy evidence provided, the model structure and costs included, any critiques by the External Assessment Group (EAG) or the New Drugs Committee (NDC), as well as the key differences and similarities between the NICE and SMC appraisals.

RESULTS

- The ten most recent NICE FTAs spanned several therapeutic areas including arthritis (n=3), ophthalmology (n=4), plaque psoriasis (n=2), and multiple sclerosis (n=1) and went back as far as February 2021.
- **Figure 1** summarizes the number of FTAs with equivalent SMC submissions and the pathway used. **Table 1** provides a summary of the eight NICE FTAs and their SMC equivalent submissions.
- The full submission for SMC2272 was published in September 2020, before the abbreviated submission process was introduced. five of the remaining seven (71%) of the NICE FTAs were submitted via the SMC abbreviated submission process. All of the submissions to both NICE and the SMC received positive recommendations.

Equivalent SMC abbreviated submissions

- The timelines from submission to publication of advice for the SMC could not be determined from the information provided in the detailed advice document.
- The SMC report that a full submission takes 18 weeks from scheduling to publication, however, there are currently substantial delays between submission and scheduling.[5] On the other hand, the abbreviated submission process takes 18 weeks from submission to publication and is a much less resource intensive process.[4,5]
- In general, the ten identified NICE FTAs took longer than the usual 18 weeks for SMC abbreviated submissions (17–68 weeks).

Equivalent SMC full submissions

- The three cost-comparison models submitted to NICE and the SMC for full submissions are summarized in **Table 1**.
- Overall, for NICE FTAs submitted via an SMC full submission, critiques from the EAG and NDC on the comparators and modeling approaches were comparable (**Table 2**), particularly regarding cost calculations such as criticism around inputs for dosing and frequency of administrations. Potential reasons the three full SMC submissions were not considered for the abbreviated submission pathway, as considered by the authors, are also provided in **Table 2**.

1 Comparisons between NICE FTAs and their equivalent SMC submissions

Reference number	Intervention	Indication	Comparators	Cost categories included: Acquisition NICE	Acquisition SMC	Administration NICE	Administration SMC	Resource use NICE	Resource use SMC	AE NICE	AE SMC	Additional costs considered NICE	Additional costs considered SMC
NICE FTAs submitted via SMC abbreviated submissions													
TA820 SMC2508	Brolucizumab	Visual impairment due to DMO	NICE: aflibercept and ranibizumab; SMC: NR									Cost of blindness	
TA803 SMC2459	Risankizumab	Active psoriatic arthritis	NICE: guselkumab; SMC: NR									Disease-related costs	
TA800 SMC2512	Faricimab	Wet age-related MD	NICE: aflibercept and ranibizumab; SMC: NR									Cost of diagnostic testing	
TA794 SMC2444	Diroximel fumarate	Active relapsin-remitting MS	NICE: dimethyl fumarate; SMC: NR										
TA723 SMC2410	Bimekizumab	Plaque psoriasis	NICE: risankizumab, ixekizumab, and brodalumab; SMC: NR									One-off cost of diagnosis	
NICE FTAs submitted via SMC full submission													
TA829 SMC2480	Upadacitinib	Active AS	NICE: secukinumab and ixekizumab; SMC: adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, and secukinumab				Monitoring only					N/A	N/A
TA799 SMC2499	Faricimab	DMO	NICE and SMC: aflibercept and ranibizumab									N/A	N/A
TA672 SMC2272	Brolucizumab	Neovascular (wet) age-related MD	NICE and SMC: aflibercept and ranibizumab									One-off cost of diagnosis	One-off cost of diagnosis

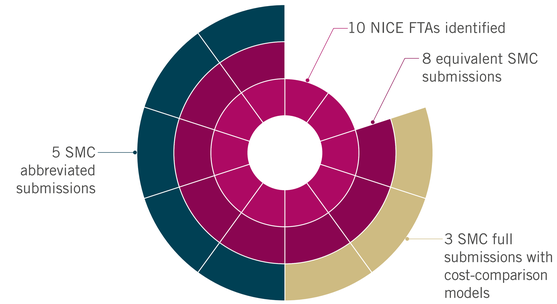
AE: adverse event; **AS:** ankylosing spondylitis; **DMO:** diabetic macular edema; **FTA:** fast-track appraisal; **MD:** macular degeneration; **MS:** multiple sclerosis; **N/A:** not applicable; **NICE:** National Institute for Health and Care Excellence; **NR:** not reported; **SMC:** Scottish Medicines Consortium.

2 Review group concerns regarding cost-comparison approach for the three NICE FTAs that used a full submission for the equivalent SMC submission

Reference number	EAG criticism	NDC criticism	SMC abbreviated submission criteria	Potential rationale for not submitting via abbreviated submission
TA829 SMC2480	• Preferred to include monitoring costs. • Assumption of equivalent discontinuation rates uncertain. • Time horizon increased from five years to nine years.	• Discontinuation rate data for upadacitinib were only available for 1 year, therefore there is uncertainty in assuming the rate is unchanged across the 5-year time horizon.	1. Similar clinical effectiveness to other medicines within class to be demonstrated in simple terms. 2. The new medicine should be pro rata cost or less, or have limited budget impact, versus within class comparators. This cost comparison is based on acquisition cost only, taking account of any patient access schemes where relevant. 3. The populations treated by medicines that are within class should be similar.	• Upadacitinib is a Janus kinase inhibitor whereas the comparators are TNFa inhibitors (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab) or IL-17a inhibitors (secukinumab) meaning within-class clinical equivalence could not be demonstrated.
TA799 SMC2499	• Uncertainty around number of faricimab injections needed beyond two years.	• Uncertainty around assumption of difference in frequency of administration . • Assumption of monitoring during treat-and-extend regimen may not be appropriate.		• Criteria appear to be met; faricimab is an Ang-2 and VEGF-A inhibitor and aflibercept and ranibizumab are both VEGF inhibitors. • Differences in administration frequencies between the intervention and comparators would have not been captured in the abbreviated submission process, as only the acquisition costs are considered.
TA672 SMC2272	• Dosing used in clinical trials may not be reflective of clinical practice. • Estimate for number of injections applied in year 1 and year 2 was inappropriate.	• Approach for calculating costs for aflibercept and ranibizumab is inappropriate as the total cost for aflibercept and ranibizumab is dependent on assumptions as to weights for individual regimens. • Uncertainty around costs associated with discontinuation due to progression to bilateral disease.		• Appears that criteria would likely have been met; brolucizumab is a VEGF-A inhibitor and aflibercept and ranibizumab are also both VEGF inhibitors. • However, this submission predated the abbreviated submission pathway.

Ang-2: angiopoietin-2; **IL-17a:** interleukin-17A; **EAG:** External Assessment Group; **NDC:** New Drugs Committee; **TNFa:** tumour necrosis factor alpha; **VEGF:** vascular endothelial growth factor.

1 Summary of submissions identified



FTA: fast-track appraisal; **NICE:** National Institute for Health and Care Excellence; **SMC:** Scottish Medicines Consortium.

CONCLUSIONS

- Our research suggests cost-comparison models developed for NICE FTAs are likely to require minimal adaptations to be suitable for SMC full submissions, as the modeling approaches and costs considered were broadly similar. Relative to the NICE FTA submissions, the SMC abbreviated submissions required a much simpler comparison of acquisition costs only.
- 71% of the eligible/published NICE FTAs identified used the abbreviated submission pathway, suggesting there could be scope for NICE to simplify the FTA process for some indications and treatments if they are comfortable with the level of review provided by the SMC abbreviated pathway.
- These lessons from the SMC abbreviated submission pathway may be valuable to inform how NICE can further streamline its piloting of Proportional Approach to Technology Appraisals (PATT).[6,7]

References

1. National Institute for Health and Care Excellence. Technology appraisal processes. Available at: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/process. [Last accessed: 10 March 2023]; **2.** National Institute for Health and Care Excellence. NICE health technology evaluations: the manual. 2022. Available at: https://www.nice.org.uk/process/pmg36/resources/nice-health-technology-evaluations-the-manual-pdf-72286779244741. [Last accessed: 28 March 2023]; **3.** Scottish Medicines Consortium. Abbreviated submissions. Available at: https://www.scottishmedicines.org.uk/how-we-decide/abbreviated-submissions/#:~:text=Abbreviated%20Submissions.%20SMC%20introduced%20the%20abbreviated%20%28therapeutic%20class%29,committee%20members%20by%20streamlining%20decisions%20on%20certain%20medicines. [Last accessed: 10 March 2023]; **4.** Scottish Medicines Consortium. Speeding up access to new medicines in Scotland: abbreviated process. Available at: https://www.scottishmedicines.org.uk/about-us/latest-update/speeding-up-access-to-new-medicines-in-scotland/. [Last accessed: 20 March 2023]; **5.** Scottish Medicines Consortium. Timelines & submission scheduling. Available at: https://www.scottishmedicines.org.uk/making-a-submission/timelines-submission-scheduling/. [Last accessed: 10 March 2023]; **6.** National Institute for Health and Care Excellence. Increasing the capacity of our technology appraisals - the proportionate way. 2022. Available at: https://www.nice.org.uk/news/blog/increasing-the-capacity-of-our-technology-appraisals-the-proportionate-way. [Last accessed: 21 March 2023]; **7.** National Institute for Health and Care Excellence. Taking a proportionate approach to technology appraisals. 2022. Available at: https://www.nice.org.uk/about/what-we-do/proportionate-approach-to-technology-appraisals. [Last accessed: 21 March 2023].

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