A Tale of Four Countries: Comparing Reimbursement Submission Requirements in Ireland, England, Wales, and Scotland

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BACKGROUND

- The requirements for a Health Technology Assessment (HTA) submission vary among Ireland and the three countries that comprise the United Kingdom (UK):
  - The Republic of Ireland: National Centre for Pharmacoeconomics (NCPE)
  - The UK:
    - England and Wales: National Institute for Health and Clinical Excellence (NICE)
    - Scotland: Scottish Medicines Consortium (SMC).
    - Wales: All Wales Medicines Strategy Group (AWMSG)

OBJECTIVES

- To compare the requirements for submission to each HTA body.
- To determine whether the likelihood of reimbursement in these markets is linked to these submission requirements.

METHODS

- Examined guidelines for submission of an HTA dossier, as issued by the NCPE,[1] NICE,[2] SMC,[3] and AWMSG[4] on their respective Web sites.
- Compared dossier requirements issued by NCPE, NICE, SMC, and AWMSG and compiled a checklist of requirements.
- Investigated the 26 HTAs reviewed by the NCPE and the 30 most recently reviewed HTAs from NICE, SMC, and AWMSG and recorded the recommendations.
- Excluded the following submissions from the analysis:
  - NICE multiple technology appraisals (only single technology appraisals included)
  - Resubmissions
  - Nonsubmissions.

RESULTS

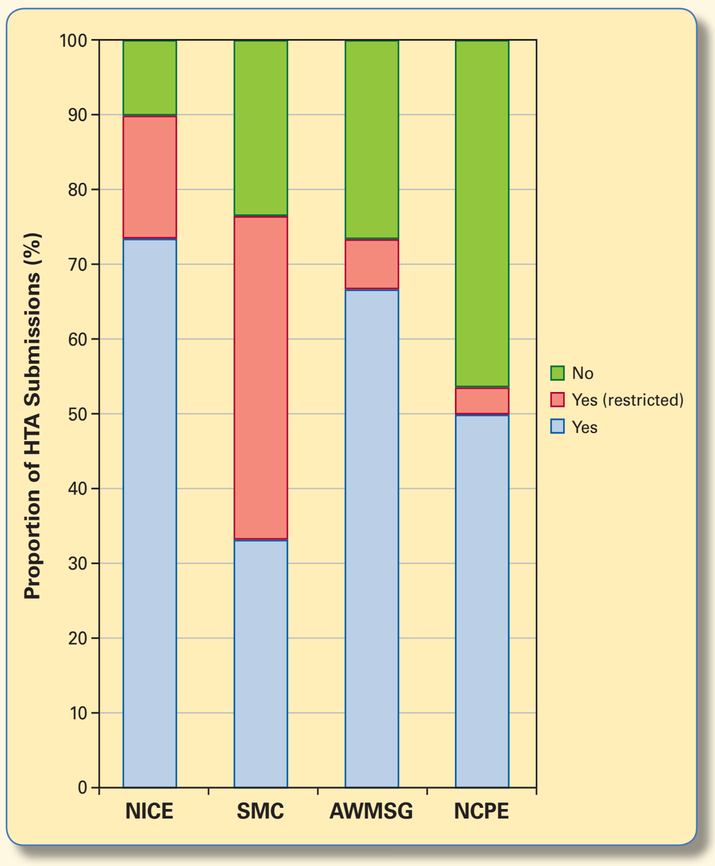
Requirements for HTA (Table 1)

- Economic analysis is the key part of an NCPE submission, although there are no specific requirements or templates for clinical data.
- Requirements for the NICE STA are the most stringent, followed by the SMC and AWMSG.
- Both the NICE STA and the SMC require a systematic review of the relevant clinical data for the technology and its comparators, including a systematic search strategy and development of a Quality of Reporting of Meta-analyses (QUOROM) statement flow diagram. The NICE STA and the SMC submissions also require systematic searches of both resource use and health-related quality of life (HRQOL) data.
- Furthermore, unlike the other HTA bodies investigated, the NICE STA requires a systematic review of relevant cost-effectiveness data for the technology, including a systematic search strategy; a QUOROM statement flow diagram; and a critical appraisal of all relevant randomised controlled trial (RCT) evidence, non-RCT evidence, and cost-effectiveness evaluations.

Summary of Recent Reimbursement Decisions From HTA Bodies

- Review of the total 26 HTAs submitted to NCPE and the 30 most recently reviewed submissions for NICE, SMC, and AWMSG indicated that:
  - NICE had the highest acceptance rate; 22 of the 30 submissions resulted in reimbursement in the indicated population, and a further 5 in restricted populations (Figure 1).
  - The SMC had the second highest acceptance rate; a total of 23 of the 30 HTAs were successful, although 13 of these were in a restricted population.
  - Of the AWMSG HTAs, 22 of the 30 were successful, including 2 in restricted populations.
  - The NCPE had the lowest acceptance rate; only 15 of the 26 were successful, including 2 that were restricted to a certain population.

Figure 1. Summary of Recent Reimbursement Decisions From NICE, SMC, AWMSG, and NCPE



CONCLUSIONS

- Rates of success vary among different HTA bodies, although there appears to be a direct correlation between the level of detail provided on the submission requirements and the likelihood of reimbursement.
- Several factors contribute to the reimbursement decision in each market. However, it appears that the availability of detailed guidance on the information required leads to submission of a comprehensive and relevant evidence package, which may be one of the factors in the decision.
- It is important to ensure that the reimbursement requirements for each HTA body are targeted appropriately to ensure successful market access.

REFERENCES

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Table 1. Checklist for Submission to the NCPE, NICE (STA only), SMC, and AWMSG

Submission Requirement	NCPE[1]	NICE STA[2]	SMC[3]	AWMSG[4]
Disease context information	No guidance provided	✓	✓	✓
Equity and equality discussion	No guidance provided	✓	✗	✗
Clinical evidence				
Systematic review of relevant clinical data for the technology and its comparators, including systematic search strategy and development of QUOROM statement flow diagram	No guidance provided	✓	✓	✗
Critical appraisal of relevant RCT and non-RCT evidence	No guidance provided	✓	✗	✗
Meta-analysis, where appropriate, including assessment of heterogeneity and development of combined results	No guidance provided	✓	Not essential	Not essential
Indirect and mixed treatment comparisons, if data from head-to-head trials are not available	No guidance provided	✓	✓	Not essential
Interpretation of the clinical evidence	No guidance provided	✓	✓	✓
Cost effectiveness				
Systematic review of relevant cost-effectiveness data for the technology, including systematic search strategy and development of QUOROM statement flow diagram	✗	✓	✗	✗
Critical appraisal of identified cost-effectiveness evaluations	✗	✓	✗	✗
De novo cost-effectiveness analysis				
Description of the patient population	✓	✓	✓	✓
Description of model structure	✓	✓	✓	✓
Description of key features of the analysis, including the time horizon, cycle length, whether the health effects were measured in QALYs, discount of 3.5% for utilities and costs, perspective (NHS and PSS)	✓	✓	✓	✓
Description of the technology and comparator(s)	✓	✓	✓	✓
Description of clinical input data	✓	✓	✓	✓
Systematic search of HRQOL data	✗	✓	✓	✗
Utility estimates	EQ-5D data not essential	Preference for EQ-5D collected from patients	Preference for validated generic utility instrument such as the EQ-5D	EQ-5D data not essential
Describe how the clinical management of the condition is currently costed in terms of NHS reference costs and the PbR tariff	NR	✓	✗	✗
Systematic search of resource use data	✗	✓	✓	✗
Costs, QALYs , and incremental cost per QALY gained	Cost per QALY gained analysis not essential	✓	✓	Cost per QALY gained analysis not essential
Cost-effectiveness acceptability curves, including cost-effectiveness acceptability frontiers	Not essential	✓	✓	Not essential
PSA	Not essential	✓	Not essential	Not essential
Budget impact analysis	No guidance provided	✓	✓	✓

✓ = guidance specifically requests this information.
✗ = guidance does not request this information.
EQ-5D = EuroQol EQ-5D questionnaire; NHS = National Health Service; NR = not relevant; PbR = payment by results; PSA = probabilistic sensitivity analysis; PSS = Personal Social Services; QALY = quality-adjusted life-year.