NICE National Institute for Health and Care Excellence

Guidance producer:	**Midlands Therapeutics Review and Advisory Committee**
Guidance product:	**Commissioning support summaries**
Date:	**13 March 2017**
Version:	**1.3**

Final Accreditation Report

Contents

Introduction

The NICE Accreditation Programme recognises organisations that demonstrate high standards in producing health or social care guidance. Users of the accredited guidance can therefore have high confidence in the quality of the information. Organisations may publicly display a seal of approval called an Accreditation Mark for 5 years after their processes have been accredited. The process for accrediting producers of guidance and recommendations for practice is described in the process manual.

Accreditation recommendation

NICE has accredited the process used by the **Midlands Therapeutics Review and Advisory Committee** to produce **Commissioning support summaries**. Accreditation is valid for 5 years from **7 March 2017** and is retrospectively applicable to guidance produced using the processes described in the **MTRAC Handbook (2017)**.

Background to the guidance producer

The Midlands Therapeutics Review and Advisory Committee (MTRAC) is based at the not-for-profit Keele Centre for Medicines Optimisation (KCMO), which is part of Keele University. It produces commissioning support summaries, which are evidence summaries and advice for commissioners around new medicines. The commissioning support summaries are restricted to paying subscribers for a period of 3 months, before they are made available to the public.

Commissioning support summaries are designed to be concise and fit on 1 double-sided sheet of paper. They describe the evidence around efficacy, safety and cost impact. They also provide advice on a medicine's place in therapy and any important practical considerations, where this is supported by the evidence. Further information is provided in accompanying evidence review documents.

Summary

The Accreditation Advisory Committee considered that the processes used by the Midlands Therapeutics Review and Advisory Committee to produce Commissioning support summaries demonstrated compliance with 23 of the 25 criteria for accreditation.

The scope and purpose of the guidance is clear. Development is multidisciplinary, including target users and lay representatives. Evidence is gathered and appraised systematically and transparently. Risks and benefits are considered and it is clear how decisions are reached. The guidance is reviewed by the wider community of subscribers and there are processes for both scheduled and ad-hoc updating of the guidance.

The guidance is suitable for the specified target audience, providing advisory points from the evidence along with details of any pharmacological treatment options. The guidance considers organisational and financial barriers and is supported by slide sets to aid implementation. An annual survey monitors uptake of the guidance. The guidance is funded by subscriptions. Editorial independence is maintained through the breadth of the MTRAC membership, given the necessity of involving target users who are subscribers in development. All MTRAC members and specialist advisers are required to declare any interests, but it is not clear that peer reviewers are required to declare any interests. Consequently there is some possibility of bias in the process.

Suggestions to improve the process used to develop commissioning support summaries include:

- Making it explicit in the process that external peer reviewers should declare any interests and ensuring they are managed appropriately
- Formally documenting the annual uptake survey process

Professor Martin Underwood

Chair, Accreditation Advisory Committee

March 2017

Implementation

Following accreditation, guidance from the accredited producer will be identified on NICE Evidence Search by the Accreditation Mark. The accredited guidance producer is also granted a royalty-free, worldwide licence to use the NICE Accreditation Mark in accordance with the Conditions and Terms of Use. Providing these conditions are met, a guidance producer's accreditation will last for 5 years from the date of the accreditation decision.

Accredited guidance producers must take reasonable steps to ensure the accredited processes are followed when generating the type of evidence for which they are accredited. Accredited guidance producers should have quality assurance mechanisms in place and must inform NICE accreditation within 30 days if any significant change is made to a process.

Figure 1: The NICE Accreditation Mark

Appendix A: NICE Accreditation analysis

The Accreditation Advisory Committee considered the following analysis of the guidance producer's compliance with NICE Accreditation criteria, which covers 6 discrete domains. The full analysis leading to the accreditation decision is shown below.

	Criterion	Evidence for meeting the criterion	Accreditation decision
Scope and purpose	**Does the guidance producer have a policy in place and adhered to that requires them to explicitly detail:**		
	1.1 Overall objective	The process[1] and the hosting website for the guidance state that the overall objective is to inform prescribing of new drugs. The process[1] requires the guidance to include background information on the topic. The guidance examples[2,3,4] clearly state their overall objectives.	Criterion met
	1.2 The clinical, healthcare or social questions covered	The process[1] states that key questions around the safety, efficacy and cost-effectiveness of medicines should be included in the guidance and are provided as section headings in the guidance template. The process[1] states that the key questions should be stated in the search strategies in the accompanying evidence review documents. The key questions are clear in the guidance examples[2,3,4] and their accompanying evidence reviews[5,6,7].	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	1.3	Population and/or target audience to whom the guidance applies	The process[1] states that the target audience is local NHS decision-making bodies such as area prescribing committees and other local formulary or drug and therapeutics committees. The guidance template[1] is clear that it is aimed at commissioners and prescribers. It includes sections describing the condition and medicine in question, in which the patient population is described[1]. The intended audience and target population are clear in the guidance examples[2,3,4].	Criterion met
	1.4	Guidance includes clear recommendations in reference to specific clinical, healthcare or social circumstances	The process[1] states that the guidance should include the commissioning guidance points agreed by the committee, based on their discussion of the evidence review. The guidance template[1] includes a prominent section for these points. The guidance examples[2,3,4] provide advice on the place in therapy, dosages and information on relative costs to guide decision making.	Criterion met
Stakeholder involvement	**Does the guidance producer have a policy in place and adhered to that means it includes:**			
	2.1	Individuals from all relevant stakeholder groups, including patient groups, in developing guidance	The process[1] states that the MTRAC is an independent multidisciplinary committee of general practitioners, various prescribers, a health economist, topic specialists and 3 lay members (with 2 attending each meeting). The MTRAC membership list[8] demonstrates the involvement of relevant professionals and lay people.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	2.2	Patient and service user representatives and seeks patient views and preferences in developing guidance	The process[1] states that the MTRAC includes 3 lay members, of which 2 should attend each meeting. The role specification[9] states that they are offered training and support to help them participate as equal members. The MTRAC membership list[8] demonstrates the involvement of lay people.	Criterion met
	2.3	Representative intended users in developing guidance.	The process[1] states that the MTRAC includes target users such as prescribers and general practitioners, along with other topic-specific experts as required. The MTRAC membership list[8] demonstrates the involvement of target users of the guidance.	Criterion met
Rigour of development	**Does the guidance producer have a clear policy in place that:**			
	3.1	Requires the guidance producer to use systematic methods to search for evidence and provide details of the search strategy	The process[1] requires systematic searches based on questions around the safety, efficacy and costs of medicines. The process[1] suggests databases for different kinds of information and provides a form for documenting searches in detail. It states that search strategies should be included in the evidence review documents that accompany the guidance[1]. Examination of the evidence reviews[5,6,7] confirms the search strategies are provided.	Criterion met
	3.2	Requires the guidance producers to state the criteria and reasons for inclusion or exclusion of evidence identified by the evidence review	The process[1] states that the inclusion and exclusion criteria for evidence should be documented in search protocols in the evidence reviews, which accompany the guidance. The evidence reviews[5,6,7] provide the search strategies and the inclusion and exclusion criteria for evidence.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	3.3	Describes the strengths and limitations of the body of evidence and acknowledges any areas of uncertainty	The process[1] requires the evidence reviews to grade evidence on a scale from 1++ for high quality meta-analyses to 4 for expert opinion. This can be seen in the evidence reviews examined[5,6,7]. The guidance template[1] includes a section on the strength of the evidence base overall. The guidance examples[2,3,4] include this information.	Criterion met
	3.4	Describes the method used to arrive at recommendations (for example, a voting system or formal consensus techniques like Delphi consensus)	The process[1] states that recommendations are arrived at by consensus. If consensus is not possible the Chair makes the final decision, and is obliged to choose the most conservative option[1]. The guidance[2,3,4] does not provide this information as it is intended to be very succinct, but the process[1] is available online to subscribers.	Criterion met
	3.5	Requires the guidance producers to consider the health benefits against the side effects and risks in formulating recommendations	The process[1] states that information on risks, side-effects and adverse events should be gathered from studies and summaries of product characteristics. The guidance and evidence review templates include sections on potential adverse events[1]. The guidance examples[2,3,4] and their accompanying evidence reviews[5,6,7] include information on safety and efficacy, including adverse events.	Criterion met
	3.6	Describes the processes of external peer review	The process[1] states that the guidance is reviewed by the Keele Oversight Group (KOG), which is a multidisciplinary group of subscribers who commission and quality assure the guidance. Although 2 members of the KOG are on the MTRAC[8], they represent their professions rather than representing the KOG. The guidance is reviewed by the wider membership of the KOG and not the 2 individuals who are on the MTRAC, meaning the review is sufficiently external to guidance development.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	3.7	Describes the process of updating guidance and maintaining and improving guidance quality	The process[1] states that the guidance is reviewed 5 years after publication, or sooner, if triggered by practice changes, new trials evidence or the publication of new or updated NICE guidance. The process[1] is available online to subscribers. The hosting website[10] states that the guidance will be reviewed 5 years after publication, or sooner if important new evidence emerges.	Criterion met
Clarity and presentation	**Does the guidance producer ensure that:**			
	4.1	Recommendations are specific, unambiguous and clearly identifiable	The process[1] provides a template for guidance, including a prominent box on the first page for the key advisory points. The guidance examples[2,3,4] provide advice that is clearly identifiable and specific to the medicines in question. The advisory points[2,3,4] are less directive than explicit recommendations, highlighting relevant points from the evidence to guide decision making, but they are suitable for the target audience.	Criterion met
	4.2	Different options for the management of the condition or options for intervention are clearly presented	The process[1] states that the evidence reviews should identify and discuss current treatment options. The evidence reviews inform the guidance and are published alongside them[1]. The example guidance[2,3,4] and their accompanying evidence reviews[5,6,7] discuss current pharmacological treatment options for the conditions covered by the medicines.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	4.3 The date of search, the date of publication or last update and the proposed date for review are clearly stated	The standard format for guidance includes the date of publication[1]. The dates of search are documented in the search protocols provided in the evidence summaries[1]. The process[1] and the hosting website[10] both state that guidance will be reviewed 5 years after publication, or sooner if important new evidence emerges. The guidance examples[2,3,4] and accompanying evidence reviews[5,6,7] provide the required dates.	Criterion met
	4.4 The content of the guidance is suitable for the specified target audience. If patients or service users are part of this audience, the language should be appropriate.	The guidance template[1] summarises the key information on 1 sheet of paper, which should help busy commissioners and prescribers. The template[1] includes headings addressing key questions around efficacy, safety and cost, along with a prominent box for the main advice. Additional background information is provided in the evidence review documents that accompany the guidance[1]. The example guidance[2,3,4] and evidence reviews[5,6,7] are suitable for the target audience.	Criterion met
Applicability	**Does the guidance producer routinely consider:**		
	5.1 Publishing support tools to aid implementation of guidance	The process[1] includes an essential shared-care agreement (ESCA) template for situations in which the evidence review suggests an ESCA should be used. The guidance is accompanied by the evidence reviews[5,6,7] that explain the advice in more detail, and by slide presentations[11,12,13] for explaining the guidance to local formulary committees.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	5.2	Discussion of potential organisational and financial barriers in applying its recommendations	The process[1] requires consideration of the financial implications of prescribing including unit costs and the likely total costs, with cost comparisons where possible. The process[1] also aims to consider practical issues such as initiation, monitoring and the need for specialist support. The guidance[2,3,4] provides details of the likely cost impacts and states where specialist support is required.	Criterion met
	5.3	Review criteria for monitoring and/or audit purposes within each product.	An annual uptake survey[14] provides evidence of a process to monitor the uptake of guidance, although this is not explicitly stated in the process[1].	Criterion met
Editorial independence	**Does the guidance producer:**			
	6.1	Ensure editorial independence from the funding body	The process[1] states that guidance development is funded by subscriptions and that the MTRAC includes subscribers. This is acceptable because subscribers are the target users of the guidance and need to be involved to ensure adequate stakeholder involvement. The breadth of MTRAC membership[8] ensures the views of the subscribers do not influence the recommendations disproportionately.	Criterion met
	6.2	Demonstrate transparency about the funding mechanisms for its guidance	The process[1] and the hosting website[10] state that guidance development is funded by guidance subscriptions. Subscribers will be aware that they have paid for the guidance. The guidance is also made available to non-subscribers after 3 months, which is stated on the website[10].	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	6.3 Record and state any potential conflicts of interest of individuals involved in developing the recommendations	The process[1] explains how different kinds of interest are declared and managed, for example through recusal or restricted involvement. The Chair cannot have any conflicts for the item under consideration and is replaced for that item if necessary[1]. All MTRAC members[8] are required to declare any interests annually[1]. Specialist advisors to the MTRAC on specific topics must also declare any links to the pharmaceutical industry[1]. The declarations of interest[15] show this process has been followed. It is not clear if peer reviewers are required to declare any interests however.	Criterion not fully met
	6.4 Take account of any potential for bias in the conclusions or recommendations of the guidance	The process[1] is systematic and multidisciplinary with transparent funding. It is as editorially independent as possible, given the necessity of subscriber representation in guidance development. All those directly involved in guidance development must declare any interests[1,15], but it is not clear that this extends to peer reviewers. This allows some possibility of bias in the process.	Criterion not fully met

Criterion	Evidence for meeting the criterion	Accreditation decision
Documents referenced above: 1 MTRAC handbook (2017) 2 Perampanel (Fycompa®) (2016) 3 Safinamide (Xadago®) (2016) 4 Brivaracetam (Briviact®) (2016) 5 Perampanel (Fycompa®) – Evidence review (2016) 6 Safinamide (Xadago®) (2016) – Evidence review (2016) 7 Brivaracetam (Briviact®) (2016) – Evidence review (2016) 8 MTRAC membership list (2017) 9 Lay Member of the MTRAC Committee: Job Description and Person Specification (2016) 10 Hosting website for commissioning support summaries 11 Perampanel (Fycompa®) – slide set (2016) 12 Safinamide (Xadago®) – slide set (2016) 13 Brivaracetam (Briviact®) – slide set (2016) 14 MTRAC annual uptake survey (2016) 15 MTRAC register of interests (2017)		

Appendix B: Bibliography

Appendix B lists the additional information taken into account in the analysis and considered by the committee.

Document name	Description	Location
Enclosure 1 Instructions for accessing information on the KCMO website	Instructions for accessing subscriber area	Supplied
Enclosure 2 Handbook October 2016	Process document	Supplied
Enclosure 3 Person specification and job description for lay member of the committee 2016	Lay member person specification	Supplied
Enclosure 4 MTRAC uptake survey results	Evidence of monitoring	Supplied
Enclosure A MTRAC membership January 2017	Membership list	Supplied
Enclosure B Handbook January 2017	Process document	Supplied
Enclosure C MTRAC anonymised register of interests January 2017	Declarations of interest	Supplied
Enclosure D Declarations of Interest_collected MTRAC	Declarations of interest	Supplied
Enclosure E DRAFT MTRAC guidance on opicapone	Guidance document	Supplied
Enclosure F MTRAC uptake survey results	Survey results	Supplied
Guidance producer feedback form_MTRAC_1.2	Guidance producer feedback form	Supplied
Membership of MTRAC November 2016	Membership list	Supplied
MTRAC - Perampanel update guidance May 2016	Guidance product	Subscriber area of website

Document name	Description	Location
MTRAC anonymised register of interests	Declarations of interest	Supplied
MTRAC Brivaracetam guidance October 2016_subscriber	Guidance product	Subscriber area of website
MTRAC Brivaracetam review final	Guidance product	Subscriber area of website
MTRAC Minutes 19.5.16 web	Meeting minutes	Subscriber area of website
MTRAC Minutes 21.7.16 final	Meeting minutes	Subscriber area of website
MTRAC Safinamide August 2016	Guidance product	Subscriber area of website
MTRAC Safinamide August 2016	Guidance product	Subscriber area of website
MTRAC-Perampanel-update-presentation	Support tool	Subscriber area of website
Safinamide presentation final	Support tool	Subscriber area of website
Safinamide review final Jan 2016	Guidance product	Subscriber area of website

Appendix C: NICE Accreditation Advisory Committee, external advisers and NICE Accreditation team

NICE Accreditation Advisory Committee

The NICE Accreditation Advisory Committee operates as a standing advisory committee of the Board of the National Institute for Health and Care Excellence (NICE). The Committee provides advice to NICE on a framework for accrediting sources of evidence that should be recognised as trusted sources of information for the NHS. The Chair of the Committee is appointed by the NICE Board and the meetings are conducted by the chair or in his/her absence the vice chair. The current Chair is Martin Underwood. A full list of the Accreditation Advisory Committee membership is available on the NICE website. Members are appointed for a period of 3 years. This may be extended by mutual agreement for a further 3 years, up to a maximum term of office of 10 years.

The decisions of the Committee are arrived at by a consensus of the members present. The quorum is set at 50% of committee membership. The Committee submits its recommendations to the NICE Publications executive which acts under delegated powers of the NICE Board in considering and approving its recommendations.

Committee members are asked to declare any interests in the guidance producer to be accredited. If it is considered that there is a conflict of interest, the member(s) is excluded from participating further in the discussions. Committee members who took part in the discussions for this accreditation decision are listed below.

Title	Name	Surname	Role	Organisation
Mr	Richard	Brownhill	Independent health care improvement manager	Royal Bolton Hospitals Trust
Mrs	Susan	Cervetto	Senior Appraisal Pharmacist	All Wales Therapeutics & Toxicology Centre

Mrs	Lynda	Cox	Knowledge and implementation lead (formerly)	NHS England (formerly)
Ms	Ailsa	Donnelly	Lay member	N/A
Ms	Joyce	Epstein	Lay Member	N/A
Dr	Elvira	Garcia	Consultant in Public Health Medicine - Health Protection Lead	NHS Ayrshire & Arran
Mrs	Diana	Gordon	Company Director	DRG Consultants
Dr	Steve	Hajioff	Director of Public Health	Hillingdon Borough Council
Dr	Anthony	Larkin	General Practitioner	The Alexandra Practice
Dr	Mahendra	Patel	Principal Enterprise Fellow (Senior Academic Pharmacist)	University of Huddersfield
Ms	Mandy	Sainty	Research and Development Manager	College of Occupational Therapists
Mr	Duncan	Service	Evidence Manager	SIGN
Dr	Sara	Twaddle	Director of Evidence	Healthcare Improvement Scotland
Prof.	Martin	Underwood	Professor of Primary Care Research,	The University of Warwick

			Director of Warwick Clinical Trials Unit	
Ms	Ruth	Wakeman	Assistant Director of Professional Development and Support	Royal Pharmaceutical Society

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