National Institute for Health and Care Excellence

Health Technology Evaluation

Atogepant for treating migraine [ID6615]
Response to stakeholder organisation comments on the draft remit and draft scope

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	British Association for the Study of Headache	BASH agrees that this topic is appropriate and agrees with the evaluation route	Comments noted. No action required.
	UK Clinical Pharmacy Association (UKCPA) Neurosciences Committee	Single technology appraisal is appropriate	Comments noted. No action required.
	AbbVie Ltd	AbbVie consider the cost-comparison route to be the most appropriate route for this appraisal. The NICE manual section 4.2.20 states that: 'Cost-comparison analyses in a technology appraisal should be used for technologies likely to provide similar	Thank you for your comment. A cost comparison case can be made if a health technology is likely to provide similar or

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		health benefits at similar or lower cost than comparator(s) that are recommended in published NICE guidance for the same population.' As noted in Comment 2: the draft scope table, the relevant population for this appraisal of atogepant is the acute treatment of migraine in adults who have tried at least two triptans and they did not work well enough, or were contraindicated, or not tolerated. Given the similarity in mechanism of action and mode of administration, position in the treatment pathway, relevant patient population [redacted] AbbVie consider this topic meets the criteria for a cost-comparison appraisal.	greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication. NICE will schedule this topic into its work programme as a cost comparison.
	The Migraine Trust	This is an appropriate topic to evaluate, and an appropriate evaluation route.	Comments noted. No action required.
Wording	British Association for the Study of Headache	BASH agrees the wording is appropriate	Comments noted. No action required.
	UK Clinical Pharmacy Association (UKCPA) Neurosciences Committee	Yes	Comments noted. No action required.
	AbbVie Ltd	Yes, the wording of the remit is appropriate.	Comments noted. No action required.

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	The Migraine Trust	Yes	Comments noted. No action required.
Timing	British Association for the Study of Headache	BASH feels having a second atogepant approved for the management of acute attacks of migraine would be beneficial for patients. This evaluation should be timely but it is not urgent.	Comments noted. No action required.
	UK Clinical Pharmacy Association (UKCPA) Neurosciences Committee	Not urgent	Comment noted. No action required.
	AbbVie Ltd	There is an urgency to this appraisal as a large proportion of the 10 million people in the UK who suffer from migraine cannot achieve adequate migraine relief with currently available acute treatment options. , Moreover, current acute treatments may not be suitable for everyone and are contraindicated in some people with migraine. There are currently insufficient migraine-specific treatment options in individuals for whom triptans are ineffective or not well tolerated. Suboptimal acute treatment may increase the risk of disease progression and substantially affects quality of life and work productivity. There is a need for alternative, effective and well tolerated acute treatment options in patients with migraine who have tried at least two triptans and they did not work well enough, or were contraindicated, or not well tolerated. Given the NHS 10-Year Health Plan focus 'from sickness to prevention' as well as 'care closer to home', there is a need for improved earlier management of migraine which could lead to fewer migraine attacks, improved QoL, fewer repeat GP appointments and reduced demand in secondary care by leveraging primary care more efficiently. Additionally, the positive impact on	Thank you for your comment. In any appraisal NICE aims to publish guidance as close as possible to the granting of a marketing authorisation. No action required.

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		reduced absenteeism and improved productivity resulting from better migraine management aligns well to the government priorities of economic growth and increased productivity. Therefore, this appraisal reflects key NHS and broader government priorities and the timing of its scheduling by NICE should be considered accordingly.	
	The Migraine trust	We would say there is an urgency to this appraisal as many people do not have appropriate acute treatment for migraine. This is due to lack of efficacy, side effects, medication overuse from many of the current treatments or medical comorbidities, such as cardiovascular disease, kidney and liver disease, that exclude or limit current acute treatment options. This is exacerbated by the current issue around access to medication already on the market, making it even more important to have atogepant available as soon as possible to help alleviate this issue.	Thank you for your comment. In any appraisal NICE aims to publish guidance as close as possible to the granting of a marketing authorisation. No action required.
Additional comments on the draft remit			

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	British Association for the Study of Headache	Background information is accurate. Suggest add that Migraine is the second highest cause of global disability in the general population*, but takes first place in females aged 15−49 (GBD 2019) Steiner TJ, et al. J Headache Pain 2020;21:137	Thank you for your comment. This has been added to the scope as ‘Migraine is the second highest cause of global disability in the general

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			population but first in females aged between 15 to 49 years.'
	UK Clinical Pharmacy Association (UKCPA) Neurosciences Committee	Complete and accurate	Comment noted. No action required.
	AbbVie Ltd	We note that the burden of disease has not been fully captured in patients suffering from migraine attacks who have tried at least two triptans and these are ineffective or are not well tolerated. We propose the addition of the following paragraph to acknowledge the burden of disease in this population: "While triptans are commonly used for acute treatment, up to 25% of patients are inadequately managed with this treatment option. Moreover, many patients are unable to use triptans due to intolerable side effects or because triptans are contraindicated for them due to risk factors for vascular diseases. Triptans are associated with high discontinuation rates, with 55% of patients discontinuing use, often due to insufficient efficacy, adverse effects, or safety concerns. Therefore, there are currently insufficient acute treatment options in patients with migraine for whom triptans are ineffective or are not well tolerated." The background information is otherwise appropriate and accurate.	Thank you for your comment. To keep the scope concise and broad, we have added your suggestion to highlight the area of unmet need as 'Some people are unable to have triptans because they are ineffective or not well tolerated.'
	The Migraine trust	We would recommended reviewing the following points:	Thank you for your comments. We have

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		• According to IHS classification ICHD-3, migraine attacks typically last between 4 and 72 hours (current information states 2-72). • Latest evidence puts the prevalence of migraine as approximately 1 in 7 (14%) in the UK – a figure that is widely used by us and others. We believe the 10.4% quoted for diagnosed migraine does not reflect the many people living with migraine in the UK who have not seen a healthcare professional or had a formal diagnosis and underestimates the true prevalence of migraine.	reflected these updates in the scope.
Population	British Association for the Study of Headache	Yes	Comment noted. No action required.
	AbbVie Ltd	We propose the wording of the population is updated according to the relevant population atogepant is specifically intended for in this appraisal, which is: 'Adults with migraine requiring acute treatment, who have tried at least two triptans and they did not work well enough, or were contraindicated, or not tolerated.' There is a significant unmet need in patients who cannot tolerate, respond to, or are ineligible to receive the current standard of care, including triptans. During the TA919 appraisal it was recognised that these patients had no approved treatment options and as a result experience substantial disability, medication overuse headache (MOH), impact on work productivity, and caregiver burden. Suboptimal acute treatment may increase the risk of	Thank you for your comment. The population in the scope has been kept broad in line with the proposed marketing authorisation wording. The 'Subgroups' section of the scope has been updated to include the following subgroups, which may better reflect the intended positioning of atogepant: 'people currently having treatment for the prevention of migraine',

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		disease progression, with those with very poor acute treatment efficacy having more than a two-fold increased risk of disease progression.3 The only currently available treatment option in this population is rimegepant, which highlights the need for an alternative, effective and well tolerated treatment option.	'subgroups defined by the number of previous treatments' and 'people for whom triptans do not work well enough, are contraindicated or not tolerated'.
	The Migraine trust	Yes	Comment noted. No action required.
Subgroups	British Association for the Study of Headache	Subgroups suggested in Appendix B are appropriate	Comment noted. No action required.
	UK Clinical Pharmacy Association (UKCPA) Neurosciences Committee	I would consider the population suffering from medication overuse headache secondary to simple analgesic, complex analgesic or triptan overuse. This is important because gepants don't cause medication overuse headache (MOH). MOH is also difficult to treat and require more costly treatment options.	Comment noted. If evidence allows people with MOH will be considered as a sub-group.
	AbbVie Ltd	We note that due to a lack of consensus on the definition of, and clinical distinctiveness of high frequency episodic migraine, the NICE committee have previously concluded that there is insufficient evidence that high frequency episodic migraine is a clinically distinct subgroup during the technology appraisal processes for erenumab (TA682), fremanezumab (TA764), and galcanezumab (TA659). Therefore, subgroups defined by the frequency of episodic migraine (in those with episodic migraine) may not be appropriate for the scope.	Thank you for your comment. Subgroups in the NICE scope have been updated and/or removed where appropriate.

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		Additionally, given the relevant population focuses on patients who require acute treatment of migraine, the subgroup for people with chronic or episodic migraine is not appropriate, and neither are the subgroups defined by the number of previous preventive treatments. Atogepant is already reimbursed in migraine prevention (TA973).	
	The migraine trust	The subgroups currently listed appear to be more relevant when considering atogepant as a preventative treatment. For acute treatment, it would seem more appropriate to include the following subgroups: • subgroups defined by migraine severity • people currently having treatment for the prevention of migraine • people with or at risk of developing medication overuse • people for whom triptans are contraindicated or not tolerated • subgroups defined by the number of headache days per month.	Thank you for your comment. These subgroups have been added to the scope.
Comparators	BASH	Yes	Comment noted. No action required.
	UK Clinical Pharmacy Association (UKCPA) Neurosciences Committee	Yes	Comment noted. No action required.
	AbbVie Ltd	Given the population relevant for this appraisal is adults with migraine who have tried at least two triptans and they did not work well enough or were contraindicated, or not tolerated, the only relevant comparator for this appraisal is rimegepant for the following reasons: • Rimegepant is established in NHS clinical practice, and is the only active comparator recommended in this position in the treatment pathway.	Comment noted. The comparators included are intentionally kept broad. The technology will be appraised in line with the marketing authorisation wording and therefore other

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		• Atogepant and rimegepant have the same mechanism of action and the same mode of administration. [redacted]	treatments may need to be considered. Where a technology is expected to be evaluated through the cost comparison process, a comparison is only required against one comparator which must be established in practice and have substantial use in the NHS in England for the same indication
	The migraine trust	Yes, all relevant comparators have been included.	Comment noted. No action required.
Outcomes	British Association for the Study of Headache	Yes	Comment noted. No action required.
	UK Clinical Pharmacy Association (UKCPA) Neurosciences Committee	yes	Comment noted. No action required.
	AbbVie Ltd	Yes, the listed outcomes are appropriate and will capture the most important health related benefits and harms of the technology.	Comment noted. No action required.

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	The Migraine Trust	Yes, the outcomes are appropriate and relevant for the technology appraisal.	Comment noted. No action required.
Equality	British Association for the Study of Headache	BASH does not feel any changes are needed and that the draft remit and scope are suitable	Comment noted. No action required.
	UK Clinical Pharmacy Association (UKCPA) Neurosciences Committee	No equality issues identified	Comment noted. No action required.
	AbbVie Ltd	No equality issues identified	Comment noted. No action required.
Other considerations	British Association for the Study of Headache	None	Comment noted. No action required.
	AbbVie Ltd	None	Comment noted. No action required.
	The Migraine Trust	It would be helpful to consider whether there is any evidence of potential benefits or contraindications to taking atogepant alongside other acute treatments, including painkillers, ant-emetics and triptans. It would be helpful	Comment noted. NICE will appraise atogepant within its UK marketing

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		to review whether there is evidence of safety supporting the use of atogepant as an acute treatment in people already taking rimegepant as a preventer.	authorisation. No action required.
Questions for consultation	British Association for the Study of Headache	Where do you consider atogepant will fit into the existing care pathway for treating migraines? As per Rimegepant ie triptans contra indicated, triptans not tolerated, simple analgesics not effective Please select from the following, will atogepant be: A. Prescribed in primary care with routine follow-up in primary care. Answer A, we expect atogepant to be initiated in Primary Care for the acute treatment of migraine without referral to secondary care For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention. Answer is no, would all be in Primary Care Would atogepant be a candidate for managed access? No Do you consider that the use of atogepant can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? No Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics. Not used differently from the SmPC	Thank you for your responses to the consultation questions. These have been considered while finalising the scope.

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	UK Clinical Pharmacy Association (UKCPA) Neurosciences Committee	Where do you consider atogepant will fit into the existing care pathway for treating migraines? I consider appropriate for atogepant to be prescribed in primary care setting, secondary and tertiary care setting, but also specialised clinics in community pharmacies. Please select from the following, will atogepant be: A. Prescribed in primary care with routine follow-up in primary care B. Prescribed in secondary care with routine follow-up in primary care C. Prescribed in secondary care with routine follow-up in secondary care D. Other (please give details): as described above For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention. Follow up for Rimegepant as treatment option sits into primary care at the moment. Would atogepant be a candidate for managed access? Yes	Thank you for your responses to the consultation questions. These have been considered while finalising the scope.
	AbbVie Ltd	Where do you consider atogepant will fit into the existing care pathway for treating migraines?	Thank you for your responses to the consultation questions. These have been

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		Atogepant is expected to be used for acute treatment of migraine in adults who have tried at least two triptans and they did not work well enough, or were contraindicated, or not tolerated. What treatments would you consider to be appropriate comparators to atogepant? The only relevant comparator for this appraisal is rimegepant as described in earlier sections. Please select from the following, will atogepant be: A. Prescribed in primary care with routine follow-up in primary care B. Prescribed in secondary care with routine follow-up in primary care C. Prescribed in secondary care with routine follow-up in secondary care D. Other (please give details): For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention. [redacted] Would atogepant be a candidate for managed access? No comment	considered while finalising the scope.

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		Do you consider that the use of atogepant can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? No comment Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits. No comment Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics. NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope: • could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which atogepant will be licensed; • could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;	

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		• could have any adverse impact on people with a particular disability or disabilities. Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts. No comment NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation). Based on the reasons outlined throughout this document, AbbVie consider the cost-comparison route to be the most appropriate route for this appraisal.	
	The Migraine Trust	Where do you consider atogepant will fit into the existing care pathway for treating migraines? Atogepant should represent an alternative option to other oral CGRP antagonists, which already have a marketing authorisation for the acute treatment of migraine. This would provide two acute treatment options for people who cannot tolerate triptans or simple painkillers, have found them ineffective, or are otherwise unable to take triptans. It could also be considered as a potential treatment option earlier in the existing pathway – prior to traditional acute medication, including painkillers, anti-emetics and triptans.	Thank you for your responses to the consultation questions. These have been considered while finalising the scope.

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		Please select from the following, will atogepant be: A. Prescribed in primary care with routine follow-up in primary care Would atogepant be a candidate for managed access? Yes, because there is an urgent need for effective, better tolerated acute medicines.	
Additional comments on the draft scope			

The following stakeholders indicated that they had no comments on the draft remit and/or the draft scope

National Migraine Centre, ABN