

National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Foslevodopa-foscarbidopa for treating Parkinson's disease with motor symptoms

Response to consultee and commentator comments on the draft remit and draft scope (pre-referral)

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

Section	Consultee/ Commentator	Comments [sic]	Action
Appropriateness	AbbVie	Yes, it is appropriate to refer foslevodopa-foscarbidopa for appraisal as it is expected to provide expanded access to a novel, innovative and effective therapy for patients with severe/uncontrolled Parkinson's disease. In addition, as a subcutaneously administered treatment without the requirement for surgery, ABBV-951 can be made available through routine local commissioning in non-specialist centres.	Comment noted. No action needed.
	Ever Pharma	No Comments	No action needed.
	Parkinson's UK	Yes, there are very few effective therapies for people with Parkinson's who experience troubling motor fluctuations and 'off' periods, therefore guidance on the use of this therapy could be life-changing.	Comment noted. No action needed.
Wording	AbbVie	AbbVie request that the remit is updated to state 'within its marketing authorisation for treating Parkinson's disease with uncontrolled motor fluctuations', in order to better align with our anticipated licenced population.	Comment noted. Following the scoping workshop, the draft

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			remit has been changed from "...treating Parkinson's disease with motor fluctuations" to "...treating Parkinson's disease with uncontrolled motor symptoms " in order to align with clinical trial information available in the public domain.
	Ever Pharma	No Comments	No action needed.
	Parkinson's UK	Yes	No action needed.
Timing Issues	AbbVie	Patients with Parkinson's disease with severe/uncontrolled motor fluctuations not adequately controlled on best medical therapy have limited advanced treatment options, such as apomorphine, deep brain stimulation (DBS), and levodopa-carbidopa intestinal gel (LCIG), all of which are associated with limitations and restrictions on access. Furthermore, a significant proportion of these patients are on no advanced therapy at all, due to their inability to access treatment locally, unsuitability/contraindication, or refusal of surgery; these patients incur significantly higher resource utilisation costs and unplanned admissions to hospital for the NHS than those treated with advanced therapies. Foslevodopa-foscarbidopa will provide a valuable new treatment option for these patients and should therefore be appraised urgently.	Comment noted. No action needed.

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		Additionally, during the COVID-19 pandemic, foslevodopa-foscarbidopa provides a non-surgical treatment option that does not require inpatient care, therefore alleviating pressure on NHS resources and future hospital capacity aligned to the long-term plan.	
	Ever Pharma	No Comments	No action needed.
	Parkinson's UK	As noted above there are only a small number of therapeutic options to control motor fluctuations and 'off' periods. Therefore the Parkinson's population would welcome a new treatment to manage these troubling symptoms. The therapy could also help to reduce health and social care costs, as symptoms would be better managed and therefore people with the condition would need less support from carers and health professionals.	Comment noted. No action needed.
Additional comments on the draft remit	AbbVie	None.	No action needed.
	Ever Pharma	No Comments	No action needed.
	Parkinson's UK	None.	No action needed.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	AbbVie	Paragraph 2 states that 'It is estimated that around 10% of patients have advanced disease. ⁴ This should be updated as newly published data from UK Parkinson's Excellence Network using data from 2019 illustrates that 34% of patients present with complex disease (see the 2019 Audit Summary Report	Comment noted. This sentence has been updated in the scope.

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		here: https://www.parkinsons.org.uk/professionals/uk-parkinsons-audit-transforming-care	
	Ever Pharma	Early stages of PD show more diffused symptoms, less those 3 motoric ones...they would be expected later as the disease progresses.	Comment noted. No action needed.
	Parkinson's UK	Our latest prevalence figures report there are 145,000 people living with the condition in the UK, with this set to grow by around 18% to over 168,000 in 2025. (Parkinson's UK, 2018 - https://www.parkinsons.org.uk/professionals/resources/incidence-and-prevalence-parkinsons-uk-report) Parkinson's is the fastest growing neurological condition in the world. (Lancet, Jnauary 2020 - https://www.thelancet.com/journals/laneur/article/PIIS1474-4422(19)30432-6/fulltext).	Comment noted. Prevalence figures have been updated within the scoping document.
The technology/ intervention	AbbVie	The first paragraph of the technology section states that 'foslevodopa-foscarbidopa is administered via subcutaneous infusion.' We would like to request this be updated to clarify that the technology 'is administered via continuous subcutaneous infusion over 24 hours, without any surgical intervention'.	Comment noted. This sentence has been updated in the final scope.
	Ever Pharma	No Comments	No action needed.
	Parkinson's UK	Yes	No action needed.

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Population	AbbVie	The proposed population wording is broader than our anticipated licenced population. We request that NICE update the population to 'People with Parkinson's disease that is responsive to levodopa, with severe motor fluctuations or hyperkinesia/dyskinesia uncontrolled by standard therapy'.	<p>Comment noted.</p> <p>The population has been updated to "adults with Parkinson's disease that is responsive to levodopa, with motor symptoms uncontrolled by standard therapy" to align with clinical trial information available in the public domain.</p> <p>The remit of the scope is kept broad, partly so that confidential wording is not shared and partly to align with the clinical trial.</p>
	Ever Pharma	No Comments	No action needed.
	Parkinson's UK	Yes	No action needed.
Comparators	AbbVie	In line with the comments on population above, AbbVie consider that the comparators suggested reflect a broader population than the anticipated licenced population for foslevodopa-foscarbidopa. It would be more clinically appropriate for the standard oral medicines (levodopa, plus adjuvants: dopamine agonists, MAO-B inhibitors, COMT inhibitors, and intermittent	Comment noted. The comparator list has been updated so that amantadine is included with standard oral

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		<p>apomorphine) be grouped with amantadine into a best medical therapy (BMT) comparator, as amantadine is also an adjuvant therapy that would not be used alone in this complex/uncontrolled patient population. Intermittent subcutaneous apomorphine injections are considered a rescue therapy as part of BMT, while continuously administered (16-hour) subcutaneous apomorphine is considered as a standalone comparator with or without BMT.</p> <p>These suggestions are aligned with NICE Parkinson's disease guideline (NG71) and the expected indication for foslevodopa-foscarbidopa, which is for patients uncontrolled on combinations of standard oral medications.</p>	<p>medicines under a best medical therapy group. Apomorphine has remained as a separate comparator. The comparators are left broad to be inclusive at the scoping stage.</p>
	Ever Pharma	<p>Transdermal therapies may also need to be included.</p> <p>For "Apomorphine, with or without standard oral therapy":</p> <ul style="list-style-type: none"> - Was the effectiveness of the services established? - Was this done through a randomised, controlled clinical trial? If so, did the trial protocol reflect what would happen in regular practice? - Was effectiveness established through an overview of clinical studies? - Were observational data or assumptions used to establish effectiveness? If so, what are the potential biases in results? 	<p>Comment noted. Based on clinical expert insight during the scoping workshop, transdermal therapies are captured under "dopamine agonists" within the current scope.</p> <p>The committee will assess clinical evidence provided by the company and stakeholders during the appraisal.</p> <p>No action needed.</p>
	Parkinson's UK	<p>We would suggest amantadine is not a comparator.</p>	<p>Comment noted. Amantadine has been kept within the scope as</p>

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		Amantadine is used to treat dyskinesia. It is not generally used to treat wearing off, so it is not targeting the same therapeutic need.	a comparator. The comparators are left broad to be inclusive at the scoping stage. No action needed.
Outcomes	AbbVie	We would suggest that impact on sleep be added to this list, as it is anticipated to be an important differentiator for foslevodopa-foscarbidopa.	Comment noted. The scope has been updated to include 'sleep symptoms' in the outcomes list.
	Ever Pharma	For "cognitive functioning": MMSE? Which criteria For "adverse effects of treatment": Hardware complications should be included	Comment noted. Scoping documents are kept broad and in general do not specify tools or criteria for assessment. No action needed.
	Parkinson's UK	We agree with the outcomes in the scope document but would also suggest these are added. activities of dailing living <i>"My symptoms are usually really well controlled. I do still get some off parts of the day. If it's really bad I can use a boost, but I tend not to. The therapy gives me the right 'flow' of medication so throughout the day and night and I am significantly more balanced in terms of being 'on' and suffer far less with movement and joint ache compared to pre trial." (Person with Parkinson's)</i>	Comment noted. The scope has been updated to include 'sleep symptoms' in the outcomes list. Activities of daily living, control of fluctuations and wellbeing are considered to be captured in the 'health-

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		<p><i>“He can drive again which is great as he can get out and about. I don't monitor him as much, but keep an ear out for when he's active as sometimes I worry he's doing too much.” (Carer of someone with Parkinson's)</i></p> <p>non motor symptom burden - sleep</p> <p><i>“My sleep pattern was very erratic, but on the therapy it has started to improve as the meds are being delivered 24 hrs, which is a positive key aspect of this drugs delivery compared to some other medication.” (Person with Parkinson's)</i></p> <p>better control of fluctuations</p> <p><i>“Before foslevodopa-foscarbidopa I took multiple medicines during the day - up to 28 tablets. I had real issues with being 'on and off' throughout the day. This had an impact on my motivation, my movement and also sometimes my thinking. Overall this therapy has significantly decreased the feeling of swinging from either on or off, which was proving a major problem for me on the previous oral meds.” (Person with Parkinson's)</i></p> <p>wellbeing</p> <p><i>“His quality of life has improved a lot. He forgets a lot less, if he comes in from the garden he used to stand there and need to be reminded what he was doing .I don't have to watch him as carefully, before I felt like I needed to keep an eye all the time. [Him] being on the therapy has enabled me to have a bit more time to myself. I've been able to get out in the garden and do some work.” (Carer of someone with Parkinson's)</i></p> <p>reduction in use of healthcare services</p> <p><i>“We're regularly in touch with the consultant and the trial protocol states we have to have regular follow-ups so I can't say it's reduced our appointments yet. But I could see this in the future.” (Carer of someone with Parkinson's)</i></p>	<p>related quality of life' outcome. Additionally, the reduction in use of healthcare services is expected to be captured in the economic analysis and will be considered during the appraisal process. No further action needed.</p>

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Economic analysis	AbbVie	No comments; the model time horizon will be sufficiently long to reflect all differences in costs or outcomes between the technologies being compared, include costs from an NHS and Personal Social Services perspective, and take into account any commercials arrangements where possible.	Comment noted. No action needed.
	Ever Pharma	<p>Were all the important and relevant costs and consequences for each alternative identified?</p> <ul style="list-style-type: none"> - Was the range wide enough for the research question at hand? - Did it cover all relevant viewpoints? (Possible viewpoints include the community or social viewpoint, and those of patients and third-party payers. Other viewpoints may also be relevant depending upon the particular analysis.) - Were capital costs, as well as operating costs, included? Direct/indirect costs? <p>“Sufficiently long”: Should be at least 5 years</p> <p>For “The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account”: This should also consider any hardware related complications and therefore potential hidden costs</p>	<p>Comment noted. No action needed.</p> <p>The economic analysis section has been written based on the NICE scope template and forms a guideline for company submission. The questions noted here would be considered as part of the appraisal process.</p>
	Parkinson’s UK	N/A	No action needed.
Equality and Diversity	AbbVie	No comments.	No action needed.
	Ever Pharma	No Comments	No action needed.

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	Parkinson's UK	<p>Could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which foslevodopa-foscarbidopa will be licensed;</p> <p>We believe that the scope should be amended to ensure that these groups of people are not excluded:</p> <ul style="list-style-type: none"> • Older people who may not be deemed suitable or for deep brain stimulation (DBS) or Levodopa-carbidopa intestinal gel (LCIG). Or for whom it is not accessible, for instance those living in rural populations and not close to a specialist centre. • Also DBS and LCIG while life-changing are very invasive, whereas this therapy is fairly easy to administer. <ul style="list-style-type: none"> ○ <i>“This therapy isn't massively invasive, yes you have to carry a pump round, but you're still able to get out and about and be active. I'd like there to be a longer tube from the pump to the needle as it makes it difficult when I go out cycling. I have to put the pump in a specific place, which can sometimes could result in the pump falling or pulling on the tubing.” (Person with Parkinson's)</i> ○ <i>“You do get used to it, but it isn't easy at first. We do the medication together as a team, you could do it on your own if needed, but we find it's better for us if we do it together.” (Carer of someone with Parkinson's)</i> • Those people who have apomorphine contraindicated, they either exhibit psychosis or orthostatic hypotension. <p>Could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g.</p>	<p>Comment noted. Based on discussions at the scoping workshop, no changes are required to the scope. The appraisal committee will consider equality considerations further during the appraisal process. No action needed.</p>

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		<p>by making it more difficult in practice for a specific group to access the technology;</p> <p>We believe the scope should reflect the issues people with Parkinson’s may face accessing and using the technology.</p> <ul style="list-style-type: none"> • People need to have access to a fridge to keep the medication refrigerated. For those who may wish to travel this may be difficult. <ul style="list-style-type: none"> ○ “Also you need access to a fridge to store the medication. This could be an issue for travelling or holidays. We’ve bought a fridge we travel with in the car. However not all will be able to do that.” (Carer of someone with Parkinson’s) • The pump is generally easy to use once you have practised. However it would be useful to involve patients in the design of future devices to ensure they are as easy to use as possible. <ul style="list-style-type: none"> ○ “I would imagine there would be some who might struggle if they have poor or very limited dexterity as the pump does require a degree of managing and some of the elements used in administering the drug can be fiddly but this could be overcome with the right support.” (Person with Parkinson’s) ○ “It’s a steep learning curve to get to grips with the pump.” (Person with Parkinson’s) ○ “If you have poor cognition it might be tricky to use. If you’re based in a nursing home you’d need to depend on staff who are trained to administer the therapy and that might be tough.” (Carer of someone with Parkinson’s) <p>Could have any adverse impact on people with a particular disability or disabilities.</p>	

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		<ul style="list-style-type: none"> Someone with visual impairment may have difficulties with the connectors and managing the pump. 	
Other considerations	AbbVie	<p>If evidence allows, we will provide analyses for the proposed subgroups in our evidence submission.</p> <p>Additionally, if evidence allows, we would also wish to consider the subgroup of patients for whom surgery is contraindicated or refused. This subgroup represents a significant number of patients in the UK who, for various reasons, are not eligible for surgical interventions (DBS and LCIG), and as such remain on ineffective oral medications with uncontrolled motor fluctuations.</p>	Comment noted. The scope has been updated to specify “people for whom apomorphine, deep brain stimulation or levodopa-carbidopa intestinal gel is not suitable” as potential subgroups.
	Ever Pharma	No Comments	No action needed.
	Parkinson’s UK	It might be useful to explore evidence and or the impact of time spent in the off-state. For instance what is the impact of being in the ‘off-state’ for someone who is still in work.	Comment noted. No action needed. Subgroups based on the proportion of time spent in the ‘off’ state is already included within the scope.
Innovation	AbbVie	Yes, we consider foslevodopa-foscarbidopa to represent a step-change in management of severe/uncontrolled Parkinson’s disease, as it is expected to offer comparable efficacy to the currently available advanced therapies while avoiding their key drawbacks, such as the need for invasive surgery (DBS/LCIG) and the management of a complex adverse event profile (apomorphine). As a novel molecule with a unique conversion from prodrug to	Comment noted. No action needed. Innovation will be considered by the committee during the appraisal process.

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		<p>active substance, foslevodopa-foscarbidopa is expected to have better bioavailability, and much lower concentrations of foscarbidopa (levodopa:carbidopa ratio of 20:1) are required vs. all other forms of levodopa-based therapies (i.e., orals and LCIG where a ratio of 4:1 is required). This is expected to reduce the risk of adverse events.</p> <p>Furthermore, levodopa is the mainstay of treatment that all patients will have received; as such, foslevodopa-foscarbidopa represents a treatment option without surgery that patients are likely to have already responded well to, but who have exhausted oral options. It is also anticipated to be made available through local commissioning in non-specialist centres, offering the potential for broader access (particularly at a time when access to NHS specialist services has been curtailed due to COVID-19), and lower healthcare resource use.</p> <p>Finally, foslevodopa-foscarbidopa offers greater opportunities for personalised treatment, with individual dose titrations, additional patient-controlled bolus doses when required, a 24-hour dosing period, and the ability to remove the infusion pump for short periods to enable unimpeded activities of daily living without experiencing OFF time. In particular, the 24-hour dosing period is expected to provide benefits to sleep that are unlikely to be captured in the QALY calculation.</p>	
	Ever Pharma	No Comments	No action needed.
	Parkinson's UK	<p>Yes.</p> <p>A Parkinson's professional we spoke to who is running a trial of the therapy stated that once patients are on it, it's like treating a different condition. Fluctuations are almost gone, people are able to sleep and wake up more rested. Their anxiety (particularly related to being in an 'off state') is better managed. They are able to be more active and possibly stay in work.</p>	<p>Comment noted. No action needed.</p> <p>Innovation will be considered by the committee during the appraisal process.</p>

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		<p>They also added that there are huge impacts on the carer too as the person with Parkinson's is less reliant for assistance and support.</p> <p><i>"I feel like I've been able to press the pause button on Parkinson's. I know the condition is progressing, but I'm much more in control of it and how I can help myself. I'm still trying to be active and the therapy enables me to do that. My energy levels stay fairly static throughout the day (in a good way), this helps me to prepare and plan activities."</i> (Person with Parkinson's)</p> <p>Carer experience: <i>The therapy allows carers to live their own life and possibly even stay in work.</i></p> <p><i>"It frees me up a lot, I don't have to chase my husband to take his tablets."</i> (Carer of someone with Parkinson's)</p> <p><i>"It's great not to have to constantly clock watch to make sure [my husband] has taken his tablets. It is lovely to see him able to get up and move around at night without pain. Having a 24/7 therapy makes a huge difference."</i> (Carer of someone with Parkinson's)</p> <p>Falls: According to Hospital Episodes Statistics data for 2019/20 there were 77,318 emergency hospital admissions for Parkinson's which cost the NHS £301 million. Emergency admissions were for bladder infections (£26 million), pneumonia (£19m) falls (£18m) and sepsis (£15m).</p> <p>(Wilmington Healthcare, NHS Digital, 2020 - https://wilmingtonhealthcare.com/what-we-do/nhs-service-improvement/disease-insight-reports/parkinsons-disease-the-impact-of-covid-19/)</p> <p><i>"I used to be worried about [my husband] falling, but on the therapy I'm a lot less worried about this now."</i> (Carer of someone with Parkinson's)</p> <p>Hospital Episodes Data as above.</p>	

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		Trial data, but we believe it would be useful to review data from LCIG studies, although we would hope the cost of the therapy is greatly reduced.	
Questions for consultation	AbbVie	<p>Would foslevodopa-foscarbidopa only be offered to people with advanced Parkinson's disease?</p> <p>Yes, in line with our answers above, foslevodopa-foscarbidopa is anticipated to be indicated for the treatment of PD with severe/uncontrolled motor fluctuations when best medical therapy has not given satisfactory results, which represents a narrower population than that proposed.</p> <p>Which treatments are considered to be established clinical practice in the NHS for treating Parkinson's disease that is responsive to levodopa, with motor fluctuations uncontrolled by standard therapy?</p> <p>AbbVie consider that the pathway for Parkinson's disease that is responsive to levodopa, with motor fluctuations uncontrolled by standard therapy is as follows:</p> <ul style="list-style-type: none"> • Best medical therapy (including levodopa, dopamine agonists, MAO-B inhibitors, COMT inhibitors, and amantadine) • Apomorphine with or without BMT • Deep Brain Stimulation • Levodopa-carbidopa intestinal gel <p>Have all relevant comparators for foslevodopa-foscarbidopa been included in the scope? In particular:</p> <ul style="list-style-type: none"> • Is levodopa-carbidopa intestinal gel a relevant comparator? <p>Yes, levodopa-carbidopa intestinal gel is routinely commissioned by NHS England through Clinical Commissioning Policy Levodopa-Carbidopa</p>	Comments noted. No action needed.

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		<p>Intestinal Gel (Reference: NHS England D04/P/e). Patients must be unable to tolerate or unsuitable for apomorphine, and unsuitable for DBS, have refused to consent for or failed DBS.</p> <p>Is deep brain stimulation a relevant comparator?</p> <p>Yes, DBS is recommended in NG71 for people with advanced Parkinson's disease whose symptoms are not adequately controlled by best medical therapy.</p> <p>Are other forms of surgery for Parkinson's disease (e.g. ultrasound thalamotomy, subthalamotomy) relevant comparators?</p> <p>No, ultrasound thalamotomy and subthalamotomy are not routinely used for the treatment of Parkinson's disease, and are only recommended by NICE for use in the context of research.</p> <p>Which other treatments for Parkinson's disease (if any) will foslevodopa-foscarbidopa be used in combination with?</p> <p>Patients will be initiated on monotherapy, however clinicians would be able to add in any of the enzyme inhibitors commonly used to increase levodopa bioavailability (listed below). Due to the continuous nature of the infusion of foslevodopa-foscarbidopa, it would be reasonable to assume the inhibitors with a smooth pharmacokinetic profile (such as those given once per day) would be best to given alongside foslevodopa-foscarbidopa.</p> <p>COMT inhibitors:</p> <ul style="list-style-type: none"> • Opicapone (once per day) • Entacapone • Tolcapone <p>MOAB inhibitors</p>	

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		<ul style="list-style-type: none"> • Rasagiline (once per day) • Selegiline • Safinamide (once per day) <p>Are the outcomes listed appropriate?</p> <p>We would suggest that impact on sleep be added to this list, as it is anticipated to be an important differentiator for foslevodopa-foscarbidopa</p> <p>Are the subgroups suggested in ‘other considerations appropriate? Are there any other subgroups of people in whom foslevodopa-foscarbidopa is expected to be more clinically effective and cost effective or other groups that should be examined separately?</p> <p>If evidence allows, we will provide analyses for the proposed subgroups in our evidence submission.</p> <p>Additionally, if evidence allows, we would also wish to consider the subgroup of patients for whom surgery is contraindicated or refused. This subgroup represents a significant number of patients in the UK who, for various reasons, are not eligible for surgical interventions (DBS and LCIG), and as such remain on ineffective oral medications with uncontrolled motor fluctuations.</p> <p>Where do you consider foslevodopa-foscarbidopa will fit into the existing NICE pathway, Parkinson’s disease?</p> <p>Foslevodopa-foscarbidopa is anticipated to be indicated for [REDACTED]</p>	<p>The scope has been updated to include ‘sleep symptoms’ in the outcomes list.</p>

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		<p>██████████ As such, we anticipate that it will fit into the pathway after best medical therapy and as a potential option vs. apomorphine, DBS, and LCIG.</p> <p>To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.</p> <p>We do not expect there to be any barriers to adoption of this technology into practice. In fact, due to the expected wider access to foslevodopa-foscarbidopa via routine commissioning in non-specialist centres and lack of surgical implantation of a device, we anticipate easier access vs. currently available device-aided therapies.</p> <p>NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process.</p> <p>Yes, it is appropriate to appraise foslevodopa-foscarbidopa through the STA process, as it is expected to provide expanded access to an effective therapy for patients with severe/uncontrolled Parkinson's disease, without the requirement for surgery, and through routine local commissioning in non-specialist centres.</p>	
	Ever Pharma	No Comments	No action needed.
	Parkinson's UK	<p>Would foslevodopa-foscarbidopa only be offered to people with advanced Parkinson's disease?</p> <p>We would suggest that the scope is amended so that the therapy is also offered to anyone who is affected by 'wearing off' of their oral medication (4 or more doses a day with 2 or more hours of off time).</p>	<p>Comment noted.</p> <p>No changes have been made to the population. The remit of the scope is kept broad, partly so that confidential wording is not shared</p>

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		<p>Which other treatments for Parkinson’s disease (if any) will foslevodopa-foscarbidopa be used in combination with?</p> <ul style="list-style-type: none"> • MOA - B inhibitor. • Dopamine agonists. • Other treatments for non motor symptoms. • COMT inhibitors, however these are not included in the current trial protocol. But using a COMT inhibitor could improve the bioavailability of the drug and therefore reduce the flow rates required, possibly improving the cost-effectiveness of the therapy. • People who would not use apomorphine, this therapy might be better tolerated - for instance those with orthostatic hypotension or cognitive impairment and impulse control disorder side effects. <p>Are the outcomes listed appropriate? Yes, but we would recommend that the scope includes carer wellbeing.</p> <p>Are the subgroups suggested in ‘other considerations appropriate?’</p> <ul style="list-style-type: none"> • People for whom LCIG is not suitable. <p>Are there any other subgroups of people in whom foslevodopa-foscarbidopa is expected to be more clinically effective and cost effective or other groups that should be examined separately? No. We would suggest the therapy is only appropriate for those who are known to be dopa-responsive.</p> <p>Where do you consider foslevodopa-foscarbidopa will fit into the existing NICE pathway, Parkinson’s disease?</p>	<p>and partly to align with the clinical trial.</p> <p>Carer wellbeing has not been added as an outcome. However, the evaluation can consider the health effects for carers, when relevant, according to the NICE reference case.</p> <p>The scope has been updated to specify “people for whom apomorphine, deep brain stimulation or</p>

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		<p>Under the management of motor symptoms of the condition.</p> <p>We believe the therapy should be seen as an equivalent to apomorphine. It's simply a different way of getting levodopa into the body.</p> <p>Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.</p> <p>It might be useful to develop a registry of use and monitor this across the patient population</p> <p>To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.</p> <p>Takes time to understand the dosage, there needs to be clinical workforce education</p> <p>There also needs to be a comprehensive patient education programme rolled out to ensure patients are carers are familiar with the technology and how to use it.</p> <p>If the therapy is costed too high, for instance as an equivalent to LCIG, rather than apomorphine.</p>	levodopa-carbidopa intestinal gel is not suitable" as potential subgroups.
Additional comments on the draft scope	AbbVie	None.	No action needed.
	Ever Pharma	No Comments	No action needed.
	Parkinson's UK	None.	No action needed.

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

GSK