NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Patient/carer expert statement (STA)

Naloxegol for treating opioid induced constipation

Thank you for agreeing to give us your views on this treatment that is being appraised by NICE and how it could be used in the NHS. Patients, carers and patient organisations can provide a unique perspective on conditions and their treatment that is not typically available from other sources. We are interested in hearing about:

- the experience of having the condition or caring for someone with the condition
- the experience of receiving NHS care for the condition
- the experience of having specific treatments for the condition
- the outcomes of treatment that are important to patients or carers (which might differ from those measured in clinical studies, including health-related quality of life)
- preferences for different treatments and how they are given
- expectations about the risks and benefits of the treatment.

We have already asked your nominating organisation to provide an organisation's view. We are asking you to give your views as an individual whether you are:

- a patient
- a carer (who may be voicing views for a patient who is unable to) or
- **somebody who works or volunteers for a patient organisation**.

To help you give your views, we have provided a questionnaire. You do not have to answer every question — the questions are there as prompts to guide you. The response area will expand as you type. The length of your response should not normally exceed 10 pages.

1. About you

Your name: Karen Irwin
Name of your nominating organisation: PromoCon
Do you know if your nominating organisation has submitted a statement?

☐ √ **Yes**

Do you wish to agree with your nominating organisation's statement?

☐ √ **Yes**

(We would encourage you to complete this form even if you agree with your nominating organisation's statement.)

Are you:

- a patient with the condition?

☐√ No

- a carer of a patient with the condition?

☐√ No

- a patient organisation employee or volunteer?

☐√ Yes

Do you have experience of the treatment being appraised?

☐ Yes ☐√ No

If you wrote the organisation submission and do not have anything to add, tick here ☐ (If you tick this box, the rest of this form will be deleted after submission.)

2. Living with the condition

What is your experience of living with the condition as a patient or carer?

People inform us how difficult it is sometimes, to talk to someone about constipation (and associated bladder and bowel symptoms) "going to the toilet is supposed to be private" is what we commonly hear. People are sometimes unaware of the treatment options that are available to them in managing OIC, or alternatively, they feel they have exhausted all treatment options.

Pain, discomfort, irregular and unpredictable bowel movements are a significant reported concern for people with OIC. We are informed this has a major negative impact on quality of life for some individuals, hindering or even stopping them from being able to participate in day to day activities. It is also reported that they experience disabling complications as a result of their constipation.

Other common reported problems include abdominal pain, bloating, nausea, reduced appetite, not fully emptying their bowel, going long periods without a bowel movement or experiencing unpredictable, lengthy times spent in the toilet. For some, it is intolerable sometimes to manage these symptoms.

People inform us that they have tried a variety of oral laxative and rectal interventions, not always gaining the desired, reliable or effective result they would expect.

We are informed that other problems can be experienced as a result of OIC; these include not emptying their bladder fully, incontinence, obstruction, rectal bleeding, and mood and behaviour changes. We have been informed by some people that there have been occasions when they have attended their local A&E for help or have been admitted to hospital.

Individuals inform us they are keen to find out where they can access help and advice and also to enquire if there are any alternative or new treatments available to manage their constipation problem.

Some people are unaware of services and professionals that are available to help them within their locality.

3. Current practice in treating the condition

Which treatment outcomes are important to you? (That is, what would you like treatment to achieve?) Which of these are most important? If possible, please explain why.

People taking opioid medication are keen to have more regular, predictable bowel routines, with a reduction in other associated symptoms and problems caused by the OIC as outlined above in (2)

Improvement in individuals quality of life

Additional choice for treatment for OIC

What is your experience of currently available NHS care and of specific treatments? How acceptable are these treatments – which did you prefer and why?

People manage OIC differently. Some will self manage with either what has been prescribed or with addition of other preparations such as OTC medications. We are informed by some individuals, that they sometimes feel that they have exhausted options of prescribed laxatives and doses, and whilst they may continue to take whatever is prescribed , they are looking to find alternative ways to manage the OIC better. This can be most frustrating for both the individual and those caring for them.

Alternatively, some people report having frequent meetings with their health care provider, for review of regimes, dose alteration and alteration in medications prescribed: trying to manage the symptoms in the best way then can, enabling them to reach a point where OIC is best managed for the individual.

Some people report to us that they mange quite well on laxative regimes for their OIC, however, find it comforting to know there are other treatment options available to them, if ever required.

Some people need assistance with their bowel management; time spent on this will vary according to the individuals needs. Some may require a nurse or carer to administer rectal preparations, such as enemas and suppositories. Bowel care procedures such as manual evacuation are sometimes undertaken, these can be invasive and time consuming for the patient and they are also reliant on others to manage their bowel care times and routines.

Some people need a combination of oral and rectal intervention.

People inform us they want to have more control over their bowels; they want to know if a medication for the constipation is no longer effective or is unsuitable for them, that they have choices and that they can discuss with their practitioner options and feasibility of trying an alternative. It is very much a personal choice between what people are willing and able to tolerate and try or not. For example, it may suit one person to use suppositories/enemas, whilst for another; this is something they would totally want to avoid. .

People tell us they like to be informed of current and new treatment options, and what's available to them. This important to all of us.

4. What do you consider to be the advantages of the treatment being appraised?

Benefits of a treatment might include its effect on:

- the course and/or outcome of the condition
- physical symptoms
- pain
- level of disability
- mental health
- quality of life (such as lifestyle and work)
- other people (for example, family, friends and employers)
- ease of use (for example, tablets rather than injection)

- where the treatment has to be used (for example, at home rather than in hospital)
- any other issues not listed above

Please list the benefits that you expect to gain from using the treatment being appraised.

Improved treatment outcomes

Improved quality of life

Possibly reduce the need for further invasive treatments e.g. rectal intervention, manual evacuation

Please explain any advantages that you think this treatment has over other NHS treatments in England.

This technology offers patients further choice in managing OIC

Patients who have tried or who are intolerant to other medications might benefit form this technology

Ease of use – Oral , (other known technology, injection) , therefore may be easier/alternative for patients?

If you know of any differences in opinion between you and other patients or carers about the benefits of the treatment being appraised, please tell us about them.

5. What do you consider to be the disadvantages of the treatment being appraised?

Disadvantages of a treatment might include:

- aspects of the condition that the treatment cannot help with or might make worse
- difficulties in taking or using the treatment (for example, injection rather than tablets)

- Side effects (for example, type or number of problems, how often, for how long, how severe. Please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- where the treatment has to be used (for example, in hospital rather than at home)
- impact on others (for example, family, friends and employers)
- financial impact on the patient and/or their family (for example, the cost of travel to hospital or paying a carer)
- any other issues not listed above

Potential adverse effects

Please list any concerns you have about current NHS treatments in England.

Please list any concerns you have about the treatment being appraised.

If you know of any differences in opinion between you and other patients or carers about the disadvantages of the treatment being appraised, please tell us about them.

6. Patient population

Do you think some patients might benefit more from the treatment than others? If so, please describe them and explain why.

Would other groups of people with OIC benefit from this technology?

Do you think some patients might benefit less from the treatment than others? If so, please describe them and explain why.

7. Research evidence on patient or carer views of the treatment

Are you familiar with the published research literature for the treatment?

☐ No

If you answered 'no', please skip the rest of section 7 and move on to section 8.

Please comment on whether your experience of using the treatment as part of routine NHS care reflects the experience of patients in the clinical trials.

Do you think the clinical trials have captured outcomes that are important to patients? Are you aware of any limitations in how the treatment has been assessed in clinical trials?

If the treatment being appraised is already available in the NHS, are there any side effects that were not apparent in the clinical trials but have emerged during routine NHS care?

Are you aware of any relevant research on patient or carer views of the condition or existing treatments?

☐ Yes ☐ No

If yes, please provide references to the relevant studies.

8. Equality

NICE is committed to promoting equality of opportunity and eliminating discrimination. Please let us know if you think that recommendations from this appraisal could have an adverse impact on any particular groups of people, who they are and why.

Could other groups of patients with OIC benefit from this technology and be considered, i.e. not just those adults with opioid induced constipation with chronic non cancer pain?

9. Other issues

Do you consider the treatment to be innovative?

☐ **Yes**

If yes, please explain what makes it significantly different from other treatments for the condition.

Available orally, may be more effective than conventional laxatives that are offered

Is there anything else that you would like the Appraisal Committee to consider?

Clarify, is this 1st 2nd line treatment for OIC

Who will be able to prescribe, is this consultant / specialist or can this technology be prescribed in the community by GPs' nurse prescribers.

Would patients need any additional monitoring / appointments if on this medication?

10. Key messages

In no more than 5 bullet points, please summarise the key messages of your submission.

- potential to improve choice for patients in managing OIC
- potential to Improve quality of life
- may reduce need for rectal interventions /time spent on bowel care for patients (and their carers)
- Clarification of how patient can access this technology e.g. what setting, specialist / primary care , who can prescribe, also is this 1st 2nd line treatment
- Could this technology be offered to other groups of people with OIC