Appendix G – patient/carer organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Nalmefene for reducing alcohol consumption in people with alcohol dependence

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Patients and patient advocates can provide a unique perspective on the technology, which is not typically available from the published literature.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Please do not exceed the 8-page limit.

About you

Your name: [redacted]

Name of your organisation: Alcohol Concern

Are you (tick all that apply):

- an employee of a patient organisation that represents patients with the condition for which NICE is considering the technology?

  [redacted]

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What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition?

1. Advantages

(a) Please list the specific aspect(s) of the condition that you expect the technology to help with. For each aspect you list please describe, if possible, what difference you expect the technology to make.

Alcohol dependency is a spectrum of severity that affects 1.6 million in England alone. Nalmefene offers a new option for treating some people with 'mild' dependence. By helping people cut down their drinking Nalmefene may be suitable for those who may be unwilling or have no medical need to completely give up alcohol. This intervention is aimed at dependent drinkers who have 'psychological' symptoms of dependence but not physical withdrawal symptoms – a large subgroup of the high risk drinking population. Many within this subgroup may not even realise they are exhibiting signs of dependence. Nalmefene therefore may be an effective option in helping to challenge dependent drinking before dependence exacerbates in severity.

Whilst it is recommended that abstinence is the primary goal of treatment alcohol dependence where this is not possible harm reducing approaches may be appropriate. Currently only between 6% of those in need access treatment annually due to a range of factors. A new treatment option may help to increase patient engagement by appealing to populations currently unsatisfied with or unable to engage with existing largely abstinence based treatment approaches. Treatment for alcohol dependence needs to offer as wide a range of approaches as possible to suit the needs of the patient. Alcohol dependence has a significant social cost and places a great burden on the NHS; it is estimated alcohol issues costs the NHS £3.5b each year. Alcohol dependence is associated with increased criminal activity and domestic violence, and an increased rate of significant mental and physical disorders. Controlling the drinking behaviour of dependent drinkers will help to reduce the social and medical cost of alcohol.

(b) Please list any short-term and/or long-term benefits that patients expect to gain from using the technology. These might include the effect of the technology on:

- the course and/or outcome of the condition
- physical symptoms
- pain
- level of disability
- mental health
- quality of life (lifestyle, work, social functioning etc.)
- other quality of life issues not listed above
- other people (for example family, friends, employers)
- other issues not listed above

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In clinical trials Nalmefene reduced the mean number of heavy drinking days and total alcohol consumption at differing stages up to six months. Whilst the goal of treatment should generally be abstinence, interventions that support patients to take a harm-reduction approach by controlling their drinking are likely to reduce alcohol-related harms. Alcohol dependence is associated with increased criminal activity and domestic violence, and an increased rate of significant mental and physical disorders. Any reduction in consumption is likely to have a positive impact reducing alcohol-related consequences.

2. Disadvantages
Please list any problems with or concerns you have about the technology. Disadvantages might include:
- aspects of the condition that the technology cannot help with or might make worse
- difficulties in taking or using the technology
- side effects (please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- impact on others (for example family, friends, employers)
- financial impact on the patient and/or their family (for example cost of travel needed to access the technology, or the cost of paying a carer)

If used with the correct patient segmentation for which it is licensed and prescribed alongside continuous psychosocial support, we see no disadvantages to Nalmefene's use. Nalmefene complements but should not replace the wide range of existing treatment approaches including abstention.

3. Are there differences in opinion between patients about the usefulness or otherwise of this technology? If so, please describe them.

Some believe abstinence should be encouraged for all patients with alcohol dependence. Others believe harm-reduction approaches are suitable for some patient groups. Alcohol Concern believes treatment should offer as wide a range of effective approaches as possible to meet the needs of all patient groups.

There is debate about the definition of dependence. Some view physical problems arising from withdrawal as a symptom of alcohol dependence with implications for the proposed population Nalmefene has being developed for. It is Alcohol Concern's position that physical withdrawal is sometimes a state of alcohol dependence but not always. 'Mild' dependence of alcohol may exhibit psychological symptoms but not necessarily physical withdrawal symptoms.

4. Are there any groups of patients who might benefit **more** from the technology than others? Are there any groups of patients who might benefit **less** from the technology than others?

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Nalmefene is proposed for alcohol dependent adult patients without physical withdrawal symptoms and who do not require immediate detoxification. Therefore, it may be an option for patients who may not necessarily recognise the significance of their condition due to the absence of physical withdrawal symptoms typically associated with dependence. It is also may be an intervention option for patients unwilling to consider abstinence approaches. As an entirely new option Nalmefene may appeal to those patients within the licensing criteria who are unsatisfied with existing treatment options.

Comparing the technology with alternative available treatments or technologies

NICE is interested in your views on how the technology compares with existing treatments for this condition in the UK.

(i) Please list any current standard practice (alternatives if any) used in the UK.

There are a range of treatments available for alcohol dependence. Most options are abstinence focused. For adults considered to have ‘mild’ dependence recommended interventions include:

Psychological interventions (such as cognitive behavioural therapies)

Naltrexone (in conjunction with psychosocial support):

(ii) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them. Advantages might include:
- improvement of the condition overall
- improvement in certain aspects of the condition
- ease of use (for example tablets rather than injection)
- where the technology has to be used (for example at home rather than in hospital)
- side effects (please describe nature and number of problems, frequency, duration, severity etc)

Nalmefene is a drug suitable - alongside psychological support - for those patients not willing to give up drinking, who will continue to drink during treatment but who want to control and reduce their drinking. In contrast, other pharmacotherapy drugs for alcohol dependence such as Naltrexone, are designed for people who have stopped drinking, and work by reducing the craving for alcohol which many alcohol dependent people experience when they quit drinking. In cases where abstinence cannot or will not be attained harm reduction is the next best goal and Nalmefene may aid this process.

Psychological interventions can be classified into behavioural, cognitive, psychodynamic, humanistic, systemic, motivational, disease, and social and

environmental. The emphasis of each therapy is different depending on the theoretical underpinning of the approach. These interventions alone do not work for all patients and in some instances a pharmacotherapy option such as Nalmefene supported by psychological interventions, may be appropriate.

Nalmefene is easily orally administered on a daily basis.

(iii) If you think that the new technology has any **disadvantages** for patients compared with current standard practice, please describe them. Disadvantages might include:
- worsening of the condition overall
- worsening of specific aspects of the condition
- difficulty in use (for example injection rather than tablets)
- where the technology has to be used (for example in hospital rather than at home)
- side effects (for example nature or number of problems, how often, for how long, how severe).

None - other than the limited adverse side effects highlighted in the clinical study.

Research evidence on patient or carer views of the technology
If you are familiar with the evidence base for the technology, please comment on whether patients' experience of using the technology as part of their routine NHS care reflects that observed under clinical trial conditions.

Unable to comment in this section.

Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?

None that we are aware of.

Are you aware of any research carried out on patient or carer views of the condition or existing treatments that is relevant to an appraisal of this technology? If yes, please provide references to the relevant studies.

None that we are aware of.

Availability of this technology to patients in the NHS
What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?

The availability of Nalmefene on the NHS would offer an important new option to addressing alcohol dependence by opening alcohol treatment to those unwilling or unable to stop drinking.

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What implications would it have for patients and/or carers if the technology was **not** made available to patients on the NHS?

It is likely that a significant numbers of dependent drinkers are currently deterred from accessing treatment due to an unwillingness or inability to abstain. Treatment already has proven results with 57% of people exiting treatment in 2011-12 no longer dependent on alcohol. A failure to not make this drug available would be missing an opportunity to increase the numbers of dependent drinkers accessing the treatment process. The availability of a treatment option for those dependent on alcohol but not showing symptoms of physical withdrawal is likely to improve engagement with the treatment process. Such a treatment option is also likely to improve understanding of the spectrum of alcohol dependency, as it is common for dependence to only be associated with physical withdrawal.

Are there groups of patients that have difficulties using the technology?

None that we are aware of.

Equality
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 this appraisal:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/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;
- could lead to recommendations that 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.

None that we are aware of.

Other Issues
Please consider here any other issues you would like the Appraisal Committee to consider when appraising this technology.

Alcohol Concern receives project funding from Lundbeck the makers of Nalmefene.