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NICE technology appraisal guidance 325: Nalmefene for reducing alcohol consumption in people with alcohol dependence

Issued: November 2014
Summary for Commissioners.

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Nalmefene for reducing alcohol consumption in people with alcohol dependence

NICE TAG 325 Published date: November 2014

Purpose

This paper is designed to give an executive summary of the key points in relation to medicines optimisation arising from NICE TAG 325.

It highlights some issues CCGs may wish to consider in terms of implementation of the guidance.

Technology appraisals cover the use of new and existing medicines and treatments within the NHS in England. The commissioners including clinical commissioning groups, NHS England and, with respect to their public health functions, local authorities are required to comply with the recommendations in this appraisal within 3 months of its date of publication.The Committee highlighted that it would be reasonable for NICE to reflect on whether the standard 3 month implementation period is appropriate, but in the absence of guidance to the contrary this requirement still stands.

Summary

Nalmefene is recommended by NICE, within its marketing authorisation, as an option for reducing alcohol consumption, for people with alcohol dependence:

- who have a high drinking risk level (defined as alcohol consumption of more than 60 g per day for men and more than 40 g per day for women, according to the World Health Organization's drinking risk levels) without physical withdrawal symptoms, and
- who do not require immediate detoxification.

The marketing authorisation states that nalmefene should:

- only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption, and
- be initiated only in patients who continue to have a high drinking risk level 2 weeks after initial assessment.

It is anticipated that there may be media interest in this approval as nalmefene (plus psychosocial support) is the first pharmacological intervention that is specifically for alcohol reduction rather than abstinence.

Commissioning Considerations

The main points for consideration in relation to this guidance are:

- The licence and economic modelling only support the use of Nalmefene in conjunction with the appropriate psychosocial support.
- In the trials submitted to NICE the psychosocial support was in the form of a specific model called BRENDA which focussed on treatment adherence and reduction of alcohol consumption. All sessions were provided by trained professionals and were delivered at weekly intervals for the first 2 weeks and then monthly. Sessions lasted for 15–30 minutes except for the first longer session, which was 30–40 minutes. NICE acknowledged that although Alcohol-use disorders (NICE clinical guideline 115) recommends that psychosocial intervention should typically consist of weekly sessions of 60 minute duration over a 12 week period, the current services available in England have difficulty providing this level of treatment. They have therefore confirmed that either brief, or extended brief, interventions, as commonly undertaken in the UK, are appropriate although the review group suggested a greater response may be seen with higher-intensity psychosocial intervention.
- People in the nalmefene plus psychosocial support group had fewer heavy drinking days per month and total alcohol consumption per day compared with those who received placebo plus psychosocial support . However, the differences between the treatment groups were relatively small (13% in heavy drinking days and 11% in total alcohol consumption), suggesting that most of the treatment gain from nalmefene could be attributed to the psychosocial support. It is therefore important to ensure that this is delivered effectively.
- Treatment adherence for both nalmefene and psychosocial support is an important consideration for physicians when prescribing treatment.
- The NICE clinical advisers did not agree with the assumption that people would remain on treatment (regardless of drinking level) for the full year. They believed that GPs would not let patients drink at very high risk levels for more than 6 months without recommending intensification of psychosocial intervention and additional expert input, and that 3 months might be a more likely cut-off point.
- NICE have noted the uncertainty and conflicting opinions regarding the most appropriate setting for prescribing nalmefene in conjunction with psychosocial support. They state that making specific recommendations about the setting for prescribing nalmefene is outside the scope of a technology appraisal and is down to local determination.
- There is variation in current arrangements in place with Local Authority Public Health Partners in terms of commissioning of psychosocial support services in alcohol misuse. This will require further local discussion.
- There is also variation in current arrangements with Local Authority Public Health Partners in terms of responsibility for costs associated with prescribing medications for patients being treated in the community for alcohol misuse.

- **The cost impact of prescribing and the potential eligible population**

The annual cost associated with implementing the guidance (full implementation over 5 years) is estimated as £49,700 per 100,000 population, based on the standard assumptions in the model.

The costing model makes the following assumptions:

- The prevalence of alcohol dependence in the population is expected to be 6% of adults, of these 84% are expected to have alcohol dependency without physical withdrawal symptoms and not requiring immediate detoxification. A proportion of this group will be consistent with the marketing authorisation of nalmefene (high risk drinking level).

- Of the eligible population, only 6% are estimated to present annually to receive treatment.

- 90% of these people return for a 2 week follow-up appointment to confirm their alcohol dependence diagnosis and 50.9% currently go onto have psychosocial intervention alone. In future, clinical expert opinion expects the proportion of people receiving psychosocial intervention alone to reduce to 20.4%. The remaining 30.5% will receive nalmefene plus psychosocial intervention.

- Psychosocial intervention is expected to incur a cost of £951 per person, which consists of 12 sessions per year, costing £79.25 each.

- It is estimated that following psychosocial intervention, 14.3% of people who complete the treatment will be in the medium drinking risk level group. This is expected to be lower (12.8%) in people who have nalmefene plus psychosocial intervention. It is assumed that this group will receive the same treatment a second time to try and reduce their alcohol consumption further, or else will receive no further treatment.

- It is estimated that following psychosocial intervention, 31.2% of people who complete the treatment will have a low drinking risk level or will abstain from drinking alcohol. This is expected to increase to 52% in people who have nalmefene plus psychosocial intervention. In this group, it is assumed that 19% will relapse, re-entering the high or very high drinking risk level group and go on to seek the same treatment they had before a second time, or receive no further treatment.

  Nalmefene for reducing alcohol consumption in people with alcohol dependence falls under the programme budgeting category 5A mental health disorders – substance misuse. The commissioners for this technology will be local authorities, clinical commissioning groups and NHS England.

References

1. NICE TAG 325 Published date: November 2014: Nalmefene for reducing alcohol consumption in people with alcohol dependence
2. Costing report: Implementing the NICE guidance on nalmefene for reducing alcohol consumption in people with alcohol dependence (TA325)

Costing template	Cost for selected population using standard NICE assumptions		
	Per 100,000 population		
	Unit cost (£) / proportio	Units	Total cost (£)
Total population selected		78,604	
Number of people with alcohol dependency (without physical withdrawal symptoms and not requiring immediate detoxification)		3,962	
Current practice			
First line treatment			
Number of people who have a psychosocial intervention only	951	109	103,485
Second line treatment			
High or very high drinking risk level group			
Number of people who go on to have a psychosocial intervention again	951	26	24,916
Number of people who go on to have medically assisted withdrawal with naltrexone/acamprosate	1,044	4	4,559
Medium drinking risk level group			
Number of people who go on to have a psychosocial intervention again	951	7	6,519
Low drinking risk level or abstinence group			
Number of people who relapse and receive a psychosocial intervention a second time	951	3	2,705
Estimated costs of current practice			**£142,183**
Future practice			
First line treatment			
Number of people who have nalmefene + psychosocial intervention	1,569	65	102,440
Number of people who have a psychosocial intervention only	951	44	41,394
Second line treatment- nalmefene + psychosocial intervention			
High or very high drinking risk level group			
Number of people who go on to have nalmefene plus psychosocial intervention again	1,569	10	15,928
Number of people who go on to have medically assisted withdrawal with naltrexone/acamprosate	1,044	2	1,766
Medium drinking risk level group			
Number of people who go on to have nalmefene plus psychosocial intervention again	1,569	4	5,786
Low drinking risk level or abstinence group			
Number of people who relapse and receive nalmefene plus psychosocial intervention a second time	1,569	3	4,464
Second line treatment- psychosocial intervention alone			
High or very high drinking risk level group			
Number of people who go on to have a psychosocial intervention again	951	10	9,966
Number of people who go on to have medically assisted withdrawal with naltrexone/acamprosate	1,044	2	1,823
Medium drinking risk level group			
Number of people who go on to have a psychosocial intervention again	951	3	2,608
Low drinking risk level or abstinence group			
Number of people who relapse and receive a psychosocial intervention a second time	951	6	5,694
Estimated costs of future practice			**£191,871**
Resource impact			**£49,688**